"EXPLORATION OF CLINICAL TRIAL STAKEHOLDER'S PERSPECTIVES TOWARDS GENETIC RESEARCH-DATA FOR FUTURE USE"

Thesis Submitted to

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH

(KLE DEEMED UNIVERSITY)

[Declared as Deemed-to-be-University u/s 3 &12 B of the UGC Act, 1956 vide Govt. of India Notification No.F.9-19/2000-U.3 (A)]

(Accredited 'A^{+}' Grade by NAAC) (3rd Cycle)

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For the award of the degree of

Doctor of Philosophy

In the Faculty of Pharmacy

By

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(Registration No: KLEU/Ph.D./20-21/D-007 & DO1220048)

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FEBRUARY-2025

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ACKNOWLEDGMENT

I wish to express my deepest gratitude to my esteemed research guide, ***Prof.(D)r. M.S. Ganachari,*** *for his unwavering support, patience, and invaluable guidance throughout this journey. His vast knowledge, motivation, and constant encouragement have been instrumental in shaping my research, and I will forever be indebted to him for instilling in me a passion for inquiry and a thirst for knowledge. His advice and mentorship have always pointed me in the right direction.*

I extend my heartfelt thanks to ***Dr. Nitin Gangane****, Vice-Chancellor, and* ***Dr. V.A. Kothiwale****- former Registrar, former Vice-Chancellors* ***Prof. Dr. C.K. Kokate*** *and* ***Dr. Vivek Saoji*** *for their invaluable support and leadership. My sincere appreciation also goes to* **Dr. Sunil S. Jalalpure***, Principal, KLECOP Belagavi, and Joint Secretary, KLE Society, Belagavi, for his generous assistance, Special mention to* ***KLEs Dr.Prabhakar Kore Hospital staff from the clinical research department*** *i.e. Principal Investigators, Ethics committee members and Clinical Research coordinators for their kind cooperation. I would also like to thank* ***Dr. Jyoti Nagamoti****, former COE, KAHER, and* ***Dr. M.B. Patil****, Vice Principal, KLECOP, for their continuous encouragement and moral support.*

I am deeply grateful to ***Dr. Roopa Bellad****, Director of Academic Affairs-Former, and* ***Dr. Chandra Metgud****, current Director of Academics, for their guidance, as well as* ***Dr. B.M. Patil,*** *former Principal of KLECOP, Belagavi, for their invaluable contributions.*

A special note of gratitude to my mentor and Ethics Committee Secretariat, ***Dr. Geetanjali Salimath****, for her guidance ,****Dr.P.A.Patil*** *for his support and heartfelt thanks to* ***Mr. K. Amaresh*** *and* ***Ms. Pooja Patil*** *for their continued support.*

I would like to extend my thanks to my department colleagues: ***Dr.Manjula. G, Dr. Satish Karoli, Dr. Anushree Deshpande, Dr. Ramesh Bhandari, Dr. Santosh Reddy, Dr. Pratiksha Kini, and Dr.Sanathkumar*** *[KLECOP, Hubli], for fostering an inspiring and collaborative environment.*

I would like to extend my thanks to Clinical research department colleagues: ***Mr.Maruti Patil, Mr.Vishal J, Mr.Abdul R, Mr.Vishwajit Pawar, Mr.Akshy T*** *for fostering an inspiring and collaborative environment.*

A special mention to ***Dr. Pranali Shah*** *whose contributions were invaluable in helping with the validation of KAP questionnaire.*

Special thanks to my former colleagues, ***Dr. Ashish Singh Parihar, Dr. Uday, Mr. Kiran Majjigeri, and Dr. Deepti A*** *for their contributions during my research.*

I also extend my gratitude to my office colleagues ***Mr. Kalyani****,* ***Mr. Chetan H****,* ***Ms. Darshana*** *from KLECOP, Belagavi for their cooperation and assistance with administrative matters. I am also thankful to* ***Shri. G.S Kalmath*** *for his support.*

Lastly, I could not have achieved this without the love and unwavering support of my best friend, my wife, and soulmate, ***Mrs. Jayalakshmi Devarinti****, whose encouragement and belief in me made this journey smoother. I am equally thankful to my children,* ***Chinmay Devarinti*** *and* ***Veda Devarinti****, who have been my source of comfort and inspiration, growing alongside my dreams and cheering me on during challenging times.*

Above all, I am deeply thankful to the Almighty for His blessings, strength, and wisdom that have guided me throughout this endeavour.

LIST OF ABBREVIATIONS

AIIMS	ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ART	ASSISTED REPRODUCTIVE TECHNOLOGY
ANOVA	ANALYSIS OF VARIANCE
CDSCO	*CENTRAL DRUGS STANDARD CONTROL ORGANIZATION*
CT	CLINICAL TRIAL
CRO	CONTRACT RESEARCH ORGANIZATION
CTRI	CLINICAL TRIAL REGISTRY IN INDIA
CRA	CLINICAL RESEARCH ASSISTANT
CRC	CLINICAL RESEARCH COORDINATOR
CTA	CLINICAL TRIAL ASSISTANT
CSIR	COUNCIL OF SCIENTIFIC AND INDUSTRIAL RESEARCH
CO-I	Co-INVESTIGATOR
DGFT	DIRECTORATE GENERAL OF FOREIGN TRADE
DM	DOCTOR OF MEDICINE-IN SPECIALIZATION
DNA	DEOXYRIBONUCLEIC ACID
DTC-GT	DIRECT-TO-CONSUMER GENETIC TESTS
DA	DATA ANALYST
EBN	EUROPEAN BIOBANK NETWORK
EDC	ELECTRONIC DATA CAPUTRE
EMA	EUROPEAN MEDICINES AGENCY

FDA	FOOD AND DRUG ADMINISTRATION
IEC	INSTITUTIONAL ETHICS COMMITTEE
IRB	INSTITUTIONAL REVIEW BOARD
ICMR	INDIAN COUNCIL OF MEDICAL RESEARCH
ICD	INFORMED CONSENT DOCUMENT
IW	IMPARTIAL WITNESS
IGVC	INDIAN GENOME VARIATION CONSORTIUM
KAP	KNOWLEDGE ATTITUDE PRACTICE
LAR	LEGALLY ACCEPTABLE REPRESENTATIVE
MD	DOCTOR OF MEDICINE
MOU	MEMORANDUM OF UNDERSTANDING
MTA	MATERIAL TRANSAFER AGREEMENT
MCH	MASTER OF CHIRURGIAE
MS	MASTER OF SURGERY
NIH	NATIONAL INSTITUTE OF HEALTH
NGO	NON-GOVERNMENTAL ORGANIZATIONS
NGS	NEXT GENERATION SEQUENCING
PI	PRINCIPAL INVESTIGATOR
PIS	PATEINT INFORMATION SHEET
PGX	PHARMACOGENOMICS
PM	PROJECT MANAGER

QA	QUALITY ASSURANCE
SAE	SERIOUS ADVERSE EVENT
SD	STANDARD DEVIATION
THSTI	TRANSLATIONAL HEALTH SCIENCE AND TECHNOLOGY INSTITUTE BIOREPOSITORY
TMCTB	TATA MEMORIAL CENTRE TISSUE BANK
USA	UNITED STATES OF AMERICA
WHO	WORLD HEALTH ORGANIZATION

ABSTRACT

Introduction: Adhering to Good Clinical Practice (GCP) guidelines, it is essential that personnel engaged in clinical trials and genetic research are adequately educated and trained. Clinical trial investigators bear the responsibility to protect participant privacy and prevent the unauthorized reuse of research data.

Aim: This study aims to evaluate the knowledge, attitudes, and practices (KAP) of clinical trial stakeholders regarding the reuse of genetic data for future research.

Settings and Design: A cross-sectional study was conducted involving a one-time assessment of KAP among stakeholders from tertiary care hospitals, academic institutions, ethics committees, and clinical research organizations. A validated questionnaire assessing KAP toward the reuse of genetic research data was administered.

Statistical Analysis: Data were analyzed using SPSS version 21.
Results: A total of 225 stakeholders participated. Median knowledge scores differed significantly among groups ($p < 0.001$), with sponsors and contract research organizations (CROs) showing the highest median score (8, IQR 7–8), followed by ethics committee members (7, IQR 1–8), and clinical trial investigators (6, IQR 4–7). Stakeholders generally expressed positive attitudes toward genetic data reuse, with a high median score of 10. Practice patterns revealed that sponsors and CROs were most engaged in data reuse activities, while participants and pathologists were less involved, potentially due to limited roles in data management.
Conclusion: The study highlights a shared recognition of the value of genetic data reuse among clinical trial stakeholders, while also identifying disparities in knowledge and involvement. Ethical and procedural concerns warrant attention to guide future data-sharing practices.

Keywords: Genetic Research, Bioethics, Genetic Consent Forms, Genetic Data-Coding, and Biorepository

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1. INTRODUCTION

EXPLORATION OF CLINICAL TRIAL STAKEHOLDER'S PERSPECTIVES TOWARDS GENETIC RESEARCH-DATA FOR FUTURE USE

1.1 BACKGROUND

INTRODUCTION TO CELLS, GENOMES, AND DNA & Its DATA:

Human Cells serve as the basic building blocks and operational units of all living organisms. DNA in all organisms is composed of 04 chemical bases: adenine (**A**), thymine (**T**), guanine (**G**), and cytosine (**C**). The entirety of an organism's genetic material, known as genome, is organized into larger structures called chromosomes. In humans, chromosomes are distinct molecules that vary in size, ranging from 50 to 250 million base pairs in length. Human cells typically contain 2 sets of chromosomes, one from each parent, 23 pairs. These include 22 autosomes and a pair of sex chromosomes.

At the molecular level, genetic disorders are often caused by mutations, which leads to changes in the DNA sequence. These mutations can vary widely in their impact, ranging from single nucleotide changes to large deletions or duplications of genetic material. Regardless of the mechanism, mutations can lead to the production of proteins that are either non-functional or dysfunctional. These altered proteins may disrupt normal cellular functions, ultimately leading to disease. The study of genetic disorders is critical for understanding the mechanisms of disease, improving diagnostic methods, and developing targeted therpaies. As advances in genetic research continue, there is hope that more effective interventions for these disorders; offering new possibilities for disease prevention and personalized medicine can also

decreases the cost effectiveness. The most common type of gene mutation involves a change or "misspelling" of a single base in the DNA sequence. Furthermore, different genes may activated during developmental stages or in response to environmental factors like infections or stress [1].

Introduction to Genetic research: Genetic research holds immense potential for advancing personalized medicine, understanding disease mechanisms, and developing targeted therapies with safe and effective. Clinical trials translating research findings into clinical practice, often involve the collection of vast amounts of genetic samples and its research data. The re-use of this data can accelerate scientific discovery, reduce redundancy, and enhance the value derived from research investments. However, the re-use of genetic data also raises significant ethical, legal, and social concerns [32]. Understanding the perspectives of various stakeholders involved in clinical trials is crucial for developing policies and practices that balance the benefits and risks of genetic data re-use.

Health sectors is a rapidly evolving field that integrates aspects of precision medicine, such as genomics research, to enhance health outcomes more effectively. While there is growing interest in leveraging genomics to advance precision public health, the field's current applications and potential remain largely untapped. This presents opportunities to explore and expand the role of genomics across five key public health domains: biostatistics, environmental health, epidemiology, health policy maker social and behavioural sciences. By examining these areas, can identify promising applications and outline strategic directions for the future aspects. To advance the use of genomics in precision, three main challenges need to be addressed: creating policies that support multi-level precision public health initiatives, enhancing data

integration and methodology, and promoting health equity. Fully realizing the integration of human genomics in precision health will require collaborative, cross-disciplinary efforts that capitalize the strengths of both precision medicine and public health. [04]

Technological advancements, substantial funding opportunities both nationally and internationally, increased commercial interest, heightened public awareness of personalized medicine (which is still developing significantly in India) [02]. Outsourcing in drug development and global research has become increasingly popular in the pharmaceutical industry, mainly due to cost considerations and the inherent uncertainties of the process. India is emerging as a leading destination for contract pharmaceutical research and development, its large treatment-naïve population, skilled workforce, technical capabilities, evolving regulatory framework, and dynamic economic landscape. However, the significant steps needed to meet the necessary requirements for India's success in the genetic research field [03]. However, the advancements have also brought forth numerous ethical issues associated with genetic research. Two primary tools safeguard clinical trial participants in any clinical research: written informed consent and ethics committee (EC) review.

Data sharing has the potential to accelerate new scientific discoveries by preventing duplicative trials, fostering innovative research ideas, and maximizing the scientific knowledge and benefits derived from the efforts of clinical trial participants and investigators. However, sharing clinical trial data also involves a number of risks, challenges, and responsibilities. These include the imperative to protect participant privacy and to their consent, safeguard the legitimate economic interests of

pharmaceutical sponsors, and prevent invalid secondary analyses that could damage public trust in clinical trials or harm public health.

The clinical research industry, which is responsible for assessing the safety and effectiveness of health related research and navigating medical decisions, is set to undergo major transformations due to ongoing and persistent challenges, such as the lengthy time frames, high costs, and often limited applicability of the research it generates[05]. A significant factor driving these upcoming changes is the growing influence of consumers and patients in research and healthcare. The traditional model, where investigators, sponsors, and journal editors serve as gatekeepers for clinical trials and their outcomes, is being challenged by increasing demands for "open science" and the democratization of clinical research. While shift toward these new practices is still in progress and faces considerable obstacles, many believe that those who embrace open science early will benefit. [06]

Currently, data is considered exploratory—either non-validated or hypothesis generating. However, there is a growing trend toward allowing clinical trial participants access to their personal genetic data if they wish. This shift has prompted researchers, sponsors, patient advocacy groups, ethics committees, and regulatory bodies to address the complex issue of whether, and how, individual results should be shared with study participants. The authors present "Points-to-Consider" for returning results in drug development trials, drawing on their expertise and experience. These considerations include the clinical relevance of the data, the qualifications of laboratories, the processes for obtaining informed consent, the confidentiality of medical information, and the competence of those delivering results to participants [29]

Human genetics testing and research: No other area of biomedical and health research has raised more ethical concerns than human genetics. These concerns have intensified in recent years due to the rise of direct-to-consumer genetic testing and the potential for embryo manipulation. Although advancements in DNA technology have given humanity powerful tools to explore and manipulate the human genome, they have also sparked significant worries about how scientists manage this information. The line between standard genetic testing and research is quite thin, bringing up numerous ethical, legal, and social issues that require ongoing monitoring of the clinical trials [08].

INTRODUCTION TO CLINICAL TRIALS:

Clinical research involves investigating human subjects or materials of human origin to understand disease mechanisms, evaluate therapeutic interventions, develop new technologies, and study epidemiological and behavioural aspects, as well as outcomes and health services. [30]

- **Prospective Studies**
- **Retrospective Studies**
- **Cohort Studies**
- **Cross-Sectional Studies**

Evolution of research ethics guidelines:

Nuremberg "Doctor's Trial" (1946): A tribunal held to prosecute Nazi doctors who conducted unethical medical experiments on concentration camp prisoners. This trial highlighted the need for ethical standards in research [38].

Nuremberg Code (1947): Established because of the Nuremberg trials, it set out fundamental principles for conducting ethical research, including informed consent and the necessity of avoiding unnecessary suffering [38].

UN Universal Declaration of Human Rights (1948): Enshrined human rights principles, including the right to be free from inhumane and degrading treatment, which influenced ethical standards in research.

Declaration of Helsinki (1964): Developed by the World Medical Association, it built on the Nuremberg Code and provided detailed ethical guidelines for medical research involving human subjects [39].

Belmont Report (1979): Issued in the U.S., it outlined key ethical principles and guidelines for research involving human subjects, emphasizing respect for persons, beneficence, and justice.

International Ethical Guidelines for Biomedical Research (CIOMS) (1993, updated 2016): Published by the Council for International Organizations of Medical Sciences, these guidelines offered comprehensive standards for ethical biomedical research on a global scale.

Ethical consideration in Genetic Research: Ethics in genetic and clinical research is a critical field that addresses the moral principles guiding the conduct of research involving human subjects, particularly when it involves genetic data. As advancements in genetic technologies and clinical practices accelerate, ethical considerations become increasingly complex and essential to ensuring that research is conducted responsibly, respecting the rights, dignity, and welfare of participants and See **figure no: 01** ethics in genetic/clinical research. Ethical considerations in genetic and clinical research are fundamental to maintaining public trust and ensuring the integrity of scientific investigations. Adherence to ethical principles not only protects participants but also enhances the credibility and social value of research. As genetic

and clinical research continues to evolve, ongoing dialogue and rigorous ethical scrutiny will be essential in addressing new challenges and dilemmas [09-13].

A dataset denotes an organized compilation of data and information that is upheld in either physical or electronic/digital manifestation. This compilation serves the purpose of facilitating biomedical and health research. In addition to data pertaining to bio specimens within biobanks, there exist various repositories such as disease registries, health surveys, disease surveillance systems, census data, personal health records and clinical trial registry within healthcare institutions. These repositories hold immense potential for subsequent research endeavours [20-23].



FIGURE 01: ETHICS IN GENETIC RESEARCH

Participants who initially signed the consent forms had a limited understanding of what would happen to their biological samples. While they were aware that their samples would be used for research, many could not recall specific details regarding how leftover samples might be utilized in future studies. There was also a common assumption that the samples would be stored by third-party vendors, but participants were often unclear on who these vendors were or how long the samples would be retained. This lack of clarity contributed to uncertainty and, many participants reflected on the consent process and described it as rushed, leaving them with little time to fully comprehend the implications of their participation. Some felt that they were not given enough opportunity to ask questions or seek clarification about the long-term use of their samples. Additionally, several individuals expressed a desire for more time to discuss the research with their family members before making a decision. This suggests that a more thorough and patient-oriented consent process could improve participants' understanding and comfort with their involvement in research studies. Participants who went through the supplemental consent process better informed about the use and storage of their samples. [29]

Key clinical trial stakeholders:-

- Pharmaceutical Sponsors and Contract Research Organizations
- Clinical trial investigators
- Human Ethics Committee members
- Clinical trial participants
- Pathologists

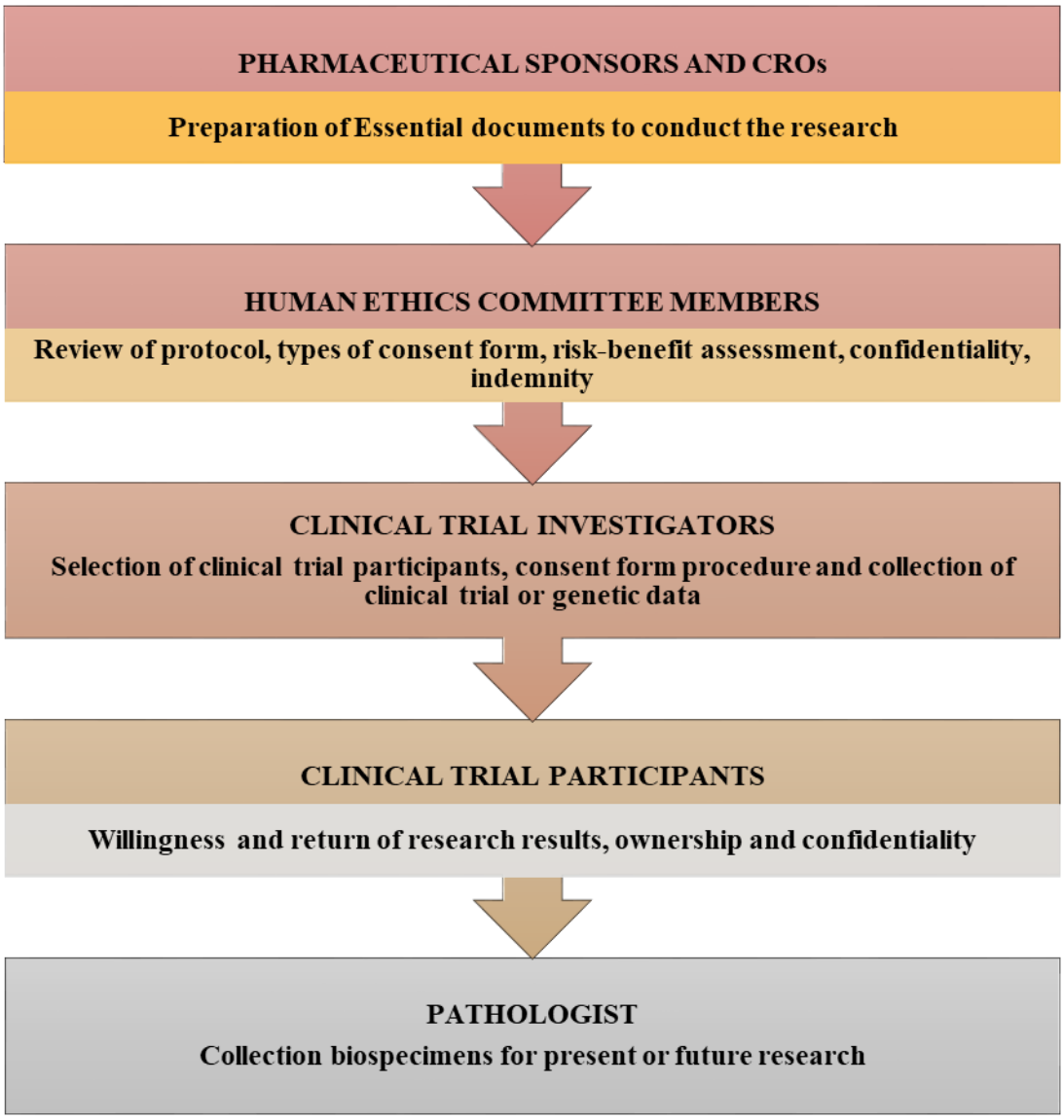


FIGURE: 02-PROCESS OF INVOLVEMENT OF CLINICAL TRIAL STAKEHOLDERS IN THE GENETIC/CLINICAL RESEARCH

PHARMACEUTICAL SPONSORS AND CONTRACT RESEARCH ORGANIZATIONS: Play a significant role in the genetic or clinical research and its operations, commencing with the initial stages of planning and in the actual execution of the clinical trials. The clinical trials give rise to ethical dilemmas that encompass a range of aspects including the obtaining of general or genetic consent, the possibility of optional research, the storage and utilization of genetic data and specimens, as well as the disclosure of investigation findings to the clinical trial participants or the

research institute. They are also involved in conducting clinical research to assess the safety and efficacy of new drugs or treatments. These trials often involve the collection of genetic data to understand how individuals respond to specific interventions. Sharing the data can contribute to broader scientific knowledge and benefit the research community. Pharmaceutical sponsors often provide significant financial support for genetic research projects. This funding helps cover the costs associated with data collection, analysis, and interpretation. These sponsors may contribute specialized expertise, equipment, and laboratory facilities to enhance the research process. Pharmaceutical sponsors generate large amounts of genetic and clinical data through research and development efforts. Sharing research data allows other researchers to explore new hypotheses, validate findings, and identify potential biomarkers or therapeutic targets. Collaborative data sharing can accelerate the pace of discovery and innovation.

Most of the pharmaceutical sponsors actively participate in or establish consortia and partnerships with academic institutions and government hospitals. These collaborations facilitate data sharing and pooling of resources, leading to more robust and comprehensive datasets. Genetic research is essential for understanding the genetic basis of diseases and developing targeted therapies. By sharing genetic data, pharmaceutical sponsors can contribute to the identification of potential drug targets, biomarkers, and patient subpopulations, ultimately accelerating drug development and improving patient outcomes. Pharmaceutical sponsors must adhere to ethical standards and guidelines when handling genetic data. They play a role in ensuring that data sharing is conducted responsibly, with appropriate measures in place to protect patient privacy and confidentiality. Pharmaceutical sponsor and contarct research organization must comply with national and international regulatory requirements.

Genetic research often requires a global perspective due to the diverse genetic makeup of populations. Pharmaceutical sponsors, by participating in data-sharing initiatives, contribute to global collaboration, allowing researchers to access a broader range of genetic information. The pharmaceutical sponsors contribute significantly to genetic research data sharing by providing financial support, resources, expertise, and a collaborative framework.

HUMAN ETHICS COMMITTEE MEMBERS: Ethics Committees (ECs) are crucial in the assessment of ethical and risk benefits, overseeing and managing the use of biorepositories and data repositories, scientific, and public health initiatives. Any research proposal that involves biorepository services, such as material transfer or access to available datasets, should undergo review by an Ethics Committee either an institutional committee or one specific to the biorepository. [08]

Key ethical issues related to genetic research:

Informed Consent: Obtaining informed consent is crucial in genetic or any type research which is involving human participants. Participants should fully understand the purpose, risks, and potential benefits of the research and returns of research results to study participants or research institute. Informed consent becomes more complex when dealing with genetic information that may have long-term implications.

Privacy and Confidentiality: Genetic information is inherently sensitive and personal. Researchers must take measures to protect the privacy and confidentiality of participants' genetic data.

Direct-to-Consumer Genetic Testing (DTC-GT) Companies: **[14-16]** Since the mid-2000s, companies have emerged offering direct-to-consumer (DTC) genetic testing

services, bypassing traditional research or clinical settings. These companies assert that their services empower individuals by providing access to personal genetic information, which they believe consumers have a fundamental right to access. They further argue that this information can be utilized for a range of personal benefits, including enabling individuals to make more informed decisions about their health and well-being.

Transfer of bio specimens: When bio specimens are to be shipped from the host, institution to collaborating research institutions, either within the country or internationally, within a Material Transfer Agreement (MTA) should executed. The Ethics Committee (EC) should oversee the entire process of material transfer, both domestically and internationally. For international transfers, mandatory regulatory clearances and an appropriate Memorandum of Understanding (MoU) are required. Additionally, the Directorate General of Foreign Trade (DGFT) has issued a notification concerning the transfer of human biological material for commercial purposes [37].

Ownership of biological samples and data: Research subjects retain ownership of the biological samples and its related data, giving them the right to withdraw both the donated biological material and related data, unless the data is essential for outcome measurement and was explicitly stated in the initial informed consent. However, complete anonymization of the data effectively negates the original donor's ownership rights. Biobanks or institutions, through Ethics Committees (ECs), act as custodians or trustees of the samples and data, ensuring their current and future use may supervised by the respective ethics committees. Researchers, on the other hand, do not have any claim to ownership or custodianship of the samples or data.

Secondary or extended uses of stored samples/re-consent: The Ethics Committee (EC) is responsible for reviewing the conditions under which the biological material or data were originally collected, as well as the informed consent that was obtained at that time.

When stored samples are to be used:

- The proposed use is aligned with the original consent given for the earlier research and scrutinize the validity of the objectives of the new research
- The provisions for ensuring anonymity of the samples for secondary use are stated
- The permission of LAR-Legally acceptable representative is obtained for future uses of samples
- The consent form mentions retention and various possible future uses of tissues in the form of a tiered consent.

CLINICAL TRIAL INVESTIGATORS: The clinical trial investigator overseeing the clinical trial must ensure the preservation of the confidentiality of participants in the study and the avoidance of unintentional missuses of research results. In addition, ethical factors are of concern to clinical trial investigators, encompassing the acquisition of appropriate consent, the gathering and retention of bio-specimens, and the accessibility of data. The potential advantages associated with the exchange and encoding of information is imperative in the realm of genetic investigations or clinical trials. There is an active participation from clinical trial investigators in the preservation of genetic material and its data during clinical trials. Furthermore, clinical trial investigator perceive data sharing and re-using practices in genetic

research in clinical trials with varying perspectives. However, they express concerns regarding privacy and confidentiality. They seek clarity on the sharing research data, including the recipients of the data and their intended utilization. The clinical trial investigators are advised to elucidate the precise nature of the confidentiality of the data resulting from genetic testing and research to the patient or participant.

CLINICAL TRIAL PARTICIPANTS: Clinical trial participants are individuals who voluntarily engage in research studies designed to assess the safety and effectiveness of new medical treatments, interventions, or devices. These trials play a crucial role in advancing medical knowledge and contributing to the development of innovative strategies for preventing, diagnosing, and treating various health conditions.

Voluntary Participation: Clinical trial participation is voluntary since Belmont report. Individuals choose to enrol in a trial after receiving detailed information about the research proposals, including its purpose, potential risks and benefits, and the procedures involved.

Informed Consent: Before participating in a clinical trial research, clinical trial, individuals must provide informed consent. This involves a thorough understanding of the study, its objectives, potential risks, and any other relevant information. Participants have the right to ask questions and can withdraw from the trial at any time.

Diverse Backgrounds: Genetic research/Clinical trial participants come from diverse backgrounds, including different ages, genders, ethnicities, and health statuses. This

diversity is crucial for ensuring that the results of the trial are applicable to a broader population.

Pre-Screening: Before joining, any research activities on human participants, potential participants often go through a pre-screening process to assess the criteria, if they meet specific eligibility criteria. These criteria may include age, health status, medical history, and other factors relevant to the study.

Study Phases: Clinical trials typically progress through different phases, each designed to answer specific research questions. Phase I trials focus on safety, Phase II trials assess effectiveness and Phase III trials compare the new treatment to standard treatments. Phase IV trials occur after a treatment is approved and are conducted to gather additional information about its long-term effects.

Close Monitoring: clinical trial participants are closely monitored throughout the study. This may involve regular check-ups, medical tests, and close communication with the research team to track any changes in health or treatment response.

Confidentiality: The privacy and confidentiality of clinical trial participants are of utmost importance. To safeguard their personal information, are identified using unique codes rather than their names in study records, ensuring their privacy is protected throughout research process.

Rights and Protections: clinical trial participants have specific rights and protections, and research studies must adhere to ethical principles to ensure their well-being. Institutional Ethics committee (IECs) review and approve the study protocols to safeguard participants' rights and welfare. Participating in a clinical trial is a valuable contribution to medical research, but individuals considering participation

should carefully weigh the potential benefits and risks and make an informed decision based on their individual circumstances.

PATHOLOGIST: Pathologists play a crucial role in medical research, contributing their expertise in the study of diseases and understanding the underlying pathology. Pathologists are involved in research in some ways. Pathologists are responsible for diagnosing diseases by examining tissues, cells, and organs. In research, they contribute to understanding the pathology of various diseases, classifying different subtypes, and characterizing the molecular and cellular features associated with specific conditions and coding of the bio specimens.

Biomarker Discovery: Pathologists are involved in identifying and validating biomarkers – measurable indicators of normal or abnormal biological processes. Biomarkers are essential in research for diagnosing diseases, predicting treatment responses, and monitoring disease progression. Pathologists may use various techniques, including immunohistochemistry and molecular pathology, to identify and validate these markers.

Tissue Banking: Pathologists often contribute to the establishment and maintenance of tissue banks. These repositories store biological samples, such as tissues and blood, for research purposes. Tissue banks are providing researchers with necessary materials to study diseases and develop new treatments.

Experimental Pathology: pathologists actively participate in experimental pathology, conducting studies to investigate the mechanisms underlying diseases. This can involve animal models, cell cultures, and molecular techniques to explore the pathways and processes associated with specific diseases.

Genomic Medicine: With advancements in genomics, pathologists contribute to genomic medicine research by analysing genetic information to understand the genetic basis of diseases. This includes identifying genetic mutations associated with specific conditions and exploring personalized medicine approaches based on an individual's genetic profile.

Publication and Education: Most of the pathologists engage in publishing research findings in scientific journals, contributing to the dissemination of knowledge in their field. Additionally, they may be involved in educating the next generation of researchers, medical professionals, and pathologists.

BIOBANKS AND DATA SETS:

Bio-specimens and its associated data for scientific research and medical research purposes. A biobanks are systematically curated assortment of human biological substances, typically accompanied by a corresponding dataset, which is retained within suitable establishments for extensive durations intended for research and possible commercial objectives, incorporating inherent guidelines promoting openness. The examination of these biological specimens or samples and/or associated datasets might not necessarily entail direct participation. Biobanks encompass the governance of the collection of biological materials, their processing and storage, along with the associated data, as well as the dissemination of samples and/or data through researchers. These activities are subject to an overarching ethical supervision. The biological materials held within these biobanks can serve various purposes, such as research, assisted reproductive technology (ART), or forensic investigations. The stored samples within these biobanks can vary in quantity, ranging from small numbers kept in researchers' refrigerators to larger quantities stored in

departments, research institutions (including universities and non-profit organizations), judiciary custody, and pharmaceutical companies. In some cases, these samples may be stored in large warehouse-like facilities at a single site or within a network of facilities that are centrally coordinated. These facilities offer access to medical, genetic, and lifestyle-related data. Biobanks are repositories that store and manage biological samples, such as blood, tissues, cells, and DNA, along with associated data like medical records and demographic information. Biobanks play a crucial role in advancing genetic and biomedical research by providing scientists with access to a large and diverse collection of biological materials.

Sample Storage: Biobanks store various types of biological samples, including blood, urine, tissue, and DNA, often collected from donors who provide informed consent.

Data Integration: In addition to biological samples, biobanks typically collect and manage associated data requires careful management, and transparent and accountable governance structures that are clearly communicated to patients/participants and citizen [14].

Research Advancements: Biobanks facilitate large-scale studies and research projects by providing researchers with access to a vast and diverse pool of samples. This accelerates the discovery of genetic markers, biomarkers, and associations with diseases.

Disease Research: Biobanks are particularly valuable in studying genetic factors contributing to diseases. They aid in identifying genetic variations associated with specific conditions and contribute to personalized medicine initiatives.

Supporting Research: Providing high-quality biological samples and data to researchers for studies on genetic, environmental, and lifestyle factors affecting health.

Improving Healthcare: Facilitating the development of personalized medicine, early diagnostics, and targeted therapies.

Enhancing Disease Understanding: Enabling comprehensive studies on the epidemiology, pathogenesis, and progression of various diseases prevalent in the Indian population.

Promoting Collaboration: Fostering collaboration between national and international research institutions to share resources and knowledge.

TABLE 01: TYPES OF BIO SPECIMEN SAMPLES

<table>
<tr><th>SL.NO</th><th>TYPE OF SAMPLES</th><th colspan="2">DESCRIPTION</th></tr>
<tr><td>1.</td><td>Anonymous or unidentified</td><td colspan="2">No identifiers are present from the start or if collected, are not maintained. Such samples are received by biobanks without any identifiers and supplied to researchers</td></tr>
<tr><td rowspan="2">2.</td><td rowspan="2">Anonymized</td><td>Coded or reversibly anonymized</td><td>Irreversibly anonymized</td></tr>
<tr><td>There is an indirect link of sample/ data to the participant’s identity with restricted access. This link could be re-linked if required; therefore, it may also be termed reversible anonymization.</td><td>Link to the participant’s identity is removed and cannot be re-linked.</td></tr>
<tr><td>3.</td><td>Identifiable</td><td colspan="2">A direct link of sample/data to the participant’s identity exists.</td></tr>
</table>

LIST OF NATIONAL AND INTERNATIONAL BIOBANKS [27]:

TABLE: 02-LIST OF INTERNATIONAL BIOBANKS

Sl.No	INTERNATIONAL-BIOBANKS
1.	**UK Biobank:** A large-scale biomedical database and research resource containing in-depth genetic and health information from half a million UK participants
2.	**BioVU:** Vanderbilt University's biobank, which links DNA samples to de-identified electronic medical records for research purposes
3.	**European Biobank Network (EBN):** A collaboration of biobanks across Europe aiming to facilitate biomedical research and improve public health.
4.	**The 1000 Genomes Project:** An international collaboration that created the largest public catalog of human genetic variation by sequencing the genomes of over a thousand individuals.
5.	**H3Africa Biobank:** A biobank network supported by the Human Heredity and Health in Africa (H3Africa) initiative, facilitating genomic research to improve the health of African populations.
6.	**The International HapMap Project:** Was undertaken to create a haplotype map of the human genome, aiming to identify and describe the common patterns of human genetic variation. This resource has been instrumental in advancing our understanding of how genetic differences influence health, disease, and responses to treatments.

TABLE: 03-LIST OF NATIONAL BIOBANKS

Sl.No	NATIONAL BIOBANKS
1.	**Indian Council of Medical Research (ICMR) National Biobank:** ICMR has established a national biobank at the National Institute of Cancer Prevention and Research (NICPR) to facilitate research in cancer and other diseases. This biobank stores biological samples, including tissues, blood, and DNA, from various population cohorts
2.	**IndiGen Programme:** Launched by the Council of Scientific and Industrial Research (CSIR), the IndiGen Programme aims to collect genetic data from diverse Indian populations to create a comprehensive genome database. This initiative supports personalized medicine and health research in India
3.	**Indian Genome Variation Consortium (IGVC):** This collaborative effort by various Indian research institutions focuses on cataloging genetic variations in the Indian population. The data generated supports studies on population genetics, disease susceptibility, and pharmacogenomics.
4.	**All India Institute of Medical Sciences (AIIMS):** One of India's premier medical institutions has established biobanks to support research in various fields, including oncology, cardiology, and neurology. These biobanks store a wide range of biological samples and associated clinical data.
5.	**Translational Health Science and Technology Institute (THSTI) Biorepository:** An autonomous institute under the Department of Biotechnology operates a biorepository that collects and stores biological samples from mother-child cohorts, supporting research in maternal and child health.
6.	**Tata Memorial Centre Tissue Bank:** Located at the Tata Memorial Centre in Mumbai, focuses on collecting and storing cancer tissue samples to support oncology research and improve cancer treatment in India

INTERNATIONAL SCENARIO ON GENETIC RESEARCH DATA RE-USE:

The global growth of genetics in clinical research, supported by extensive data repositories in biobanks, is driven by the aspiration to revolutionize healthcare. These research efforts aim to enhance disease prevention and treatment by enabling innovative drug targeting, developing tailored treatment protocols, and identifying disease risk factors pre-emptively [17-19]. However, it must be acknowledged that the potential use of archived genetic information, as well as its susceptibility to commercial exploitation, is a valid concern. The prioritization of open permission standards for data access and usage is of utmost importance. However, the clinical patient descriptions associated with patient informed consent for research or diagnostics are often challenging to locate and repurpose due to their disparate collection and storage across diverse biobanks. This fragmented environment poses significant problems for healthcare users attempting to locate specific patients or reuse data for personalized medicine applications, such as drug response or disease risk prediction.

The encouragement by the World Health Organization (WHO) for the dissemination of pathogen genome data is rooted in the aim of safeguarding global public health. The sharing of such data is of utmost importance in the prevention, identification, and response to epidemics and pandemics, both within national and across international. This holds significant value for all Member States. Furthermore, the systematic acquisition and dissemination of information plays a crucial role in the surveillance and control of endemic diseases, as well as in the monitoring of antimicrobial resistance, thereby informing policy decisions. The establishment of ethical, fair,

efficient, and effective practices and policies for the sharing of genome data is imperative.

World Health Organization also carried out the Genomic surveillance, is revolutionizing the implementation of public health measures by providing a more profound comprehension of pathogens and their evolutionary processes. The amalgamation of epidemiological and various other multi-source data with genomic information pertaining to pathogens that possess the potential to cause pandemics and epidemics significantly contributes to risk evaluations, the development of vaccines and therapeutics, the creation of diagnostic assays, and the determination of public health and social interventions. Recent years have witnessed the emergence of novel sequencing and bioinformatics technologies, with certain nations making notable advances in the establishment and enhancement of their capacities and capabilities in research areas. The Genetic research advances depend on sufficient numbers of samples and high-quality clinical trials data. Although genetics is a field of science that is quickly developing, we are just now beginning to understand the complexity of the genetic data coding. As a result, drug development programme are an invaluable asset and a singular chance for highly beneficial genetics research. Research samples or data gathered today will be an invaluable resource for further study as scientific discoveries continue to produce. This might result in the future development of novel medications more effectively tailored to certain individuals and disease subtypes [18]. Bio-specimens or samples that are characteristic of their type along with their associated data.

The scientific field of genetics research focuses on the investigation of the function of genes, such as the emergence of disease. It is essential for both identifying

possible therapeutic targets and comprehending genetic differences in response to therapeutic interventions. The individuals with whom the data are shared and by whom they are most likely to be used influence the attitude toward donation. Studies show a preference for private healthcare over public healthcare in India, despite that private healthcare is offered in the USA. However, there are no similar international recommendations to regulate or ease concerns with ethics and consent on genetic research. India has ICMR criteria for biology, materials, and databases.

RISKS AND BENEFITS OF GENETIC RESEARCH DATA SHARING:

RISKS [30]

Privacy Concerns: Genetic data is highly sensitive, capable of uncovering intimate details about individuals and their families. Sharing such data raises significant concerns about potential misuse or unauthorized access, which could result in serious privacy breaches.

Informed Consent Challenges: Ensuring proper informed consent for data sharing poses significant challenges, particularly when participants may not fully grasp the potential implications, including how their data will be used, with whom it will be shared, and the long-term consequences of such sharing.

Stigmatization and Discrimination: Genetic information has the potential to stigmatize individuals or groups by highlighting their predisposition to certain conditions. This creates a risk of discrimination, not only in healthcare and employment but also in personal and social relationships, potentially leading to exclusion or prejudice.

Data Security: The security of genetic data is of critical importance. Breaches in data security can result in unauthorized access, data manipulation, or theft, which not only jeopardize the privacy and well-being of individuals but also compromise the integrity and credibility of research outcomes.

Misuse for Non-Research Purposes: Sharing genetic data for research purposes carries the risk of misuse, such as its exploitation for non-scientific, commercial, or discriminatory purposes, raising ethical concerns and the potential for harm to individuals.

BENEFITS [30]

Accelerated Scientific Discovery: Sharing genetic data fosters collaboration among researchers, enabling them to pool resources and expedite scientific discoveries.

Validation and Reproducibility: Data sharing allows researchers to validate and replicate findings, strengthening the reliability of scientific research and enhancing the robustness and credibility of knowledge generated from genetic or clinical studies.

Precision Medicine Advancements: Sharing genetic data advances the development of personalized and precision medicine by uncovering genetic variations linked to individual treatment responses, paving the way for more targeted and effective healthcare interventions

Improved Patient Outcomes: Sharing genetic data enables researchers and clinicians to deepen their understanding of the genetic foundations of diseases, facilitating the development of improved diagnostic tools, prognostic markers, and safer, more effective therapeutic strategies.

Global Collaboration: Genetic research often involves studying diverse populations. Data sharing promotes global collaboration, allowing researchers to analyse data from different ethnicities and geographic regions, leading to a more comprehensive understanding of genetic factors.

Resource Efficiency: Collaborative data sharing reduces redundancy in research efforts and maximizes the use of available resources. Researchers can build upon existing datasets, avoiding the need to collect the same information repeatedly.

Advancements in Genomic Medicine: Genetic data sharing is critical for advancing genomic medicine, including the development of gene therapies, genetic testing, and the identification of novel drug targets.

Population Health Research: Large-scale genetic datasets enable population-level research, allowing for the identification of patterns and trends that can inform public health policies and interventions. Balancing the risks and benefits of genetic research data sharing requires careful consideration of ethical, legal, and social implications. Implementation of robust data protection measures, informed consent, protocols, and adherence to ethical guidelines are essential to mitigate potential risks.

GLOBAL REGULATORY REUIREMENTS:

Although regulatory agencies like European Medicines Agency (EMA) and the Food and Drug Administration (FDA) recommend collecting DNA samples for pharmacogenomics analysis throughout all phases of clinical development, various legislative and regulatory frameworks, along with the perspectives of Institutional Review Boards (IRBs) and Independent Ethics Committees (IECs), often restrict or complicate DNA collection and data use. Conducting global clinical trials involving

DNA and derived data for pharmacogenomics research thus requires navigating a complex landscape of prerequisites and constraints.

Challenges for Pharmacogenomics during clinical development: Genetic analyses of clinical trial data play a crucial role in informed decision-making throughout the clinical development lifecycle, offering significant potential for patient stratification and enhancing therapeutic value propositions. However, these analyses face challenges such as limited study sizes, inadequate global representation, and difficulties in validating research findings, which can constrain their impact and generalizability.

BIOREPOSITORY PROCESS: The curation of biological specimens and its data, inclusive their preservation, dissemination, retrieval for the benefit of researchers, is a crucial undertaking. A dataset, on the other hand, is a well-organized collection of verifiable facts and information that is sustained in either physical, electronic, or digital format and is deemed appropriate for utilization in biomedical and clinical trials or research. Repositories, such as cancer trial registry and individual data, may include a wealth of information for future research in addition to information on bio specimens, such as that found in biobanks [17-19].

Informed consent documents and its considerations: [23-26]

Blanket or broad consent: An open consent given only once to collect the sample, store it and use it for any research at any time in future without the need to revert to the individual for a re-consent. A consent model that allows for current and future access and use of samples or data for research without necessarily specifying what the focus of such studies might be.

Tiered consent: offers several options from which participants can choose. It includes an opt-in option for future use specifying general permission, or use only related to some aspects of research, sharing of bio specimens/data benefit sharing, etc. It also takes into consideration return of results for which options are also provided for consent.

Specific consent: Consent is obtained for a specific research purpose. Participants are contacted for every new use of their stored samples/data if the scope of research is outside that for which they had originally given consent.

Delayed consent: It may be administered in the post-medical procedure period when bio specimen or data may be collected for appropriate research from critically ill patients who may not have given prior consent for research.

Dynamic consent: This consent is different from one of static, paper-based consent and involves an ongoing engagement and interactions over time with participants to re-contact in response to changing circumstances using technology based platforms. It incorporates a flexible, configurable, technology-based design accommodating both participant and researcher needs. Modern longitudinal biobanks equipped with advanced technology strive for this type of consent

Participants in clinical trials typically provide informed consent for a specific study, and the use of their data beyond that study might not have been explained. Reusing data without clear informed consent raises issues of autonomy and respect for individuals' choices. For consent to be valid, the person making the decision should be competent, have the appropriate information and understand it, and should make their decision voluntarily

Privacy and Confidentiality: Respecting participants' privacy and ensuring confidentiality become critical. Investigators must take measures to de-identify or anonymize data to protect participants.

Data Security: As data is re-used for various purposes, ensuring its security becomes more complex. Protecting data from unauthorized access or breaches is essential to maintain the trust of participants and safeguard their sensitive information.

Stigmatization and Discrimination: Genetic information, in particular, may reveal predispositions to certain conditions or traits. Reusing data may lead to potential stigmatization or discrimination against individuals based on their genetic makeup. Steps must be taken to prevent such negative consequences.

Benefit Sharing: Participants may not directly benefit from the secondary uses of their data. There is an ethical obligation to consider how the benefits of research, including any financial gains or advancements, are distributed and whether participants should share in those benefits.

Community Engagement: Data may come from specific communities or populations. Engaging with these communities to ensure their values and perspectives are considered, and that research benefits are shared equitably, becomes important.

Long-Term Impact: The long-term consequences of data reuse may be difficult to predict. Researchers must consider the potential impact on individuals and communities over time and strive to mitigate any negative effect.

OPPORTUNITIES AND CHALLENGES IN GENETIC DATA RE-USE:

The accumulation of genomics data in public repositories is rapidly expanding, driven by large consortia and individual laboratories that are generating vast datasets using both established and novel technologies. The surge in data generation has its roots in the Human Genome Project, launched in the era of systems biology and was followed by ambitious efforts to characterize non-coding regions, genetic variations across species, and differences between populations. The decreasing costs of genomic technologies have enabled smaller labs to contribute numerous high-throughput datasets, creating an enormous wealth of information available for research. These developments offer significant opportunities for advancing scientific understanding and improving public health. However, to capitalize on these opportunities, the scientific community must develop strategies to use these resources, ensuring that the data is accessible and useful for a wide range of research purposes. Despite the clear benefits of data sharing, there are substantial challenges need to be addressed. As technology evolves, the types of data generated also change, making it necessary to continuously redefine and adapt sharing mechanisms. Additionally, the process of sharing genomics data is well established, but other types of data, such as clinical data faces more significant obstacles due to their data sharing platforms. Furthermore, the ethical considerations surrounding data sharing, particularly in sensitive areas like paediatric researches. Balancing the protection of participant rights with the need for data sharing to generate health benefits requires careful consideration and innovative solutions, such as the proposed models of consent that aim to strike an appropriate balance [28].

GLOBAL PUBLIC PERCEPTION ON GENETIC RESEARCH DATA-REUSE:

Globally, public awareness and understanding of DNA, genetics, and genomics are generally low. Consequently, the willingness to donate DNA or health data for research purposes is also limited, and there is a significant lack of trust in the process of sharing this data with multiple users, such as doctors, researchers, and governments. Participants were most inclined to donate their DNA or health information when the recipient was a medical doctor, and least willing when the recipient was a for-profit researcher. Those who had a better understanding of genetics and trusted the entities requesting their data were more likely to agree to donate. However, fewer than half of the participants trusted more than one potential data user, with this level of trust varying by country. While genetic information was not universally perceived as distinct from other types of health information, those who viewed it as special were more willing to donate their data. The global insights from the "Your DNA, Your Say" study was crucial for shaping international policies and practices concerning the sharing of genomic data [31].

Trust, Legal, and Ethical Implications of Genetic Testing: The social, legal, and ethical implications of genetic testing are complex and far-reaching, affecting individuals, families, and society as a whole. Socially, genetic testing raises concerns about privacy, discrimination, and the psychological impact of knowing one's genetic risks. Individuals may face difficult decisions about sharing their genetic information with family members and may experience concerns or stress from test results that predict high-risk diseases. Additionally, there is the potential for social stigma, where individuals with certain genetic traits may be treated differently or unfairly.

Legally, genetic testing intersects with issues of confidentiality, informed consent, and the potential misuse of genetic information. However, there are ongoing debates about the adequacy of these protections, especially as genetic testing becomes more widespread. Ethically, the implications of genetic testing involve questions of autonomy, the right to know or not to know one's genetic information, and the potential for creating inequalities in access to testing and treatment [32]**.** Trust plays a significant role in influencing public opinions on genetics and their willingness to engage in genomics research and big data projects. Researchers working for companies were the least likely to be trusted [33].

ADVANTAGES AND DISADVANTAGES OF GENETIC RESEARCH REUSE

ADVANTAGES [34]

Accelerated Discoveries: Reusing genetic data allows researchers to build upon existing datasets, leading to faster discoveries in understanding genetic links to diseases, drug responses, and potential therapeutic targets. This acceleration can lead to quicker development of new treatments and personalized medicine.

Cost Efficiency: Reusing existing genetic data is more cost-effective than generating new datasets from scratch. It reduces the need for repeated sample collection and sequencing, making research more affordable and accessible.

Enhanced Data Power: Combining multiple datasets increases the statistical power of studies, allowing for conclusions that are more robust. Larger, pooled datasets can help identify rare genetic variants that may not be detectable in smaller studies.

Ethical and Resource Optimization: Reusing data aligns with ethical considerations by maximizing the use of biological samples, particularly in cases where obtaining new samples might be difficult or invasive.

DISADVANTAGES [35, 36]

Privacy and Consent Issues: Reusing genetic data can raise significant privacy concerns. Individuals may not have given explicit consent for their genetic data to be used in multiple studies, particularly if the new research objectives differ from the original intent.

Data Misinterpretation: Genetic data reuse can lead to misinterpretation if the context or quality of the original data is not fully understood. Different studies may have varying methods, populations, and purposes, which can complicate the analysis and lead to biased or incorrect conclusions.

Ethical Concerns: There may be ethical issues related to the ownership and control of genetic data. The original participants or data generators might not agree with the new uses of the data, leading to potential ethical dilemmas.

Lack of Diversity: Many genetic datasets lack diversity, particularly from underrepresented populations. Reusing these datasets could perpetuate existing biases and inequalities in genetic research, limiting the generalizability of findings.

1.2 JUSTIFICATION OF THE STUDY

Based on previous literature reviews and the current landscape of clinical trial regulations and guidelines, it is clear that incidents such as the thalidomide tragedy and Nazi trials led to the establishment of Good Clinical Practice (GCP) guidelines for human research. However, there remains an absence of universally recognized guidelines for conducting genetic research. This study aimed to assess and evaluate the Knowledge, Attitude, and Practices (KAP) of various clinical stakeholders regarding the reuse of genetic research data.

Lack of Standardized ICH Guidance on Genetic Research: Currently, there is no globally standardized guidance from the International Council for Harmonisation (ICH) specific to genetic research, creating inconsistencies in genetic sample collection and data management practices. These inconsistencies pose significant challenges for pharmaceutical sponsors and researchers, who must navigate varying national regulations and ethical considerations. Without clear guidance, researchers face ethical uncertainties, particularly around data security, participant privacy, and the potential for re-use of data. The lack of standardized guidelines in this area may also influence participant trust and data sharing between institutions, affecting the broader goal of advancing genetic research.

Consent Form Complexities: Informed consent is foundational in ethical research, and the integration of genetic research adds layers of complexity. As genetic research advances, there is an increasing need for specific "Genetic Consent" forms, which address the collection, storage, and future use of genetic samples. These consent forms must also clearly outline the purposes for which the genetic data may be used, including future research and potential sharing with third-party researchers. Given the

sensitive nature of genetic information, these forms must also address participants' right to privacy, data re-use, and data sharing transparency. However, creating these forms is challenging because they must balance providing participants with adequate information while ensuring comprehensibility.

Lack of Information Regarding the Return of Genetic Results: One of the ethical dilemmas in genetic research is whether to return individual results to participants or research institute, particularly in biomarker studies. Most genetic studies do not return individual results to participants, raising ethical concerns regarding transparency and participant rights. The absence of a clear policy on result sharing can lead to mistrust among participants, who may feel entitled to know the outcomes of the genetic tests performed on their samples. Furthermore, withholding results can impact future genetic studies, as potential participants may hesitate to consent to studies where they will not receive results. The ethical implications of returning results involve considerations of psychological impact, medical follow-up, and participant autonomy, underscoring the need for clear guidelines on who has the authority to decide on result-sharing—the clinical trial investigator, the research institution, or another governing body.

The present study KAP assessment results are expected to contribute to the development of standardized guidelines in future, addressing the identified ethical challenges and developed the genetic consent model to better align with ethical considerations in genetic research. Also, assessed who has authority to return the genetic results-Clinical trial investigator or the institute.

1.3 OBJECTIVES

The objectives focus on understanding the perspectives of various stakeholders involved in clinical trials regarding the re-use of genetic research data. The study aimed to explore and identify the ethical, legal, and practical considerations that influence stakeholders' attitude toward data re-use.

1.3.1. PRIMARY OBJECTIVES:

- To Assess the knowledge, attitude and practices of Clinical trial stakeholders on Genetic Data Sharing
- To Assess the ethical challenges in Genetic research data use for future research

1.3.2. SECONDARY OBJECTIVE:

- To develop a genetic consent model for a genetic research & its Data for Re-Use

2. REVIEW OF LITERATURE

The Review of Literature provides a comprehensive examination of existing research and scholarly work related to the study's focus. This section synthesizes previous findings, highlights gaps in the current knowledge, and establishes the theoretical framework guiding the research. By critically analysing relevant studies, the review places the present work within the broader academic context, demonstrating its contribution to the field.

2.1 Understanding Genetics-A New York, Mid-Atlantic Guide for Patients and Health Professionals. Washington (DC): Genetic Alliance were published the Understanding of genetic research book previewed that the human traits and diseases are influenced by genetics, whether through inherited factors or through behaviours like physical activity. Genetic elements can also affect how the body reacts to environmental influences, such as exposure to toxins. A solid understanding of human genetics, including the interactions between genes, behaviour, and the environment, is crucial for the effective collection and application of genetic and genomic data in clinical settings. This knowledge is also essential for enhancing the diagnosis and treatment of diseases. This chapter introduces key concepts in genetics, such as cell structure, the molecular and biochemical foundations of diseases, the main categories of genetic disorders, inheritance laws, and the effects of genetic variation [1].

2.2 Kadam R, Karandikar S et al. are investigated on the ethics committee and regulatory authorities roles and responsibilities. Over the past few years, there has been a significant increase in the number of clinical trials conducted in

India. This growth is often attributed to the country's large patient population, genetic diversity, and a robust pool of technical expertise. However, the economic expansion of the clinical trial industry has also raised concerns regarding the effectiveness of Regulatory Agencies and Ethics Committees (ECs). The ECs play a crucial role in overseeing clinical research at the local level, but it has been observed that many ECs are unaware of their roles and responsibilities. Reports indicate that some ECs lack of standard operating procedures, suffer from improper composition, and have inadequate representation, which hampers their ability to effectively regulate the clinical research. Furthermore, ECs often operate in isolation, functioning as independent entities with little to no communication with regulatory agencies or other Ethics committees. This situation underlevels the necessity for ECs to collaborate, share experiences, and refine their functions. There is also a pressing need to focus on capacity building, centralized registration of ECs, and the establishment of an oversight mechanism.[2-3]

2.3 Roberts, M.C.,et al., Conducted a research on precision medicine in public populations: Precision public health is an emerging field that brings together elements of precision medicine, like human genomics research, with public health frameworks to improve population health. Although there is considerable interest in using genomics to support precision public health, the field’s current and future potential is still largely underexplored. In this context, we present examples of promising opportunities and current applications of genomics within precision public health and suggest future directions across five key public health areas: biostatistics, environmental health, epidemiology, health policy and health services, and social and behavioural science. To advance the use of genomics in precision public

health, three main challenges need to be addressed: creating policies that support multi-level precision public health initiatives, enhancing data integration and methodology, and promoting health equity.

2.4 Laine et al., 2007, **Zarin 2011**., The Food and Drug Administration Modernization Act of 1997 required that clinical trials, whether federally or privately funded and conducted under Investigational New Drug applications (INDs), be registered on ClinicalTrials.gov. This mandate specifically targeted trials testing the efficacy of experimental drugs for patients with serious or life-threatening conditions. The International Committee of Medical Journal Editors reinforced the importance of trial registration by making it a requirement for publication consideration in 2004. Additionally, in 2003, the National Institutes of Health (NIH) issued a policy requiring that all investigator-initiated applications with direct costs exceeding $500,000 in any single year include a plan for data sharing (NIH, 2003). That same year, the Annals of Internal Medicine launched its Reproducible Research initiative, which required that all original articles include a statement indicating the authors' willingness to publicly share the study protocol, any amendments, the statistical code used to generate results, and the data set from which the results were derived [5-6]

2.5 Renegar G, Webster CJ et al., The study aimed to assess the discussion among international research stakeholders about the practice of returning individual genetic research results to study participants. As studies in pharmacogenomics and disease genetics become more widespread, there is an increasing accumulation of data on genetic associations related to drug response and disease susceptibility, which holds the potential to enhance healthcare. Currently, much of this data is considered exploratory—either non-

validated or hypothesis generating. However, there is a growing trend toward allowing research participants access to their personal genetic data if they wish. This shift has prompted researchers, sponsors, patient advocacy groups, ethics committees, and regulatory bodies to address the complex issue of whether, and how, individual results should share with study participants. The paper reviews notable international ethical and legal guidelines, as well as public policy stances in Europe and the United States. The authors present "Points-to-Consider" for returning results in drug development trials, drawing on their expertise and experience. These considerations include the clinical relevance of the data, the qualifications of laboratories, the processes for obtaining informed consent, the confidentiality of medical information, and the competence of those delivering results to participants. The discussion is framed within a benefit-to-risk assessment, aiming to balance the potential advantages and disadvantages for participants while ensuring the integrity and viability of genetic research studies [07].

2.6 **Das NK, Sil A et al., 2017** was conducted study on ethics in clinical research. Ethics are the moral values of human behaviour and the principles, which govern these values. The situation becomes challenging for a doctor when he assumes the role of researcher. The doctor-researcher has to serve both the roles and at times, the zeal of an investigator has the potential to cloud the morality of the physician inside. It is very important to realize that exploiting the faith of patients is an offence tantamount to a crime. Medical science is one discipline where the advancement of knowledge is hugely guided by research and humankind has benefitted from many experiments. However, benefit and risk are the two faces of the same coin. Various unethical human experiments made us realize that the whims of researchers need to be reined

and led to the evolution of the first guidelines for researcher, the Nuremberg code. Thereafter the Good Clinical Practice guidelines serve as the guiding doctrine of clinical research. The principles of ethics rest on the four pillars of autonomy, beneficence, justice, non-maleficence and recently two more pillars are added, which includes, confidentiality and honesty. Ethics committees serve as a guardian of these principles. The multidisciplinary Ethics Committee ensures a competent review of the ethical aspects of the project proposal submitted and does it free from any bias or external influence. Ethical review of clinical trial applications follows a decentralized process in India, and requires Ethics Committee approval for each trial site [09].

2.7 Delgado, I.S., Outterson, A., Ramesh, V. *et al*. explored the Genetic research involving collaborations between high-income and low-income countries raises significant ethical, legal, and social implications (ELSI). These issues can be both universal and context-specific. This study explores perceptions of genetic research in Nicaragua, Central America, where local and U.S.-based researchers have collaborated for over a decade. The research involved interviews with 43 residents from north western Nicaragua, a region grappling with high mortality rates due to chronic kidney disease of non-traditional causes (CKDnt)[10-13].

2.8 Panacer KS et al., study conducted on Direct-to-consumer genetic testing (DTC-GT) is rapidly becoming a lucrative industry, offering genetic testing kits directly to consumers. These companies often market themselves as a way for individuals to take control of their health, assess their risk for various diseases and conditions, and explore their ancestry. As the range of services provided by these companies expands, there is a concern that consumers may not fully understand the scope and limitations of the tests they are purchasing.

The testing methods used by DTC-GT companies have certain limitations that could potentially lead to harm, particularly if the results are misunderstood or misinterpreted. Additionally, the data collected through these tests could contribute to the formation or reinforcement of negative stereotypes about certain populations, potentially exacerbating existing biases and discrimination. The controversy surrounding the use of this data also raises questions about how many people will choose to engage with these services. This review seeks to provide a comprehensive overview of the services offered by DTC-GT companies, while also addressing critical ethical issues such as the quality of information provided privacy concerns, the potential for negative psychosocial effects, and the implications for clinical practice. Ethical Issues Associated With Direct-to-Consumer Genetic Testing[14-16]

2.9 Model framework for governance of genomic research and bio banking in Africa—a content description lead by the **Yakubu A, Tindana P, Matimba A, Littler K, Munung NS, Madden E, et al.** Genomic research and bio-banking are rapidly expanding worldwide, offering significant potential to accelerate advancements in disease treatment and prevention through collaborative efforts like the Human Heredity and Health in Africa (H3Africa) initiative. A crucial element of this research is ensuring the availability of samples and data, which in turn raises various ethical concerns. These concerns include issues of privacy and confidentiality, as well as the equitable access and capacity to utilize these resources, particularly between scientists from high-income and low-income countries. Promoting genomic research, especially in Africa, necessitates the establishment of a robust governance framework to address these ethical challenges. A Framework for Best Practice for Genomics Research and bio banking in Africa was developed under the

H3Africa initiative. This framework is designed to be adaptable and broadly applicable across African nations, allowing each country to tailor guidelines to their specific needs. The aim is to enhance the governance and conduct of genomic research in a manner that upholds ethical standards, ensuring that the benefits of such research are shared equitably while safeguarding the rights and interests of participants [17-19].

2.10 Assessing public and patient expectations and concerns regarding genomic data sharing is crucial for promoting effective data governance and engagement in rare disease genomics research. In a cross-sectional study conducted in Northern Portugal, the views of 159 rare disease patients, 478 informal carers, and 63 healthcare professionals were compared to understand their perspectives on the benefits and risks associated with genomic data sharing. The study revealed significant differences between the groups. The majority of patients (84.3%) and informal carers (87.4%) identified the discovery of cures for untreatable diseases as the most important benefit of data sharing, while healthcare professionals prioritized the development of new drugs and treatments (71.4%), a benefit that was also significant for carers (48.3%), particularly those with higher levels of education[21-23]

2.11 **Amorim M et al.,** When considering the risks, patients and carers were most concerned about the lack of security and control over information access (72.6% of patients and 60.0% of carers) and the potential for data to be used beyond the intended research objectives (50.3% of patients and 60.6% of carers). In contrast, healthcare professionals were primarily worried about genomic data being used to discriminate against citizens (68.3%), with concerns about data being used beyond research objectives following closely (54.0%). These concerns were particularly prevalent among more educated

carers, while those with blue-collar jobs or other occupations were less likely to express these worries. The study underlevels the need for tailored communication strategies and consent processes that align with the specific expectations and concerns of different participant groups, which is essential for fostering inclusive and patient-centred genomics research [30].

2.12 Thiese MS et al., The utility of biomedical research hinges on several critical factors, including appropriate study design, high-quality measurements, careful selection and application of statistical methods, and accurate interpretation of analytical results. Biostatistics serves as a crucial set of tools for evaluating relationships within biomedical research, playing an essential role in advancing scientific knowledge and understanding. However, the use of statistics is fraught with challenges. These issues have been a concern in the scientific community since the 1980s and remain relevant today. Common concerns include poor planning, ineffective communication, or a lack of understanding of the conceptual framework behind the statistical tools being used. Often, the root of these issues lies in inappropriate study design, which is a fundamental step in research and has been widely discussed in the literature. Problems with data collection and analysis often stem from flaws in study design and are frequently inadequately reported in scientific publications. Recently, new guidelines have been proposed to enhance the reporting of study methods and results, aiming to improve the quality of biomedical research and reduce instances of misconduct[20]

2.13 Chaouch, A., Ulph, F., Alder, J. *et al* This study aims was to explore strategies to better assist patients, their families, and healthcare providers in managing the complex issues related to consent within a busy general clinic setting, especially given the rapidly changing landscape of genetic testing. By

focusing on the fundamental ethical principles that underpin consent, the article seeks to highlight and address key challenges, while proposing practical solutions where applicable. Over the past few years, the field of genetic testing in the UK has experienced significant advancements, particularly with the implementation of whole genome sequencing (WGS) and the introduction of the NHS Genomic Test Directory in 2018. These developments have made WGS more widely accessible, increasing the chances of obtaining a genetic diagnosis, clarifying the reproductive implications of germline genetic variants, and, in some cases, guiding patient management. Furthermore, the adoption of hybrid consent forms, which cover both clinical and research aspects, may broaden opportunities for patients to engage in research studies and clinical trials[23-26]

2.14 Ahmed M and Kim Dr (2023) et al., Opportunities and challenges in re-using genomics data: the editorial explored the opportunities and challenges of reusing public genomics data, emplacing the need for data sharing in the scientific community. Genomics data is accumulating in public repositories at an increasing rate**.** The challenges of data sharing can be technical, economic, legal, or political, and mechanisms to facilitate data sharing are often specific to data types. Sharing clinical data is still in a nascent phase compared to genomics data, and there is a strong ethical imperative to protect data while balancing the need for the research and health benefits.

2.15 Ruth Horn et al., 2022. The study was focused on how collection, storage and sharing of genomic data may pose challenges to established principles and values such as trust, confidentiality, and privacy in countries that have implemented, or are about to implement, large-scale national genomic initiatives. The third parties partake as stakeholders, transparent consent

protocols relative to data access and use come centre stage, and patient benefits must clearly outweigh commercial interests. Any cross-border data transfer needs to be carefully managed to address incoherencies between regional, national, and supranational regulations and recommendations. Managing expectations, rights, and duties in large-scale genomics initiatives: a European comparison [23].

2.16 **McKeown A at al. 2021** research overview the new paradigm for carrying out health research. In the platform model, datasets are pooled for remote access and analysis, so novel insights for developing better stratified and/or personalised medicine approaches can be derived from their integration. Nevertheless, public legitimacy for the proposal is essential. Even though there should be a presumption of data reuse in research, given that live in a democracy, it is vital to secure assent to this new norm for optimising the benefits potentially derivable from it in future, given that, trust in the institutions responsible will be required to achieve them, and this may be difficult [47].

2.17 **Stephanie B. Johnson et al, (2020)** studied on rethinking the ethical principles of genomic medicine services. Clinical genome and exome sequencing is currently used in only a small fraction of patients, yet large scale genomic initiatives are becoming more embedded in clinical services. This paper examines the ethical principles that should guide regulatory processes regarding consent and data sharing in this context. We argue that a genomic dataset administered by the health system carries substantial societal benefits, and that the collective nature of this initiative means that at least those patients who benefit from genome sequencing have an ethical obligation to share their health information. The obligation is grounded in considerations of fairness.

Furthermore, that the use of genomic data for the advancement of medical knowledge should permitted without explicit consent and those international and other bodies should granted access to these data provided certain conditions should be satisfied.

2.18 Vidgen, M.E., Kaladharan, S., Malacova, E. *et al-2020*-sharing genomic data from clinical testing with researchers: public survey of expectations of clinical genomic data management in Queensland, Australia. Considerable investment and strategic planning have been dedicated to integrating genomic testing into Australia's public health system. As more patients' genomic data becomes stored in the public health system, researchers are increasingly seeking access to this valuable information. It is crucial that public policy aligns with public expectations regarding the utilization of genomic data generated from clinical tests. To contribute to the formulation of public policy and discussions on genomic data sharing, we gathered public opinions on the use of genomic data contained in medical records for research purposes in the Australian state of Queensland. Between February and May 2019, 1494 participants completed an online questionnaire. The majority expressed a desire to have the choice to permit the use of their genomic data from medical records in research. Their preferences on whether and how frequently they should be approached for permission depended on the identifiability of the data. Willingness to share data for research hinged on factors such as the type of information shared, the nature of the research, and the entity conducting the research. Participants were primarily concerned about genomic data sharing that could result in discrimination (e.g., insurance and employment), data being used for marketing, data security, or commercial use. While most participants were open to sharing genomic data from medical records with

researchers, they insisted that permission for use should be sought. However, existing policies in Queensland do not align with participant expectations, particularly concerning anonymous genomics data. Addressing this inconsistency may involve process changes, such as incorporating research consent into clinical consent or implementing general research data consent programs [44].

2.19 Polyxeni Vassilakopoulou et al,-2019 was conducted study on data sharing and re-use in clinical genetics. Starting more than 3 decades ago, different scientific communities within molecular biology used database management software and computer networks to create communal data repositories advancing collaborative genetic research. The research findings point to six different human-driven activities related to expanding, disambiguating, sanitizing and assessing the relevance, validity and combinability of data. We contribute to research within Health Informatics with a framework that foregrounds human-driven activities for data interoperability [48].

2.20 Tessa E. Pronk et al. 2019 respondents stated the benefits of sharing research data are time efficiency or increased productivity. The assumption is that reuse or secondary use of research data saves researchers time in not having to produce data for a publication themselves. this study investigated and estimated the theoretical break-even point in efficiency gain for the scientific community in preparing research data for sharing (implicating a time cost) and its consecutive reuse (implicating a time gain). The results exemplify that sharing research data may indeed cause an efficiency revenue for the scientific community. The scientific community with the lowest reuse needed to reach a break-even point is one that has few sharing researchers and low time investments for sharing and reuse [49].

2.21 Andrea Martani et al 2019 Frontier genetics-December-2019-Volume-10-arctile-1254 regulating the Secondary Use of Data for Research: Arguments against Genetic Exceptionalism. As accessing, collecting, and storing personal information become increasingly easier, the secondary use of data has the potential to make healthcare research more cost and time effective. The main of the study endorse genetic exceptionalism and grant genetic data an exceptional status with respect to secondary use requirements. First, although genetic data have particular features, also other non-genetic data can be extremely sensitive. Second, having different regulatory requirements depending on the nature of data hinders the creation of comprehensible consent forms. The empirical evidence about public preferences concerning data reuse suggests that exceptional protection for genetic data alone is not justified. This study concludes it is claimed that regulation concerning data reuse should treat genetic data as important, but not exceptional [50].

2.22 Haeusermann, Tobias et al.,-2018. This research presents findings from 13 semi structured in-depth interviews that qualitatively explore the experiences of individuals. The focus of the study was on understanding participants' perspectives on privacy. Interviewees revealed that the likelihood and extent of privacy concerns are influenced by factors such as gender, ethnicity, and sexual orientation, the stigma associated with specific clinical conditions, the presence of adequate legislation, and the characteristics of national healthcare systems. Some participants expressed the belief that individuals with higher socioeconomic status or better legal protection in their respective countries have a responsibility to share their genetic data. Contrary to the assumption that those who share genetic data publicly online might be indifferent to privacy risks, our study underlevels that these individuals possess a nuanced

understanding of the social, relational, and contextual dimensions of genetic privacy [51].

2.23 Lisa M. Federer et al. June 24, 2015- based on the survey done was a significant effort are underway within the biomedical research community to encourage sharing and reuse of research data in order to enhance research reproducibility and enable scientific discovery. Even within the scope of biomedical research, addressing the unique concerns of diverse research communities is important to encouraging researchers to share and reuse data. Efforts at promoting data sharing and reuse should be aimed at solving not only technological problems, but also addressing researchers' concerns about sharing their data [52].

2.24 Traore, K., Bull, S., Niare, A. et al. -2015- qualitative study of the views of MalariaGEN participants in Mali. Addressing ethical challenges in low-income settings during the acquisition of informed consent for participation in genomic research is crucial. Specific issues involve effectively communicating information about complex and unfamiliar research methods, navigating intricate infrastructure and data sharing requirements, and anticipating potential ramifications of future research involving samples and data. This research delves into the experiences of researchers and parents of participants in a genome-wide association study of malaria among children aged five and under in Mali. The goal is to glean insights that can contribute to optimal practices in recruiting participants for genomic research. Employing a qualitative rapid ethical assessment, this study conducted 55 semi-structured interviews with parents. The findings reveal varying understandings among participants' parents in the MalariaGEN study regarding the causes of malaria, the rationale behind collecting blood samples, the study's objectives, and the

information it aims to generate. Notably, conveying genomic aspects, such as the gene/environment interaction influencing susceptibility or resistance to severe malaria, posed considerable challenges in explanation and comprehension. This study identifies key areas for improvement in the design of consent processes for genomic research, necessitating careful ethical analysis. This involves determining the extent of information to provide on different aspects of the research and devising effective strategies to enhance understanding of genomic research [53].

2.25 Clifford S. duke and John h. Porter-2013 the Ethics of Data Sharing and Reuse in Biology: Recent increases in capabilities for gathering, storing, accessing, and sharing data are creating corresponding opportunities for scientists to use data generated by others in their own research. Although sharing data and crediting sources are among the most basic of scientific ethical principles, formal ethical guidelines for data reuse have not been articulated in the biological sciences community. The development of both greater demand and greater resources for public data sharing raises important ethical questions for data generators and for those who use data generated by others [54].

2.26 Bingjie Xue et al.2013 Opportunities and challenges in sharing and reusing genomic interval data- Major advances in genome sequencing technology have driven a dramatic increase in the production of epigenome data. Epigenomic data result from various experiments, such as chromatin immunoprecipitation, DNA methylation, and chromatin accessibility assays. There are many challenges to handling growing data resources across disciplines. Genomic interval data are a major resource for biological research, but the challenges

with sharing and reusing genomic interval data prevent the community from making the most of it [55]

2.27 Beatrice Godard et al., 2003 there was a significant increase in the collection and analysis of human DNA samples and associated data. This growing activity is strategically vital for advancing genetic research, improving clinical care, and developing future treatments. To maximize their potential, these collections should be well maintained and their utilization optimized. Human DNA, tissue, and cell collections, along with their corresponding databases, are frequently shared for scientific purposes. However, the legal and ethical status of these collections and databases is often ambiguous, and many institutions lack formal policies or agreements governing their use. Regulatory frameworks are still in their infancy in most European countries, creating a complex landscape of multiple actors and varying rules that are challenging to navigate. The guidelines for exchanging and sharing information and materials remain unclear. Additionally, the concept of returning benefits to research participants or their communities is a relatively new consideration in this field. Data storage and DNA banking for biomedical research: technical, social and ethical issues. [56]

2.28 Ohmann C, Banzi R, Canham S, et al-2017 This study addresses key challenges associated with the sharing of individual clinical trial data and presents a consensus document aimed at facilitating access to individual participant data. The approach taken was interdisciplinary and inclusive of diverse stakeholders. The study employed a consensus-building process among a multi stakeholder task force composed of experts from various fields, including researchers, patient advocates, methodologists, IT specialists, and representatives from funding bodies, infrastructure organizations, and

standards development entities. An independent facilitator guided the process, utilizing the nominal group technique. Over the course of a year, the consensus was developed through three workshops, supplemented by document exchanges and teleconferences within focused subgroups as necessary. This effort was part of the Horizon 2020-funded CORBEL project (Coordinated Research Infrastructures Building Enduring Life-science Services), coordinated by the European Clinical Research Infrastructure Network, with a focus on non-commercial trials from a predominantly European perspective. The results was achieved on 10 guiding principles and 50 specific recommendations that outline the essential components of any framework designed for clinical trial data sharing. The document addresses several key areas, including: promoting a culture of data sharing (e.g., academic incentives, funding), obtaining consent for data sharing, protecting trial participants (e.g., through de-identification), setting data standards, managing rights and access to data (e.g., data request and access models), data management and repositories, and ensuring data discoverability and proper metadata usage. The implementation of these recommendations will enhance data sharing and reuse among researchers, ensure that trial participants are well informed and their rights protected, and provide effective systems for data preparation, storage, and access. The next steps involve putting these recommendations into practice and integrating them with similar efforts from regions and academic fields [57].

2.29 Anna Middleton et al., an Understanding the role of genetic factors in health and disease heavily depends on analysing genomic data across diverse populations. For this process to succeed, public support for data sharing is crucial, as it hinges on people's willingness to donate their genomic and health

data for research, knowing it will be shared with others. However, studies on public perceptions of genomic data sharing have been limited to specific regions, making global comparisons difficult. This paper presents findings from an extensive public survey on attitude toward genomic data sharing, involving 36,268 participants across 22 countries and conducted in 15 languages. The survey reveals that global public awareness and understanding of DNA, genetics, and genomics are generally low. Consequently, the willingness to donate DNA and health data for research is relatively low, and trust in sharing this data with multiple users, such as doctors, researchers, and governments, is also limited. Participants were most willing to donate when the recipient was identified as a medical doctor and least willing when the recipient was a for-profit researcher. Those with a better understanding of genetics and higher trust in the data users were more inclined to donate. However, fewer than half of the participants trusted more than one potential data user, with trust levels varying by country. Although genetic information was not uniformly seen as distinct from other health data, participants who viewed it as special were more likely to donate. The global insights from the "Your DNA, Your Say" study are critical for shaping international policies and practices related to genomic data sharing. The findings emphasize the need for the research community to earn and maintain public trust and underscore the importance of effectively communicating the necessity of genomic research and the role of data donation and sharing in advancing this field. [31].

2.30 Vaught J, Kelly A et al., Biobanks and bio banking networks play crucial roles in the collection, processing, storage, and dissemination of biological specimens for research purposes. This review examines the strategies employed by 16 major biobanks and bio banking networks across Europe,

North America, Australia, and Asia, highlighting their approaches to specimen collection and distribution, scientific initiative management, and financial sustainability. Biobanks range from small operations, often limited to a few freezers in a research or clinical laboratory, to larger academic and commercial biobanks that support extensive clinical and epidemiological studies. The operational and business models of these biobanks are shaped by the medical and research missions of their respective institutions and countries. Some national biobanks operate centralized facilities that collect samples from multiple locations, while others follow a federated model, where individual institutions maintain their collections but contribute to a shared central database. Collections may be "project-driven," aimed at addressing specific research questions, or "general," created to serve as a reference resource for a broad range of research needs. These biobanking systems, whether individual or networked, typically operate under business models that include partial cost recovery, often supplemented by public or government funding. They all adhere to strict biospecimen-access policies, which outline the ethical and technical criteria researchers must meet to obtain samples. The success of these bio-banking models relies on several factors, including clearly defined goals, robust business plans, and stringent quality and operational controls in specimen collection and management [27].

2.31 Amorim M,et al., Understanding and addressing public and patient expectations and concerns about genomic data sharing is crucial for fostering effective data governance and engagement, particularly in the context of rare disease genomics research. This cross-sectional study conducted in Northern Portugal examines and compares the perspectives of 159 rare disease patients, 478 informal carers, and 63 healthcare professionals regarding the perceived

benefits and risks of sharing genomic data for research purposes, along with the factors influencing these views. The study reveals notable differences among the three groups. A significant majority of patients (84.3%) and informal carers (87.4%) prioritized the discovery of cures for untreatable diseases as the primary benefit of genomic data sharing. In contrast, healthcare professionals predominantly valued the development of new drugs and treatments (71.4%), a benefit that was also the second most selected by carers (48.3%), particularly those with higher levels of education (OR (95% CI): 1.58 (1.07–2.34)). Regarding risks, patients and carers were most concerned about the lack of security and control over information access (72.6% and 60.0%, respectively) and the extraction of information beyond the intended research objectives (50.3% and 60.6%, respectively). Healthcare professionals, on the other hand, were primarily worried about the potential for genomic data to be used in discriminatory ways (68.3%), followed by concerns about data being used beyond its original research scope (54.0%). These concerns were particularly prevalent among more educated carers (OR (95% CI): 1.60 (1.06–2.41)) and less so among those in blue-collar or other occupations (OR (95% CI): 0.44 (0.25–0.77) and 0.44 (0.26–0.74), respectively). The findings suggest that tailoring communication strategies and consent processes to the specific expectations and concerns of different participant groups could enhance the inclusiveness and patient-centeredness of genomics research [30].

2.32 Milne R et al., Trust plays a crucial role in shaping public attitude toward genetics and influencing intentions to engage in genomics research and big data initiatives. To explore this, we investigated trust in data sharing among diverse populations. We conducted a cross-sectional online survey with a representative sample from the USA, Canada, the UK, and Australia (n =

8,967). The findings revealed that participants exhibited the highest trust in their medical doctors, while trust was significantly lower for other entities, with company researchers being the least trusted. Using latent class analysis, we identified three trust categories: Low, Variable, and High Trust. Individuals in the High Trust category were predominantly younger than 50, male, parents, religious were, had personal experience with genetics, and were from the USA. This group showed the greatest willingness to donate their genomic and health data for clinical and research purposes. Conversely, the Low trust group expressed greater scepticism about legal protections against the misuse of donated data. The study examines variations in trust, its impact on concerns regarding genomic data usage, and the potential influence of legislation. These insights are important for advancing genomic medicine and promoting data sharing beyond individuals with personal genetic experiences or research participants [33]

3. MATERIALS AND METHOD

The Methodology in research outlines the systematic approach taken to conduct the study, ensuring rigor and reproducibility. It describes the research design, data collection methods, and tools used to gather and analyse information. This section also includes the selection criteria for participants, settings, and any ethical considerations.

3.1 STUDY SITE DETAILS: The present research was conducted in the KLE Clinical research department, located at KLES-Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi, Karnataka, India (590010). This research centre is known for its state-of-the-art medical or clinical trial facilities and its involvement in a wide range of clinical trials. It served as the primary location for recruiting participants and gathering data from key stakeholders involved in clinical research**.**

3.2 STUDY PARTICIPANTS: The study involved a diverse group of stakeholders actively engaged in clinical trials at the research site, including:

a) **Pharmaceutical Sponsors and Representatives:** Organizations or individuals funding the clinical trials. These stakeholders are invested in the research outcomes and provide financial and logistical support for the trials.

b) **Human Ethics Committee Members:** Individuals responsible for overseeing and ensuring the ethical integrity of the research process. They review and approve protocols, ensuring compliance with ethical guidelines and protecting the rights of trial participants.

c) **Clinical Trial Investigators:** Researchers and medical professionals conducting clinical trials. These individuals are responsible for managing the

research, interacting with participants, and ensuring that trials are conducted according to established protocols.

d) **Clinical Trial Participants:** Individuals who are enrolled in clinical trials as subjects. They provide data through their participation, contributing to the study's objectives while receiving medical interventions under investigation.

e) **Pathologists:** Medical professionals involved in analysing bio-specimens collected during the routine practices. Their role is essential for diagnosing and understanding the biological aspects related to the research.

3.3 STUDY DESIGN: This study is a cross-sectional observational study[Useful for identifying associations that can be explored further in longitudinal or experimental studies], designed to assess the attitude, practices, and perspectives of various stakeholders involved in clinical trials at the study site and research organizations or pharmaceutical companies. The cross-sectional design allows for the collection of data at a specific point in time to observe the current KAP status of the clinical trials stakeholders. This method is particularly useful for gaining an exposure of how different groups involved in clinical trials perceive and engage with genetic research and data re-use for future perspectives.

The sample size was determined using a statistical formula, with a 95% confidence interval and a 15% allowable error. The margin of error represents the level of precision expected in the study's results, indicating that the true population values are within 15% of the measured values. To accommodate potential attrition (i.e., participants dropping out or not responding), an additional 15% was added to the calculated sample size. This ensures that the study maintains sufficient statistical power, even in the case of non-response or dropout.

The formula used for calculating the sample size involves several key variables:

- **n** represents the required sample size.
- **Z** is the standard normal value, corresponding to the desired confidence level (for a 95% confidence interval, Z = 1.96).
- **SD** represents the standard deviation of the population, which accounts for the variability of the population's responses.
- Original Sample Size Calculation: $n = (EZ1 - \alpha/2 \cdot SD)2$

Where:

- $Z_{1-}\alpha/2$: Standard normal value (1.96 for 95% confidence interval).
- SD: Standard deviation.
- E: Allowable error (15% of the standard deviation).

- Adjustment for Allowable Error:

E=015 ✕ SD

So, substituting E in the formula:

n= (0.15·SD/1.96·SD) 2

Simplified to $n=(0.151.96)2$

- Adjusting for Attrition: Given a 15% attrition rate was multiply the calculated sample size by 1/0.151=1.176.

Final Sample calculation: $n=(0.151.96)2\times1.176$

$0.151.96)2\approx171.11$

Adjusting for attribution: $n=171.11\times1.176\approx201.35$

Original Sample Size Calculation: 171.11

Attrition Adjustment: To achieve a 95% confidence interval with a 15% allowable error and accounting for a 15% attrition rate was sample size of approximately 201.

N=201 samples were selected in order to obtain a feasible clinical trial stakeholders that aligns with the present research requirements. The involvement of clinical trials stakeholders and implementation significant attention in terms of sample size. During IV-PhD report presentation, committee members suggested to include the Pathologist in the present research. The total clinical trial stakeholders were enrolled n=225.

3.4 STUDY CRITERIAS:

INCLUSION CRITERIAS:

a) Pharmaceutical sponsors and their representatives

b) The clinical trial investigators who are involved in the Clinical trial with a minimum of 02 years of experience

c) Human Ethics Committee members of Northern Karnataka region [Registered with the CDSCO, New Delhi]

d) Selected Clinical trial participants

e) Pathologist

EXCLUSION CRITERIA:

a) Declined interest to provide written informed consent

3.5 STUDY PROCEDURE: The study began after the ethics committee clearance from the Human Ethics committee for PhD dissertation-KLE Academy of Higher Education and Research, Belagavi-590010 letter refferance no: KAHER/EC/21-22 dated 29.06.2021 and clinical trial registry India

CTRI/2011/11/032811 registered on 23.11.2021 with the selection or identification of clinical trial stakeholders, ensuring that all key participants relevant to the research. Once identified, the informed consent process was carried out that all stakeholders fully understood their role and the research objectives, a set of criteria applied to assess the eligibility using specific inclusion criteria's such as their roles, experience, and regional or organizational affiliations. Clinical trial stakeholders who either declined to participate or did not meet these criteria were excluded after eligibility was determined, demographics of the selected stakeholders were collected and the participants formally enrolled in the present research. The next step involved distributing validated Knowledge, Attitude, and Practices (KAP) questionnaires to gather data on the stakeholders' perspectives on genetic research and clinical trials. Once all the questionnaires were completed, the data were explored the stakeholders' knowledge, attitude, and practices on genetic research data re-use

The important phase of the study involved a thorough evaluation of the KAP questionnaires to understand the stakeholders' viewpoints on genetic research. In addition, ethical challenges raised by the participants were identified and examined. Based on the research findings, the study developed a model for genetic consent aimed at addressing these ethical concerns and ensuring that genetic data could be ethically reused in future research. The study spanned a total of four years from 1.08.2020 to 31.07.2024, which included one year dedicated to regular program classes, 2.5 years for data collection, and the remaining five months allocated for data analysis and thesis writing.

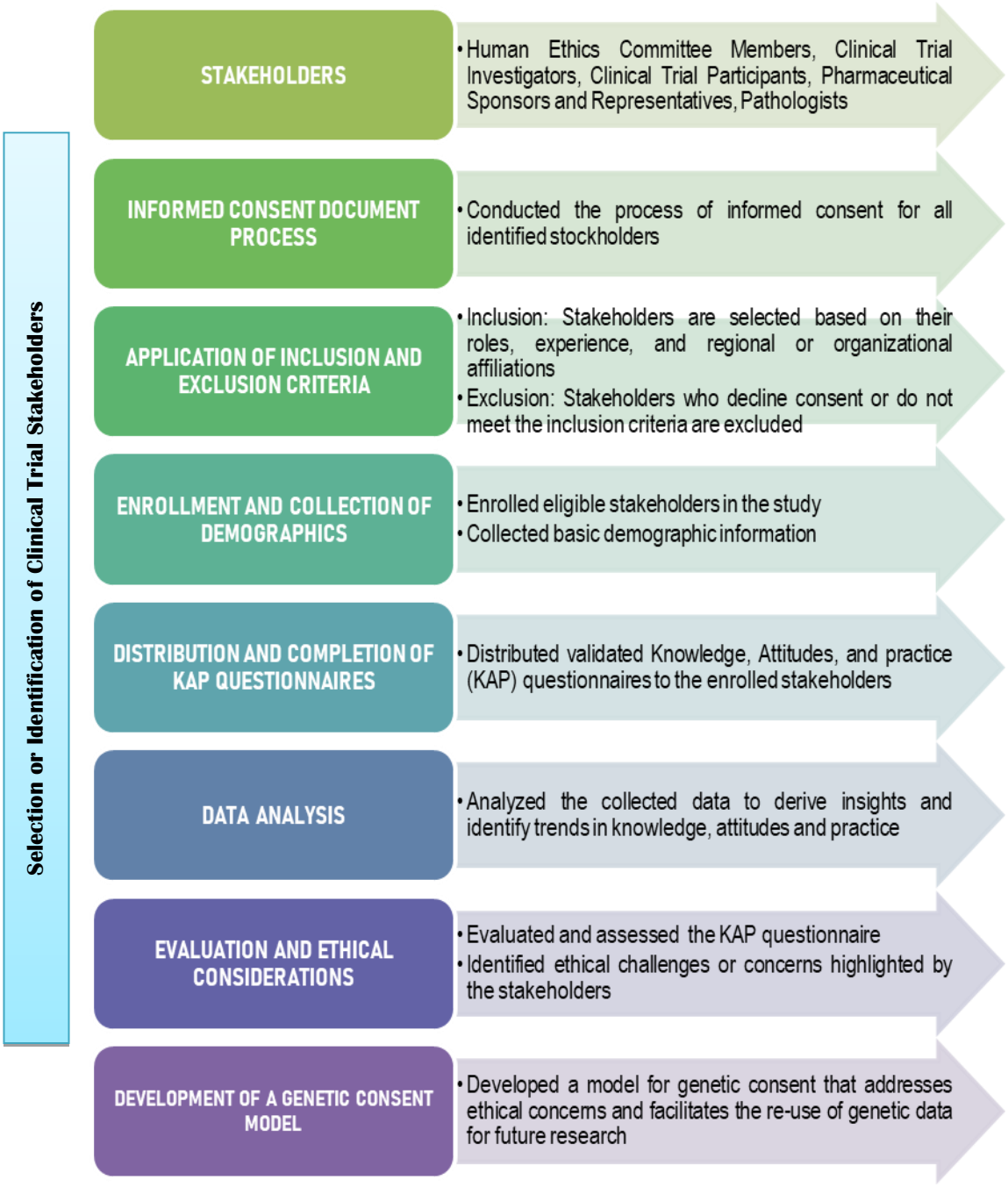


FIGURE: 03-STUDY PROCESS

3.6 VALIDATION OF KAP QUESTIONNAIRES': The validation process of the KAP (Knowledge, Attitude, and Practices) questionnaires began with the design and development phase, which included a thorough literature review. This review was conducted to understand the existing frameworks and guidelines related to genetic research data re-use. Based on this research, a set of questions

was developed to accurately capture participants' knowledge, attitude, and practices regarding the re-use of genetic data for future studies. 30 KAP Validation responses were collected from the different clinical trials stakeholders i.e. 06 responses from each groups

A pilot test was conducted using a small sample of participants. The purpose of test was to identify any potential issues with the questionnaire and to gather feedback from the selected clinical trials stakeholders. The pilot test ensured that the questionnaire was understandable and capable of collecting the necessary data effectively.

The next step was a validity assessment, ensuring that the KAP questionnaire comprehensively covered all aspects of the topic. This involved confirming that the questions accurately measured the theoretical constructs related to knowledge, attitude, and practices in the context of genetic research data re-use. Lastly, the questionnaire underwent reliability testing, where Cronbach's alpha, a statistical method was used to assess the internal consistency of responses. This step ensured that the clinical trials stakeholders responded consistently across similar questions, establishing the reliability of the KAP questionnaire.

K	30
k-1	29
k/k-1	1.03
item var/total var	0.30
1-item/total	0.70
Alpha	**0.73**
Cronbach's Alpha interpretation:	
< 0.9	Excellent
< 0.8	Good
< 0.7	**Acceptable**
< 0.6	Questionable
< 0.5	Poor

TABLE-: 04 CRONBACH'S ALPHA CALCULATION

- **k**: Number of items in the questionnaire (30 items).
- **k-1**: One less than the number of items (29 items).
- **k/k-1**: Ratio of the number of items to one less than the number of items (30/29 = 1.03).
- Item var/total var: Proportion of the variance of a single item to the total variance (0.30).
- 1-item/total: The complement of the item variance ratio (1 - 0.30 = 0.70).

Cronbach's Alpha Calculation: The Cronbach's alpha value of 0.73 suggests that the questionnaire exhibits an acceptable level of internal consistency. The items within the questionnaire are sufficiently correlated, indicating that they measure the same underlying construct or concept. An alpha value between 0.7 and 0.8 is typically considered acceptable for social sciences research, implying that the questionnaire is reliable in terms of consistency across different items.

The k/k-1 ratio of 1.03 reflects an adjustment based on the number of items in the questionnaire, which is a part of the formula used to calculate Cronbach's alpha. The item variance to total variance ratio (0.30) reveals that 30% of the variance in the responses is attributable to differences in individual items. Additionally, the 1-item/total ratio of 0.70 shows that 70% of the total variance is not due to individual item variances but is shared among the items, reinforcing the idea that the items work well together in measuring the same concept.

Formula for Cronbach's Alpha:

$$\alpha = \frac{N \cdot \bar{c}}{\bar{v} + (N-1) \cdot \bar{c}}$$

Where:

- **NN**: The number of items in the scale.
- **c¯\overline{c}**: The average covariance between item pairs.
- **v¯\overline{v}**: The average variance of individual items.

Alternatively, using the sum of item variances and the total scale variance, it can be expressed as:

$$\alpha = \frac{N}{N-1}\left(1 - \frac{\sum_{i=1}^{N} \sigma_i^2}{\sigma_T^2}\right)$$

Where:

- **∑σi2\sum \sigma^2_i**: The sum of the variances of all individual items.
- **σT2\sigma^2_T**: The variance of the total score (sum of all items).

3.7 INFORMED CONSENT PROCESS: The informed consent form, which is a legal document included ICH-required elements (ICH-GCP-section 4.8. 10) includes the purpose, duration, risks, benefits, costs and a description of the trial procedures and volunteers' rights.

3.8 DATA COLLECTION: Date collected through data collection form with validated questionnaires includes, demographics, knowledge attitude practices questionnaires.

3.9 STUDY MATERIALS:

- Validated Knowledge, attitude and practices Questionnaires [Perception applied only for clinical trial participants)

  Annexure: E Knowledge attitude and Practices Questionaries' to explore the clinical trial stakeholders towards Genetic Research data re-uses

- Informed consent forms with all vernacular languages

  Ref:Annexure: D Informed consent documents with all the vernacular languages

- Data Collection tools

  Ref:Annexure: E Knowledge attitude and Practices Questionaries' to explore the clinical trial stakeholders towards Genetic Research data re-uses

- Administrative approvals

  Ref:Annexure:C Permission Letter [Ethics committee clearance & Admission letter]

3.10 STUDY OUTCOMES:

- **Primary Outcomes:**
  - Evaluated the knowledge, attitude and practices of Clinical Trial Stakeholders on Genetic Data Sharing
  - Listed the ethical challenges in Genetic research data use for future research
- **Secondary Outcomes:**
  - Developed the genetic consent model for genetic research & its Data for Re-Use

4. RESULTS

The results section of the present research provides a detailed overview of the demographics, knowledge, attitude, and practices of all the stakeholders involved in clinical trials (Pharmaceutical sponsor/CROs, Clinical trial investigators, Human ethics committee members, clinical trial participants and Pathologist) have extended a comprehensive understanding of their perspectives on sharing genetic samples/bio-specimens and their data re-use.

1. **Pharmaceutical sponsors and contract research organizations (CROs) (n=50):** Consists of representatives from both national and international pharmaceutical sponsors and contract research organizations (CROs), key stakeholders in the clinical research operations and drug development process.

2. **Clinical trial investigators (n=50**): Comprises clinical research professionals from the KLE Clinical Research Department of Dr. Prabhakar Kore Hospital and Medical Research Centre in Belagavi, as well as staff from other research institutions in the Belagavi region.

3. **Clinical trial participants (n=50):** Participants were recruited from the KLE Clinical Research Department, encompassing individuals who either have previously participated in clinical trials or are actively involved in the clinical trial process.

4. **Human ethics committee members (n=50):** This group comprises members affiliated with ethics committees from the Northern Karnataka region, approved by the Central Drugs Standard Control Organization (CDSCO) in

New Delhi. These members are instrumental in ensuring that clinical trials comply with ethical standards and regulations, providing valuable insights into the ethical oversight and considerations to clinical research.

5. **Pathologists (n=25):** Pathologists from various research institutes across Belagavi are also included in the study. Their expertise is critical in the analysis and interpretation of clinical trial data, providing valuable information on the pathology aspects of the research.

The present study aimed to explore the perceptions of above clinical trial stakeholders regarding the re-use of genetic research data for future research. This research is critical as it addresses the growing need for transparency and ethical considerations in genetic research, particularly in how data is shared and re-used in future research. The clinical trial stakeholders in this study were invited to complete a validated Knowledge, Attitude, and Practices (KAP) questionnaire. Responses were collected both in person at KLE Hospital from research staff and stakeholders, and online via Google Forms from other groups, including pharmaceutical sponsors, contract research organizations (CROs), and ethics committee members. From the collected data, the researchers identified the KAP levels from the different stakeholders and highlighted the ethical issues surrounding the re-use of genetic research data. Understanding these persepectives is crucial in guiding future policies and practices in genetic research and ensuring that data re-use aligns with ethical standards and stakeholders' expectations.

In this study, the Chi-Square test was utilized to assess the significance of the selected clinical trial stakeholders' understanding, knowledge, and practices concerning genetic research data re-use. This statistical tool helped to determine whether there

were meaningful differences in knowledge, attitude and practices among the stakeholders, offering insights into potential gaps or strengths in their understanding. Additionally, applied One-Way ANOVA to analyse the KAP levels across different the demographic variables, providing a more nuanced view of how various factors, such as age, education, or professional background, might influence stakeholders' perceptions and practices.

The attitude of the stakeholders was assessed using the Mantel-Haenszel Chi-Square test, focusing on trends rather than simple associations. By examining trends, the study could identify patterns in stakeholders' attitude towards genetic research data re-use, offering a broader understanding of how these attitude may evolve over time or under different circumstances. This approach provided valuable insights into the factors driving stakeholders' support or concerns regarding data re-use, which could inform future educational and policy initiatives.

Data analysis was performed using SPSS software (version 21) and MSO-PP-Excel-2016, with categorical variables presented as frequencies and continuous variables as Mean ± SD or Median (Min, Max). The study set a statistical significance threshold with a p-value of less than 0.05, indicating that the findings were strong and reliable. This conscientious statistical approach ensured that the present study conclusions based on solid evidence, contributing to the broader understanding of clinical trial stakeholders' perceptions of genetic research data re-use and the ethical implications of these practices.

In addition to demographic characteristics, the present study applied a Knowledge, Attitude, and Practices (KAP) questionnaire to assess the stakeholders' understanding related to the re-use of genetic research data. The process of validation included with

the use of Cronbach's Alpha Calculation [**Table-04**], a statistical tool used to measure the internal consistency or reliability of the questionnaire. The resulting score of 0.73 indicates an acceptable level of internal consistency. The KAP (Knowledge, Attitude, and Practice) questions showed a strong correlation and reliably measured the intended constructs among clinical trial stakeholders.

The KAP questionnaire played a crucial role in gathering comprehensive data on stakeholders' knowledge, attitude, and practices concerning genetic data re-use. Knowledge questions explored stakeholders' understanding of genetic research, data sharing, and ethical considerations. Attitude questions have assessed opinions about these practices, while practice questions examined how the stakeholders actually engaged with or applied these concepts in their professional activities. The data collected through this questionnaire provided valuable insights into the current state of knowledge, attitude and ethical practice among various clinical research stakeholders.

The reliability of the KAP questionnaire, as indicated by the Cronbach's Alpha score, ensured that the study's findings are based on consistent and trustworthy data. By validating the questionnaire and achieving a solid internal consistency score, the researchers ensured that the responses accurately reflected the stakeholders' true knowledge, attitude, and practices, making the study a valuable resource for informing future policies and educational initiatives in the realm of genetic research and clinical

TABLE: 05- DEMOGRAPHICS OF CLINICAL TRIAL STAKEHOLDERS

	Clinical trial Investigators	Clinical trial Participants	Pharmaceutical Sponsor / CROs	Human Ethics committee members	Pathologist	P value
	n=50	n=50	n=50	n=50	n=25	
AGE RANGE						
20-29	0	18	29	2	0	**<0.001***
30-39	10	10	17	12	7	
40-49	31	10	4	29	10	
50-59	6	7	0	3	8	
60-69	3	3	0	4	0	
70-79	0	2	0	0	0	
80-100	0	0	0	0	0	
	44.46 ± 7.34	36.22 ± 13.41	30.06 ± 5.21	43.16 ± 8.41	44.72 ± 8.12	
GENDER						
Male	40 (80)	25 (50)	39 (78)	26 (52)	17 (68)	0.002
Female	10 (20)	25 (50)	11 (22)	24 (48)	8 (32)	
MARITAL STATUS						
Married	50 (100)	31 (62)	20 (40)	48 (96)	23 (92)	**<0.001***
Unmarried	0	19 (38)	30 (60)	2 (4)	2 (8)	

4.1. DEMOGRAPHICS OF CLINICAL TRIAL STAKEHOLDERS:

The present study involves a diverse group of stakeholders from the clinical trials operations and review process. **Table-05** categorizes n=225 stakeholders into distinct groups: clinical trial investigators, clinical trial participants, Pharmaceutical sponsors or contract research organization (CRO), Human ethics committee members, and pathologists. Each group of stakeholders comprises 50 participants except for the pathologists group, which includes 25 members. This distribution ensured a comprehensive representation of the various population involved in clinical trials, allowing the research to capture a broad spectrum of perspectives on sharing & re-use of genetic research data for future research.

In terms of age, the present study found significant differences across all the clinical trial stakeholder groups. Clinical trial investigators had a mean age of 44.46 ± 7.34 years, while Clinical trial participants were younger, with a mean age of 36.22 ± 13.41 years might be due to most of the clinical trail participant from the skin department. The Pharmaceutical sponsors or CRO representatives were the youngest group, with a mean age of 30.06 ± 5.21 years. Human ethics committee members and Pathologists had mean ages of 43.16 ± 8.41 years and 44.72 ± 8.12 years, respectively. The present research analysis revealed a statistically significant difference in age among these groups, with a p-value of less than 0.001, indicating that age could be a contributing factor to the varying perceptions and attitude towards genetic data re-use. The present study gender distribution was another critical characteristic analysed. The data revealed the significant differences in the gender distribution across the stakeholder groups, with a p-value of 0.002.

The present study detailed analysis of stakeholder characteristics, including age and gender, provides valuable insights into the factors that may influence the perceptions and practices related to the re-use of genetic research data. By examining these demographic variables, the present research highlights the importance of considering the diverse backgrounds and experiences of stakeholders in shaping ethical policies and practices in clinical research.

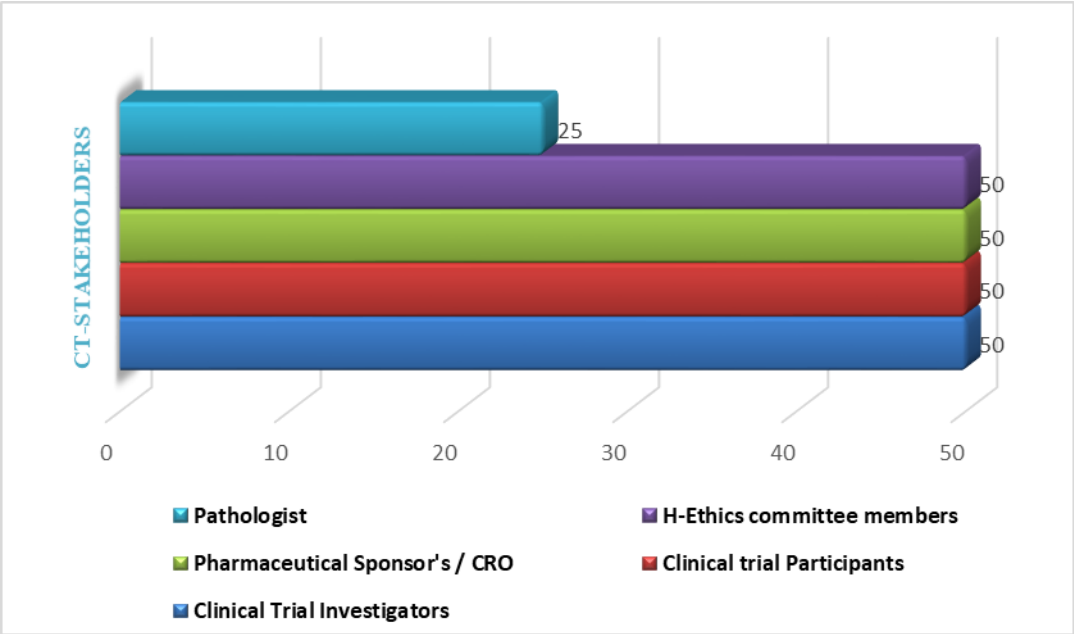


FIGURE NO: 04- CATEGORIES OF CLINICAL TRIAL STAKEHOLDERS

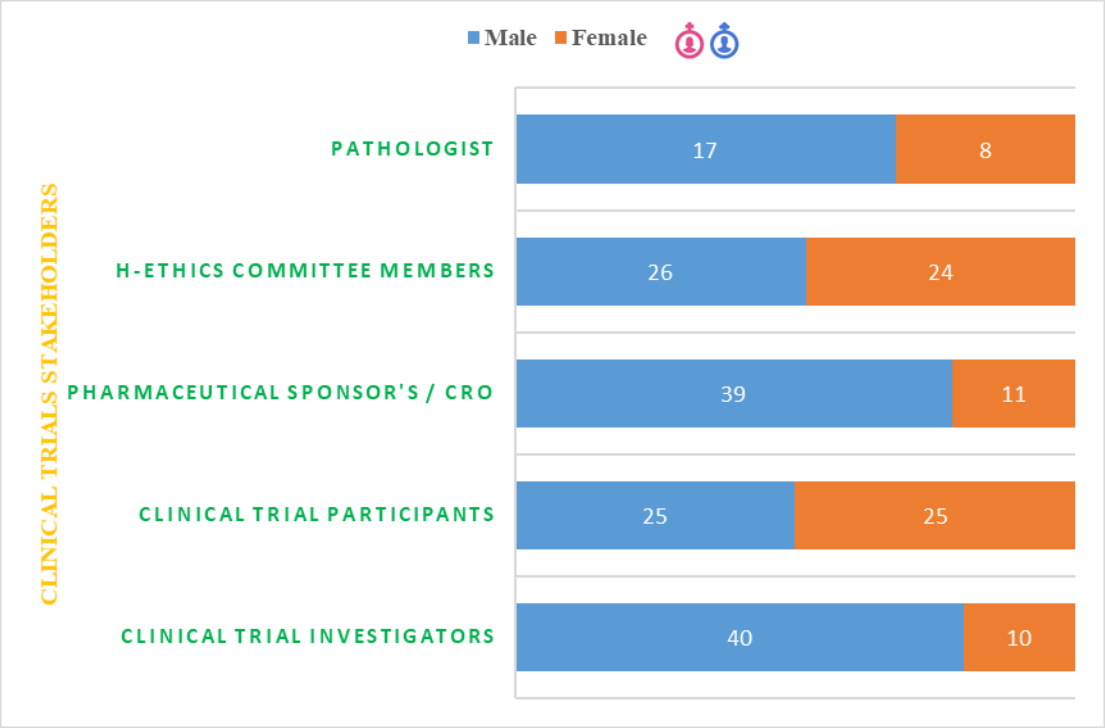


FIGURE NO: 05- GENDER WISE GRAPHICAL PRESENTATION OF CLINICAL TRIAL STAKEHOLDER

CLINICAL TRIAL INVESTIGATORS: The clinical trial investigators group in the study is characterized by a mean age of 44.46 years, with the youngest investigator being 34 years old and the oldest 51 years old. This range in the diversity in experience and career stages among the clinical trial investigators, shows substantial proportion likely being mid-career professionals. The age distribution which could influence their approach to clinical trial management and ethical considerations, particularly in relation to the re-use of genetic research data-**Table-05.**

The average experience of the clinical trials investigators in this group is 8.33 years, indicating that most have substantial experience in conducting clinical trials and met the study inclusion criteria's which was set to minimum of two years of experience. This level of experience suggests that the investigators are well versed in the complexities of trial management, patient recruitment, data collection, and adherence

to regulatory standards. Their extensive experience likely contributes to a deep understanding of the ethical and practical challenges associated with genetic data re-use, making them critical voices in shaping guidelines and practices in the research and development. However, their views may also be influenced by entrenched practices or institutional norms that have developed over their careers.

Most of the clinical trial investigators hold postgraduate degrees, with 80% (n=40) having advanced education, predominantly from the Department of General Medicine. The high level of education, coupled with specialized training in general medicine, positions them as experts in their field, capable of making informed decisions about the ethical use of genetic data.

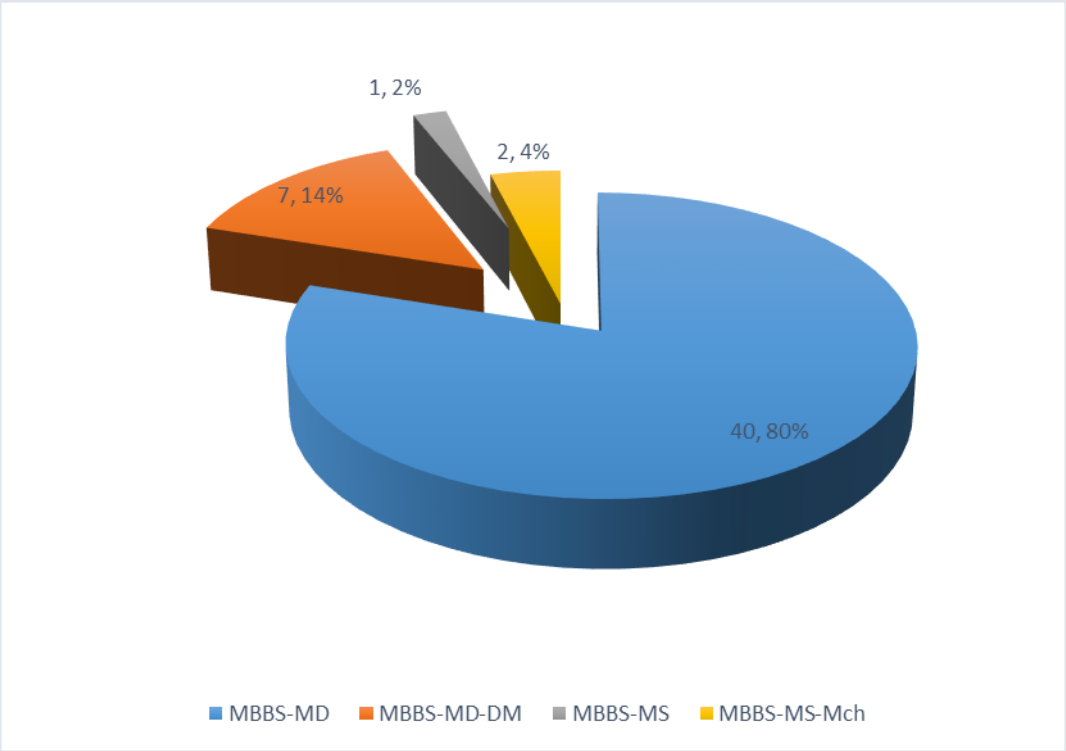


FIGURE NO: 06 EDUCATIONAL BACKGROUND OF CLINICAL TRIAL INVESTIGATORS

CLINICAL TRIAL PARTICIPANTS: The clinical trial participants involved in the present study represent a diverse group, with an average age of 36.22 years and a standard deviation of 13.41 years. This indicates a wide range of ages among participants, from younger adults to those in the middle age, reflecting a broad demographic data that can provide varied perspectives on the ethical considerations and personal implications of participating in clinical research. The age diversity is crucial as it allows the study to capture insights from individuals at different life stages, each with potentially different health concerns, risk perceptions, and motivations for participating in clinical trials. The present study involved the most of them from the department of dermatology.

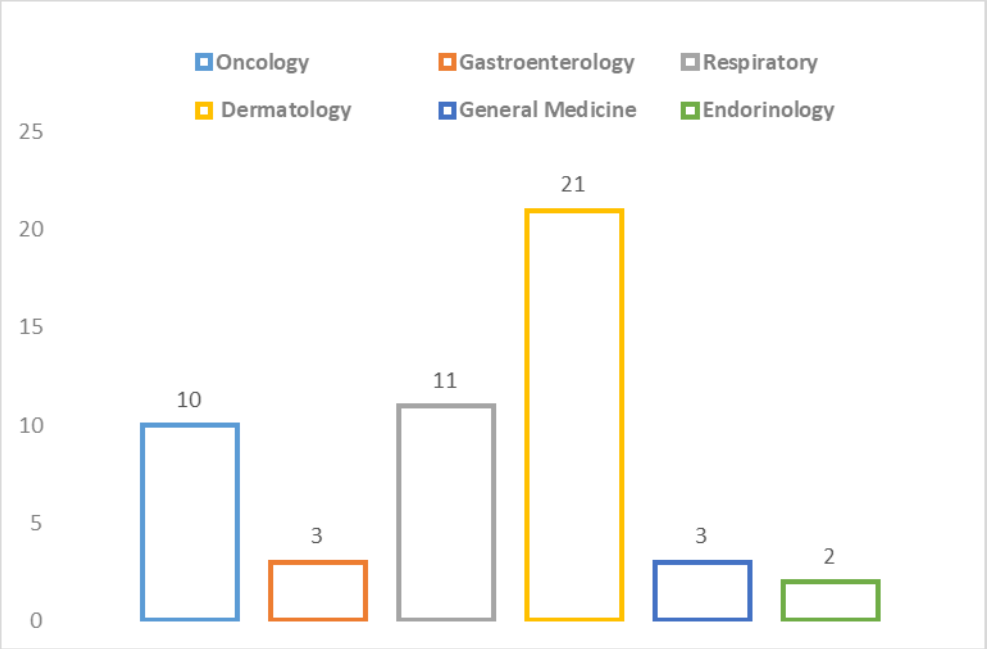


FIGURE NO: 07-CLINICAL TRIAL PARTICIPANTS FROM THE DEPARTMENTS

Regarding marital status, the majority of clinical trial participants are married (62%), with the remaining 38% being unmarried. Marital status can influence participants' views on clinical trials and genetic data re-use. Married participants might also be

more cautious about consenting to the use of their genetic data, considering potential long-term implications for their family members. Unmarried participants may approach clinical trials with different priorities, possibly viewing the trials as opportunities for personal benefit or contribution to scientific knowledge.

The present study also highlights the importance of obtaining informed consent from participants, with consent forms provided in multiple vernacular languages—English (n=19), Kannada (n=12), Hindi (n=8), and Marathi (n=11) **Figure No: 08**. This approach ensured that participants fully understand the trial's nature, risks, and benefits, which is crucial for ethical research practices. The use of vernacular languages helps to overcome language barriers, making the consent process more inclusive and ensuring that participants from diverse linguistic backgrounds are adequately informed.

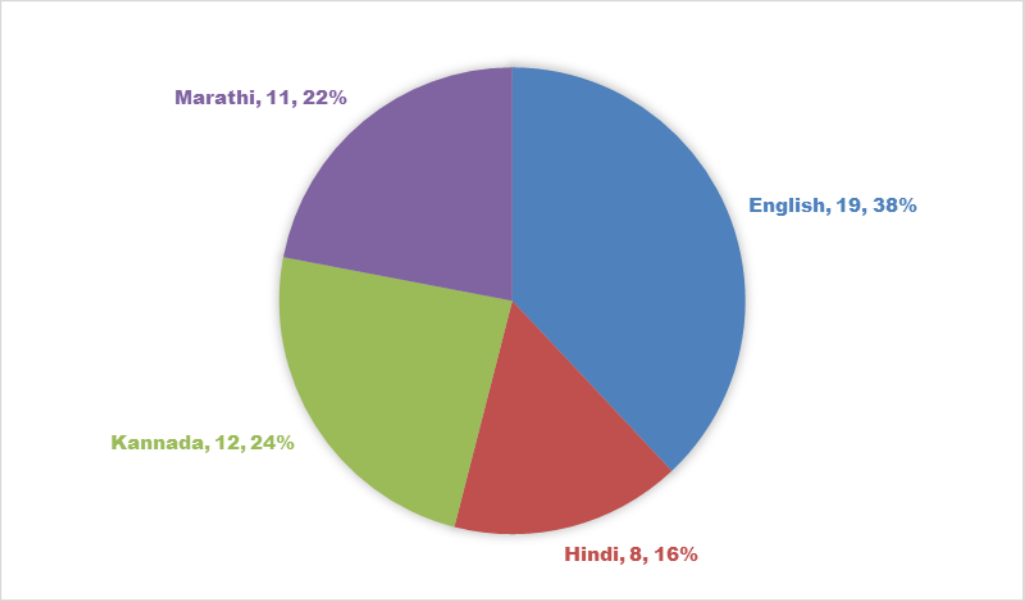


FIGURE NO: 08 DIFFERENT LANGUAGE OF CONSENT FORMS USED BY CLINICAL TRIAL PARTICIPANTS

Based on the inclusion criteria selected for the study, all selected participants were literate, as presented in **Figure 09**. The majority of these participants possessed undergraduate qualifications, such as degrees in Bachelor of Science (BSc), Master of Arts (MA), and Bachelor of Commerce (B.Com). This indicates that the study primarily attracted individuals with higher education backgrounds, reflecting their ability to comprehend and engage with the study materials, protocols, and informed consent requirements. The representation of these educational qualifications suggests a potential alignment between the study's literacy prerequisites and the educational profiles of the participants.

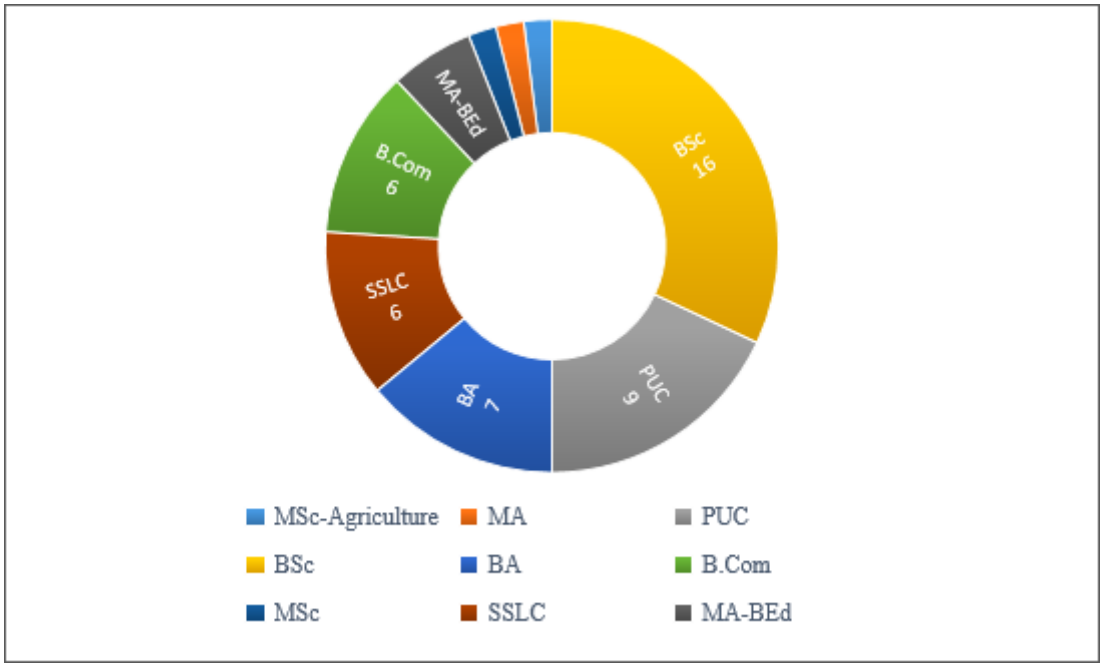


FIGURE NO: 09- GRAPHICAL PRESENTATION OF CLINICAL TRIAL PARTICIPANTS

Additionally, a notable portion of the participants held pre-university qualifications (PUC) ans SSLC, numbering nine and six, respectively. This diversity in educational levels demonstrates the study's inclusivity within the bounds of literacy requirements,

enabling a broader demographic representation while maintaining the necessary literacy threshold. The distribution of educational qualifications among participants may also influence the outcomes of the research, as educational attainment can correlate with comprehension of trial procedures, adherence to study protocols, and overall engagement in clinical trials.

PHARMACEUTICAL SPONSORS AND CROs: The present study represents a crucial segment of the clinical trials landscape, particularly in their role of overseeing the design, execution, and management of clinical trials. The demographic data shows an age range between 30.06 ± 5.21 years, with the mean age falling within range. The age profile suggest that many of the professional in group are early mid-career individuals.

Gender distribution within the pharmaceutical sponsors and CROs group shows a significant skew towards male participation, with 78% (n=39) of the group being male and only 22% (n=11) female. The differing experiences and views that could bring to discussions around patient consent, data privacy, and ethical research practices might be less prominent, potentially limiting the range of ethical considerations taken into account by organizations. The experience level within this group is notable, with an average of 8.33 years in the field or role. Their experience is critical in understanding the complexities of trial management, including regulatory requirements, ethical considerations, and the logistical challenges of conducting large-scale clinical trials. **Table- 05**. **Figures 10 and 11** provide a summary of respondents affiliations with various pharmaceutical sponsors and Contract Research Organizations (CROs), highlighting their diverse educational backgrounds. 88% of the participants were associated with pharmaceutical fields, reflecting the nature of work in pharmaceutical

drug development that necessitates specialized knowledge and skills. This high representation underscores the alignment between the demands of the pharmaceutical industry and the participants' qualifications, which are essential for understanding the intricacies of drug development, regulatory compliance, and clinical trial processes.

In contrast, only 6% of the participants were from medical backgrounds, indicating a relatively lower representation of individuals directly involved in clinical practice or healthcare delivery.

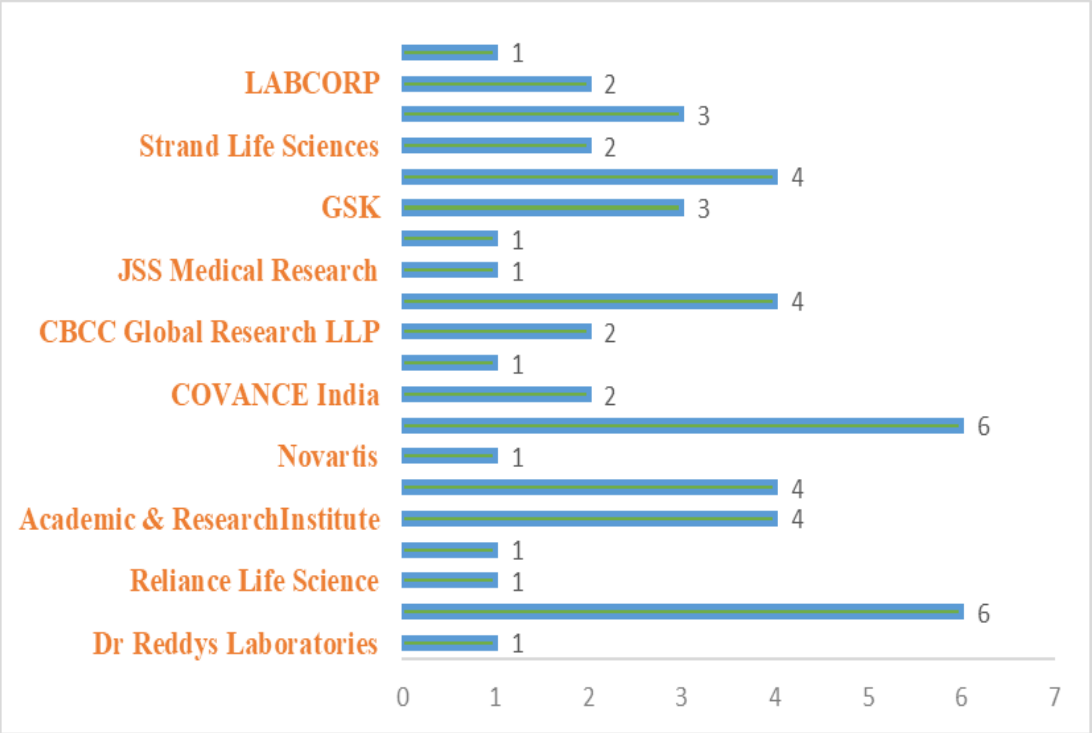


FIGURE NO: 10 PARTICIPANTS FROM DIIFFERENT PHARMACEUTICAL SPONSOR AND CROs

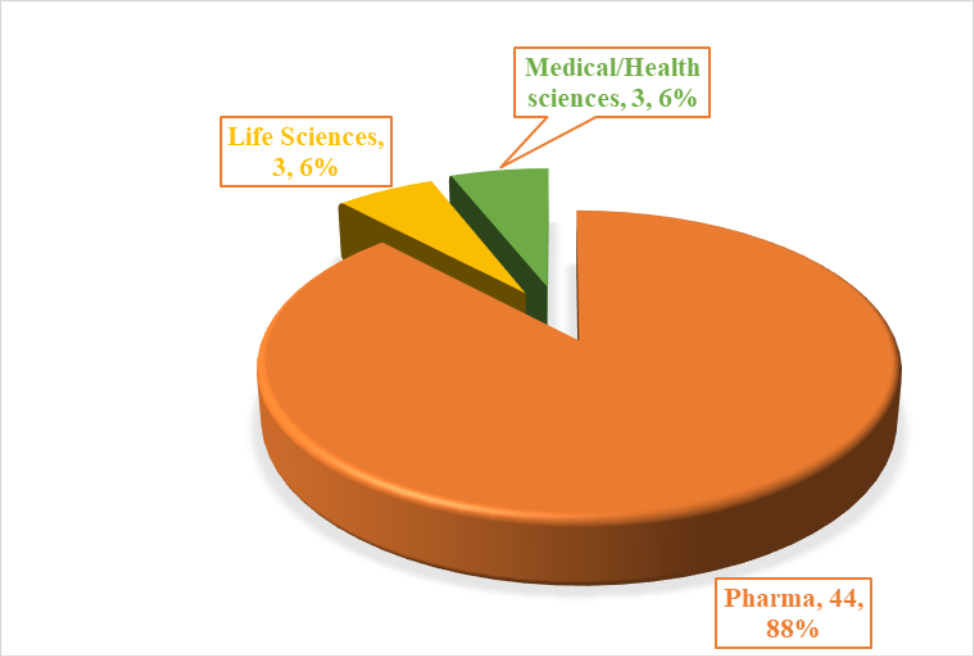


FIGURE NO: 11- EDUCATIONAL BACKGROUND OF P-SPONSOR AND CROs

HUMAN ETHICS COMMITTEE MEMBERS: The present study provides detailed demographic information, assessment of knowledge, attitude, practices about the Human ethics committee members, focusing on various characteristics such as age, gender, educational background, and their specific roles in the ethics committee. The gender distribution among the committee members was balanced, with an equal number of 26 male and 24 female members. The study revealed that medical scientists and clinicians, holding medical degrees, constituted the majority of ethics committee members (50%). This predominance aligns with mandatory regulatory requirements, which necessitate the inclusion of clinicians, Layperon, NGO representatives, Legal Expert and medical scientists in the committee in accordance with new drugs and clinical trial rules-2019.

This indicates a strong presence of individuals with clinical expertise within the committees. Additionally, legal experts were the second largest group, with 7

members (14%), reflecting the importance of legal knowledge in overseeing ethical review process in clinical or genetic research. This distribution underlevels the multidisciplinary nature of ethics committees in ensuring comprehensive ethical oversight in clinical trials. [**Table-05**]

PATHOLOGISTS: The present study results highlights that the number of pathologists enrolled were relatively small, consisting of 17 males and 8 females who participated based on the study's specific criteria. This limited sample size could potentially affect the generalizability of the findings, as a larger and more diverse group of participants might offer a broader perspective on the variables under investigation.

4.2. KAP LEVELS OF CLINICAL TRIAL STAKEHOLDERS:

The present study aimed to assess the Knowledge, Attitude, and Practices (KAP) levels among different stakeholders involved in the clinical research including clinical trial investigators, clinical trial participants, Human ethics committee members, pharmaceutical sponsors/CROs, and pathologists. The findings provide valuable insights into the variability among clinical trial stakeholders. **[Table-06 and Figure-12]**

KNOWLEDGE LEVEL ASSESSMENT: The median knowledge levels showed significant variability in all the clinical trial stakeholder groups ($p < 0.001$). Sponsors/CROs shown the highest median knowledge levels **(8, IQR 7-8),** followed by ethics committee members **(7, IQR 1-8**) and clinical trial investigators **(6, IQR 4-7).** This indicates that sponsors/CROs and ethics committee members are generally more knowledgeable about the genetic research datashaing and re-use possibly due to their roles which necessitates a deep understanding of trial protocols and regulatory requirements. Conversely, clinical trial participants demonstrated the lowest median

knowledge levels **(1, IQR 0-3).** Pharmaceutical sponsors and CROs possess greater knowledge regarding genetic research data sharing and reuse, likely due to their direct involvement in core activities such as clinical trial operations and the execution of clinical trial processes. Their hands-on experience with data management and regulatory compliance in research settings positions them as key stakeholders in understanding the complexities of data sharing and its practical applications.

Next is ethics committee members, their comprehensive understanding of genetic data practices stems from their routine engagement in reviewing clinical research proposals. These proposals frequently address critical aspects such as data privacy, informed consent, ethical data usage, and compliance with national and international regulatory frameworks. This continuous exposure equips committee members with the knowledge needed to evaluate whether research practices align with ethical standards, safeguard participants' rights, and maintain public trust in scientific endeavors.

Additionally, the ethics committee's role in assessing genetic research proposals often involves scrutinizing data-sharing protocols, long-term storage plans, and potential implications of genetic information on participants and their families. This responsibility necessitates a thorough understanding of ethical dilemmas specific to genetic research, such as the risk of re-identification and the need for robust safeguards to prevent misuse of sensitive data.

ATTITUDE LEVELS ASSESSMENT: Attitude levels were relatively high across all clinical trial stakeholder groups, with ethics committee members showing the highest median score **(10, IQR 10-1**0) and clinical trial participants **(10, IQR 7.5-10)**. This uniformity in positive attitude suggests a consensus on the importance and ethical considerations of clinical trials, reflecting the stakeholders' commitment to the

process. However, the slightly lower median attitude levels among the clinical trial investigators and Pharmaceutical sponsors might indicate areas where their concerns or understandings about the genetic or clinical research.

PRACTICES LEVELS ASSESSMENT: Practice levels varied significantly, with sponsors/CROs displaying the highest median score **(6, IQR 4-7),** indicating strong adherence to best practices in the clinical research operations. Clinical trial subjects and pathologists had the lowest median levels **(1, IQR 1-2),** suggesting a need for improved training and support in the practical aspects of trial participation and pathology procedures. These differences underscore the necessity for targeted interventions to elevate the practice standards among all stakeholders, ensuring the overall integrity and success of genetic research in clinical trials.

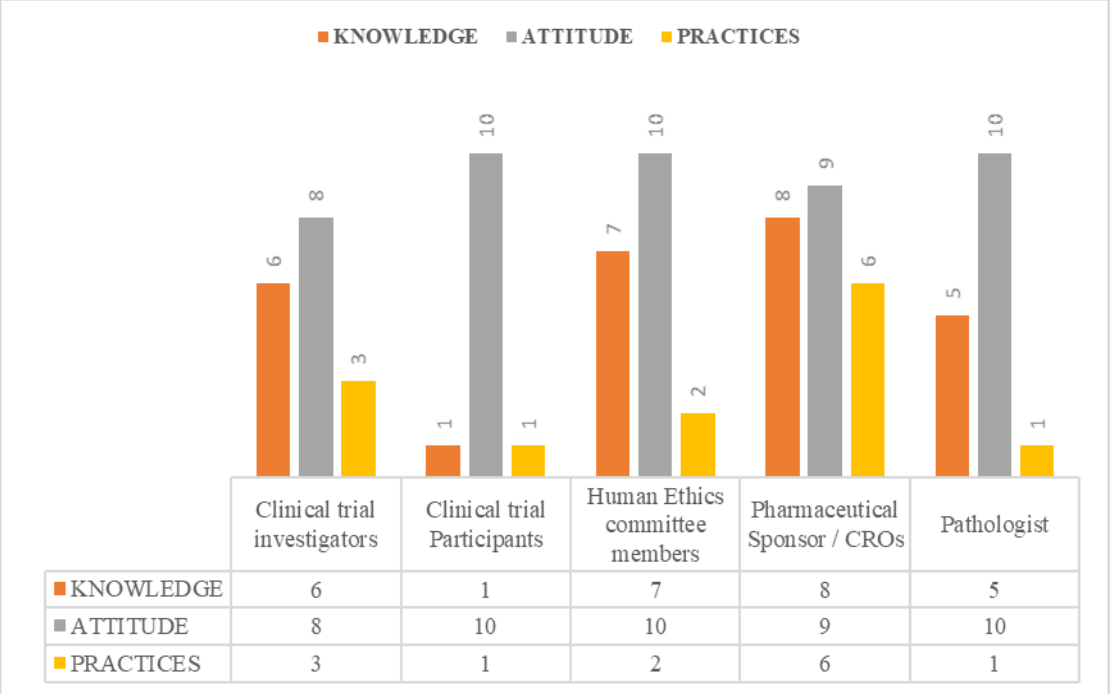
Pharmaceutical sponsors and CROs have more practical experience with genetic research data sharing and reuse, likely because of their active role in managing and utilizing research data as part of trial workflows equips them with hands-on expertise in navigating the complexities of data sharing and reuse within the clinical research landscape.

In contrast, the perception of clinical trial data sharing among clinical trial participants, such as those not directly involved in regulatory systems or clinical trial operations, may differ. These groups, while familiar with clinical research concepts, might lack the practical exposure to the operational and logistical aspects of data sharing.

Clinical trial participants often perceive data sharing differently from those deeply embedded in the regulatory and operational frameworks of clinical trials. While

participants are typically informed about the purpose and general scope of clinical research, their understanding is often limited to how the study impacts them personally. They might not be fully aware of the broader operational and logistical complexities involved in data sharing, such as data anonymization, compliance with regulatory guidelines, or the infrastructure required to securely share and manage data across multiple stakeholders.

Moreover, participants' perceptions are influenced by their trust in the research team and the assurances provided during the informed consent process. While they may recognize the potential benefits of data sharing, such as advancing medical knowledge or improving treatments, concerns about data misuse or breaches of confidentiality can impact their willingness to support extensive sharing.



	Clinical trial investigators	Clinical trial Participants	Human Ethics committee members	Pharmaceutical Sponsor / CROs	Pathologist
KNOWLEDGE	6	1	7	8	5
ATTITUDE	8	10	10	9	10
PRACTICES	3	1	2	6	1

FIGURE NO-12: GRPAHICAL REPRESENTATION OF KAP LEVELS OF CLINICAL TRIAL STAKEHOLDERS

TABLE-06: KAP LEVELS OF THE CLINICAL TRIAL STAKEHOLDERS

KAP Levels	Clinical trial investigators	Clinical trial Participants	Human Ethics committee members	Pharmaceutical Sponsor / CROs	Pathologist	P value
	n=50	n=50	n=50	n=50	n=25	
KNOWLEDGE	6 (4-7)	1 (0-3)	7 (1-8)	8 (7-8)	5 (4.5-6)	**<0.001***
ATTITUDE	8 (6-9)	10 (7.5-10)	10 (10-10)	9 (8-10)	10 (10-10)	**<0.001***
PRACTICES	3 (2-3)	1 (1-2)	2 (2-2)	6 (4-7)	1 (1-2)	**<0.001***
LEVELS-Low-Moderate-High						
KNOWLEDGE	Moderate	Low	High	High	High	--
ATTITUDE	High	High	High	High	High	--
PRACTICES	Moderate	Low	Moderate	High	Low	--

TABLE: 07-KNOWLEDGE RELATED QUESTIONS

KNOWLEDGE RELATED QUESTIONS	Clinical trial Investigators	Clinical trial Participants	Pharmaceutical Sponsor / CROs	Human Ethics committee members	Pathologist	P value
	n=50	n=50	n=50	n=50	n=25	
1. Do you know about the clinical trials in genetics & their data reuse						
Yes	32 (64)	13 (26)	43 (86)	33 (66)	11 (44)	**<0.001***
No	7 (14)	10 (20)	3 (6)	5 (10)	8 (32)	
Don't know	11 (22)	27 (54)	4 (8)	12 (24)	6 (24)	
2. Do you anticipate any difficulties with the reuse of genomic data in the future?						
Ethical and Legal	11 (22)	1 (2)	31 (62)	27 (54)	5 (20)	**<0.001***
Confidentiality	27 (24)	14 (28)	18 (36)	16 (32)	19 (76)	
Don't know	12 (24)	35 (70)	1 (2)	7 (14)	1 (4)	
3. What kind of sample analysis will be applied to genetic and clinical trials?						
Nucleic acid extracts (Blood cells , tissues , Buccal swab , Saliva etc)	33 (66)	4 (8)	22 (44)	27 (54)	23 (92)	-
Novel sources of tissue derived nucleic acids Eg ; Cell free DNA	1 (2)	0	23 (46)	5 (10)	1 (2)	
Don't know	16 (32)	46 (92)	5 (10)	18 (36)	1 (4)	
4. What does genetic research's secondary data entail?						
Personnel Health information	24 (48)	7 (14)	1 (2)	27 (54)	19 (76)	**<0.001***
Whole Exome/Genome Sequencing	6 (12)	0	40 (80)	3 (6)	0	
Don't know	20 (40)	43 (86)	9 (18)	20 (40)	6 (24)	

5 . The following conditions apply to genetic consent forms.						
Secondary Use of identified data and coded data	9 (18)	0	38 (76)	5 (10)	0	-
Return of research results	11 (22)	0	3 (6)	21 (42)	9 (36)	
Don't Know	30 (60)	50 (100)	9 (18)	24 (48)	16 (64)	
6 . What might happen if genetic data is shared?						
Intentional disclosure	5 (10)	0	9 (18)	2 (4)	1 (4)	-
Misuses	37 (74)	15 (30)	37 (74)	30 (60)	21 (84)	
Don't Know	8 (16)	35 (70)	4 (8)	18 (36)	3 (12)	
7. What are the advantages of sharing and reusing genetic information?						
To explore a wide range of research questions	24 (48)	2 (4)	34 (68)	25 (50)	13 (52)	-
To Validate of research results	11 (22)	0	13 (26)	4 (8)	5 (20)	
Don't Know	15 (30)	48 (96)	3 (6)	21 (42)	7 (28)	
8. What does optional consent mean in clinical trials and research?						
Informed consent for collection of biomarker samples may be presented	22 (44)	15 (30)	44 (88)	32 (64)	1 (4)	**<0.001***
Dummy Consent	0	0	2 (4)	0	0	
Don't Know	28 (56)	35 (70)	4 (8)	18 (36)	24 (96)	
9 . Which of the following genetic data ICF material is being used for further research?						
Controlled access repositories	7 (14)	0	39 (78)	10 (20)	0	**<0.001***
Data should be shared via unrestricted	1 (2)	0	3 (6)	2 (4)	0	
Don't know	42 (84)	50 (100)	8 (16)	38 (76)	25 (100)	
10. Which forms of consent are used for gathering genetic data for clinical trials or research?						
Blanket or broad consent	2 (4)	0	18 (36)	2 (4)	0	-
Tiered consent	11 (22)	2 (4)	16 (32)	5 (10)	0	
Don't Know	37 (74)	48 (96)	16 (32)	43 (86)	25 (100)	

4.3. KAP ASSESSMENT OF CLINICAL TRIAL STAKEHOLDERS:

KNOWLEDGE ASSESSMENT OF CLINICAL TRIAL STAKEHOLDERS: The present study included responses from n=225 clinical trial stakeholders, revealed a statistically significant difference (p-value < 0.001) in the assessment of level of awareness about genetic data re-uses, particularly regarding genetics and data reuse, among different clinical trial stakeholder. Specifically, a greater proportion of Clinical trial investigators (64%) and Pharmaceutical Sponsors/CROs (86%) demonstrated awareness compared other stakeholders (26%). This data indicates a notable knowledge gap between those directly involved in the design and execution of trials and the participants themselves.

According to data availed at the **Table-07,** there is also a statistically significant difference (p-value < 0.001) in the rates of informed consent for the collection of biomarker samples among the clinical trial stakeholder groups. Healthcare professionals, including Pathologists (96%) and Clinical trial investigators (88%), expressed the highest levels of needs of informed consent complexities, while participants showed the lowest level (4%). This suggests a potential gap in understanding informed consent procedures between medical professionals and clinical trial participants.

TABLE-08-ATTITUDE RELATED QUESTIONS

ATTITUDE RELATED QUESTIONS	Clinical trial Investigators	Clinical trial Participants	Pharmaceutical Sponsor / CROs	Human Ethics committee members	Pathologists	P value
	n=50	n=50	n=50	n=50	n=25	
1) Do you support the repurposing of genetic information in clinical trials?						
Agree	26 (52)	42 (84)	27 (54)	24 (48)	23 (92)	0.074
Disagree	1 (2)	4 (8)	4 (8)	4 (8)	0	
Strongly Agree	23 (46)	4 (8)	18 (36)	22 (44)	2 (8)	
Strongly Disagree	0	0	1 (2)	0	0	
2) Do you concur that a separate consent is required for the reuse of data in study or research?						
Agree	33 (66)	34 (68)	11 (22)	26 (52)	23 (92)	0.01
Disagree	1 (2)	9 (18)	1 (2)	2 (4)	0	
Strongly Agree	16 (32)	7 (14)	38 (76)	22 (44)	2 (8)	
3) Do you believe that the genetic data gleaned during clinical trials or research should have a separate consent?						
Agree	28 (56)	30 (60)	19 (38)	25 (50)	22 (88)	0.136
Disagree	0	12 (24)	1 (2)	2 (4)	0	
Strongly Agree	22 (44)	8 (16)	30 (60)	23 (46)	3 (12)	
4) Do you permit the return of findings from genomic research?						
Agree	35 (70)	33 (66)	27 (54)	34 (68)	20 (80)	0.21
Disagree	0	11 (22)	6 (12)	1 (2)	0	
Strongly Agree	15 (30)	5 (10)	17 (34)	13 (26)	5 (20)	
Strongly Disagree	0	1 (2)	0	2 (4)	0	
5) Do you agree to the exchange or return of participant-specific genetic research data in encrypted form?						
Agree	35 (70)	35 (70)	23 (46)	37 (74)	24 (96)	0.015
Disagree	0	11 (22)	8 (16)	0	0	
Strongly Agree	15 (30)	4 (8)	15 (30)	11 (22)	1 (4)	
Strongly Disagree	0	0	4 (8)	2 (4)	0	

6) Do you agree that sharing a single code will preserve patient privacy, especially when combined with other security measures?						
Agree	34 (68)	34 (68)	20 (40)	34 (68)	25 (100)	0.084
Disagree	2 (4)	12 (24)	5 (10)	1 (2)	0	
Strongly Agree	14 (28)	4 (8)	24 (48)	14 (28)	0	
Strongly Disagree	0	0	1 (2)	1 (2)	0	
7) Do you believe that maintaining the safety and security of sensitive genetic information is a major challenge?						
Agree	24 (48)	41 (82)	24 (48)	30 (60)	23 (92)	1
Disagree	3 (6)	4 (8)	3 (6)	4 (8)	0	
Strongly Agree	23 (46)	5 (10)	22 (44)	16 (32)	2 (8)	
Strongly Disagree	0	0	1 (2)	0	0	
8) Do you agree that disclosing genetic information to third parties could result in misuse?						
Agree	27 (54)	41 (82)	15 (30)	34 (68)	24 (96)	**<0.001***
Disagree	0	4 (8)	5 (10)	2 (4)	0	
Strongly Agree	23 (46)	4 (8)	27 (54)	13 (26)	1 (4)	
Strongly Disagree	0	1 (2)	3 (6)	1 (2)	0	
9) Do you agree that transferring samples to foreign countries requires correct knowledge?						
Agree	32 (64)	41 (82)	31 (62)	37 (74)	25 (100)	0.441
Disagree	0	8 (16)	5 (10)	3 (6)	0	
Strongly Agree	18 (36)	1 (2)	14 (28)	10 (20)	0	
10) Do you think the biobanks are securely and safely storing participant data and sample data?						
Agree	31 (62)	41 (82)	26 (52)	41 (82)	24 (96)	0.019
Disagree	9 (18)	9 (18)	5 (10)	3 (6)	0	
Strongly Agree	9 (18)	0	19 (38)	6 (12)	1 (4)	
Strongly Disagree	1 (2)	0	0	0	0	

ATTITUDE ASSESSMENT OF CLINICAL TRIAL STAKEHOLDERS: The attitude assessment of clinical trial stakeholders is a valuable way to understand perspectives, concerns, and support for various aspects of clinical trials, including ethical, regulatory, operational, and scientific dimensions. The assessment of attitude towards the disclosure of genetic information among clinical trial stakeholders reveals a range of opinions. Generally, there is considerable apprehension about sharing genetic data with third parties. Most of the clinical trial stakeholders, with the exception of Human ethics committee (H-Ethics) members, showed varying degrees of concern. Specifically, a significant proportion of Clinical trial investigators (82%) and Pharmaceutical sponsors/CROs (68%) expressed strong agreement regarding the potential misuse of genetic information. These findings underscore the need for robust data security and privacy of protocols to address and to overcome these concerns.

Disclosing genetic information to third parties raises serious concerns about the potential for data misuse, especially when this data is shared with external biobanks or research institutions. The present research applied a rigorous statistical approach to investigate these concerns across various clinical trial stakeholders, revealing that the perception of risk is both prevalent and significant. With a p-value of <0.001, the findings indicate that most stakeholders acknowledge the potential for misuse when genetic data is shared beyond the immediate clinical trial stakeholders.

The present study findings suggest that data misuse, whether intentional or accidental, is a key issue that could undermine trust in genetic research and its broader applications. As clinical trials increasingly rely on the storage and re-use of genetic data by third parties, it becomes essential to establish stringent governance frameworks that prioritize participant privacy and consent.

TABLE-09- PRACTICE RELATED QUESTIONS

Practice related Questions/Characteristics	Clinical trial Investigators	Clinical trial Participants	Pharmaceutical Sponsor/ CROs	Human Ethics committee members	Pathologists	P value
	n=50	n=50	n=50	n=50	n=25	
1) What kinds of samples were used in clinical trials and research for genetic analysis?						
Blood samples	44 (88)	41 (82)	31 (62)	32 (64)	0	-
Tissues	1 (2)	3 (6)	19 (38)	12 (24)	25 (100)	
Don't Know	5 (10)	6 (12)	0	6 (12)	0	
2) Have any clinical trial genetic data results been returned to you in recent years?						
Yes	2 (4)	1 (2)	16 (32)	2 (4)	0	**<0.001***
No	48 (96)	49 (98)	34 (68)	48 (96)	25 (100)	
3) Have you ever seen the genetic consent for the analysis of genomic data in any research protocols?						
Yes	8 (16)	0	31 (62)	5 (10)	0	**<0.001***
No	42 (84)	50 (100)	19 (38)	45 (90)	25 (100)	
4) Is there a clinical study protocol that addresses the reuse of genetic sample data and their return?						
Yes	2 (4)	0	17 (34)	2 (4)	0	**<0.001***
No	48 (96)	50 (100)	33 (66)	48 (96)	25 (100)	
5) Have you seen any instances of consent for the reuse of genetic data in clinical studies or trials?						
Yes	2 (4)	1 (2)	21 (42)	2 (4)	0	**<0.001***
No	48 (96)	49 (98)	29 (58)	48 (96)	25 (100)	
6) What types of issues might be encountered while requesting consent for genetic research?						
Mention of Optional research on genomics in clinical trials	2 (4)	0	25 (50)	2 (4)	0	-
Return of results to study participants in clinical trials	20 (40)	1 (2)	15 (30)	23 (46)	2 (8)	
Don't Know	28 (56)	49 (98)	10 (20)	25 (50)	23 (92)	

7) Who has the authority to request the sponsors' return of study results or data?						
Investigator or research institute	27 (54)	17 (34)	26 (52)	6 (12)	8 (32)	**<0.001***
Study Participants	10 (20)	1 (2)	20 (40)	18 (36)	0	
Don't Know	13 (26)	32 (64)	4 (8)	26 (52)	17 (68)	
8) What ethical issues surround the sharing and reuse of genetic data?						
Ownership of the biological samples and its data	30 (60)	0	44 (88)	22 (44)	0	**<0.001***
Return of research results to individual/groups	10 (20)	0	6 (12)	28 (56)	4 (16)	
Don't Know	10 (20)	50 (100)	0	0	21 (84)	
9) Have you heard of any of the repositories and biobanks mentioned?						
Any Pharma industry biorepositories	1 (2)	1 (2)	17 (34)	3 (6)	0	**<0.001***
Cancer trial registry	6 (12)	1 (2)	18 (36)	2 (4)	0	
Don't Know	43 (86)	48 (96)	15 (30)	45 (90)	25 (100)	
10) Choose any one of the alternatives in a multi-layered consent process.						
Allow sample/bio specimen to be stored for future use	4 (8)	0	24 (48)	4 (8)	0	**<0.001***
The sample/bio specimen to be stored for future use for other pre-specified health problems, such as diabetes, heart disease	3 (6)	1 (2)	19 (38)	1 (2)	0	
Don't Know	43 (86)	49 (98)	7 (14)	45 (90)	25 (100)	

PRACTICE ASSESSMENT OF CLINICAL TRIAL STAKEHOLDERS: A practices assessment of clinical trial stakeholders is essential to evaluate current behaviours, processes, and adherence to protocols across the clinical trial lifecycle. This type of assessment identifies gaps, best practices, and areas for improvement in conducting trials efficiently, ethically, and in compliance with regulations. Based on the practices

responses from the stakeholders, there is a statistically significant difference (p-value < 0.001) with ethical concerns among the various stakeholder groups involved in clinical trials. For instance, a high percentage of respondents from Pathology (84%) and Clinical trial investigators (74%) expressed concern about misuses of data, whereas a lower percentage of clinical trial participants (30%) might be due to less involvement and understanding about the genetics in research . The present results suggests a difference in priorities between those directly involved in research and the participants themselves. The sharing and re-use of genetic data from clinical trial bio specimen samples is rife with ethical complexities, particularly surrounding the issue of ownership. Stakeholders, including Human ethics committee members, pharmaceutical sponsors, Contract Research Organizations (CROs), and clinical trial investigators, have consistently voiced concern over who truly owns biological samples and their corresponding data. This question of ownership is not merely theoretical; it directly affects decisions about who has the authority to use or share the data and how it can be applied in future research. The level of concern among these groups is statistically significant, with a p-value of <0.001, highlighting a broad consensus on the importance of clear ownership guidelines.

The ethical issue becomes even more critical as clinical trials increasingly involve collaborative networks where data is often stored, shared, and re-used by multiple entities. Each stakeholder group recognizes the potential risks to participant privacy and autonomy if ownership is not clearly defined and regulated.

4.4 ASSESSMENT OF KNOWLEDGE, ATTITUDES, AND PRACTICES (KAP) BASED ON ROLES AND DEPARTMENTS OF CLINICAL TRIAL STAKEHOLDERS

TABLE-10 ASSESSMENT OF KNOWLEDGE BASED ON ROLES OF THE PHARMACUETICAL SPONORS/CROs

Knowledge related Questions	CTA	CRA-I	CRA-II	CRC	DA	DM	Dosing Monitor	PM	QA-Auditor	P value
	n=13	n=15	n=9	n=2	n=2	n=1	n=1	n=6	n=1	
Age	28.54 ± 3.67	28.47 ± 3.62	33.89 ± 5.80	28.50 ± 0.71	26.50 ± 0.71	-	-	35.53 ± 7.34	-	0.021
Gender										
Male	9 (69.23)	13 (86.67)	7 (77.78)	1 (50)	2 (100)	0	0	6 (100)	1 (100)	0.177
Female	4 (30.77)	2 (13.33)	2 (22.22)	1 (50)	0	1 (100)	1 (100)	0	0	
Marital status										
Married	3 (23.08)	5 (33.33)	6 (66.67)	1 (50)	0	0	0	5 (83.33)	0	0.077
Unmarried	10 (76.92)	10 (66.67)	3 (33.33)	1 (50)	2 (100)	1 (100)	1 (100)	1 (16.67)	1 (100)	
1. Do you know about the clinical trials in genetics & their data reuse										
Yes	11 (84.62)	13 (86.67)	8 (88.89)	1 (50)	1 (50)	1 (100)	1 (100)	6 (100)	1 (100)	0.421
No	1 (7.69)	0	1 (11.11)	1 (50)	0	0	0	0	0	
Don't know	1 (7.69)	2 (13.33)	0	0	1 (50)	0	0	0	0	
2 . Do you anticipate any difficulties with the reuse of genomic data in the future?										
Ethical and Legal	8(61.5)	13(86.7)	3(33.3)	1(50)	1 (50)	1 (100)	0	3(50)	1 (100)	0.04
Confidentiality	5(38.5)	2(13.3)	6(66.7)	1(50)	0	0	1 (100)	3(50)	0	
Don't Know	0	0	0	0	1(50)	0	0	0	0	
3. What kind of sample analysis will be applied to genetic studies and trials?										
Nucleic acid extracts	5(38.5)	9(60)	3(33.3)	1(50)	0	0	0	4(66.7)	0	0.512
Novel sources of tissue derived nucleic acids	5(38.5)	5(33.3)	6(66.7)	1(50)	1 (50)	1 (100)	1 (100)	2(33.3)	1(100)	
Don't Know	3 (23.08)	1(6.7)	0	0	1 (50)	0	0	0	0	
4 . What does genetic research's secondary data entail?										
Whole Exome/Genome Sequencing	10(76.9)	11(73.3)	7(77.8)	2(100)	1(50)	1(100)	1(100)	6 (100)	1(100)	0.849
Personnel Health information	1(7.7)	0	0	0	0	0	0	0	0	
Don't know	2(15.4)	4(26.7)	2(22.2)	0	1(50)	0	0	0	0	

5. The following conditions apply to genetic consent forms.										
Secondary Use of identified data and coded data	10(76.9)	12(80)	7(77.8)	1(50)	1 (50)	1 (100)	1 (100)	4(66.7)	1 (100)	0.916
Return of research results	1(7.7)	1(6.7)	0	0	0	0	0	1 (16.67)	0	
Don't Know	2 (15.38)	2(13.3)	2(22.2)	1(50)	1(50)	0	0	1(16.7)	0	
6 . What might happen if genetic data is shared?										
Intentional disclosure	3(23.1)	5(33.3)	0	0	0	0	0	1(16.7)	0	0.871
Misuses	9(69.2)	9(60)	7(77.8)	2(100)	2(100)	1(100)	1(100)	5(83.3)	1(100)	
Don't Know	1 (7.69)	1(6.7)	2(22.2)	0	0	0	0	0	0	
7. What are the advantages of sharing and reusing genetic information?										
To explore a wide range of research questions	9(69.2	12(80)	6(66.7)	2(100)	0	1 (100)	0	3(50)	1 (100)	0.349
Validation of research results	3(23.1)	2(13.3)	3(33.3)	0	1 (50)	0	1 (100)	3(50)	0	
Don't Know	1 (7.69)	1(6.7)	0	0	1 (50)	0	0	0	0	
8. What does optional consent mean in clinical trials and research?										
Dummy Consent	1(7.7)	1(6.7)	0	0	0	0	0	0	0	0.377
Informed consent for collection of biomarker samples	11(84.6)	14(93.3)	8(88.9)	1(50)	1(50)	1(100)	1(100)	6 (100)	1(100)	
Don't Know	1(7.7)	0	1	1(50)	1(50)	0	0	0	0	
9 . Which of the following genetic data ICF material is being used for further research?										
Data should be shared via unrestricted	0	1(6.7)	1(11.1)	0	0	1 (100)	0	0	0	0.053
Controlled access repositories	11 (84.62)	13(86.7)	6(66.7)	0	1 (50)	0	1 (100)	6 (100)	1 (100)	
Don't know	2(15.4)	1(6.7)	2(22.2)	2(100)	1(50)	0	0	0	0	
10. Which forms of consent are used for gathering genetic data for clinical trials or research?										
Blanket or broad consent	4 (30.77)	4(26.7	5(55.6)	0	0	1 (100)	0	3 (50)	1 (100)	0.577
Tiered consent	5(38.5)	4(26.7	2(22.2)	1(50)	1(50)	0	0	3 (50)	0	
Don't Know	4(30.8	7(46.7)	2(22.2)	1(50)	1(50)	0	1 (100)	0	0	

CTA: Clinical Trial Assistant
CRA: Clinical Research Assistant
CRC: Clinical Research Coordinator
PM: Project Manager
DA: Data Analyst

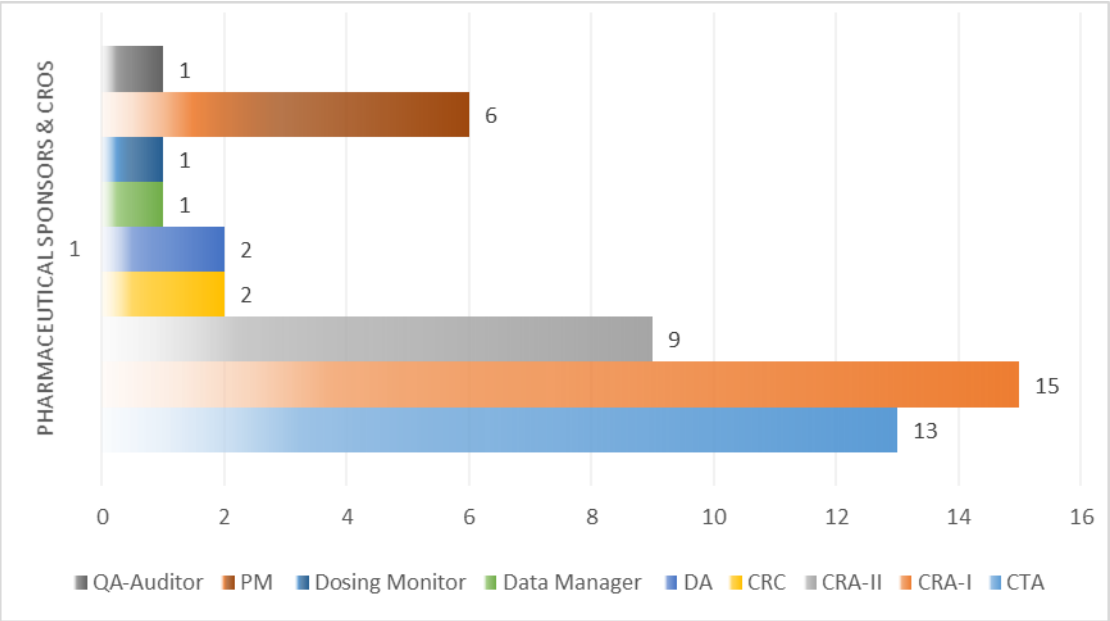


FIGURE NO: 13-GRAPHICAL REPRENTATION OF ROLES OF PHARMACEUTICAL SPONSOR AND CRO

ASSESSMENT OF KNOWLEDGE BASED ON ROLES OF THE PHARMACUETICAL SPONORS/CROs: The present study correlates Knowledge with their roles in the pharmaceutical company and contract research organization but there is no statistical significance in between and it compares different characteristics of individuals based on their roles in pharmaceutical sponsors or contract research organizations (CROs).Age is presented as Mean ± Standard Deviation.

- CTA: 28.54 ± 3.67
- CRA-II: 33.89 ± 5.80
- PM: 35.53 ± 7.34

There is a statistically significant difference in the average ages of individuals across different roles (P-value = 0.021). wheras, there is no statistically significant difference with gender (P-value = 0.177) or marital status (P-value = 0.077) distribution among different roles. **Table-05** helps in understanding the demographic distribution of individuals in various roles within pharmaceutical sponsors and CROs, highlighting that age may play a significant role in the assignment of these roles, whereas gender and marital status do not show significant variation.

TABLE-11: ATTITUDE ASSESSMENT BASED ON THE ROLE OF PHARMACUETICAL SPONORS/CROs

Attitude related Questions/Characteristics	CTA	CRA-I	CRA-II	CRC	DA	Data Manager	Dosing Monitor	PM	QA-Auditor	P value
	n=15	n=9	n=13	n=2	n=1	n=1	n=2	n=6	n=1	
1) Do you support the repurposing of genetic information in clinical trials?										
Agree	9 (60)	2 (22.22)	6 (46.15)	1 (50)	1 (100)	0	2 (100)	5 (83.33)	1 (100)	0.507
Disagree	0	2 (22.22)	2 (15.38)	0	0	0	0	0	0	
Strongly Agree	6 (40)	5 (55.56)	4 (30.77)	1 (50)	0	1 (100)	0	1 (16.67)	0	
Strongly Disagree	0	0	1 (7.69)	0	0	0	0	0	0	
2) Do you concur that a separate consent is required for the reuse of data in study or research?										
Agree	2 (13.33)	2 (22.22)	3 (23.08)	0	1 (100)	1 (100)	0	1 (16.67)	1 (100)	0.174
Disagree	0	0	0	0	0	0	0	1 (16.67)	0	
Strongly Agree	13 (86.67)	7 (77.78)	10 (76.92)	2 (100)	0	0	2 (100)	4 (66.67)	0	
3) Do you believe that the genetic data gleaned during clinical trials or research should have a separate consent?										
Agree	6 (40)	4 (44.44)	3 (23.08)	2 (100)	1 (100)	1 (100)	0	1 (16.67)	1 (100)	0.141
Disagree	0	0	0	0	0	0	0	1 (16.67)	0	
Strongly Agree	9 (60)	5 (55.56)	10 (76.92)	0	0	0	2 (100)	4 (66.67)	0	
4) Do you permit the return of findings from genomic research?										
Agree	9 (60)	7 (77.78)	5 (38.46)	1 (50)	1 (100)	0	2 (100)	2 (33.33)	0	0.157
Disagree	2 (13.33)	1 (11.11)	1 (7.69)	1 (50)	0	1 (100)	0	0	0	
Strongly Agree	4 (26.67)	1 (11.11)	7 (53.85)	0	0	0	0	4 (66.67)	1 (100)	
Strongly Disagree	0	0	0	0	0	0	0	0	0	
5) Do you agree to the exchange or return of participant-specific genetic research data in encrypted form?										
Agree	7 (46.67)	6 (66.67)	6 (46.15)	1 (50)	1 (100)	0	0	2 (33.33)	0	0.153
Disagree	2 (13.33)	1 (11.11)	1 (7.69)	0	0	1 (100)	2 (100)	1 (16.67)	0	
Strongly Agree	4 (26.67)	2 (22.22)	6 (46.15)	0	0	0	0	3 (50)	0	
Strongly Disagree	2 (13.33)	0	0	1 (50)	0	0	0	0	1 (100)	

6) Do you agree that sharing a single code will preserve patient privacy, especially when combined with other security measures?										
Agree	5 (33.33)	4 (44.44)	4 (30.77)	1 (50)	1 (100)	0	1 (50)	4 (66.67)	0	0.166
Disagree	2 (13.33)	0	1 (7.69)	0	0	1 (100)	1 (50)	0	0	
Strongly Agree	8 (53.33)	5 (55.56)	8 (61.54)	0	0	0	0	2 (33.33)	1 (100)	
Strongly Disagree	0	0	0	1 (50)	0	0	0	0	0	
7) Do you believe that maintaining the safety and security of sensitive genetic information is a major challenge?										
Agree	5 (33.33)	7 (77.78)	3 (23.08)	2 (100)	1 (100)	1 (100)	1 (50)	4 (66.67)	0	0.043
Disagree	1 (6.67)	0	1 (7.69)	0	0	0	0	1 (16.67)	0	
Strongly Agree	9 (60)	2 (22.22)	9 (69.23)	0	0	0	1 (50)	1 (16.67)	0	
Strongly Disagree	0	0	0	0	0	0	0	0	1 (100)	
8) Do you agree that disclosing genetic information to third parties could result in misuse?										
Agree	5 (33.33)	3 (33.33)	1 (7.69)	0	1 (100)	0	0	5 (83.33)	0	**<0.001***
Disagree	0	1 (11.11)	2 (15.38)	1 (50)	0	0	1 (50)	0	0	
Strongly Agree	10 (66.67)	5 (55.56)	10 (76.92)	0	0	0	1 (50)	1 (16.67)	0	
Strongly Disagree	0	0	0	1 (50)	0	1 (100)	0	0	1 (100)	
9) Do you agree that transferring samples to foreign countries requires correct knowledge?										
Agree	11 (73.33)	5 (55.56)	6 (46.15)	1 (50)	1 (100)	1 (100)	2 (100)	4 (66.67)	0	0.487
Disagree	0	2 (22.22)	1 (6.59)	1 (50)	0	0	0	1 (16.67)	0	
Strongly Agree	4 (26.67)	2 (22.22)	6 (46.15)	0	0	0	0	1 (16.67)	1 (100)	
10) Do you think the biobanks are securely and safely storing participant data and sample data?										
Agree	5 (33.33)	6 (66.67)	6 (46.15)	1 (50)	1 (100)	1 (100)	1 (50)	4 (66.67)	1 (100)	0.957
Disagree	3 (20)	0	2 (15.38)	0	0	0	0	0	0	
Strongly Agree	7 (46.67)	3 (33.33)	5 (38.46)	1 (50)	0	0	1 (50)	2 (33.33)	0	
Strongly Disagree	0	0	0	0	0	0	0	0	0	

CTA: Clinical Trial Assistant
CRA: Clinical Research Assistant
CRC: Clinical Research Coordinator
PM: Project Manager
DA: Data Analyst

ATTITUDE ASSESSMENT BASED ON THE ROLES OF PHARMACUETICAL SPONORS/CROs: **Table-11** represents the attitude of various roles within pharmaceutical sponsors and CROs reveal perspectives on key issues related to the handling of genetic research data in clinical trials. The support for the repurposing of genetic information (60% of CTAs, 83.33% of PMs, and 100% of DA, Dosing Monitors, and QA Auditors) shows a willingness, although the P-value of 0.507 indicates no significant difference across roles. When asked about the necessity of separate consent for data reuse, a strong majority across roles agreed or strongly agreed (e.g., 86.67% of CTAs and 77.78% of CRA-Is), with a P-value of 0.174, again showing no significant role-based differences. Similarly, the belief that genetic data requires separate consent (e.g., 100% agreement from DAs and Data Managers) had a P-value of 0.141, indicating non-significance. Concern with return of genomic research findings, 60% of CTAs and 66.67% of PMs agreed or strongly agreed, with a P-value of 0.157. For the exchange of participant-specific genetic data in encrypted form, agreement varied, with 46.67% of CTAs and 50% of PMs agreeing, and a P-value of 0.153. The idea that a single code could preserve patient privacy saw mixed support, with 33.33% of CTAs and 66.67% of PMs agreeing, and a P-value of 0.166.

However, significant differences emerged regarding the challenges of maintaining genetic information security, where 77.78% of CRA-Is and 100% of DAs and Data Managers agreed or strongly agreed, resulting in a significant P-value of 0.043. The risk of misuse by third parties was a major concern, with a striking 83.33% of PMs agreeing and a significant P-value of <0.001. Lastly, the necessity of correct knowledge for transferring samples abroad and the security of biobanks were generally agreed upon across roles (e.g., 73.33% of CTAs for sample transfer and 66.67% for biobank security), with non-significant P-values of 0.487 and 0.957, respectively.

TABLE-12 PRACTICE ASSESSMENT BASED ON THE ROLES OF PHARMACUETICAL SPONORS/CROs

Practices related Questions/Characteristics	CTA	CRA-I	CRA-II	CRC	DA	Data Manager	Dosing Monitor	PM	QA-Auditor	CTA	P value
	n=15	n=9	n=13	n=2	n=2	n=1	n=1	n=2	n=6	n=1	
1) What kinds of samples were used in clinical trials and research for genetic analysis?											
Blood samples	10(66.7)	5(55.6)	10(76.9)	1(50)	1(50)	1 (100)	1 (100)	1(50)	2(33.3)	0	0.553
Tissues	5(33.3)	4(44.4)	3(23.1)	0	1(50)	0	0	0	4(66.7)	1(100)	
Don't Know	0	0	0	0	0	0	0	0	0	0	
2) Have any clinical trial genetic data results been returned to you in recent years?											
Yes	3 (20)	4 (44.44)	4 (30.77)	0	1 (50)	0	1 (100)	0	3 (50)	0	0.586
No	12 (80)	5 (55.56)	9 (69.23)	2 (100)	1 (50)	1 (100)	0	2 (100)	3 (50)	1 (100)	
3) Have you ever seen the genetic consent for the analysis of genomic data in any research protocols?											
Yes	9 (60)	7 (77.78)	6 (46.15)	1 (50)	1 (50)	1 (100)	1 (100)	1 (50)	5 (83.33)	0	0.605
No	6 (40)	2 (22.22)	7 (53.85)	1 (50)	1 (50)	0	0	1 (50)	1 (16.67)	1 (100)	
4) Is there a clinical study protocol that addresses the reuse of genetic sample data and their return?											
Yes	5 (33.33)	4 (44.44)	4 (30.77)	0	0	1 (100)	0	0	3 (50)	0	0.799
No	10 (66.67)	5 (55.56)	9 (69.23)	2 (100)	2 (100)	0	1 (100)	2 (100)	3 (50)	1 (100)	
5) Have you seen any instances of consent for the reuse of genetic data in clinical studies or trials?											
Yes	5 (33.33)	6 (66.67)	4 (30.77)	0	1 (50)	1 (100)	0	0	4 (66.67)	0	0.301
No	10 (66.67)	3 (33.33)	9 (69.23)	2 (100)	1 (50)	0	1 (100)	2 (100)	2 (33.33)	1 (100)	
6) What types of issues might be encountered while requesting consent for genetic research?											
Mention of Optional research on genomics in clinical trials	6 (40)	7 (77.78)	7 (53.85)	0	1 (50)	1 (100)	0	0	3 (50)	0	0.342
Return of results to study participants in clinical trials	6(40)	1(11.1)	5(38.5)	1(50)	0	0	0	1(50)	2(33.3)	0	
Don't Know	3(20)	1(11.1)	1(7.7)	1(50)	1 (50)	0	1 (100)	1(50)	1(16.7)	1 (100)	

7) Who has the authority to request the sponsors' return of study results or data?											
Principal Investigator /Institute	7 (49.67)	4 (44.44)	7 (53.85)	0	1 (50)	1 (100)	1 (100)	0	4 (66.67)	1 (100)	0.467
Study Participants	6(40)	5 (55.56)	6 (46.15)	1(50)	0	0	0	1(50)	2 (33.33)	0	
Don't Know	2(13.3)	0	0	1(50)	1(50)	0	0	1(50)	0	0	
8) What ethical issues surround the sharing and reuse of genetic data?											
Secondary or extended uses of stored samples/re-consent	12(80)	3(33.3)	5(38.5)	0	2 (100)	1 (100)	0	0	3(5.)	1 (100)	0.03
Ownership of the biological samples and its data	2(13.3)	6(66.7)	6(46.2)	2 (100)	0	0	0	2 (100)	1(16.7)	0	
Return of research results to individual/groups	1(6.7)	0	2(15.4)	0	0	0	1 (100)	0	2(33.3)	0	
9) Have you heard of any of the repositories and biobanks mentioned?											
Cancer trial registry	4(26.7)	4 (44.44)	5(38.5)	0	1(50)	1(100)	0	0	2 (33.33)	1 (100)	0.33
Any Pharma industry biorepositories	6(40)	4(44.4)	3(23.1)	0	0	0	0	0	4 (66.67)	0	
Don't Know	5(33.3)	1(11.1)	5(38.5)	2 (100)	1(1)	0	1 (100)	2 (100)	0	0	
10) Choose any one of the alternatives in a multi-layered consent process.											
Allow sample/bio specimen to be stored for future use for any biomedical	7(53.8)	5(55.6)	7 (53.85)	1(50)	1(50)	0	0	1(50)	3 (50)	0	0.35
The sample/bio specimen to be stored for future use for other pre-specified health problems	5(33.3)	3 (33.33)	6 (46.15)	0	0	1 (100)	0	0	3 (50)	1 (100)	
Don't Know	3(20)	1(11.1)	0	1(50)	1(50)	0	1 (100)	1(50)	0	0	

CTA: Clinical Trial Assistant
CRA: Clinical Research Assistant
CRC: Clinical Research Coordinator
PM: Project Manager
DA: Data Analyst

PRACTICE ASSESSMENT BASED ON THE ROLES OF PHARMACEUTICAL SPONSORS/CROs: As per the **Table-12** practices assessment among different roles within pharmaceutical sponsors and CROs reveals significant variability in responses to questions about genetic data handling. For example, the use of blood samples in genetic analysis is commonly reported across roles, with 76.9% of CRA-IIs and 100% of Data Managers, while tissue samples are less frequently used, notably by 66.7% of QA-Auditors and not at all by CRCs (P=0.553). Regarding the return of genetic data results, 44.44% of CRA-Is and 50% of QA-Auditors have received results, in contrast to 100% of CRCs who have not (P=0.586). Awareness of genetic consent in research protocols is high among CRA-Is (77.78%) and QA-Auditors (83.33%), yet this does not differ significantly across roles (P=0.605). The existence of clinical study protocols addressing the reuse of genetic data shows no significant difference, with 66.67% of CTAs and 100% of CRCs indicating absence (P=0.799). Lastly, ethical issues around sharing genetic data, such as secondary uses of stored samples, are a major concern for 80% of CTAs and 100% of Data Managers, with a statistically significant difference (P=0.03), underscoring the varied ethical perspectives among different roles.

TABLE-13 KNOWLEDGE ASSESSMENT BASED ON ROLES OF ETHICS COMMITETE MEMBERS

Knowledge related Questions/Characteristics	Chairperson	clinician	IEC administrator	IEC coordinator	Layperson	Legal expert	Medical scientist	Member secretary	NGO-Representatives	Scientific member	Social scientist	P Value
	n=3	n=10	n=1	n=4	n=3	n=8	n=12	n=2	n=2	n=1	n=4	
age	53.33 ± 13.32	42.2 ± 3.82	-	33.75 ± 11.21	42.33 ± 9.82	43.38 ± 3.38	43.5 ± 10.24	50 ± 14.14	44.5 ± 3.54	-	40 ± 1.41	0.179
Gender												
Male	2(66.7)	4(40)	0	1(25)	0	8(100)	1(8.3)	2(100)	0	1(100)	4(100)	**<0.001***
Female	1(33.3)	6(60)	1(100)	3(75)	3(100)	0	11(91.7)	0	2(100)	0	0	
Marital status												
Married	3(100)	10(100)	1(100)	3(75)	2(66.7)	8(100)	12(100)	2(100)	2(100)	1(100)	4(100)	0.191
Unmarried	0	0	0	1(25)	1(33.3)	0	0	0	0	0	0	
1. Do you know about the clinical trials in genetics & their data reuse												
Yes	2(66.7)	9(90)	1(100)	3(75)	0	1(12.5)	12(100)	2(100)	1(50)	1(100)	1(25)	**<0.001***
No	1(33.3)	1(10)	0	1(25)	1(33.3)	0	0	0	1(50)	0	0	
Don't know	0	0	0	0	2(66.7)	7(87.5)	0	0	0	0	3(75)	
2 . Do you anticipate any difficulties with the reuse of genomic data in the future?												
Ethical and Legal	3(100)	4(40)	0	3(75)	2(66.7)	4(50)	9(75)	1(50)	0	1(100)	0	0.007
Confidentiality	0	6(60)	1(100)	1(25)	0	1(12.5)	3(25)	1(50)	2(100)	0	1(25)	
Don't Know	0	0	0	0	1(33.3)	3(37.5)	0	0	0	0	3(75)	
3. What kind of sample analysis will be applied to genetic studies and trials?												
Nucleic acid extracts	2(66.7)	7(70)	0	1(25)	0	0	12(100)	2(100)	0	1(100)	2(50)	**<0.001***
Novel sources of tissue derived nucleic acids	1(33.3)	2(20)	0	2(50)	0	0	0	0	0	0	0	
Don't Know	0	1(10)	1(100)	1(25)	3(100)	8(100)	0	0	2(100)	0	2(50)	
4) What does genetic research's secondary data entail?												
Whole Exome/Genome Sequencing	0	1(10)	0	1(25)	0	0	1(8.3)	0	0	0	0	0.004
Personnel Health information	2(66.7)	8(80)	1(100)	2(50)	0	1(12.5)	9(75)	2(100)	0	1(100)	1(25)	
Don't know	1(33.3)	1(10)	0	1(25)	3(100)	7(87.5)	2(16.7)	0	2(100)	0	3(75)	

5) The following conditions apply to genetic consent forms.												
Secondary Use of identified data and coded data	0	2(20)	0	2(50)	0	0	1(5.3)	0	0	0	0	0.024
Return of research results	1(33.3)	6(60)	0	1(25)	0	1(12.5)	8(66.7)	2(100)	0	1(100)	1(25)	
Don't Know	2(66.7)	2(20)	1(100)	1(25)	3(100)	7(87.5)	3(25)	0	2(100)	0	3(75)	
6) What might happen if genetic data is shared?												
Intentional disclosure	0	1(10)	0	0	0	0	1(8.3)	0	0	0	0	**<0.001***
Misuses	2(66.7)	8(80)	1(100)	2(50)	1(33.3)	0	11(91.7)	2(100)	1(50)	1(100)	1(25)	
Don't Know	1(33.3)	1(10)	0	2(50)	2(66.7)	8(100)	0	0	1(50)	0	3(75)	
7) What are the advantages of sharing and reusing genetic information?												
To explore a wide range of research questions	3(100)	8(80)	0	2(50)	1(33.3)	0	7(58.3)	2(100)	0	1(100)	1(25)	**0.001***
To Validate of research results	0	0	1(100)	1(25)	0	0	2(16.7)	0	0	0	0	
Don't Know	0	2(20)	0	1(100)	2(66.7)	8(100)	3(25)	0	2(100)	0	3(75)	
8) What does optional consent mean in clinical trials and research?												
Informed consent for collection of biomarker samples	2(66.7)	10(100)	1(100)	3(75)	1(33.3)	1(12.5)	10(83.3)	2(100)	0	1(100)	1(25)	**<0.001***
Dummy consent	0	0	0	0	0	0	0	0	0	0	0	
Don't Know	1(33.3)	0	0	1(25)	2(66.7)	7(87.5)	2(16.7)	0	2(100)	0	2(75)	
9) Which of the following genetic data ICF material is being used for further research?												
Data should be shared via unrestricted	0	1(10)	0	1(25)	0	0	0	0	0	0	0	0.385
Controlled access repositories	1(33.3)	3(30)	0	2(50)	0	0	4(33.3)	0	0	0	0	
Don't know	2(66.7)	6(60)	1(100)	1(25)	3(100)	8(100)	8(66.7)	2(100)	2(100)	1(100)	4(100)	
10) Which forms of consent are used for gathering genetic data for clinical trials or research?												
Blanket or broad consent	0	0	0	1(25)	0	0	1(8.3)	0	0	0	0	0.835
Tiered consent	3(100)	8(80)	1(100)	2(50)	3(100)	8(100)	9(75)	2(100)	2(100)	1(100)	4(100)	
Don't Know	0	2(20)	0	1(25)	0	0	2(16.7)	0	0	0	0	

KNOWLEDGE ASSESSMENT BASED ON ROLES OF ETHICS COMMITTEE MEMBERS: The present study statistics highlights the diverse perspectives on clinical trials in genetics and the reuse of genetic data among different stakeholder roles of the Ethics committee members roles, including chairpersons, clinicians, and Ethics committee administrators. Age distribution varied, with the average age ranging from 33.75 years for Ethics committee coordinators to 53.33 years for chairpersons ($p=0.179$). Gender distribution showed significant variation, with roles legal expert being entirely male (100%), while roles such as layperson and NGO representatives were predominantly female (100%) ($p<0.001$). Marital status was predominantly married across all roles ($p=0.191$). Awareness about clinical trials in genetics and data reuse varied, with clinicians (90%) and medical scientists (100%) reporting the highest awareness, while laypersons and legal experts had lower awareness ($p<0.001$).

TABLE-14 ATTITUDE ASSESSMENT BASED ON THE ROLE OF ETHICS COMMITTEE MEMBERS

Attitude related Questions/Human Ethics committee members	Chairperson	clinician	IEC administrator	IEC coordinator	Layperson	Legal expert	Medical scientist	Member secretary	NGO-Representatives	Scientific member	Social scientist	P Value
	n=3	n=10	n=1	n=4	n=3	n=8	n=12	n=2	n=2	n=1	n=4	
1) Do you support the repurposing of genetic information in clinical trials?												
Agree	2(66.7)	4(40)	0	2(50)	2(66.7)	4(50)	4(33.3)	0	2(100)	0	4(100)	0.267
Disagree	0	0	0	1(25)	1(33.3)	1(12.5)	1(8.3)	0	0	0	0	
Strongly Agree	1(33.3)	6(60)	1(100)	1(25)	0	3(37.5)	7(58.3)	2(100)	0	1(100)	0	
Strongly Disagree	0	0	0	0	0	0	0	0	0	0	0	
2) Do you concur that a separate consent is required for the reuse of data in study or research?												
Agree	2(66.7)	4(40)	0	2(50)	2(66.7)	6(75)	3(25)	1(50)	2(100)	0	4(100)	0.034
Disagree	0	0	0	1(25)	1(33.3)	0	0	0	0	0	0	
Strongly Agree	1(33.3)	6(60)	1(100)	1(25)	0	2(25)	9(75)	1(50)	0	1(100)	0	
Strongly Disagree	0	0	0	0	0	0	0	0	0	0	0	
3) Do you believe that the genetic data gleaned during clinical trials or research should have a separate consent?												
Agree	0	6(60)	0	2(50)	2(66.7)	4(50)	4(33.3)	0	2(100)	1(100)	4(100)	0.055
Disagree	0	0	0	0	1(33.3)	1(12.5)	0	0	0	0	0	
Strongly Agree	3(100)	4(40)	1(100)	2(50)	0	3(37.5)	8(66.7)	2(100)	0	0	0	
Strongly Disagree	0	0	0	0	0	0	0	0	0	0	0	
4) Do you permit the return of findings from genomic research?												
Agree	2(66.7)	5(50)	1(100)	2(50)	2(66.7)	6(75)	8(66.7)	1(50)	2(100)	1(100)	4(100)	0.561
Disagree	0	0	0	0	1(33.3)	0	0	0	0	0	0	
Strongly Agree	1(33.3)	5(50)	0	1(25)	0	1(12.5)	4(33.3)	1(50)	0	0	0	
Strongly Disagree	0	0	0	1(25)	0	1(12.5)	0	0	0	0	0	
5) Do you agree to the exchange or return of participant-specific genetic research data in encrypted form?												
Agree	3(100)	6(60)	1(100)	4(100)	2(66.7)	5(62.5)	8(66.7)	1(50)	2(100)	1(100)	4(100)	0.642
Disagree	0	0	0	0	0	0	0	0	0	0	0	
Strongly Agree	0	4(40)	0	0	0	2(25)	4(33.3)	1(50)	0	0	0	
Strongly Disagree	0	0	0	0	1(33.3)	1(12.5)	0	0	0	0	0	
6) Do you agree that sharing a single code will preserve patient privacy, especially when combined with other security measures? (For instance, storage with restricted access in a secure area)												
Agree	1(33.3)	8(80)	1(100)	2(50)	2(66.7)	7(87.5)	5(41.7)	1(50)	2(100)	1(100)	4(100)	0.065

Disagree	0	0	0	0	1(33.3)	0	0	0	0	0	0	
Strongly Agree	2(66.7)	2(20)	0	2(50)	0	0	7(58.3)	1(50)	0	0	0	
Strongly Disagree	0	0	0	0	0	1(12.5)	0	0	0	0	0	
7) Do you believe that maintaining the safety and security of sensitive genetic information is a major challenge?												
Agree	1(33.3)	7(70)	1(100)	2(50)	2(66.7)	6(75)	4(33.3)	1(50)	2(100)	1(100)	3(66.7)	0.103
Disagree	0	0	0	2(50)	1(33.3)	1(12.5)	0	0	0	0	0	
Strongly Agree	2(66.7)	3(30)	0	0	0	1(12.5)	8(66.7)	1(50)	0	0	1(33.3)	
Strongly Disagree	0	0	0	0	0	0	0	0	0	0	0	
8) Do you agree that disclosing genetic information to third parties could result in misuse?												
Agree	2(66.7)	10(100)	0	2(50)	2(66.7)	5(62.5)	6(50)	0	2(100)	1(100)	4(100)	0.02
Disagree	0	0	0	1(25)	1(33.3)	0	0	0	0	0	0	
Strongly Agree	1(33.3)	0	1(100)	1(25)	0	2(25)	6(50)	2(100)	0	0	0	
Strongly Disagree	0	0	0	0	0	1(12.5)	0	0	0	0	0	
9) Do you agree that transferring samples to foreign countries requires correct knowledge?												
Agree	1(33.3)	8(80)	0	2(50)	2(66.7)	6(75)	10(83.3)	1(50)	2(100)	1(100)	4(100)	0.295
Disagree	0	0	0	1(25)	1(33.3)	1(12.5)	0	0	0	0	0	
Strongly Agree	2(66.7)	2(20)	1(100)	1(25)	0	1(12.5)	2(16.7)	1(50)	0	0	0	
Strongly Disagree	0	0	0	0	0	0	0	0	0	0	0	
10) Do you think the biobanks are securely and safely storing participant data and sample data?												
Agree	3(100)	9(90)	1(100)	2(50)	1(33.3)	7(87.5)	10(83.3)	1(50)	2(100)	1(100)	4(100)	0.135
Disagree	0	0	0	0	2(66.7)	1(12.5)	0	0	0	0	0	
Strongly Agree	0	1(10)	0	2(50)	0	0	2(16.7)	1(50)	0	0	0	
Strongly Disagree	0	0	0	0	0	0	0	0	0	0	0	

ATTITUDE ASSESSMENT BASED ON THE ROLE OF ETHICS COMMITTEE MEMBERS: The attitude assessment of Human Ethics Committee members towards the reuse of genetic information in the research highlights varying levels of support across different roles. When asked about their support for repurposing genetic information, 66.7% of chairpersons, 40% of clinicians, and 50% of IEC coordinators agreed. Laypersons (66.7%) and legal experts (50%) also showed substantial agreement. A significant proportion of medical scientists (33.3%) and NGO representatives (100%) were supportive. However, strong agreement was highest among clinicians (60%), IEC administrators (100%), and member secretaries (100%) ($p=0.267$). This data reveals a complex landscape of attitude within Human Ethics Committee members, emphasizing the importance of clear ethical guidelines and consensus building within diverse committees. The overall differences in Clinical trials investigator on underscore the need for ongoing dialogue and education to align the perspectives of all stakeholders in the ethical governance of genetic data reuse in clinical research.

TABLE-15: PRACTICE ASSESSMENT BASED ON ROLE OF HUMAN ETHICS COMMITTEE MEMBERS

Practices related Questions/ Human Ethics committee members	Chairperson	clinician	IEC administrator	IEC coordinator	Laypers on	Legal expert	Medical scientist	Member secretary	NGO-Representatives	Scientific member	Social scientist	P Value
	n=3	n=10	n=1	n=4	n=3	n=8	n=12	n=2	n=2	n=1	n=4	
1) What kinds of samples were used in clinical trials and research for genetic analysis?												
Blood Samples	2(66.7)	8 (80)	1(100)	2(50)	0	4(50)	10(83.3)	2(100)	1(50)	0	2(50)	0.052
Tissues	1 (33.3)	2 (20)	0	1(25)	0	2(25)	2(16.7)	0	1(50)	1(100)	2(50)	
Don't know	0	0	0	1(25)	3(100)	2(25)	0	0	0	0	0	
2) Have any clinical trial genetic data results been returned to you in recent years?												
Yes	0	1(10)	0	1(25)	0	0	0	0	0	0	0	0.212
No	3(100)	9(90)	1(100)	3(75)	3(100)	8(100)	12(100)	2(100)	2(100)	1(100)	4(100)	
3) Have you ever seen the genetic consent for the analysis of genomic data in any research protocols?												
Yes	0	1(10)	0	2(50)	0	1(12.5)	1(8.3)	0	0	0	0	0.033
No	3(100)	9(90)	1(100)	2(50)	3(100)	7(87.5)	11(91.7)	2(100)	2(100)	1(100)	4(100)	
4) Is there a clinical study protocol that addresses the reuse of genetic sample data and their return?												
Yes	0	1(10)	0	1(25)	0	0	0	0	0	0	0	0.332
No	3(100)	9(90)	1(100)	3(75)	3(100)	8(100)	12(100)	2(100)	2(100)	1(100)	4(100)	
5) Have you seen any instances of consent for the reuse of genetic data in clinical studies or trials?												
Yes	0	1(10)	0	1(25)	0	0	0	0	0	0	0	0.357
No	3(100)	9(90)	1(100)	3(75)	3(100)	8(100)	12(100)	2(100)	2(100)	1(100)	4(100)	
6) What types of issues might be encountered while requesting consent for genetic research?												
Mention of Optional research on genomics in clinical trials	0	1(10)	0	1(25)	0	0	0	0	0	0	0	0.204
Return of results to study participants	2(66.7)	4(40)	1(100)	2(50)	0	2(25)	8(66.7)	2(100)	0	1(100)	1(25)	
Don't Know	1(33.3)	5(50)	0	1(25)	3(100)	6(75)	4(33.3)	0	2(100)	0	3(75)	

7) Who has the authority to request the sponsors' return of study results or data?												
Principal Investigator /Institute	1(33.3)	2(20)	0	2(50)	0	0	1(8.3)	0	0	0	0	0.22
Study Participants	1(33.3)	4(40)	0	1(25)	0	1(12.5)	7(58.3)	2(100)	1(50)	0	1(25)	
Don't Know	1(33.3)	4(40)	1(100)	1(25)	3(100)	7(87.5)	4(33.3)	0	1(50)	1(100)	3(75)	
8) What ethical issues surround the sharing and reuse of genetic data?												
Secondary or extended uses of stored samples/re-consent	0	1(10)	0	2(50)	0	0	0	0	0	0	0	0.131
Ownership of the biological samples and its data	0	4(40)	0	1(25)	0	4(50)	4(33.3)	2(100)	0	1(100)	3(75)	
Return of research results to individual/groups	3(100)	5(50)	1(100)	1(25)	3(100)	4(50)	8(66.7)	0	2(100)	0	1(25)	
9) Have you heard of any of the repositories and biobanks mentioned?												
Cancer trial registry	0	0	0	1(25)	0	0	1(8.3)	0	0	0	0	0.561
Any Pharma industry biorepositories	0	2(20)	0	1(25)	0	0	0	0	0	0	0	
Don't Know	3(100)	8(80)	1(100)	2(50)	3(100)	8(100)	11(91.7)	2(100)	2(100)	1(100)	4(100)	
10) Choose any one of the alternatives in a multi-layered consent process.												
Allow sample/bio specimen to be stored for future use for any biomedical research	0	2(20)	0	2(50)	0	0	0	0	0	0	0	0.411
The sample/bio specimen to be stored for future use for pre-specified health problems	0	0	0	0	0	0	1(8.3)	0	0	0	0	
Don't Know	3(100)	8(80)	1(100)	2(50)	3(100)	8(100)	11(91.7)	2(100)	2(100)	1(100)	4(100)	

PRACTICE ASSESSMENT BASED ON ROLE OF ETHICS COMMITTEE MEMBERS ROLE: The **table-15** Presents practices data on the types of samples used in clinical trials and genetic research across various roles in a human ethics committee. Blood samples are most commonly utilized, with percentages varying among committee roles: Chairpersons (66.7%), Clinicians (80%), IEC Administrators (100%), IEC Coordinators (50%), Laypersons (0%), Legal Experts (50%), Medical Scientists (83.3%), Member Secretaries (100%), NGO Representatives (50%), Scientific Members (0%), and Social Scientists (50%). Tissue samples were less frequently used, with percentages ranging from 16.7% (Medical Scientists) to 100% (Social Scientists and Scientific Members). A notable portion of respondents indicated uncertainty about sample types (Do not know), particularly among Laypersons (100%) and Legal Experts (25%). The analysis suggests variability in sample use across committee roles, with a p-value of 0.052 indicating a trend towards significance.

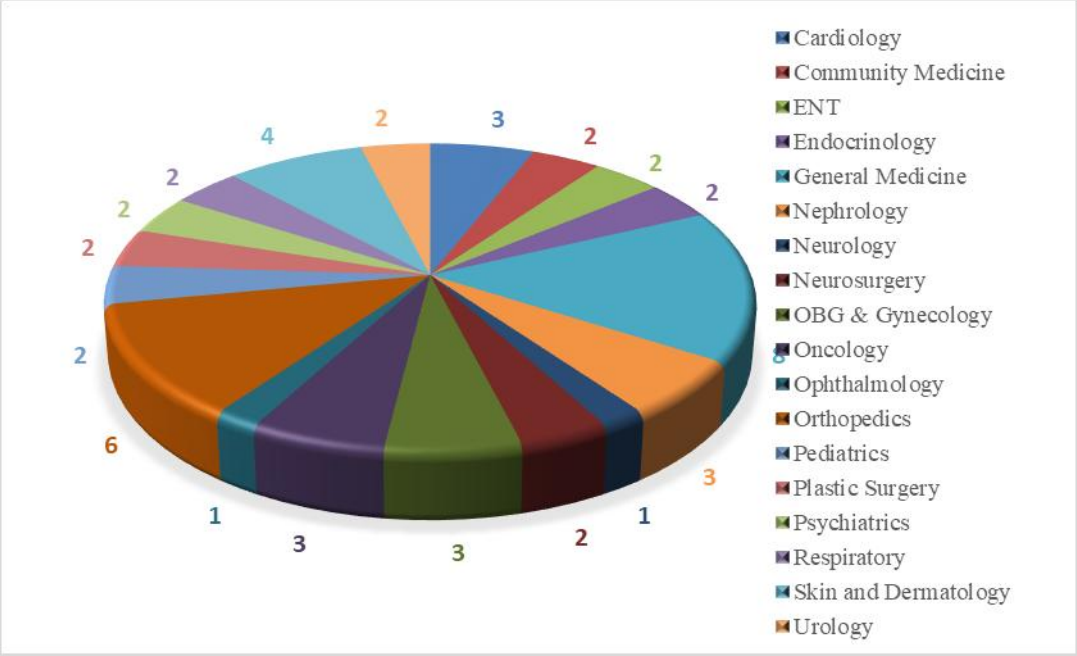


FIGURE NO: 14- DEPARTMENT WISE DISTRIBUTION OF CLINICAL TRIAL INVESTIGATORS

TABLE-16: DEPARTMENT-WISE KNOWLEDGE ASSESSMENT OF CLINICAL TRIAL INVESTIGATORS

Knowledge related Questions-Clinical trials investigators	Cardiology	Community Medicine	ENT	Endocrinology	General Medicine	Nephrology	Neurology	Neurosurgery	OBG & Gynaecology	Oncology	Ophthalmology	Orthopaedics	Paediatrics	Plastic Surgery	Psychiatrics	Respiratory	Dermatology	Urology	P value
	n=3	n=2	n=2	n=2	n=8	n=3	n=1	n=2	n=3	n=3	n=1	n=6	n=2	n=2	n=2	n=2	n=4	n=2	
Age	45.33 ± 1.15	41.50 ± 2.12	40 ± 2.83	39 ± 1.41	44.50 ± 7.07	46.33 ± 5.86	-	38.50 ± 6.36	52 ± 12.17	41.33 ± 3.21	-	47.33 ± 11.91	47.50 ± 0.71	47.50 ± 10.61	42.50 ± 9.19	38.50 ± 2.12	41 ± 1.41	53.50 ± 12.02	0.685
Gender																			
Male	3 (100)	2 (100)	0	2 (100)	6 (75)	3 (100)	1 (100)	2 (100)	1 (33.33)	3 (100)	0	5 (83.33)	2 (100)	2 (100)	2 (100)	1 (50)	3 (75)	2 (100)	0.232
Female	0	0	2 (100)	0	2 (25)	0	0	0	2 (66.67)	0	1 (100)	1 (16.67)	0	0	0	1 (50)	1 (25)	0	
Marital status																			
Married	3 (100)	2 (100)	2 (100)	2 (100)	8 (100)	3 (100)	1 (100)	2 (100)	3 (100)	3 (100)	1 (100)	6 (100)	2 (100)	2 (100)	2 (100)	2 (100)	4 (100)	2 (100)	-
Unmarried	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
1. Do you know about the clinical trials in genetics & their data reuse																			
Yes	2 (66.67)	1 (50)	1 (50)	1 (50)	6 (75)	2 (66.67)	0	1 (50)	1 (33.33)	2 (66.67)	0	5 (83.33)	2 (100)	1 (50)	1 (50)	2 (100)	2 (50)	2 (100)	0.726
No	0	0	0	0	2 (25)	0	0	0	1 (33.33)	1 (33.33)	0	0	0	1 (50)	1 (50)	0	1 (25)	0	
Don't know	1 (33.33)	1 (50)	1 (50)	1 (50)	0	1 (33.33)	1 (100)	1 (50)	1 (33.33)	0	1 (100)	1 (16.67)	0	0	0	0	1 (25)	0	
2 . Do you anticipate any difficulties with the reuse of genomic data in the future?																			
Ethical and Legal	0	1 (50)	1 (50)	0	2 (25)	2 (66.67)	1 (100)	0	0	0	0	2 (33.33)	0	0	0	1 (50)	0	1 (50)	0.065

Confidentiality	3 (100)	0	1 (50)	2 (100)	5 (62.50)	0	0	0	3 (100)	2 (66.67)	1 (100)	2 (33.33)	1 (50)	2 (100)	0	1 (50)	4 (100)	0	
Don't Know	0	1 (50)	0	0	1 (12.50)	1 (33.33)	0	2 (100)	0	1 (33.33)	0	2 (33.33)	1 (50)	0	2 (100)	0	0	1 (50)	
3. What kind of sample analysis will be applied to genetic studies and trials?																			
Nucleic acid extracts	3 (100)	1 (50)	0	2 (100)	7 (87.50)	2 (66.67)	1 (100)	0	2 (66.67)	2 (66.67)	1 (100)	3 (50)	0	2 (100)	1 (50)	2 (100)	3 (75)	1 (50)	
Novel sources of tissue derived nucleic acid	0	0	0	0	0	0	0	0	0	0	0	0	1 (50)	0	0	0	0	0	0.269
Don't Know	0	1 (50)	2 (100)	0	1 (12.50)	1 (33.33)	0	2 (100)	1 (33.33)	1 (33.33)	0	3 (50)	1 (50)	0	1 (50)	0	1 (25)	1 (50)	
4 . What does genetic research's secondary data entail?																			
Personnel Health information	2 (66.67)	0	1 (50)	2 (100)	6 (75)	0	1 (100)	0	2 (66.67)	2 (66.67)	1 (100)	2 (33.33)	0	1 (50)	0	0	2 (50)	0	
Whole Exome/Genome Sequencing	0	1 (50)	0	0	1 (12.50)	1 (33.33)	0	0	0	0	0	0	1 (50)	0	1 (50)	0	0	1 (50)	0.333
Don't know	1 (33.33)	1 (50)	1 (50)	0	1 (12.50)	2 (66.67)	0	2 (100)	1 (33.33)	1 (33.33)	0	4 (66.67)	1 (50)	1 (50)	1 (50)	2 (100)	2 (50)	1 (50)	
5 . The following conditions apply to genetic consent forms.																			
Secondary Use of identified data and coded data	0	0	0	0	3 (37.50)	2 (66.67)	0	0	0	0	0	2 (33.33)	1 (50)	0	0	1 (50)	0	0	
Return of research results	0	0	0	1 (50)	1 (12.50)	0	1 (100)	0	1 (33.33)	2 (66.67)	1 (100)	1 (16.67)	0	0	0	0	2 (50)	1 (50)	0.64
Don't Know	3 (100)	2 (100)	2 (100)	1 (50)	4 (50)	1 (33.33)	0	2 (100)	2 (66.67)	1 (33.33)	0	3 (50)	1 (50)	2 (100)	2 (100)	1 (50)	2 (50)	1 (50)	
6 . What might happen if genetic data is shared?																			
Intentional disclosure	0	1 (50)	1 (50)	0	1 (12.50)	0	0	0	0	0	0	1 (16.67)	0	0	0	0	0	1 (50)	
Misuses	3 (100)	0	0	2 (100)	6 (75)	3 (100)	1 (100)	1 (50)	3 (100)	2 (66.67)	1 (100)	5 (83.33)	1 (50)	2 (100)	2 (100)	0	4 (100)	1 (50)	0.106

Don't Know	0	1 (50)	1 (50)	0	1 (12.50)	0	0	1 (50)	0	1 (33.33)	0	0	1 (50)	0	0	2 (100)	0	0	
7. What are the advantages of sharing and reusing genetic information?																			
To explore a wide range of research questions	1 (33.33)	1 (50)	1 (50)	1 (50)	5 (62.50)	1 (33.33)	0	0	2 (66.67)	2 (66.67)	1 (100)	2 (33.33)	1 (50)	1 (50)	1 (50)	1 (50)	2 (50)	1 (50)	
To Validate of research results	1 (33.33)	0	0	0	1 (12.50)	1 (33.33)	0	1 (50)	1 (33.33)	0	0	3 (50)	0	0	1 (50)	0	1 (25)	1 (50)	0.999
Don't Know	1 (33.33)	1 (50)	1 (50)	1 (50)	2 (25)	1 (33.33)	1 (100)	1 (50)	0	1 (33.33)	0	1 (16.67)	1 (50)	1 (50)	0	1 (50)	1 (25)	0	
8. What does optional consent mean in clinical trials and research?																			
Informed consent for collection of biomarker samples	1 (33.33)	1 (50)	0	1 (50)	5 (62.50)	2 (66.67)	1 (100)	0	2 (66.67)	2 (66.67)	0	2 (33.33)	1 (50)	0	0	1 (50)	2 (50)	1 (50)	
Dummy Consent	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0.915
Don't Know	2 (66.67)	1 (50)	2 (100)	1 (50)	3 (37.50)	1 (33.33)	0	2 (100)	1 (33.33)	1 (33.33)	1 (100)	4 (66.67)	1 (50)	2 (100)	2 (100)	1 (50)	2 (50)	1 (50)	
9 . Which of the following genetic data ICF material is being used for further research?																			
Controlled access repositories	0	1 (50)	0	0	0	2 (66.67)	0	0	1 (33.33)	0	0	1 (16.67)	0	0	0	1 (50)	0	2 (100)	
Data should be shared via unrestricted	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.039
Don't know	3 (100)	1 (50)	2 (100)	2 (100)	8 (100)	1 (33.33)	1 (100)	2 (100)	2 (66.67)	3 (100)	1 (100)	5 (83.33)	2 (100)	2 (100)	2 (100)	1 (50)	4 (100)	0	
10. Which forms of consent used for gathering genetic data for clinical trials or research?																			
Blanket or broad consent	0	0	0	0	0	0	0	0	0	1 (33.33)	0	0	0	0	1 (50)	0	0	0	
Tiered consent	0	1 (50)	0	0	1 (12.50)	2 (66.67)	0	0	1 (33.33)	0	0	2 (33.33)	0	0	0	1 (50)	1 (25)	2 (100)	0.39
Don't Know	3 (100)	1 (50)	2 (100)	2 (100)	7 (87.50)	1 (33.33)	1 (100)	2 (100)	2 (66.67)	2 (66.67)	1 (100)	4 (66.67)	2 (100)	2 (100)	1 (50)	1 (50)	3 (75)	0	

TABLE- 17: DEPARTMENT-WISE ATTITUDE ASSESSMENT OF CLINICAL TRIAL INVESTIGATORS

Attitude related Questions/ *Clinical trial investigators*	Cardiology	Community Medicine	ENT	Endocrinology	General Medicine	Nephrology	Neurology	Neurosurgery	OBG & Gynaecology	Oncology	Ophthalmology	Orthopaedics	Paediatrics	Plastic Surgery	Psychiatrics	Respiratory	Dermatology	Urology	P value
	n=3	n=2	n=2	n=2	n=8	n=3	n=1	n=2	n=3	n=3	n=1	n=6	n=2	n=2	n=2	n=2	n=4	n=2	
1) Do you support the repurposing of genetic information in clinical trials?																			
Agree	1 (33.33)	2 (100)	0	1 (50)	4 (50)	2 (66.67)	1 (100)	2 (100)	0	0	0	3 (50)	0	0	2 (100)	2 (100)	4 (100)	2 (100)	0.015
Disagree	0	0	0	0	0	0	0	0	0	0	0	0	0	1 (50)	0	0	0	0	
Strongly Agree	2 (66.67)	0	2 (100)	1 (50)	4 (50)	1 (33.33)	0	0	3 (100)	3 (100)	1 (100)	3 (50)	2 (100)	1 (50)	0	0	0	0	
Strongly Disagree	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
2) Do you concur that a separate consent is required for the reuse of data in study or research?																			
Agree	3 (100)	0	1 (50)	2 (100)	4 (50)	1 (33.33)	1 (100)	2 (100)	2 (66.67)	2 (66.67)	1 (100)	5 (83.33)	1 (50)	1 (50)	2 (100)	1 (50)	4 (100)	0	0.203
Disagree	0	0	0	0	0	0	0	0	0	1 (33.33)	0	0	0	0	0	0	0	0	
Strongly Agree	0	2 (100)	1 (50)	0	4 (50)	2 (66.67)	0	0	1 (33.33)	0	0	1 (16.67)	1 (50)	1 (50)	0	1 (50)	0	2 (100)	
3) Do you believe that the genetic data gleaned during clinical trials or research should have a separate consent?																			
Agree	2 (66.6)	0	1 (50)	1 (50)	2 (25)	1 (33.33)	1 (100)	2 (100)	2 (66.67)	3 (100)	1 (100)	4 (66.67)	1 (50)	1 (50)	1 (50)	1 (50)	4 (100)	0	0.342

Disagree	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Strongly Agree	1 (33.3)	2 (100)	1 (50)	1 (50)	6 (75)	2 (66.67)	0	0	1 (33.33)	0	0	2 (33.33)	1 (50)	1 (50)	1 (50)		0	2 (10)	
4) Do you permit the return of findings from genomic research?																			
Agree	3 (100)	1 (50)	2 (100)	2 (100)	5 (62.50)	3 (100)	1 (100)	2 (100)	2 (66.67)	2 (66.67)	1 (100)	3 (50)	0	1 (50)	2 (100)	0	4 (100)	1 (50)	0.282
Disagree	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Strongly Agree	0	1 (50)	0	0	3 (37.50)	0	0	0	1 (33.33)	1 (33.33)	0	3 (50)	2 (100)	1 (50)	0	2 (100)	0	1 (50)	
Strongly Disagree	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
5) Do you agree to the exchange or return of participant-specific genetic research data in encrypted form?																			
Agree	2 (66.6)	1 (50)	2 (100)	2 (100)	5 (62.50)	2 (66.67)	0	2 (100)	2 (66.67)	2 (66.67)	1 (100)	5 (83.33)	1 (50)	1 (50)	2 (100)	1 (50)	4 (100)	0	0.677
Disagree	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Strongly Agree	1 (33.3)	1 (50)	0	0	3 (37.50)	1 (33.33)	1 (100)	0	1 (33.33)	1 (33.33)	0	1 (16.67)	1 (50)	1 (50)	0	1 (50)	0	2 (100)	
Strongly Disagree	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
6) Do you agree that sharing a single code will preserve patient privacy, especially when combined with other security measures?																			
Agree	3 (100)	0	1 (50)	2 (100)	5 (62.50)	1 (33.33)	1 (100)	2 (100)	3 (100)	3 (100)	0	6 (100)	1 (50)	1 (50)	1 (50)	1 (50)	2 (50)	1 (50)	0.153
Disagree	0	0	0	0	0	1 (33.33)	0	0	0	0	0	0	0	0	1 (50)	0	0	0	
Strongly Agree	0	2 (100)	1 (50)	0	3 (37.50)	1 (33.33)	0	0	0	0	1 (100)	0	1 (50)	1 (50)	0	1 (50)	2 (50)	1 (50)	
Strongly Disagree	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
7) Do you believe that maintaining the safety and security of sensitive genetic information is a major challenge?																			
Agree	0	1 (50)	1 (50)	0	3 (37.50)	1 (33.33)	1 (100)	1 (50)	2 (66.67)	2 (66.67)	1 (100)	4 (66.67)	1 (50)	1 (50)	1 (50)	1 (50)	3 (75)	0	0.719
Disagree	1 (33.3)	0	0	0	0	0	0	0	0	1 (33.33)	0	0	0	0	0	1 (50)	0	0	
Strongly Agree	2 (66.6)	1 (50)	1 (50)	2 (100)	5 (62.50)	2 (66.67)	0	1 (50)	1 (33.33)	0	0	2 (33.33)	1 (50)	1 (50)	1 (50)	0	1 (25)	2 (100)	
Strongly Disagree	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	

8) Do you agree that disclosing genetic information to third parties could result in misuse?																		
Agree	3 (100)	1 (50)	1 (50)	0	4 (50)	1 (33.33)	0	2 (100)	1 (33.33)	2 (66.67)	1 (100)	5 (83.33)	1 (50)	0	1 (50)	2 (100)	2 (50)	0	0.399
Disagree	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Strongly Agree	0	1 (50)	1 (50)	2 (100)	4 (50)	2 (66.67)	1 (100)	0	2 (66.67)	1 (33.33)	0	1 (16.67)	1 (50)	2 (100)	1 (50)	0	2 (50)	2 (100)	
Strongly Disagree	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
9) Do you agree that transferring samples to foreign countries requires correct knowledge?																			
Agree	3 (100)	0	2 (100)	2 (100)	4 (50)	1 (33.33)	1 (100)	2 (100)	2 (66.67)	3 (100)	1 (100)	3 (50)	1 (50)	0	2 (100)	1 (50)	4 (100)	0	0.081
Disagree	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Strongly Agree	0	2 (100)	0	0	4 (50)	2 (66.67)	0	0	1 (33.33)	0	0	3 (50)	1 (50)	2 (100)	0	1 (50)	0	2 (100)	
10) Do you think the biobanks are securely and safely storing participant data and sample data?																			
Agree	2 (66.6)	2 (100)	2 (100)	1 (50)	5 (62.50)	1 (33.33)	0	2 (100)	2 (66.67)	1 (33.33)	1 (100)	3 (50)	1 (50)	1 (50)	2 (100)	2 (100)	2 (50)	1 (50)	0.963
Disagree	1 (33.3)	0	0	1 (50)	2 (25)	0	1 (100)	0	1 (33.33)	1 (33.33)	0	1 (16.67)	0	0	0	0	1 (25)	0	
Strongly Agree	0	0	0	0	1 (12.50)	2 (66.67)	0	0	0	1 (33.33)	0	2 (33.33)	1 (50)	1 (50)	0	0	0	1 (50)	
Strongly Disagree	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1 (25)	0	

TABLE-18: DEPARTMENT-WISE PRACTICE ASSESSMENT OF CLINICAL TRIAL INVESTIGATORS

Practices related Questions/ *Clinical trials investigators*	Cardiology	Community Medicine	ENT	Endocrinology	General Medicine	Nephrology	Neurology	Neurosurgery	OBG & Gynaecology	Oncology	Ophthalmology	Orthopaedics	Paediatrics	Plastic Surgery	Psychiatrics	Respiratory	Dermatology	Urology	P value
	n=3	n=2	n=2	n=2	n=8	n=3	n=1	n=2	n=3	n=3	n=1	n=6	n=2	n=2	n=2	n=2	n=4	n=2	
1) What kinds of samples were used in clinical trials and research for genetic analysis?																			
Blood samples	2 (66.67)	2 (100)	2 (100)	2 (100)	6 (75)	3 (100)	1 (100)	2 (100)	3 (100)	3 (100)	1 (100)	6 (100)	2 (100)	2 (100)	0	2 (100)	4 (100)	1 (50)	0.305
Tissues	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1 (50)	0	0	0	
Don't Know	1 (33.33)	0	0	0	2 (25)	0	0	0	0	0	0	0	0	0	1 (50)	0	0	1 (50)	
2) Have any clinical trial genetic data results been returned to you in recent years?																			
Yes	0	1 (50)	0	0	0	0	0	0	1 (33.33)	0	0	0	0	0	0	0	0	0	0.382
No	3 (100)	1 (50)	2 (100)	2 (100)	8 (100)	3 (100)	1 (100)	2 (100)	2 (66.67)	3 (100)	1 (100)	6 (100)	2 (100)	2 (100)	2 (100)	2 (100)	4 (100)	2 (100)	
3) Have you ever seen the genetic consent for the analysis of genomic data in any research protocols?																			
Yes	1 (33.33)	1 (50)	0	0	1 (12.50)	0	0	0	1 (33.33)	1 (33.33)	0	1 (16.67)	0	0	0	1 (50)	0	1 (50)	0.855
No	2 (66.67)	1 (50)	2 (100)	2 (100)	7 (87.50)	3 (100)	1 (100)	2 (100)	2 (66.67)	2 (66.67)	1 (100)	5 (83.33)	2 (100)	2 (100)	2 (100)	1 (50)	4 (100)	1 (50)	

4) Is there a clinical study protocol that addresses the reuse of genetic sample data and their return?																			
Yes	0	1 (50)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1 (50)	0.191
No	3 (100)	1 (50)	2 (100)	2 (100)	8 (100)	3 (100)	1 (100)	2 (100)	3 (100)	3 (100)	1 (100)	6 (100)	2 (100)	2 (100)	2 (100)	2 (100)	4 (100)	1 (50)	
5) Have you seen any instances of consent for the reuse of genetic data in clinical studies or trials?																			
Yes	0	1 (50)	0	0	0	0	0	0	1 (33.33)	0	0	0	0	0	0	0	0	0	0.382
No	3 (100)	1 (50)	2 (100)	2 (100)	8 (100)	3 (100)	1 (100)	2 (100)	2 (66.67)	3 (100)	1 (100)	6 (100)	2 (100)	2 (100)	2 (100)	2 (100)	4 (100)	2 (100)	
6) What types of issues might be encountered while requesting consent for genetic research?																			
Mention of Optional research on genomics in clinical trials	0	0	1 (50)	0	0	0	0	0	0	0	0	0	0	1 (50)	0	0	0	0	0.579
Return of results to study participants	1 (33.33)	1 (50)	0	0	4 (100)	0	1 (100)	0	1 (33.33)	1 (33.33)	1 (100)	4 (66.67)	2 (100)	0	1 (50)	1 (50)	1 (25)	1 (50)	
Don't Know	2 (66.67)	1 (50)	1 (50)	2 (100)	4 (100)	3 (100)	0	2 (100)	2 (66.67)	2 (66.67)	0	2 (33.33)	0	1 (50)	1 (50)	1 (50)	3 (75)	1 (50)	
7) Who has the authority to request the sponsors' return of study results or data?																			
Principal Investigator /Institute	1 (33.33)	2 (100)	1 (50)	2 (100)	5 (62.50)	2 (66.67)	1 (100)	0	0	1 (33.33)	1 (100)	2 (33.33)	2 (100)	1 (50)	1 (50)	1 (50)	2 (50)	2 (100)	0.708
Study Participants	1 (33.33)	0	0	0	0	0	0	1 (50)	1 (33.33)	1 (33.33)	0	1 (16.67)	0	1 (50)	1 (50)	1 (50)	2 (50)	0	
Don't Know	1 (33.33)	0	1 (50)	0	3 (37.50)	1 (33.33)	0	1 (50)	2 (66.67)	1 (33.33)	0	3 (50)	0	0	0	0	0	0	

8) What ethical issues surround the sharing and reuse of genetic data?																		
Ownership of the biological samples and its data	3 (100)	2 (100)	0	1 (50)	2 (25)	3 (100)	1 (100)	0	2 (66.67)	2 (66.67)	1 (100)	5 (83.33)	1 (50)	1 (50)	2 (100)	0	2 (50)	2 (100)	0.105
Return of research results	0	0	1 (50)	0	4 (50)	0	0	0	1 (33.33)	0	0	0	1 (50)	1 (50)	0	2 (100)	0	0	
Don't Know	0	0	1 (50)	1 (50)	2 (25)	0	0	2 (100)	0	1 (33.33)	0	1 (16.67)	0	0	0	0	2 (50)	0	
9) Have you heard of any of the repositories and biobanks mentioned?																			
Any Pharma industry biorepositories	0	0	0	0	0	0	0	0	0	0	0	1 (16.67)	0	0	0	0	0	0	0.371
Cancer trial registry	0	1 (100)	0	0	0	1 (33.33)	0	0	0	2 (66.67)	0	1 (16.67)	0	0	0	0	0	1 (50)	
Don't Know	3 (100)	1 (100)	2 (100)	2 (100)	8 (100)	2 (66.67)	1 (100)	2 (100)	3 (100)	1 (33.33)	1 (100)	4 (66.67)	2 (100)	2 (100)	2 (100)	2 (100)	4 (100)	1 (50)	
10) Choose any one of the alternatives in a multi-layered consent process.																			
The sample/bio specimen to be stored for future use	0	0	0	0	0	1 (33.33)	0	0	0	0	0	0	0	0	1 (50)	0	0	1 (50)	0.675
Allow sample/bio specimen to be stored for future use	0	1 (50)	0	0	1 (12.50)	0	0	0	0	1 (33.33)	0	1 (16.67)	0	0	0	0	0	0	
Don't Know	3 (100)	1 (50)	2 (100)	2 (100)	7 (87.50)	2 (66.67)	1 (100)	2 (100)	3 (100)	2 (66.67)	1 (100)	5 (83.33)	2 (100)	2 (100)	1 (50)	2 (100)	4 (100)	1 (50)	

DEPARTMENT WISE DISTRIBUTION OF CLINICAL TRIAL INVESTIGATORS: Tables 16-18 results states that there is no significance difference between department wise lists of clinical trial investigators variables regarding Genetic research data re-uses. Participants who were aware of clinical trials in genetics and data reuse had significantly higher knowledge. For example, in General Medicine, those aware scored 6 (50) compared to those unaware. Awareness of clinical trials in genetics and data reuse is strongly associated with higher knowledge levels, emphasizing the need for comprehensive educational programs to increase awareness and understanding of these critical areas among healthcare professionals.

The present study results explores the significant variations in knowledge levels across different demographics and specialties, underscoring the need for targeted educational interventions to bridge these gaps. By addressing these disparities through age-specific training, gender-inclusive and education for unmarried professionals, and increased awareness of clinical trials, the overall knowledge and competence of healthcare professionals can be enhanced, leading to better clinical trial outcomes and improved patient care.

4.4. MULTIPLE GROUPS COMAPARISION OF KAP LEVELS: The Bonferroni test was used to adjust p-values when conducting multiple comparisons to control for Type I errors (false positives). Even after applying the Bonferroni correction, all comparisons remain statistically significant, as the adjusted p-values are still below the 0.05 threshold.

TABLE-19: MULTIPLE GROUP COMPARISON OF KAP LEVELS

KNOWLEDGE			
Clinical trial stakeholders	**Test Statistic**	**Std. Error**	**P value**
Clinical Trial Participants Vs Pathologist	**-68.35**	**15.833**	**<0.001***
Clinical Trial Participants Vs Clinical trial investigators	**72.8**	**12.927**	**<0.001***
Clinical Trial Participants Vs Human Ethics committee members	**85.15**	**12.927**	**<0.001***
Clinical Trial Participants Vs Sponsor/CROs	**-133.18**	**12.927**	**<0.001***
Pathologist Vs Clinical trial investigators	4.45	15.833	1
Pathologist Vs Human Ethics Committee members	16.8	15.833	1
Pathologist Vs Sponsor/CROs	**-64.83**	**15.833**	**<0.001***
Clinical trial investigators Vs Sponsor/CROs	**-60.38**	**12.927**	**<0.001***
Human Ethics committee members Vs Sponsor/CROs	-48.03	12.927	0.002
ATTITUDE			
Clinical trial investigators Vs Sponsor's/CRO	-30.78	11.574	0.078
Clinical trial investigators Vs Clinical trial Participants	-44.37	11.574	0.001
Clinical trial investigators Vs Human Ethics committee	**74.53**	**11.574**	**<0.001***
Clinical trial investigators Vs Pathologist	**-89.17**	**14.176**	**<0.001***
Sponsor/CROs Vs Clinical trial Participants	13.59	11.574	1
Sponsor/CROs Vs Human Ethics committee	43.75	11.574	0.002
Sponsor/CROs Vs Pathologist	**58.39**	**14.176**	**<0.001***
Clinical trial Participants Vs Human Ethics committee	30.16	11.574	0.092
Clinical trials Participants Vs Pathologist	-44.8	14.176	0.016
Human Ethics Committee Vs Pathologist	-14.64	14.176	1
PRACTICES			
Clinical trial participants Vs Pathologist	-8.05	15.457	1
Clinical trial participants Vs Human ethics committee members	48.64	12.62	0.001
Clinical trial participants Vs Clinical trial investigators	**67.95**	**12.62**	**<0.001***
Clinical trial participants Vs Sponsor/CROs	**-129.36**	**12.62**	**<0.001***
Pathologist Vs Human ethics committee	40.59	15.457	0.086
Pathologist Vs Clinical trials investigators	59.9	15.457	0.001
Pathologist Vs Sponsor/CROs	**-121.31**	**15.457**	**<0.001***

Human ethics committee members Vs Clinical trial investigators	-19.31	12.62	1
Human Ethics Committee Members Vs Sponsor/CROs	**-80.72**	**12.62**	**<0.001***
Clinical Trials Investigators Vs Sponsor/CROs	**-61.41**	**12.62**	**<0.001***
APPLIED-BONFERRONI TEST			

MULTIPLE GROUPS COMPARISON Vs KNOWLEDGE:

Clinical Trial Participants: The largest differences in knowledge levels were observed between clinical trial participants and sponsors/CROs ($p < 0.001$). This significant gap indicates that clinical trial participants have substantially lower knowledge levels compared to sponsors/CROs. Significant differences were also noted between clinical trial participants and clinical trial investigators ($p < 0.001$), human ethics committee members ($p < 0.001$), and pathologists ($p < 0.001$).

Pathologists: Significantly, lower knowledge compared to sponsors/CROs ($p < 0.001$). This suggests a need for enhanced training and resources for pathologists to ensure they are adequately informed about clinical trial processes.

Ethics Committee Members: Comparisons involving Ethics Committee members showed smaller differences and higher p-values, indicating more uniform knowledge levels with pathologists ($p = 1$), clinical trial investigators ($p = 1$), and sponsors/CROs ($p = 0.002$). This suggests that ethics committee members possess a balanced knowledge level that aligns more closely with other stakeholders, except sponsors/CROs.

Sponsors/CROs: Sponsors/CROs consistently displayed higher knowledge levels, with significant differences noted in comparisons with clinical trial participants, pathologists, and ethics committee members. This reflects their critical role and need for comprehensive knowledge in overseeing and managing clinical trials**.**

MULTIPLE GROUPS COMPARISON Vs ATTITUDE: The **table-19** provides a comparative analysis of the attitude levels among various stakeholders involved in clinical trials. The test statistics and p-values indicate the significance of differences in attitude between these groups.

Clinical Trial Investigators Vs. Other Groups: Significant differences were observed between clinical trial investigators and clinical trial participants (Test Statistic: -44.37, $p = 0.001$), human ethics committee members (Test Statistic: 74.53, $p < 0.001$), and pathologists (Test Statistic: -89.17, $p < 0.001$). This suggests that clinical trial investigators generally have positive attitude compared to participants and pathologists, but less positive compared to ethics committee members**.**

Sponsors/CROs: Compared to clinical trial participants, sponsors/CROs did not show a significant difference in attitude (Test Statistic: 13.59, $p = 1$), indicating similar levels of attitude. However, significant differences were found between sponsors/CROs and human ethics committee members (Test Statistic: 43.75, $p = 0.002$) and pathologists (Test Statistic: 58.39, $p < 0.001$).

Clinical Trial Participants: Clinical trial participants displayed significantly different attitude compared to pathologists (Test Statistic: -44.8, $p = 0.016$) and showed some difference with human ethics committee members (Test Statistic: 30.16, $p = 0.092$), though not statistically significant.

Ethics Committee Members: Comparisons involving ethics committee members generally showed significant differences, reflecting higher attitude levels compared to most other groups except sponsors/CROs (Test Statistic: -43.75, $p = 0.002$).

MULTIPLE GROUPS COMPARISON Vs PRACTICE:

Clinical Trial Participants Vs. Other Groups: Significant differences in practice levels were observed between clinical trial participants and sponsors/CROs ($p < 0.001$), human ethics committee members ($p = 0.001$), and clinical trial investigators ($p < 0.001$). Comparisons with pathologists did not show significant differences $p = 1$, indicating similar practice levels between participants and pathologists.

Pathologists: Pathologists displayed significantly lower practice levels compared to sponsors/CROs ($p < 0.001$), but no significant difference was found with human ethics committee members ($p = 0.086$) and clinical trial investigators ($p = 0.001$)

Sponsors/CROs: consistently showed higher practice levels compared to other groups, with significant differences noted in comparisons with clinical trial participants, pathologists, human ethics committee members, and clinical trial investigators.

Ethics Committee Members: Comparisons involving ethics committee members generally showed significant differences, reflecting higher practice levels compared to clinical trial participants ($p = 0.001$) and lower compared to sponsors/CROs ($p < 0.001$).

Clinical Trial Investigators: Clinical trial investigators has higher practice levels compared to clinical trial participants ($p < 0.001$) and pathologists, but lower compared to sponsors/CROs ($p < 0.001$).

4.5. KAP ASSESSMENT BASED ON THE EDUCATIONAL BACKGROUND OF CLINICAL TRIAL STAKEHOLDERS: The **table-20** provides a comparison of Knowledge, Attitude, and Practices (KAP) among clinical trial investigators with

different educational backgrounds. The results were evaluated using the Kruskal-Wallis Test to determine statistically significant differences between the different clinical trials stakeholders.

TABLE -20: KAP ASSESSMENT BASED ON THE EDUCATIONAL BACKGROUND OF CLINICAL TRIAL INVESTIGATORS

Ct-Investigators	MBBS-MD	MBBS-MD-DM	MBBS-MS	MBBS-MS-Mch	P value
Educational background	n=40	n=7	n=1	n=2	
KNOWLEDGE	6 (4-7)	6 (5-7)	6 (6-6)	5.5 (4-0)	0.932
ATTITUDE	8 (6.25-9.75)	8 (7-9)	5 (5-5)	7 (6-0)	0.402
PRACTICES	3 (2-3)	2 (2-3)	5 (5-5)	3 (3-3)	0.183
Median (Interquartile Range (IQR))-Kruskal-Wallis Test					

Knowledge: The median knowledge levels for clinical trial investigators with different educational backgrounds are as follows: MBBS-MD (6, IQR 4-7), MBBS-MD-DM (6, IQR 5-7), MBBS-MS (6, IQR 6-6), and MBBS-MS-MCh (5.5, IQR 4-0). A P-value of 0.932 suggests that there is no statistically significant difference in the knowledge levels across these groups.

Attitude: The median attitude levels for clinical trial investigators from various educational backgrounds are as follows: MBBS-MD has a median score of 8, with an interquartile range (IQR) of 6.25-9.75; MBBS-MD-DM also shows a median score of 8, with a narrower IQR of 7-9; MBBS-MS has a lower median score of 5, with an IQR of 5-5, indicating no variability; and MBBS-MS-MCh has a median score of 7, with an IQR of 6-0. The P-value of 0.402 suggests that there is no statistically significant difference in attitude levels across the groups.

Practices: The median practices levels for clinical trial investigators with different educational backgrounds are as follows: MBBS-MD has a median score of 3, with an interquartile range (IQR) of 2-3; MBBS-MD-DM has a median score of 2, with an IQR of 2-3; MBBS-MS shows a higher median score of 5, with an IQR of 5-5, indicating no variability; and MBBS-MS-MCh has a median score of 3, with an IQR of 3-3, also indicating no variability. The P-value of 0.183 suggests that there is no statistically significant difference in practices levels across these educational groups.

TABLE -21: KAP ASSESSMENT BASED ON THE EDUCATIONAL BACKGROUND OF HUMAN ETHICS COMMITTEE MEMBERS

EC-Members and Their educational backgournd	B.Com	BA	BA-LLB	BSW-MSW	Eng.	M.Pharm	M.Pharm-PhD	MBBS-MD	MSc	MSc-PhD	P value
	n=4	n=2	n=8	n=1	n=3	n=3	n=4	n=23	n=1	n=1	
KNOWLEDGE	0.5 (0-1)	4.5 (1-0)	1 (1-1)	3 (3-3)	1 (0-0)	9 (7-0)	7 (6-8)	7 (7-8)	8 (8-8)	9 (9-9)	**<0.001**
ATTITUDE	10 (2.5-10)	10 (10-10)	10 (10-10)	10 (10-10)	10 (9-0)	7 (6-0)	10 (10-10)	10 (10-10)	10 (10-10)	10 (10-10)	0.177
PRACTICES	1.5 (1-2)	2 (2-2)	2 (1.25-2)	2 (2-2)	1 (1-0)	5 (2-0)	2 (2-2)	2 (2-2)	2 (2-2)	2 (2-2)	0.042

The above **table-21** represents the comparison of Knowledge, Attitude, and Practices (KAP) among Ethics Committee (EC) members with various educational backgrounds, including B.Com, BA, BA-LLB, BSW-MSW, Engineering, M.Pharm, M.Pharm-PhD, MBBS-MD, MSc, and MSc-PhD.

Knowledge: Levels are vary significantly among ethics committee members based on educational background, with median levels ranging from 0.5 (B.Com) to 9 (M.Pharm). The Kruskal-Wallis Test yields a P-value of less than 0.001, indicating a statistically significant difference in knowledge levels among different educational backgrounds. In the present study, Ethics committee members with an M.Pharm-PhD or M.Pharm degree have higher median knowledge levels (7-9), while those with a BA or BA-LLB have lower levels (1-4.5).

Attitude: levels are more consistent across different educational backgrounds, with most groups having a median score of 10, indicating a generally positive attitude towards their role. The IQRs are narrow, reflecting little variation within groups. The Kruskal-Wallis Test P-value is 0.177, suggested no statistically significant difference in attitude levels among the educational backgrounds.

Practices: Levels shows variability among different educational backgrounds, with median levels ranging from 1 (Engineering) to 5 (M.Pharm). The Kruskal-Wallis Test P-value of 0.042 suggests a statistically significant difference in practice levels among the educational backgrounds. This indicates that educational background does influence the practical application of knowledge and skills in Ethics committee members roles, with those holding advanced degrees like M.Pharm-PhD showing higher practical engagement compared to those with bachelor's degrees.

TABLE-22: PAIRWISE COMPATISION OF KNOWLEDGE OF H-ETHICS COMMITTEE MEMBERS

Comparison	Test Statistic	Std. Error	P value
B.Com Vs BA, LLB	-3.38	8.82	1
B.Com Vs Eng	-3.83	10.99	1
B.Com Vs BSW-MSW	-9.5	16.1	1
B.Com Vs BA	-18	12.47	1
B.Com Vs M.Pharm, PhD	-24.25	10.18	0.776
B.Com Vs MBBS, MD	-26.87	7.8	0.026
B.Com Vs MSc	-32.5	16.1	1
B.Com Vs M.Pharm	-34.5	10.99	0.077
B.Com Vs MSc-PhD	-40	16.1	0.584
BA, LLB Vs Eng	-0.46	9.75	1
BA, LLB Vs BSW-MSW	-6.13	15.27	1
BA, LLB Vs BA	14.63	11.38	1
BA, LLB Vs M.Pharm, PhD	-20.88	8.82	0.807
BA, LLB Vs MBBS, MD	-23.49	5.91	0.003
BA, LLB Vs MSc	-29.13	15.27	1
BA, LLB Vs M.Pharm	-31.13	9.75	0.063
BA, LLB Vs MSc-PhD	-36.63	15.27	0.742
Eng Vs BSW-MSW	5.67	16.63	1
Eng Vs BA	14.17	13.15	1
Eng Vs M.Pharm, PhD	-20.42	10.99	1
Eng Vs MBBS, MD	-23.04	8.84	0.412
Eng Vs MSc	-28.67	16.63	1
Eng Vs M.Pharm	-30.67	11.76	0.41
Eng Vs MSc-PhD	-36.17	16.63	1
BSW-MSW Vs BA	8.5	17.64	1
BSW-MSW Vs M.Pharm, PhD	-14.75	16.1	1
BSW-MSW Vs MBBS, MD	-17.37	14.71	1
BSW-MSW Vs MSc	-23	20.37	1
BSW-MSW Vs M.Pharm	-25	16.63	1
BSW-MSW Vs MSc-PhD	-30.5	20.37	1
BA Vs M.Pharm, PhD	-6.25	12.47	1
BA Vs MBBS, MD	-8.87	10.62	1
BA Vs MSc	-14.5	17.64	1
BA Vs M.Pharm	-16.5	13.15	1
BA Vs MSc-PhD	-22	17.64	1
M.Pharm, PhD Vs MBBS, MD	-2.62	7.81	1
M.Pharm, PhD Vs MSc	-8.25	16.1	1
M.Pharm, PhD Vs M.Pharm	10.25	10.99	1
M.Pharm, PhD Vs MSc-PhD	-15.75	16.1	1
MBBS, MD Vs MSc	-5.63	14.71	1
MBBS, MD Vs M.Pharm	7.63	8.84	1
MBBS, MD Vs MSc-PhD	-13.13	14.71	1
MSc Vs M.Pharm	2	16.63	1
MSc Vs MSc-PhD	-7.5	20.37	1
M.Pharm Vs MSc-PhD	-5.5	16.63	1

The **table-22** shows the pairwise comparisons of the knowledge levels of Ethics Committee (EC) members across various educational backgrounds. The comparisons are based on test statistics, standard errors, and P-values to determine the significance of the differences. A wide range of comparisons was made, such as B.Com vs. BA, B.Com vs. MSc-PhD, and M.Pharm vs. MBBS-MD, among the clinical trials stakeholders. The P-values indicate whether the observed differences are statistically significant. Most of the comparisons have P-values of 1, indicating no statistically significant difference in knowledge levels between those pairs. However, there are a few comparisons with P-values less than 0.05, suggesting significant differences. For example, the comparison between BA, LLB and MSc-PhD has a P-value of 0.046, indicating a significant difference in knowledge between these two groups. Similarly, BA, LLB and MSc-PhD has a P-value of 0.021, also indicating a significant difference. These significant results suggest that ethics committee members with certain educational backgrounds, such as MSc-PhD, have notably different (often-higher) knowledge levels compared to those with backgrounds like BA, LLB.

TABLE 23: KAP ASSESSMENT ON THE EDUCATIONAL BACKGROUND OF P-SPONSORS AND CROs

Pharmaceutical sponsors & CROs	Life Sciences	Medical/Health Sciences	Pharma	Non-scientific	P value
	n=5	n=4	n=40	n=1	
KNOWLEDGE	8 (7-8)	8 (8-8.75)	8 (7-8)	5 (5-5)	0.256
ATTITUDE	10 (9-10)	9.5 (8.25-10)	9 (8-10)	8 (8-8)	0.356
PRACTICES	4 (3-7.5)	6.5 (6-7)	6 (4-7)	4 (4-4)	0.618

The above **table-23** results indicate no statistically significant differences in knowledge (p=0.256), attitude (p=0.356), or practices (p=0.618) across life sciences (n=5), medical/health sciences (n=4), pharma (n=40), and other backgrounds (n=1) of the pharmaceutical sponsors and CROs. Descriptive statistics showed median levels with interquartile ranges for each category.

4.6. ETHICAL CHALLENGES IN GENETIC RESEARCH DATA USE FOR FUTURE ACCORDING TO THE STAKEHOLDERS: The present study also investigated a list of ethical challenges associated with sharing genetic research data for future research as part of secondary objective of the research. A predominant issue identified was the potential misuse of clinical or genetic data. The misuses concern was expressed by among all clinical trial stakeholders, reflecting widespread apprehension about how such sensitive information might be improperly utilized, leading to unintended consequences for individuals and communities. The misuse of genetic data could include unauthorized access, manipulation, or the use of the data for purposes beyond the original research intentions.

TABLE 24- Ethical challenges in Genetic Research data use for future according to the stakeholders

Ethical Issues/Challenges	Human Ethics committee Members n=50	Clinical trial Investigators n=50	Clinical trials Participants n=50	Pathologists n=25	P'Sponsor's/CRO n=50
Ethical and Legal	27 (62.79)	11 (28.95)	1 (6.67)	5 (20.83)	31 (63.27)
Confidentiality	16 (37.21)	27 (71.05)	14 (93.33)	19 (79.17)	18 (36.73)
Secondary Use of identified data and coded data	5 (19.23)	9 (45)	0	0	38 (92.68)
Return of research results	21 (80.77)	11 (55)	0	9 (100)	3 (7.32)
Intentional disclosure	2 (6.25)	5 (11.9)	0	1 (4.55)	9 (19.57)
Misuses	30 (93.75)	37 (88.1)	15 (100)	21 (95.45)	37 (80.43)
Importance of Genetic Coding	14 (29.17)	14 (29.17)	4 (10.53)	0	24 (54.55)
Ownership of the biological samples and its data	22 (44)	30 (75)	0	0	44 (88)
Return of research results to individual/groups	28 (56)	10 (25)	0	4 (100)	6 (12)
Data should be shared via unrestricted	2 (16.67)	1 (12.5)	0	0	3 (7.14)
Controlled access repositories	10 (83.33)	7 (87.5)	0	0	39 92.86)

Based on the Table no:24 and Fig No-15 graphical representation.

Ethical and Legal Concerns Majority of Human Ethics Committee Members (62.79%) and P' Sponsors/CROs (63.27%) emphasized ethical and legal considerations. Clinical trial investigators (28.95%) and pathologists (20.83%) showed moderate concern. Clinical trial participants showed very low concern (6.67%).

Confidentiality

Highly prioritized by clinical trial participants (93.33%), pathologists (79.17%), and investigators (71.05%). Less emphasis among Human Ethics Committee Members (37.21%) and P' Sponsors/CROs (36.73%).

Secondary Use of Data

Strong support from P' Sponsors/CROs (92.68%) and moderate from investigators (45%). Very low support from Human Ethics Committee Members (19.23%). No support from participants or pathologists.

Return of Research Results

Pathologists (100%) and Ethics Committee Members (80.77%) supported this. Investigators showed moderate support (55%), while participants and P' Sponsors/CROs showed minimal interest (0% and 7.32% respectively).

Intentional Disclosure: Minimal agreement across all groups, with highest from P' Sponsors/CROs (19.57%).

Concerns about Misuse: High across all groups, especially participants (100%), pathologists (95.45%), Ethics Committee Members (93.75%), and investigators (88.1%).

Importance of Data Coding: Most pronounced among P' Sponsors/CROs (54.55%), with low agreement from other groups.

Ownership of Biological Samples and Data: Strongly emphasized by P' Sponsors/CROs (88%) and investigators (75%). Moderate emphasis from Ethics Committee Members (44%), none from participants or pathologists**.**

Return of Research Results to Individuals/Groups

Strongly supported by Ethics Committee Members (56%) and pathologists (100%). Low to no support from other stakeholders.

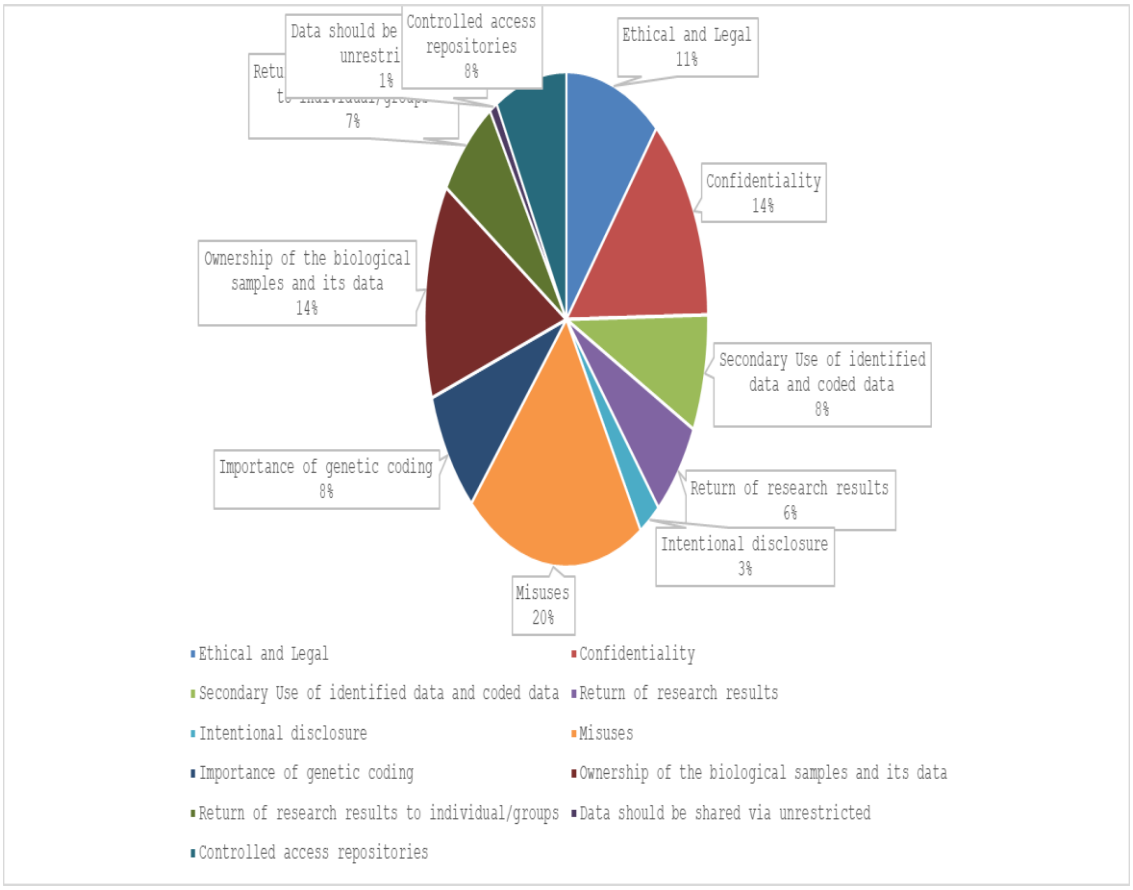
Unrestricted Data Sharing

Very low support across all groups, highest being Ethics Committee Members (16.67%).

Controlled Access Repositories

Strong support among all professional groups: P' Sponsors/CROs (92.86%), investigators (87.5%), and Ethics Committee Members (83.33%). No support from participants and pathologists

FIGURE NO: 15- ETHICAL CHALLENGES IN GENETIC RESEARCH DATA USE FOR FUTURE ACCORDING TO THE STAKEHOLDERS



4.7. DEVELOPED THE GENETIC CONSENT MODEL FOR GENETIC RESEARCH DATA REUSE FOR FUTURE RESEARCH

GENETIC CONSENT MODEL FOR GENETIC RESEARCH DATA REUSE FOR FUTURE RESEARCH

PART-A: GENETIC RESEARCH STUDY INFORMATION

Research Title and No:

Protocol Version and date:

Name of the Sponsor/Contact Research Organization:

Name of the Government/External Funding Agencies: [Ex: NIH, ICMR, Bill Melinda gates etc]

Name of the bio-banking/ Genetic analysis Centre:

Dear Participants!

You have been invited to join this research study due to your specific medical condition. Your written consent is essential for your inclusion in the study. Prior to making a decision about your participation, you will receive detailed information about the study, encompassing the collection, storage, and utilization of your data and biological samples. Additionally, the process of sharing research findings with both participants and attenders will be explained. It is important to note that the study has undergone review by an institutional ethics committee or independent review board.

1 **Introduction:** We are conducting the study about the_____. We would like to understand the disease and related health problems in a better way as future perspectives

1.1. **Genetic research:** The primary emphasis is on understanding how genes contribute to various characteristics, particularly the development of diseases. This exploration is crucial for Clinical trials investigators pointing potential therapeutic targets and

gaining insights into genetic variations that influence responses to therapeutic interventions.

1.2. **Genetic Samples:** Samples of uncertain or unidentified origin collected from humans may encompass various biological materials. These include liquid blood or bloodstains, liquid saliva or saliva stains, and liquid semen, along with genital/vaginal/cervical samples collected on swabs and penile swabs. Additionally, tissue/skin can be part of these collected samples.

1.3. **Consent for future use:** Although it may be challenging to precisely outline the specifics of future research endeavours:

I-PWG Views:

- The research is scientifically sound
- Participants are informed of the scope of the intended future research
- Autonomy is respected by providing the option to consent separately for future research or by providing the option to terminate further use of samples upon request
- Good Clinical practices standards

2. Return of Research Results: Within pharmaceutical companies, policies regarding the disclosure of biomarker results to participants who request them involve numerous considerations. These considerations encompass various factors such as:

2.1. The conditions under which genetic results were generated

2.2. Whether results will have impact on medical care of the participant

2.3. Whether genetic counselling is recommended

2.4. The ability to accurately link the results to individual from whom the samples was collected

2.5. International and national, guidelines and policies regarding the participant's rights access the data to them

3. Collecting of bio-samples and its data: The study team will collect information related to your identity, such as your name, occupation, address, and contact number,

along with data essential for assessing your health conditions and medical history as part of the study participant's information. The data obtained from the research will be handled as coded data.

Biomarker Research, including research on pharmacogenomics biomarkers, serves as a



valuable tool to enhance pharmaceutical development and deepen our understanding of diseases. This approach involves the analysis of biomolecules such as DNA, RNA, proteins, and lids, as well as other measurements, in relation to specific clinical endpoints of interest. Biomarker research can significantly influence all stages of drug development, spanning from drug discovery and preclinical evaluation to clinical development and post-marketing studies.

4 What do I need my data and bio-samples for?

4.1. Know how the study medications & same drugs work in the body

4.2. Know disease related health problems

4.3. To develop diagnostic tests for disease

4.4. To explore a wide range of research questions

4.5. To validate the research results

5 Who can Access my data and bio-samples?

5.1. The present study Investigator

5.2. Health authorities

5.3. IEC/IRB

5.4. Sponsors/CROs

The research site will share your data and bio-samples with the sponsors/CROs, but only after the data has been coded. In the context of drug discovery and development, the sponsor or their representatives may share your coded data and bio-samples with third parties, facilitated by a Memorandum of Understanding (MOU) or a Material Transfer Agreement.

6 **Type of data coding:** Coding of your personnel data will be done as per the ICMR guidelines-2017.

I.e. single coded anonymized data shall share with the study participants or relatives

7 **How long will my data and coded bio samples be retained?**

After completion of the study, as per the regulatory requirements study related data and document required keep for 25 Years. Your coded data will be deleted or anonymized, and your bio-samples returned to your study investigator.

8 **Benefits of data Sharing:**

8.1. The document should describe whether donors, their families, or communities would receive any financial or non-financial benefits by having access to the products, tests, or discoveries resulting from the research.



8.2. The benefits accrued, if any, should be returned to the communities from where the donors were drawn in community-based studies or from the research institutes.

8.3. To the maximum extent possible, benefits should be indirect or in kind

9 **Ownership of the biological samples and data:** The participant retains ownership of the biological samples and data collected from them. Consequently, the participant has the right to withdraw both the biological material contributed to the biobank and the associated data, unless the data is essential for outcome measurement and explicitly mentioned in the initial informed consent document. It is important to note that complete anonymization may lead to the practical loss of the original donor's ownership rights.

Biobanks or institutes function as custodians or trustees of the samples and data, overseen by their Ethics Committees (ECs). The present and future use of these materials are conducted under the supervision of the respective ECs. Researchers, in turn, do not possess any claim to ownership or custodianship of the biological samples and data.

10 **Bio banking:** is a systematically curated repository of human biological materials, typically accompanied by associated datasets, preserved over an extended period in suitable facilities for research and potentially commercial purposes, incorporating transparent policies. As bio-banking involves the storage and future research utilization of biological materials, ethical considerations revolve around consent requirements for the collection, banking, and subsequent uses of tissue, DNA samples, and/or data.

11. **Any other optional tests and procedures:** Collecting of additional blood samples/tissues for genetic analysis may be done as part of this study.

12. **Contact details for the additional questions I might have.**



Name of the Researcher	
Phone Number	
Email	
Sub-Investigator-Research Coordinator	
Phone Number	
Name and address of the Medical Research Centre/Hospital	

Name and Address of the IEC/IRB	
Name of the Member Secretary/Chairperson	
Phone Number	
E Mail ID	

Name of the bio-banking/Genetic analysis Centre	
Name of the contact Person	
Address – India or Other country	
Phone Number	
E Mail ID	

PART-B: FUTURE RESEARCH INFORMATION

1. **What is a Genetic data and its re-uses for future research**



Genetic data re-use refers to the secondary use of genetic information collected during clinical trials or biomedical research for future scientific investigations beyond the original study's scope. This practice has the potential to accelerate discoveries in personalized medicine, disease prevention, and treatment development by maximizing the utility of existing data. By re-analyzing stored genetic material and associated datasets, researchers can explore new hypotheses, validate findings, and identify genetic patterns across diverse populations. Re-use also reduces the need for repeated sampling and testing, promoting ethical resource use and reducing the burden on participants.

However, the re-use of genetic data raises several ethical, legal, and social concerns. Protecting participant privacy is paramount, especially given the unique and identifiable nature of genetic information. Informed consent models must clearly communicate the possibility of future data use, and governance frameworks must ensure transparency and accountability. Additionally, disparities in stakeholder awareness—such as among investigators, sponsors, and ethics committee members—can hinder effective data stewardship. As genetic research expands, developing robust policies, improving stakeholder training, and establishing universally accepted guidelines are essential to promote responsible, ethical, and scientifically valuable genetic data re-use.

2. **Why is Genetic research data Important?**



The importance of genetic data re-use lies in its ability to significantly enhance the efficiency, reach, and impact of biomedical research. By enabling researchers to analyze previously collected genetic information for new scientific questions, data re-use accelerates the pace of discovery without the need to repeat time-consuming and costly data collection processes. This not only conserves valuable resources but also reduces the ethical burden on participants by minimizing redundant sampling. Furthermore, re-using genetic data supports large-scale analyses and meta-studies that are critical for understanding complex diseases, improving diagnostics, and advancing personalized medicine. When governed

responsibly, genetic data re-use can drive innovation while maintaining participant trust and ethical integrity.

3. **How are Genetics and its research data Used in Drug/Vaccine Development**?

   Biomarker research is currently being used in drug/vaccine development to:

   3.1. Explain variability in response among participants in clinical trials

   3.2. Better understand the mechanism of action or metabolism of investigational drugs

   3.3. Obtain evidence of Pharmacodynamic activity (i.e., how the drug affects the body) at the molecular level

   3.4. Address emerging clinical issues such as unexpected adverse events

   3.5. Determine eligibility for clinical trials to optimize trial design

   3.6. Optimize dosing regimens to minimize adverse reactions and maximize efficacy

   3.7. Develop drug-linked diagnostic tests to identify patients who are more likely or less likely to benefit from treatment or who may be at risk of experiencing adverse events

4. **Genetic Samples from Clinical Trials: An Invaluable Resource?**

   Biomarker samples collected from clinical trials represent an invaluable resource for advancing biomarker research. The robustness of clinical trials, characterized by adequate sample sizes and high-quality data obtained through rigorous control measures, is crucial for driving progress in this field. Clinical trials offer a unique opportunity for investigating biomarkers in relation to specific drugs, drug classes, and disease areas. As a result, clinical drug development programs serve as an unparalleled resource for conducting highly productive biomarker research.

5. **Informed Consent for Collection & Banking of Biomarker Samples?**

   Collection of biological samples in clinical trials must be undertaken with voluntary informed consent of the participant (or legally acceptable representative). Policies and regulations for legally appropriate informed consent vary on national, state, and local levels, but are generally based on internationally recognized pillars of ethical conduct for research on human subjects

6. **What is Optional vs. Required Subject Participation?**

   Depending on the relevance of biomarker research to a clinical development program at the time of protocol development, the biomarker research may be a core required component of a trial (e.g., key to elucidating the drug mechanism of action or confirming that the drug is interacting with the target) or may be optional (e.g., to gain valuable knowledge that enhances the understanding of diseases and drugs). Informed consent for the collection of biomarker samples may be presented either in the main clinical informed consent form or as a separate informed consent form, with approaches varying somewhat across pharmaceutical companies.

7. **Return of Research Results to Study Participants and Research institute?**

Policies regarding the return of biomarker research results to study participants can vary among pharmaceutical companies, with several considerations influencing their decision-making process. These considerations include:

7.1. **Conditions of Result Generation:** This involves discerning whether biomarker research results were generated in an exploratory research laboratory or an accredited diagnostic laboratory, influencing the reliability and interpretability of the findings.

7.2. **Impact on Medical Care**: Pharmaceutical companies assess whether the results will have a meaningful impact on the medical care of the participant or any related individuals, if applicable, as a key factor in determining the return policy.

7.3. **Genetic Counselling Recommendations**: In cases involving genetic results, considerations extend to whether genetic counselling is recommended. This emphasizes the importance of providing additional support and information for participants facing genetic implications.

7.4. **Linking Results to Individuals:** The ability to accurately link the biomarker research result to the individual from whom the sample was collected is another crucial factor. Ensuring precision in result attribution is vital for maintaining data integrity and participant trust.

8. **Privacy, Confidentiality, and Patient Rights?** are crucial aspects of ethical research practices:

Privacy: Protecting the privacy of study participants is fundamental. This involves safeguarding their personal information and ensuring that their identity remains confidential. Researchers must implement measures to prevent unauthorized access to participant data.

Confidentiality: Confidentiality pertains to the obligation to keep sensitive information obtained during the study confidential. Researchers, regulators, and all involved parties must take steps to prevent the unauthorized disclosure of participant data.

Patient Rights: Respecting and upholding the rights of patients is paramount. This includes providing clear and comprehensive information about the study, obtaining informed consent, and ensuring participants have the right to withdraw from the study at any time without facing negative consequences.

Maintaining a balance between collecting necessary data for research and protecting the rights and privacy of study participants is critical to ethical research conduct. Adhering to these principles, helps build trust between researchers and participants, fostering the integrity of the research process.

PART: C – GENETIC CONSENT FORM

Research Title and No:

Protocol Version and date:

Name & Contact details of the site:

I confirm that

1. I have engaged in discussions with the researcher, obtaining comprehensive answers to all my queries regarding the genetic research.
2. I comprehend the intended use of my personal information, data, and genetic samples, including the entities authorized to access them for future research. I acknowledge the version and date of the genetic research form.
3. I am aware that my participation in the genetic research is voluntary, and I retain the right to withdraw from the study at any point, without any adverse consequences.
4. I acknowledge the arrangement regarding the sharing of research results, whether with the researcher or with myself.
5. I commit to refraining from placing restrictions on the utilization of any genetic data or results arising from the research**.**

Consent Particular	Date of signature	Time
Signature or thumb Impression of the participant/LAR _____		
Name of the study participant or LAR who has signed _____		
Name of the Researcher and signature _____		

*If the study participant or their legally acceptable representative is unable to read or write, an impartial witness must be present throughout the entire informed consent process. This witness will then affix their signature to the consent form, indicating their presence and attesting to the participant's or representative is understanding and voluntary agreement to participate in the study.

Consent Particular	Date of signature	Time
Name and Signature Impartial witness _____		

REFERENCES:

1. Indian Council of Medical Research Guidelines-2017 Compiled & Edited by: Dr. Roli Mathur Head,
   ICMR Bioethics Unit NCDIR, Bengaluru
2. Understanding the Intent, Scope and Public Health Benefits of Exploratory Biomarker Research by IPWG

Genetic Consent Model for Genetic Research Data re-uses ICD- Version-0.0- dated 21-Aug-2023

5. DISCUSSION

The objective of genetic research and its data can be seen through multiple lenses, each aiming to advance in understanding of genetics, improve health outcomes, and explore ethical implications. Some core objectives:

- The discovery of genetic markers that indicate disease susceptibility, which can aid in early diagnosis, prevention, and more targeted treatments.
- Developing Personalized Medicine to improve effectiveness and minimize adverse effects.
- Genetic research can reveal insights into how genetic factors contribute to disease risks in populations, helping public health strategies, screening programs, and health policies to reduce disease burden.
- Supporting Data Re-Use and Secondary Research to maximize the utility of existing data, contributing to findings that might not be possible through isolated studies.

The use of a validated Knowledge, Attitude, and Practices (KAP) questionnaire further strengthens these findings. With a Cronbach's Alpha of 0.73, the reliability of the questionnaire suggests that the stakeholders' responses consistently reflect their knowledge and attitude toward genetic data re-use. The validated tool provides a robust structure for understanding how demographic factors influence stakeholders' ethical viewpoints, analysis of critical insights for developing more inclusive and ethical clinical research practices.

The present study aimed to explore the knowledge, attitude and practices of clinical trial stakeholders towards the Genetic Research Data re-use and to identify the ethical challenges involved in the genetic research re-uses. Clinical trials stakeholders' plays vital role in the design, conduct, recording, reviewing and reporting of clinical research proposal. However, there is a lack of standard guidelines to execute the Genetic Research and its data for future. In clinical trials, all the clinical trial stakeholders followed the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice **(GCP)** guidelines serve as globally acknowledged standard principles for the design, conduct, and reporting of clinical trials involving human subjects [40].

There is no such studies found related to Genetic Research data re-uses for research on clinical trials stakeholder but several studies have been conducted on Bio banking and Public data sharing prospective. They only focused on the public and bio banking prospective.

By exploring demographic characteristics of clinical trial stakeholders, the present study provides insight into the factors that may influence the attitude and practical approaches of different stakeholders. Age, gender, and marital status all appear to significantly shape the perspectives on genetic data re-use. These differences underscore the need for tailored communication and guidelines approaches that respect the diverse backgrounds and experiences of clinical trial stakeholders. Importantly, the present study's findings suggest that a one-size-fits-all approach to guidelines may be inadequate, and that nuanced, group-specific strategies are necessary to address the ethical challenges of data re-use in clinical trials.

5.1. ASSESSMENT OF KAP LEVELS OF CLINICAL TRIAL STAKEHOLDERS:

Pereira et al 2014 studied on open access to the data sharing, many participants have shown a strong willingness to share their genomic data for research purposes, reflecting a generally positive attitude towards contributing to scientific advancement. The willingness often hinges on factors such as trust in the researchers or institutions handling the data, perceived societal benefits, and assurances of privacy and confidentiality. These studies suggest that, under the right conditions, stakeholders—particularly participants—may view data sharing as beneficial, which has important implications for ethical frameworks in genetic research, including the need for transparent consent processes and robust data protection measures [44]. However, individuals typically share such data under specific conditions and with assurances of safeguards. The present research explored the perceptions of clinical trial stakeholders towards the reuse of genetic research data.

Knowledge levels vary significantly, with Sponsors/contract research organizations and Ethics Committee members shown the highest knowledge on the genetic research data for re-use, likely due to their roles in research oversight and compliance, while Participants shown the lowest knowledge, which may stem from limited access to understanding of clinical trial information. P <0.001, differences in knowledge across the clinical trial stakeholders are statistically significant.

Attitude across all clinical trial stakeholders are generally positive, with a high median score of 10, indicating broad support for genetic data re-use, though slight variations exist among groups that could reflect differences in perceived risks or benefits. The P value of <0.001 signifies that these attitudinal differences are statistically significant.

Practices Sponsors and contract research organizations are the most actively involved, likely due to their responsibility in research conduct and data stewardship; whereas Participants and Pathologists shown the minimal engagement, possibly reflecting limited opportunities or responsibilities in data re-use practices. These discussions underscore the need for targeted educational initiatives to bridge knowledge gaps among participants and enhance practical involvement where feasible. The significant P value (<0.001) points to meaningful differences across groups in terms of actual practices.

5.2. INDIVIDUAL KAP-ASSESSMENT OF CLINICAL TRIAL STAKEHOLDERS:

CLINICAL TRIAL INVESTIGATORS: Traore, K. et al. conducted a qualitative study exploring the experiences, motivations, and beliefs of users of online data-sharing platforms who chose to openly share their genomic data. Their findings highlight the need for further research to examine how privacy concerns are addressed within these platforms and to develop frameworks for evaluating the benefits of open genetic data sharing in relation to its potential risks [41]. The present study results correlates that n=50 of whom 64% of clinical trial investigators aware of genetic data re-use in clinical or genetic research. 54% expressed concerns about confidentiality issues related to the re-use of genomic data. 48% of Clinical trial investigators expressed advantages in sharing and re-using genetic information for a diverse range of research information. Both studies shown the importance of understanding attitude towards data sharing and privacy in the genomic or clinical research. While the clinical trial investigator focuses on the perspectives within the clinical or genetic research aspects, the qualitative study investigate into the motivations and beliefs of individual participants who openly share their genomic data online. Together, these studies contribute to a broader understanding of the challenges and opportunities

associated with genetic research data sharing its re-use. Several KAP (Knowledge, Attitude, and Practices) questions and their corresponding responses were analysed.

What happen if the genetic research data is shared: According to the findings, 10% of clinical trial investigators expressed that there is a risk of intentional disclosure by third parties, which can have severe consequences, such as breaches of confidentiality and unauthorized use of sensitive information. A majority 74% concern about the potential misuse of such data, fearing that it could be exploited for unethical purposes.

Interestingly, 16% of clinical trial investigators remained uncertain about the possible outcomes of sharing genetic data, indicating a gap in knowledge or awareness of its implications. Particularly those from the department of community & respiratory medicine demonstrated limited familiarity with genetic research and its ethical challenges. This lack of awareness emphasizes the importance of interdisciplinary education and training to equip all stakeholders with a comprehensive understanding of genetic research and its implications.

Optional consent in clinical trial and research*:* In clinical trials phases, it has been observed that a considerable proportion of clinical trial investigators, specifically 44%, have reported a lack of identification of informed consent in relation to the procurement of bio-specimens. Additionally, 56% of clinical trials investigators are expressing uncertainty regarding genetic research were from specific medical specialties, reflecting their varied levels of exposure and experience. Among these, 66.67% were from the orthopaedics department, with 04 clinical trials investigators new to clinical trials, underscoring a lack of familiarity with genetic research processes and implications. Similarly, 87.50% of the clinical trial investigators from general medicine expressed uncertainty, suggesting limited interaction with genetic research in their practice. Notably, 35% of

respondents with lower clinical trial experience also displayed uncertainty, reinforcing the correlation between trial experience and understanding of genetic research. These findings, as shown in [Table-16], highlight the disparity in knowledge across departments and experience levels.

Types of consent used for gathering genetic data for clinical trials or research: Reflecting differing levels of investigator familiarity and involvement. Only 4% of clinical trial investigators reported using blanket or broad consent, a model that permits broad future use of genetic data within agreed parameters. In contrast, 22% of investigators indicated the use of tiered consent, which allows participants to choose specific levels of data use. These responses highlight the structured approaches employed by some investigators when dealing with genetic data.

However, a notable majority of investigators appeared unaware of the types of consent applied for gathering genetic research data. This lack of awareness could be attributed to their limited involvement in genetic studies, suggesting that they may not have encountered the unique consent frameworks typically required for such research.

Support of re-using of genetic information in clinical trials: The re-use of genetic information in clinical trials is strongly supported by clinical trial investigators, with 46% strongly agreeing and 52% agreeing on the value of utilizing genetic research data. This indicates a broad consensus among clinical trial investigators regarding the importance of genetic data in enhancing the efficiency and outcomes of clinical research.

Permit the return of findings from genomic research: 84% agreed to authorize the transfer of research findings back to the research participants. Many genomics researchers believe that at a minimum and after an informed consent process,

incidental findings that are medically actionable (meaning that there is an associated action to reduce the risk of a disease or to treat the disease) should be returned [57]; however, determining what is actionable is also a challenge. The volume of genomic data and the potential for new findings and changing interpretations in the future makes it particularly difficult to develop recommendations and policies regarding an infrastructure and resources for returning individual research results and research findings.

The biobanks are securely and safely storing participant genetic samples and its data: The majority of clinical trial investigators (62%) agree that biobanks securely and safely store participants' genetic samples and associated data. However, 18% of investigators express concerns regarding the security of biobank storage. Notably, this group predominantly consists of individuals from general medicine, cardiology, and nephrology departments, who also tend to have less experience in clinical trials. This statement highlights the potential influence of professional background and clinical trial experience on perceptions of biobank security.

Ethical issues surround the sharing and reuse of genetic data: Ethical considerations play a pivotal role in the sharing and reuse of genetic data, particularly regarding practices surrounding the future use of genetic research data. Among clinical trial investigators, 60% asserted ownership over genetic samples and their associated data, reflecting a belief in proprietary rights or control over the materials and information derived from research participants.

Meanwhile, 20% of clinical trial investigators emphasized the importance of returning research results to individuals or groups, underscoring a commitment to participant-cantered practices and transparency.

The remaining 20%, predominantly from the nephrology and orthopaedics departments, admitted to a lack of awareness of the ethical issues related to the sharing and reuse of genetic data.

Who has authority to request the sponsors' return of research results or its data:? Among clinical trial investigators**,** 54% believe that responsibility lies with the principal investigator, hospital, or institution, reflecting a perspective that emphasizes institutional or research leadership in managing research outputs. In contrast, 20% of clinical trial investigators identified the study participant as holding the authority to request the return of research results from pharmaceutical sponsors, aligning with a participant-centered approach that prioritizes transparency and respect for individual rights.

The remaining 20%, primarily from the departments of General Medicine and Orthopaedics, either did not express a clear understanding or were uncertain about the authority in such situations. This highlights a potential gap in awareness related to the ethical and operational frameworks governing research data management. **Table No. 18.**

CLINICAL TRIAL PARTICIPANTS: Clinical trial participants, who contribute research data in genetic and clinical studies. Their perspective is crucial, as the data they provide holds significant potential benefits for scientific advancement. However, concerns about potential harms to participants have led pharmaceutical sponsors and clinical trial investigators to advocate for caution.

In a previous study conducted by **Michelle M. Mello et al.,** found that there were strong concerns regarding the risks associated with data sharing in clinical trials. The

study underlevels the importance of addressing these concerns to ensure that data sharing practices are both ethical and beneficial to all the stakeholders involved [42].

In addition, concerned about the risks, confidentiality, and ownership of the collected research data and from the research outlined the research questions with the explanation.

Do you know about the genetic research and data re-uses in clinical trials*:* A knowledge assessment revealed that the majority of clinical trial participants were unaware of genetic research data re-uses. However, 26% of clinical trial participants indicated some level of awareness of genetic research. This awareness may have been influenced by their comprehension of the question, which was facilitated by their preference for English-language consent forms in the respective clinical trials. Clinical trial participants' reliance on English consent forms suggests that language accessibility might influence understanding. Offering consent materials in preferred or native languages could improve participant comprehension.

What does optional consent in clinical trials?: Approximately 30% of clinical trial participants are aware that informed consent encompasses provisions for the collection of biomarker samples, while the remaining 70% lack this awareness. This highlights a potential communication issue in the informed consent process, particularly in explaining specific components such as biomarker collection or future research related information. Notably, the 30% who demonstrated awareness might predominantly be participants involved in oncology-related clinical trials.

The primary objective of ICH GCP is to uphold both ethical and scientific integrity, safeguarding the rights, safety, and well-being of trial participants. However, ICH GCP provides comprehensive guidance on conducting of clinical trials. However,

there is currently no universally established set of ethical guidelines specifically addressing the responsible use and sharing of genetic information in future research and clinical investigations**.** The rapid advancements in genetic research and the increasing availability of genetic data, there is a growing need for ethical frameworks customized to the unique challenges and considerations posed by genetic research data. Different organizations, including governmental authorities, research institutions, and research communities, are actively engaged in developing guidelines and policies to ensure the responsible collection, use, and sharing of genetic research samples and its data.

Moodley K et al., in their research titled *"It's My Blood,"* highlighted the variations in regulations governing the use of biological samples and data across Sub-Saharan Africa. In South Africa, the National Health Act of 2003 mandates that research participants provide informed consent before donating biological samples and data and research participants expressed in the views of some research participants with regard to benefit sharing 39%. However, the Act lacks clear guidelines on the reuse of these samples and data in subsequent research[64-65]. The present research research participants 70% do not know about the adavantges of genetic research data reuses & also concluded that there is a lack guielines on genetic research data re-uses.

HUMAN ETHICS COMMITTEE MEMBERS: The previous study conducted by **Traore, K et al.,-2015** on understandings of genomic research in developing countries highlighted the critical importance of the consent process design, emphasizing the roles of review committees and community consultation activities in protecting the interests of research participants in genetic research [41].

Based on the findings [Table No: 07 & 13], the present research explores the ethical challenges surrounding the sharing and reuse of genetic research data. 60% of human ethics committee members expressed concerns about potential misuse of such data. Meanwhile, 36% of human committee members, comprising primarily legal experts and social scientists, were unaware of ethical issues in genetic research. This gap may stem from the nature of their professional practices and limited familiarity with the intricacies of genetic research proposals.

Secondary research in clinical trials involves repurposing data or bio-specimens initially collected for a primary research study to address research questions beyond the original objectives. This approach maximizes the scientific value of existing resources and often facilitates new discoveries without the need for additional participant recruitment or interventions.

In the present study [**Table No: 07 & 13**] 40% of human ethics committee (HEC) members indicated that they were unaware of the practices and implications of secondary research in clinical trials. Interestingly, this lack of awareness was most prevalent among members whose roles on the ethics committee were legal experts, social scientists, and laypersons.

Moreover, the necessity to coding of genetic specimens and their data emerges as a crucial measure to prevent unauthorized access and misuse of genetic research data. By encoding genetic data, researchers can ensure an added more of protection against breaches of confidentiality of the collected research data. Additionally, the establishment of standardized protocols for genetic research in clinical trials or optional studies is imperative. Such protocols not only enhance research

reproducibility and reliability but also contribute to the ethical conduct of studies involving sensitive genetic research data.

The present study results highlights the importance of a unified data code to protect patient or study subject's confidentiality. The adoption of such a code by ethics committees can significantly bolster participant trust and ensure responsible data handling practices. Encrypting research data codes adds another level of security, particularly in the genetic research clinical trials, where sensitive information is at risk of unauthorized access.

The 'Your DNA, Your Say' project provides insight into global public attitude toward genomic data sharing, highlighting a general reluctance to donate data for research and a lack of trust in multiple parties handling shared data. This is influenced by perceptions of whom the data is shared with and how it will be used. Except in India, there was a strong correlation between trust in stakeholders and the willingness to share DNA and medical data. A significant portion of participants expressed either unwillingness or uncertainty about donating their anonymous DNA and medical information for research purposes. However, in the present study, ethics committee members showed a high level of willingness to share genetic research data for future studies.

PHARMACEUTICAL SPONSORS AND CONTARCT RESEARCH ORGANIZATIONS: Trust in Pharmaceutical sponsors and **Michelle M. Mello et al.,** conducted contract research organization-The study**,** highlights a significant issue in the field of biomedical research [42]. The low levels of trust that participants have in pharmaceutical companies. This lack of trust poses a challenge for researchers and

companies alike, as trust is a crucial component in the willingness of individuals to participate in clinical trials and to share their personal data**.**

Reusing of Genetic research data in Clinical trials: The present study highlights diverse attitude among stakeholders toward the reuse of genetic research data in clinical trials. A majority of pharmaceutical sponsors and contract research organizations (CROs) (54%) expressed moderate agreement with the practice, reflecting a cautious but positive stance on the potential benefits and challenges of genetic data repurposing.

Although, 8% of the respondents from pharmaceutical sponsors and CROs disagreed with the reuse of genetic data. Notably, those who expressed disagreement were primarily individuals holding roles as Clinical Research Associates (CRA-I and-II). The disagreement among CRAs may reflect their proximity to operational and ethical challenges. CRAs often engage directly with study sites and participants, potentially encountering practical issues related to informed consent, data management, and participant understanding of genetic data reuse [**Table-07& 11**].

Need for Separate Consent for Reuse of Data: When it comes to requiring separate consent for the reuse of data, there is a statistically significant difference ($p=0.01$) among the clinical trial stakeholders. The pharmaceutical sponsors/CROs (22%) shown less support. This divergence likely reflects the operational challenges and administrative burdens that sponsors may face when introducing additional consent procedures, as well as their desire to streamline research processes. Most of the pharmaceutical sponsors & CROs 76% agree to require a separate consent. This suggests that clinical researchers, who are more directly involved in handling

sensitive genetic information, may be more attuned to the ethical implications of reusing such data.

Return of research findings from genetic research: The present study assessed the attitude of pharmaceutical sponsors and contract research organizations (CROs) toward the return of research findings from genetic research. A majority of pharmaceutical sponsors and CROs (54%) expressed support for returning findings.

However, 6% of respondents disagreed. This group primarily consisted of individuals in roles such as Clinical Trial Assistants (CTAs) and CRAs may view the return of findings as impractical or outside the scope of their operational responsibilities. Their disagreement could stem from a lack of involvement in strategic decision-making or limited exposure to the ethical dimensions of returning research results.

Types of Consent forms used for gathering genetic data in research: In the Knowledge assessment domain regarding consent practices in genetic research, it was observed that 36% of pharmaceutical sponsors reported utilizing blanket or broad **consent** forms, while 32% indicated the use of tiered consent forms. These forms differ in their scope and the level of autonomy granted to research participants. Interestingly, another 32% of respondents, primarily Clinical Research Associates (CRAs) (with 46.7% of CRA-I category respondents), were unaware of the specific types of consent utilized for gathering genetic information intended for future research. This highlights a significant knowledge gap within certain segments of research professionals, emphasizing the need for enhanced training and awareness regarding ethical and regulatory standards for genetic data collection.

Bienfait K et al. perspectives; Pharmaceutical companies are increasingly leveraging genomic data to identify drug targets and develop precision medicine strategies. Most major companies routinely collect DNA from clinical trial participants to conduct pharmacogenomics (PGx) studies. However, integrating PGx studies into clinical development presents significant challenges, including navigating a dynamic global regulatory landscape, addressing complexities in study design and clinical implementation, and managing heightened concerns over patient privacy [57].

At the same time, advancements in genomics are opening new avenues for innovation. These include access to extensive genomic databases linked to patient health information, the growing adoption of polygenic risk scores, and the direct sequencing of clinical trial participants. The Industry Pharmacogenomics Working Group (I-PWG), a collaborative network of pharmaceutical companies engaged in PGx research, provides insights into industry efforts to overcome these challenges. This perspective highlights the strategies being implemented to address regulatory, ethical, and logistical hurdles while harnessing emerging scientific opportunities to advance precision medicine.

PATHOLOGIST: Most of the pathologists 92% shown that they were aware of formal guidelines regarding the use of stored specimens collected without explicit consent or specific consent for research purposes, and only 8% were unaware of such guidelines. A 44% actively applied these practices in their work, with the rest either occasionally 32% or rarely (24%). When it comes to understanding the consent process, a significant majority 96% reported that they understand the guidelines and processes associated with the genetic samples and its data they handle. However, 4% admitted to lacking a comprehensive understanding.

Most pathologists 96% agreed that genetic inferences could made from the specimens, while 4% disagreed. Additionally, 76% believed that the use of such specimens in research is ethically permissible, compared to 24% who were uncertain. Interestingly, when asked about the ethical implications of using stored specimens without specific consent, 36% were comfortable with the practice, whereas 64% expressed concerns. When asked on their opinion about the necessity of obtaining new consent for future use of these specimens, 88% were in favour, while 12% were against it.

In terms of practice, 72% of the pathologists reported that they follow the guidelines on the use of stored specimens without specific consent, while 28% did not adhere to guidelines. A 4% stated that pathologist never used such specimens without specific consent, contrasting with the vast majority 96%. Lastly, none of the respondents indicated a complete lack of awareness or understanding of these ethical and procedural considerations, showing a universal baseline knowledge among the surveyed pathologists.

5.3. KAP ASSESSMENT OF CLINICAL TRIAL STAKEHOLDERS BASED ON ROLE & DEPARTMENTS:

PHARMACEUTICAL SPONSORS/CROS ROLE: The Knowledge, Attitude, and Practices (KAP) assessment, as detailed in **Tables 07, 08, and 09,** provides insights into how different roles within pharmaceutical sponsors and Contract Research Organizations (CROs) approach the re-use of genetic research data.

Blood samples are the primary source of genetic data across the research with tissues being used to a lesser extent. Responses from pharmaceutical sponsors indicate a varied experience, with some individuals in roles such as CRA-I and CRA-II reporting that they have received genetic data results in recent years. This mixed

response reflects the diverse practices and experiences related to the use of genetic data.

Pharmaceutical sponsors and Contract Research Organizations (CROs) demonstrate varying levels of knowledge regarding roles in clinical trials involving genetics and data reuse. High awareness is notably observed among Clinical Research Associates (CRAs) and Project Managers (PMs) might be due to nature of clinical trials experience and the training with many acknowledging challenges tied to ethical and legal concerns as well as confidentiality issues ($p=0.04$). Support for reusing genetic data is mixed across roles, but a considerable proportion of Clinical Trial Assistants (CTAs) and CRAs express agreement with the practice. However, these groups also emphasize the importance of obtaining separate consent for such reuse. There is broad consensus on the difficulties of safeguarding genetic data, with heightened concerns among CRA-Data Analysts (DAs) ($p=0.043$), underscoring the critical need for robust data protection measures.

Genetic data in clinical trials primarily comes from blood samples, with tissues being less commonly used. Feedback from pharmaceutical sponsors reflects varied experiences with genetic data, with roles like CRA-I and CRA-II reporting occasional receipt of genetic results in recent years. This variability highlights the diverse practices and experiences among stakeholders in managing and utilizing genetic data in clinical research.

ROLE IN THE ETHICS COMMITTEE: All the Human ethics committee constituted in accordance with **New Drugs and Clinical Trials (NDCT) Rules, 2019**[CDSCO] under Ministry of Health and Family Welfare, Government of India. The Ethics Committee (EC) members play a crucial role in ensuring the ethical

conduct of clinical trials. The assessment of Human Ethics Committee members' knowledge, attitude and practices regarding clinical trials in genetics and data reuse reveals notable variations across different roles.

Pysar. R et al., surveyed on Australian human research ethics committee members' confidence in reviewing genomic research applications. Human Research Ethics Committees (HRECs) are increasingly tasked with evaluating genomic research applications that present complex ethical challenges. Despite the growing volume of such applications, genomic confidence among non-genetics experts remains reportedly low. However, no prior studies have specifically assessed the genomic confidence levels of HREC members. This study addressed this gap by utilizing online surveys to evaluate the genomic confidence, predictors of confidence, and resource needs of members from 185 HRECs across Australia. 145 members participated, completing the survey either fully or partially [62].

Ethics committee members rely on various resources when reviewing genomic studies, with the NHMRC National Statement on Ethical Conduct in Human Research and scientific literature being the most frequently accessed. Committee members rated both resources as moderately to very helpful. However, despite these available tools, there remains a clear need for additional support resources to guide ethical decision-making in genomic research. This aligns with existing literature, which highlights a broader demand for enhanced resources to assist both consumers and healthcare professionals in navigating the ethical and practical complexities associated with genomic information [59- 61].

Kadam R, Karandikar S et al. are investigated on the ethics committee and regulatory authorities' roles and responsibilities. Over the past few years, there has been a significant increase in the number of clinical trials conducted in India. However, it has been observed that many ECs are unaware of their roles and responsibilities. Reports indicate that some ECs lack of standard operating procedures, suffer from improper composition, and have inadequate representation, which hampers their ability to effectively regulate the clinical research. Furthermore, ECs often operate in isolation, functioning as independent entities with little to no communication with regulatory agencies or other Ethics committees [2-3]. **Table 13** of the present research reveals that Human Ethics Committee members, particularly clinicians and medical scientists, demonstrate a high level of knowledge regarding genetic research and its reuse. Among clinicians, 90% exhibit substantial awareness, while all medical scientists (100%) display a comprehensive understanding of the subject. This reflects the significant role of these professionals in navigating the complexities of genetic research & data sharing for future use.

Additionally, 75% of medical scientists expressed concerns about ethical and legal challenges in genetic research. These concerns are likely influenced by their expertise and extensive experience in the field, which enables them to identify and evaluate the potential risks associated with genetic data reuse.

The study revealed that laypersons and legal experts had limited knowledge about genetic research, with their primary concerns centred on ethical and legal issues (50%), while a notable portion (37.5%) was unaware of these challenges. In contrast, Member Secretaries demonstrated comprehensive knowledge (100%), with their

concerns equally divided between ethical/legal issues (50%) and confidentiality (50%).

NGO representatives and social scientists showed partial knowledge of genetic research (50%) and shared similar concerns, with ethical and legal challenges cited by half of this group (50%). These findings summarise the levels of awareness and distinct areas of concern among different Human Ethics Committee member roles, underscoring the need for tailored educational initiatives to address knowledge gaps and enhance understanding across diverse stakeholder groups

Table 14 of the attitude assessment indicates strong support for repurposing genetic information among clinicians (100%), legal experts (87.5%), and social scientists (100%). This widespread acceptance underscores the recognition of the value and potential benefits of reusing genetic data within ethics committee members.

Additionally, all legal experts (100%) emphasized the necessity of obtaining separate consent for the reuse of genetic research data.

The practices assessment **table-15** explored the actions taken by ethics committee members in their roles. Chairpersons were fully aware of the types of samples used (100%) and compliant with biobank security measures. Clinicians demonstrated high awareness of sample types (80%) and support for biobank security. Medical Scientists exhibited high compliance with genetic sample usage and security measures (75%). Member Secretaries were fully compliant with security practices (100%). NGO Representatives showed partial compliance with genetic research practices (50%) and security measures (50%). Scientific Members displayed high compliance with sample

usage (83.33%) and security measures. Social Scientists showed partial compliance with security measures (66.67%).

CLINICAL TRIAL INVESTIGATORS Vs. DEPARTMENT

Tables 15-17 indicate that there are no significant differences between departments regarding clinical trial investigators' views on the re-use of genetic research data. However, participants who were aware of clinical trials in genetics and data reuse demonstrated significantly higher levels of knowledge. For instance, within General Medicine, those who were aware scored an average of 6 (50) compared to those who were not aware. The present study suggests that awareness of clinical trials and data reuse is strongly correlated with higher knowledge levels. It underlevels the importance of implementing comprehensive educational programs to enhance awareness and understanding of genetic research data re-use among healthcare professionals.

MULTIPLE GROUP'S COMPARISON Vs. KNOWLEDGE

The multiple comparisons of knowledge levels among clinical trial stakeholders reveal significant disparities, particularly between clinical trial participants and other groups such as sponsors/CROs and clinical trial investigators. These findings highlight the critical need for targeted educational interventions to bridge these knowledge gaps, especially for clinical trial participants and pathologists. By addressing these disparities, we can ensure more informed participation, better ethical oversight, and improved outcomes in clinical trials.

Clinical trial participants, in particular, require substantial educational support to enhance their understanding and engagement in trials.

MULTIPLE GROUP'S COMPARISON Vs ATTITUDE

Clinical Trial Investigators: The significant differences in attitude levels between clinical trial investigators and other groups highlight the variability in perceptions and attitude within the trial ecosystem. The more positive attitude of investigators towards the trial process suggest a deeper understanding and commitment, likely due to their pivotal role in conducting the trials.

Clinical Trial Participants: The lower attitude levels among clinical trial participants, compared to investigators and ethics committee members, suggest potential areas of concern or misunderstanding that need to be addressed. Enhancing participant engagement through education and support could improve their attitude towards participation in clinical trials.

Pharmaceutical sponsors/CROs: The similar attitude levels between sponsors/CROs and participants imply that while sponsors/CROs are knowledgeable, their attitude align closely with those of participants. This could be due to their role in managing and overseeing trials, ensuring participant welfare is maintained.

Ethics Committee Members: Ethics committee members displayed some of the highest attitude levels, underscoring their commitment to ethical standards and participant welfare. This positive attitude is crucial for maintaining the integrity and ethical conduct of clinical trials.

MULTIPLE GROUPS' COMPARISON Vs. PRACTICES

Clinical Trial Participants: The significantly lower practice levels among clinical trial participants compared to sponsors/Contract research organizations, human ethics committee members, and clinical trial investigators highlight a critical area for improvement. Participants may require more comprehensive training and support to enhance their practical engagement in clinical trials.

Pathologists: showed lower practice levels compared to sponsors/Contract research organizations, suggesting a need for targeted interventions to elevate their practical skills and adherence to best practices in clinical trials. The similar practice levels between pathologists and participants indicate a shared area of improvement.

Pharmaceutical Sponsors/CROs: Demonstrated the highest practice levels, reflecting their crucial role in managing and overseeing clinical trials. Maintaining these high standards is essential for the overall success of clinical trials.

Ethics Committee Members and Clinical Trial Investigators: The higher practice levels among ethics committee members and clinical trial investigators, compared to participants and pathologists, underline their better preparedness and adherence to trial protocols.

The significant differences in practice levels among the various stakeholders suggest the need for tailored training programs to elevate the practical skills of clinical trial participants and pathologists. Enhancing their practical engagement and adherence to best practices can improve the overall quality and success of clinical trials. Sponsors/CROs, ethics committee members, and clinical trial investigators should

continue to receive updates on the latest developments and best practices to maintain their high standards**.**

The significant differences in attitude among the various stakeholders suggest the need for tailored interventions to harmonize attitude across groups.

5.4. KAP ASSESSMENT OF CLINICAL TRIAL STAKEHOLDERS VS EDUCATIONAL BACKGROUND

CLINICAL TRIAL INVESTIGATORS Vs EDUCATIONAL BACKGROUND: This section examines the Knowledge, Attitude, and Practices (KAP) of clinical trial investigators with varying educational qualifications using the Kruskal-Wallis Test.

The median knowledge & attitude scores regarding genetic research data re-use were similar across most educational groups: MBBS-MD, MBBS-MD-DM, and MBBS-MS all had a median score of 6, with interquartile ranges (IQRs) of 4–7, 5–7, and 6–6, respectively. This suggests that higher educational qualifications may influence knowledge in this domain. However, the MBBS-MS-MCh group scored slightly lower, with a median of 5.5 and an IQR of 4–6.

The median practice scores showed slight variation among the groups. MBBS-MD had a median score of 3 (IQR: 2–3), MBBS-MD-DM scored 2 (IQR: 2–3), MBBS-MS scored 5 (IQR: 5–5), and MBBS-MS-MCh scored 3 (IQR: 3–3). The higher practice levels observed in the MBBS-MS group may be attributed to their regular involvement in surgical activities.

PAIRWISE WITH COMPARISON OF KNOWLEDGE Vs HUMAN ETHICS COMMITTEE OF MEMBERS: The pairwise comparisons of the knowledge levels of Ethics Committee (EC) members across various educational backgrounds reveal significant and non-significant differences based on test statistics, standard errors, and P-values. Most comparisons show P-values of 1, indicating no statistically significant difference in knowledge levels between those pairs. However, a few comparisons exhibit P-values less than 0.05, suggesting significant differences. Notably, the comparison between BA-LLB and MSc-PhD has a P-value of 0.046, and BA-LLB and MSc-PhD again has a P-value of 0.021, both indicating significant differences in knowledge between these groups. These significant results suggest that EC members with certain advanced educational backgrounds, such as MSc-PhD, have notably higher knowledge levels compared to those with undergraduate degrees like BA-LLB.

P-SPONSORS AND CONTRACT RESEARCH ORGANIZATION Vs EDUCATIONAL BACKGROUND

The results from the table indicate no statistically significant differences in knowledge (p=0.256), attitude (p=0.356), or practices (p=0.618) across different educational backgrounds of pharmaceutical sponsors and Contract research organizations, including life sciences (n=5), medical/health sciences (n=4), pharma (n=40), and other backgrounds (n=1). Descriptive statistics revealed median levels with interquartile ranges for each category, propound that the educational background of these

professionals does not significantly affect their knowledge, attitude, or practices in the context of their roles in pharmaceutical sponsor and Contract research organizations

KAP OF ETHICS COMMITTEE MEMBERS Vs EDUCATIONAL BACKGROUND

This section compares Knowledge, Attitude, and Practices (KAP) among Ethics Committee (EC) members with different educational backgrounds. Knowledge levels vary significantly, with median levels ranging from 0.5 (B.Com) to 9 (M.Pharm), and the Kruskal-Wallis Test shows a P-value < 0.001, indicating significant differences. Members with M.Pharm-PhD or M.Pharm degrees have high levels (7-9), while those with BA or BA-LLB have lower levels (1-4.5). Attitude levels are generally consistent across backgrounds, with most groups having a median score of 10. Practices show variability, with median levels from 1 (Engineering) to 5 (M.Pharm) and a P-value of 0.042, indicating significant differences. Members with advanced degrees like M.Pharm-PhD demonstrate higher practical engagement compared to those with bachelor's degrees.

5.5. ETHICAL CHALLENGES IN GENETIC RESEARCH DATA RE-USES:

The present study explored and identified the Ethical issues in the genetic data re-use for future research [**Table No: 24**] As genetic research continues to advance, the accumulation and re-use of genetic data have become increasingly common, offering valuable opportunities for scientific discovery and public health improvement. However, the secondary use of such data raises significant ethical concerns that merit careful consideration. Issues related to informed consent, privacy, data ownership, and the potential for misuse or discrimination challenge existing ethical frameworks and regulatory standards. This study, as part of its secondary objective, seeks to explore these ethical challenges, aiming

to contribute to the ongoing dialogue around responsible data governance and the protection of participants' rights in the evolving landscape of genetic research.

Human Ethics Committee Members place a strong emphasis on ethical/legal compliance and returning results to individuals, yet show limited support for secondary data use and unrestricted sharing—likely reflecting their mandate to protect participants.

Clinical Trial Investigators prioritize confidentiality and are supportive of secondary data use and ownership issues. However, their support for returning individual results is relatively low, possibly due to operational challenges or data interpretation concerns.

Clinical Trial Participants are most concerned with confidentiality and potential misuse, showing minimal support for data sharing or reuse—suggesting a need for better education and engagement strategies.

Pathologists emphasize the return of results and data misuse concerns but are generally non-committal about ownership or data sharing, possibly due to less direct interaction with trial governance.

Pharmaceutical Sponsors and CROs support secondary data use and controlled access repositories the most, reflecting their focus on data maximization for research, yet show limited concern for individual-level return of results.

5.6. DEVELOPED GENETIC CONSENT MODEL FOR GENETIC RESEARCH DATA RE-USE :

The President's Council of Advisors on Science and Technology has recommended the establishment of an integrated national network of standardized bio specimen repositories and the development of a standard consent template for the collection and storage of specimens and data for future research. Over time, consent forms have become longer and more complex, making them increasingly difficult for participants to understand. In response, we aimed to demonstrate the feasibility of creating a simplified consent form for bio banking that includes only the essential information needed to meet ethical and regulatory standards. Preliminary data on the content of simplified form was gathered from hypothetical biobank participants, providing valuable insights into its potential effectiveness [45].

Since the mid-2000s, direct-to-consumer genetic testing companies have made genetic information available to private individuals outside of research or clinical settings. These companies claim that their services empower consumers for personal purposes, including but not limited to gaining better control over their health, learning about their ancestry, and contributing to the development of medical knowledge. [46]

Direct-to-consumer (DTC) genetic testing has revolutionized the accessibility of genetic information, shifting it from a realm reserved for clinical and research settings to one accessible by the public. Companies like 23 and Me, Ancestry DNA, and My Heritage have led this transformation, offering services that allow individuals to uncover details about their genetic makeup from the comfort of their homes.

One of the primary appeals of DTC genetic testing is the potential for individuals to gain insights into their health. By identifying genetic predispositions to certain diseases, consumers can take proactive measures to manage their health. For example, someone with a genetic marker for a higher risk of breast cancer might opt for more frequent screenings or preventative measures. This aspect of DTC testing aligns with the broader trend towards personalized medicine, where treatments and preventive strategies are tailored to the individual's genetic profile. Moreover, many DTC genetic testing companies contribute to the advancement of medical knowledge by aggregating and analysing the genetic data of their users (with consent). This large-scale data collection can lead to new discoveries in genetics, helping researchers identify genetic variants associated with various diseases and traits. Users contribute to this collective knowledge base, potentially aiding in the development of new treatments and medical insights. However, the rise of DTC genetic testing is not without controversy. Concerns about privacy, the accuracy of the tests, and the potential psychological impact of receiving health-related genetic information are significant. Critics argue that without proper counselling, individuals might misinterpret their genetic data, leading to unnecessary concerns or false reassurance. Furthermore, the security of genetic data and its potential misuse by third parties is a growing concern in the era of big data.

The present results reveals that while there is a generally positive attitude towards genetic research data re-uses across all groups, there are significant gaps in knowledge and practice, especially among Trial Participants and Pathologists. Improving education and resources for these groups could bridge the gap between positive attitude and actual data reuse practices. For Clinical trials investigators and Sponsors/CROs, targeted interventions to translate their knowledge and attitude into

consistent practices could further enhance the benefits derived from genetic research data re-uses. Efforts to standardize practices and provide necessary support and infrastructure can promote a more effective and widespread adoption of data reuse in genetic research.

The previous investigation of the Global Public Perceptions of Genomic Data Sharing topic has concluded that the optimization of societal benefits from genomic research data necessitates the recognition and response to the factors that influence the decision to donate DNA in various social, cultural, and legal aspects. The provision of explicit, transparent, and genuine information is essential to ensure that the public can assess the importance of their participation in a collaborative effort with researchers, thereby enabling the delivery of public benefits and the protection of public interests. Nevertheless, there is a need to understand the perceptions of clinical trial stakeholders concerning of genetic research and its potential reuse for future research. The rate at which genomics data is accumulating in public repositories is steadily increasing. There are no such uniform guidelines for the globe to conduct the genetic research and or of optional research in clinical trials to collect the samples or data for future research. There exists a necessity for education pertaining to Genetics and its associated data for the re-use in clinical trials. This education is particularly crucial for clinical trial investigators, who are tasked with identifying, screening, and recruiting study subjects for research and genetic studies. Furthermore, these individuals hold the ethical responsibility of maintaining the confidentiality of study participant information.

6. SUMMARY

Clinical trial protocols and consent forms generally include provisions for genetic sample and data collection, but they often lack specificity regarding future research applications. The absence of standardized guidelines for optional research and secondary data use remains a significant concern within genetic research in India.

A key outcome of the study is the widespread support for repurposing genetic information in clinical trials, provided that separate consent is obtained for reuse. Stakeholders also express a strong preference for returning research findings to participants and emphasize the necessity of encrypting genetic data to ensure privacy and confidentiality.

Ethical challenges associated with genetic data collection, storage, and transfer—especially in cross-border research—are critical issues. The study underscores the need for well-defined policies on participant consent for future research and data sharing. Ongoing education and training for clinical trial stakeholders are essential to ensuring informed decision-making and adherence to ethical standards.

Enhanced participant engagement, standardized practices among pharmaceutical sponsors, contract research organizations (CROs), and ethics committees will be crucial for advancing responsible genetic data reuse in clinical research. Education on genetics and its associated data reuse is particularly important for clinical trial investigators, who play a key role in recruiting study subjects and maintaining confidentiality.

7. CONCLUSION

This research has provided valuable insights into the knowledge, attitude, and practices of various clinical trial stakeholders involved in clinical trials regarding the reuse of genetic data. The findings reveal a strong consensus among stakeholders on the importance of genetic data sharing for future research, but also highlight key ethical and procedural challenges. Most of the clinical trial protocols and consent forms include provisions for the collection of genetic samples and data, though they often lack specificity regarding the type of research and analysis that will be conducted in the future. The absence of standard guidelines for optional research and secondary data use is a common concern within the field of genetic research in India.

A significant outcome of this study is the identification of widespread support for the repurposing of genetic information in clinical trials, coupled with an emphasis on the need for separate consent when reusing genetic research data. There is also substantial willingness among stakeholders on the return of research findings to participants and the importance of securing genetic data through encryption to ensure privacy of the study participants.

The study has highlighted several ethical challenges, particularly regarding the collection, storage, and transfer of genetic data, especially in cross-border research. The need for well-defined policies, especially concerning participant consent for future research and data sharing, is critical to addressing these challenges.

Finally, this study concludes the necessity for ongoing education and training efforts aimed at clinical trial stakeholders to ensure informed decision-making and adherence to ethical standards. Improved engagement of participants, combined with

standardized practices among pharmaceutical sponsors, contract research organizations, and ethics committees, will be essential to advancing the responsible reuse of genetic data in clinical research and there exists a necessity for education pertaining to Genetics and its associated data for the re-use in clinical trials. This education is particularly crucial for clinical trial investigators, who are tasked with identifying, screening, and recruiting study subjects for clinical and genetic studies. Furthermore, these individuals hold the ethical responsibility of maintaining the confidentiality of study participant information.

Currently, the only guidelines available for genetic data sets and future research are those set by the Indian Council for Medical Research (ICMR-2017) and WHO Guidance for human genome data collection, access, use and sharing recommendations-2024. There are no universally accepted standards or guidelines to conduct the use of genetic research & its data for future research [63]. There is no specific consent for the genetic research data for future use in the field of genetic research. Hence, this study emphasizes the critical importance of incorporating clinical trial stakeholders' perspectives on the future use of genetic research data. By shedding light on their views and concerns, the findings contribute to a deeper understanding of the ethical, regulatory, and practical implications associated with the reuse of genetic data in research. This insight can guide policymakers, clinical researchers, and ethics committees in fostering trust and ensuring responsible data utilization in future genetic studies.

7. 1 LIMITATIONS OF THE STUDY

The Present study's key limitation is its restricted or selected sample size, as it only involved clinical trial stakeholders from a specific region. This limited geographic scope may not fully represent the views and experiences of stakeholders across the entire country, which is important for understanding the broader ethical challenges of genetic data reuse for fture research.

The present study highlights the need for national-level data collection to better capture the ethical challenges surrounding the reuse of genetic research data. Without a comprehensive dataset from various regions, institutions, and stakeholders, the findings may lack generalizability and may not adequately reflect the diversity of opinions and practices across India. This limitation underlevels the importance of expanding future research efforts to a larger and more diverse group of clinical trials stakeholders at a national level to inform the development of universally applicable guidelines and policies.

Limited Scope in Stakeholder Representation: The study may not fully capture the perspectives of all relevant stakeholders involved in clinical trials, such as patients, research institutions, Pharmaceutical sponsors-Contarct Reseearch organizations and policy makers-regulatory authority, potentially leading to an incomplete understanding of the ethical and procedural challenges.

Education and Training Gaps: Although the present study emphasizes the need for education on genetic data reuse, there are limited insights into how these educational initiatives could be implemented across clinical trial stakeholders, especially in a resource-limited setting like India.

7.2. FUTURE DIRECTIONS

Insights and challenges identified in this study, several key future directions can be proposed to advance the ethical and efficient reuse of genetic research data for future research:

Expanding Stakeholder Representation:

Future research should aim to include a broader range of stakeholders, such as multicentric patients, policymakers, regulatory authorities, large group of pharmaceutical sponsors and research institutions. This would ensure a more comprehensive understanding of diverse perspectives and enable the development of more inclusive and effective guidelines for genetic data reuse.

Developing Tailored Educational Programs:

Building on the identified education gaps, future studies should explore and design tailored training programs on genetic data reuse. These initiatives should focus on addressing the specific needs of various stakeholder groups and assess their effectiveness in improving awareness and ethical decision-making, particularly in resource-limited settings like India.

Ethical Framework for Returning Genetic Findings to Participants: Future studies should explore the development of an ethical framework for the return of research findings to participants, particularly for clinically relevant genetic information. This framework should balance the participants' right to know with the potential implications of the findings, including psychological, social, and financial impacts.

08. BIBLIOGRAPHY

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09-ANNEXURES

LIST OF ANNEXURES	
A.	**Clinical trial registry in India-CTRI/2011/11/032811 dated 23.11.21**
B.	**NPTEL Training Certificate**
C.	**Permission Letter [Ethics committee clearance & Admission letter]**
D.	**Informed Consent forms**
	- Informed Consent forms **- English-Version-1.0 dated 01-Jun-2021**
	- Informed Consent forms- Kannada translated from English- Version-1.0 dated 01-Jun-2021
	- Informed Consent forms- Hindi translated from English- Version-1.0 dated 01-Jun-2021
	- Informed Consent forms- Marathi translated from English- Version-1.0 dated 01-Jun-2021
E.	**KAP Questionaries' to explore the clinical trial stakeholders towards Genetic Research data re-uses**
F.	**Genetic consent Model-Version 1.0-2023 dated 21.08.2023**
G.	**Oral and Poster presentation**
H.	**Publications**
1.	Name of the Journal: **Perspective in clinical Research**
2.	Name of the Journal**: Asian journal of Biomedical Research and Health Care**
3.	Name of the Journal: **Current Pharmacogenomics and Precision Medicine**
I.	**Training and online certificate programme**
1.	Research Ethics Online Training by WHO on 16-Oct-2024
2.	Authoring of patient narratives by ISCR 23-Mar-2024
3.	SIDCER-FERCAP Research Ethics Training on 11-12-July -2022
4.	7th National Conference of Forum Ethics Review committees in India on 27-29-Nov-2020
	Good Clinical Practices by CDSA on 11-12, Feb-2020

A. CLINICAL TRIAL REGISTRY INDIA

FULL DETAILS (Read-only) -> Click Here to Create PDF for Current Dataset of Trial

CTRI No	**CTRI/2021/11/038211** [Registered on: 23/11/2021] **Trial Registered Prospectively**
Acknowledgement Number	REF/2021/10/048388
Last Modified On:	06/07/2024
Post Graduate Thesis	No
Type of Trial	Observational
Type of Study	Case Series study
Study Design	Single Arm Study
Public Title of Study	Clinical Trial Stakeholders Perspectives Towards Genetic Research-Data for Future Use
Scientific Title of Study Clarification(s) with Reply Modification(s)	Exploration of Clinical Trial Stakeholders Perspectives Towards Genetic Research-Data for Future Use
Trial Acronym	
Secondary IDs if Any	Secondary ID: NIL; Identifier: NIL
Details of Principal Investigator or overall Trial Coordinator (multi-center study) Clarification(s) with Reply Modification(s)	**Name:** REVANA SIDDAPPA DEVARINTI **Designation:** Clinical Research Assistant/ Asst.Prof. **Affliation:** KLE College of Pharmacy **Address:** Second Floor, ROOM No: 02 KLE Site Management Office, KLES Dr.Prabhakar Kore Hospital and MRC, Nehru Nagar Second Floor, ROOM No: 02 KLE Site Management Office, KLES Dr.Prabhakar Kore Hospital and MRC, Nehru Nagar Belgaum KARNATAKA 590010 India **Phone:** 08886042417 **Fax:** **Email:** siddu3pharma@gmail.com
Details Contact Person Scientific Query Clarification(s) with Reply Modification(s)	**Name:** DrMSGanachari **Designation:** HOD- Department of Pharmacy Practice **Affliation:** KLE COllege of Pharmacy **Address:** Third Floor, ROOM No: 12 KLE College of Pharmacy, Nehru Nagar, Belagavi-10 Third Floor, ROOM No: 12 KLE College of Pharmacy, Nehru Nagar, Belagavi-10 Belgaum KARNATAKA 590010 India **Phone:** 08312470400 **Fax:** **Email:** msganachari@gmail.com
Details Contact Person Public Query Clarification(s) with Reply Modification(s)	**Name:** MrRevana Siddappa Devarinti **Designation:** Principal Investigator **Affliation:** KLE Academy of Higher Education and Research **Address:** Dept Of Pharmacy Practice Third Floor ROOM No 12 KLE College of Pharmacy Nehru Nagar 590010 Dept Of Pharmacy Practice Third Floor ROOM No 12 KLE College of Pharmacy Nehru Nagar 590010 Belgaum KARNATAKA 590010 India **Phone:** **Fax:** **Email:** siddu3pharma@gmail.com
Source of Monetary or Material Support	KAP-Questionaries and Education Tools
Primary Sponsor Clarification(s) with Reply Modification(s)	**Name:** No Sponsor **Address:** there is no involvement of Sponsor **Type of Sponsor:** Other [NA]
Details of Secondary Sponsor	Name: NIL; Address: NIL
Countries of Recruitment	India
Sites of Study Clarification(s) with Reply Modification(s)	No of Sites = **1**

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Revana Devarinti	Human Ethics Committee members of Northern Karnataka region/ KLES Dr.Prabhakar Kore Hospital and MRC	###-Ethics Committee members and Clinical Research Investigators Northern Karnataka, Karnataka Belgaum KARNATAKA	8886042417 siddu3pharma@gmail.com

Details of Ethics Committee

No of Ethics Committees= 1

Name of Committee	Ethics Committee registered with DHR /CDSCO or not	Ethics Committee Registration No.	Approval Status	Date of Approval	Approval Document	Is IEC?
Ethical Commitee(Human) for PhD	Not Available		Approved	29/07/2021	Approval File	No

Regulatory Clearance Status from DCGI

Status	Date	Aproval Document
Not Applicable	No Date Specified	No File Uploaded

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Clinical Trial Stakeholders- Sponors Trial Participants and Ethics Committee members

Intervention / Comparator Agent

Type	Name	Details

Inclusion Criteria

Age From	18.00 Year(s)
Age To	85.00 Year(s)
Gender	Both
Details	The Principal Investigators who are involved in the Clinical trial with a minimum of 02 years of experience Human Ethics Committee members of Northern Karnataka region Selected Clinical trial participants Pharmaceutical sponsors and their representatives

Exclusion Criteria

Details	Declined interest to provide a written informed consent

Method of Generating Random Sequence: Not Applicable

Method of Concealment: Not Applicable

Blinding/Masking: Not Applicable

Primary Outcome

Outcome	TimePoints
Better understanding on Genetic data reuse for future research to the clinical trial Stakeholders. i.e. Clinical trial protocol reviewers (Ethics Committee members), Researchers/Investigators and Subjects-Study Participants on Pharmacogenic genomic data sharing for future research Development of a Genetic consent model for Genetic study data sharing for future research	02 years

Secondary Outcome

Outcome	TimePoints
Development of a Genetic consent model for Genetic study data sharing for future research	01 year

Target Sample Size

Total Sample Size="188"
Sample Size from India="188"
Final Enrollment numbers achieved (Total)= "225"
Final Enrollment numbers achieved (India)="225"

Phase of Trial: N/A

Date of First Enrollment (India): 30/11/2021

Date of Study Completion (India): 13/01/2024

Date of First Enrollment (Global): If country of recruitment is only India, global date would be not applicable.

Date of Study Completion (Global): If country of recruitment is only India, global date would be not applicable.

Estimated Duration of Trial

Years="3"
Months="0"
Days="0"

Recruitment Status of Trial (Global)
Modification(s)

If country of recruitment is only India, global status would be not applicable.

Recruitment Status of Trial (India): Completed

Publication Details
Modification(s)

Name of journal: Current Pharmacogenomic and Precision Medicine Manuscript ID: CPPM-BMS-2024-04 Date of submission: 01-Feb-2024 Date of revision: 29-Mar-2024 Date of acceptance: 04-Apr-2024 Date of publication: 17-May-2024 Name of journal: Asian Journal of Pharmaceutical Research and Health Care Manuscript ID: ajprhc_138_23 Date of submission: 26-Oct-2023 Status: Published Publisher: Medknow Received: 26 Oct 2023 Revised: 29 Jan 2024 Accepted: 31 Jan 2024 Published: 27-Mar-2024

Individual Participant Data (IPD) Sharing Statement

Will individual participant data (IPD) be shared publicly (including data dictionaries)?

Response - NO

Result Disclosure

Do you wish to upload results?

Response - Summary results have not yet been disclosed

Brief Summary
Modification(s)

STUDY PROGRESS- VII REPORT

PARTICULARS	DATE AND RESPONSES	STATUS

Presented to Ethics Committee	08-Jun-2021	√
Ethics Committee clearance	29-Jul-2021	√
Study overall sample Size	**192 [200]**	
A. Principal Investigator	48 (>35%)	**50** √
B. P'ecutical Sponsors/CROs	48 (>35%)	**50** √
C. Ethics Committee Members	48 (>35%)	**50** √
D. Clinical trial participants	48 (>35%)	**50** √
E. Pathologist	■·	**25**√

B. NPTEL CERTIFICATE

Roll No: NPTEL18GE03S2221118

To
REVANA SIDDAPPA DEVARINTI
CSSB C/O MUTEKEKAR
BELAGAVI
BELGAUM
KARNATAKA
590010
PH. NO :8886042417

Score	Type of Certificate
90-100	Elite+Gold Medal
70-89	Elite
50-69	Successfully Completed the course
<50	No Certificate

No. of credits recommended by NPTEL:2



NPTEL Online Certification

(Funded by the Ministry of HRD, Govt. of India)

This certificate is awarded to

REVANA SIDDAPPA DEVARINTI

for successfully completing the course

Health Research Fundamentals

(NIE-ICMR e-Certificate course: NIeCer 101)

with a score of **55** %

Online Assignments	21.25/25	Proctored Exam	33.75/75

Total number of candidates certified: **580**

Dr. Manoj Murhekar
Scientist 'G' & Director
ICMR-National Institute of Epidemiology, Chennai

Prof. Balram Bhargava
Secretary to Govt. of India, Dept. of Health Research &
Director-General, Indian Council of Medical Research

Prof. Andrew Thangaraj
NPTEL Coordinator
IIT Madras

ICMR - National Institute of Epidemiology

Feb to Mar 2018
(8 week course)

Roll No:
To validate and check scores: http://nptel.ac.in/noc

C. PERMISSION LETTERS

ETHICAL CLEARANCE LETTER

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Formerly known as KLE University)
(Deemed-to-be-University established u/s 3 of the UGC Act, 1956)
Accredited **'A' Grade** by NAAC (2nd Cycle) Placed in **Category 'A'** by MHRD (GoI)
JNMC Campus, Nehru Nagar, Belagavi-590 010, Karnataka State, India
☎: 0831-2444444 FAX: 0831-2493777 Web: http://www.kledeemeduniversity.edu.in E-mail: info@kledeemeduniversity.edu.in

Ref.No.KAHER/EC/21-22/022 29th July 2021

To,
Mr. Revanna Siddappa Devarinti
Full time Ph.D. Research Scholar,
2020-21Batch, Faculty of Pharmacy,
KAHER, Belagavi.

Dear Research Scholar,

The KAHER Ethics Committee on Human Subjects for Ph.D. Research Project met on **the 7th and 8th June, 2021** to consider your application for approval of the research project **"Exploration of clinical trial stakeholders perspectives towards genetic research-data for future use"**

As there are no ethical issues involved in your proposed research project, the committee has provided approval for this research project.

You are requested to report to Ethical Committee of the following:

1. Any deviation from or change of the protocol.
2. Any changes in study documents.

(Dr. Sheetal U. Harakuni)
Member-Secretary
Ethical Committee (Human) for Ph. D. Research
KAHER, Belagavi.

(Dr. B.C. Kotintot)
Chairman
Ethical Committee (Human) for Ph. D. Research
KAHER, Belagavi.

CC to:

- Special Officer to Hon. Vice Chancellor, KAHER, Belagavi
- The Registrar, KAHER, Belagavi.
- The Director Research Foundation, KAHER, Belagavi.
- The Director Academic Affairs, KAHER, Belagavi.

ADMISSSION LETTER

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH

Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)

(Deemed-to-be-University)

[Declared as Deemed-to-be-University u/s 3 of the UGC Act, 1956 vide Government of India Notification No. F.9 -19/2000-U.3 (A)]

JNMC Campus, Nehru Nagar, Belagavi - 590 010. Karnataka, INDIA.

Phone : +91 0831-2444444, 2493779 FAX : +91 0831-2493777 E-mail : info@kledeemeduniversity.edu.in Website : http://www.kledeemeduniversity.edu.in

KLE EMPOWERING PROFESSIONALS

Certificate

FOR THE DOCTOR OF PHILOSOPHY (Ph.D.) PROGRAM

This is to certify that **Mr. Revana Siddappa Devarinti** *Reg. No. :* **DO1220048** *has been provisionally admitted for the Doctor of Philosophy (Ph.D.) program of the KLE Academy of Higher Education and Research* (KAHER), *Belagavi in the Faculty of* **Pharmacy** *during the academic year 2020-21, as per the Notification No.* KAHER/Ph.D./20-21/D-007 dated 19th May 2020. *He will be governed by the Rules and Regulations of the* KAHER *For Ph.D. Course*

Date : 14th November 2020

Prof. (Dr.) Roopa M. Bellad
Director Academic Affairs

Prof. (Dr.) V. A. Kothiwale
Registrar

D. INFORMED CONSENT DOCUMENTS

(English, Kannada, Hindi & Marathi)

ENGLISH INFORMED CONSENT DOCUMENT

KLE College of Pharmacy, Belagavi
KLE Academy of Higher Education and Research, Belagavi

Informed Consent Form

Research Title: Exploration of Clinical Trial Stakeholder's Perspectives towards Genetic research -data for Future use



Name of the Researcher: Mr.Revana S Devarinti

Name of the Guide: Prof.(Dr) M.S.Ganachari

Name of the institution: KLE College of Pharmacy-Belagavi

This Informed Consent Form has two parts:

- Information Sheet (to share information about the study with you)
- Certificate of Consent (for signatures if you choose to participate)

Part I: Information Sheet

Introduction: I am working on Genetic data use for future research, the most of the researcher not aware of the Genetic samples/data and or use for future research etc. with this, we are going to assess the clinical trial stakeholders (Clinical Trial Investigator, Human Ethics Committee Members, pharmaceutical sponsors and clinical Trial Participant's) Knowledge attitude and Perception on Genetic data use for future research. The study researcher also train/Education the Trial stakeholder's topic is on Policies and Guidance of Genetic Data Sharing Policy.

Purpose of the Research:

Clinical Trials give us a better understanding of how genes can cause or influence diseases with this, Genome science is rapidly shifting from lab research to the clinical setting. Within the next decade, pharmaceuticals sponsors or its representative will begin to correlate Nucleic Acid variants with individual responses to medical treatments, identify particular subgroups of patients, participants and develop drug need towards populations.

Genetic samples may be used for a different analysis, including single genes, sets of genes, and the whole genome, which may or may not be pre-specified in the clinical trial objectives at the time of collection. There are different ways to complete the Genetic study.

- Review of Genetic study protocols
- Conduct of Genetic studies
- Future reuse of human biological/Genetic samples and associated data
- Feedback about the progress of the research

These type of expectations/challenges need to be anticipated by conducting research analysis.

We believe that you can help us by telling us what you know both about Genetic samples and Data in general. We learn to know about the issues/challenges in involving/conducting/reviewing the Genetic studies.

Anticipating the participation into Genetic research and also understands to the clinical trial stake holders about the policies Genetic data use for future research is a major objective of the study.

Type of Research Intervention:

This research will involve your participation in Pre-Post Assessment of KAP (Knowledge, Attitude and Practices) and Genetic Data Sharing Policy training programme will be scheduled for a day

Participation Selection:

You are being invited to take part in this research because you're met the all the inclusion criteria's of the study and can also contribute much to our understanding on Genetic data use for future research.

Voluntary Participation:

Your participation in this research is entirely voluntary. It is your choice whether to participate or not.

Procedure:

We are asking you to help us Understanding more about the Genetic research and samples or data use for future research and their policies.

These Survey appliances primarily of close-ended questions with open-ended options will be included and the respondents are to provide additional information on their perceptions, practices and experiences. The survey items will be arranged in four sections namely demographics, knowledge, attitudes and practices.

Duration:

The research takes place more than year. During that time, we will ask for Pre-Post assessment of KAP Visit/Schedules and One day Training/Education programme for the stakeholders.



Risks:

There is no risk or harm for the participation

Benefits:

There will be no direct benefit to you, but your participation is likely to help us find out more assessment about the KAP of individual and Ethical challenges in Genetic associated data use for research.

Confidentiality:

The research being done in the clinical research community may draw attention and if you participate you may be asked questions by researcher. We will not sharing information about you to anyone outside of research team/organization. That we collect from this research will be kept private. Any information about you will have initial on it instead of your name.

Information about your rights and Ethics:

You may have questions about:

- Your rights as person participating in research study
- How your personnel information is kept
- Self-study- (Including concerns and Complaints)



Part II: Informed Consent Form

I have been invited to participate in research to assess the KAP of clinical trial Stakeholders towards the Genetic and its associated data use for future research.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study



Print Name of Participant_____

Signature of Participant _____

Date _____

Day/month/year_____

Statement by the researcher taking consent

I have accurately read out the information sheet to the potential participant

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Signature of Researcher / taking the consent_____

Date _____ Time:_____

Sharing the results:

Nothing that you tell us today will be shared with anybody outside the research team, and nothing will be attributed to you by name. The knowledge that we get from this research will be shared with you and your community before it is made widely available to the public.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect your job or job-related evaluations in any way. You may stop participating in the [Assessment] at any time that you wish without your job being affected.

Who to Contact:

If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact any of the following: IEC-Member

Who has reviewed and approved the study:

This proposal has been reviewed and approved by _____ which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, and telephone number.]

_____

_____

_____

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

General Information about the study:

HINDI INFORMED CONSENT DOCUMENT

KLE College of Pharmacy, Belagavi
KLE Academy of Higher Education and Research, Belagavi

"सूचित सहमति पत्र"

अनुसंधान शीर्षक: जेनेटिक अनुसंधान के बावजूद भविष्य के उपयोग के लिए चिकित्सा परीक्षण स्तेकहोल्डर्स के दृष्टिकोन का अन्वेषण



अनुसंधानकर्ता का नाम: श्री रेवाणा एस देवारिंटि

मार्गदर्शक का नाम: प्रोफ़ेसर (डॉ.) एम एस गणाचारी

संस्थान का नाम: के.एल.इ. फार्मेसी कॉलेज-बेलगावी

यह सूचित सहमति पत्र दो भागों में है:

- सूचना पत्रिका (आपके साथ अध्ययन के बारे में जानकारी साझा करने के लिए)
- सहमति का प्रमाणपत्र (हस्ताक्षर यदि आप भाग लेने का चुनते हैं)

भाग I: सूचना पत्रिका

परिचय: मैं भविष्य के अनुसंधान के लिए जेनेटिक डेटा का उपयोग कर रहा हूँ, अधिकांश अनुसंधानकर्ता और परीक्षण सहभागियों को जेनेटिक सैंपल/डेटा और या भविष्य के अनुसंधान के लिए उपयोग आदि के बारे में पता नहीं है। इसके साथ, हम चिकित्सा परीक्षण स्तेकहोल्डर्स (क्लिनिकल ट्रायल जांचक, मानव नैतिक समिति के सदस्य, फार्मास्यूटिकल प्रायोजक और क्लिनिकल ट्रायल पार्टिसिपेंट्स) के जेनेटिक डेटा के भविष्य के अनुसंधान के लिए ज्ञान दृष्टिकोण और धारणाओं का मूल्यांकन करने जा रहे हैं। ये अध्ययन अनुसंधानकर्ताओं को भी जेनेटिक डेटा साझा करने की नीतियों और मार्गदर्शन का प्रशिक्षण देते हैं।

अनुसंधान का उद्देश्य: क्लिनिकल ट्रायल हमें यह बेहतर समझने में मदद करते हैं कि जेनेटिक्स कैसे बीमारियों का कारण या प्रभाव दे सकती है, इसके साथ ही, जीनोम विज्ञान अब गहरी बाधा से लैब अनुसंधान से लेकर क्लिनिकल सेटिंग में तेजी से बदल रहा है। अगले दशक के भीतर, फार्मास्यूटिकल प्रायोजक या उसके प्रतिनिधि व्यक्ति चिकित्सा उपचारों के व्यक्तिगत प्रतिस्पर्धा को न्यूक्लिक एसिड वेरिएंट्स के साथ जोड़ना शुरू करेंगे, विशेष उपग्रुप की पहचान करेंगे, प्रतिस्पर्धियों और जनसंख्याओं की ओर दवा की आवश्यकता विकसित करेंगे।

जेनेटिक सैंपल्स को विभिन्न विश्लेषणों के लिए उपयोग किया जा सकता है, जिसमें एकल जीन, जीन के सेट और पूरा जीनोम शामिल हो सकता है, जो परीक्षण के उद्देश्यों को साक्षात्कार करने के समय पूर्व-निर्धारित हो सकता है या नहीं। जेनेटिक अध्ययन को पूरा करने के विभिन्न तरीके हैं।

- जेनेटिक अध्ययन प्रोटोकॉल की समीक्षा
- जेनेटिक अध्ययन का आयोजन
- मानव जैविक/जेनेटिक सैंपल्स और संबंधित डेटा के भविष्य का पुनः उपयोग
- अनुसंधान की प्रगति के बारे में प्रतिपुष्टि

इन प्रकार की आशाएं/चुनौतियों को अनुसंधान विश्लेषण के माध्यम से पूर्वानुमानित किया जाना चाहिए। हम मानते हैं कि आप हमें जेनेटिक सैंपल्स और डेटा के बारे में जो जानते हैं, उसकी मदद कर सकते हैं। हमें जेनेटिक अध्ययनों में शामिल होने/आयोजित करने/समीक्षा करने में आने वाली समस्याओं/चुनौतियों के बारे में जानने की जरूरत है। जेनेटिक अनुसंधान में भागीदारी को

पूर्वानुमान करना और भविष्य के अनुसंधान के लिए जेनेटिक डेटा का नीतियों के बारे में चिकित्सा परीक्षण स्तेकहोल्डर्स को समझाना अध्ययन का प्रमुख उद्देश्य है।

अनुसंधान हस्तक्षेप का प्रकार: यह अनुसंधान आपके भागीदारी को पूर्वानुमानित ज्ञान, धारणा और प्रथाओं (केएपी) का पूर्व-पोस्ट मूल्यांकन में शामिल करेगा और एक दिन के लिए जेनेटिक डेटा साझा करने की नीति प्रशिक्षण कार्यक्रम को आयोजित करेगा।

भागीदारी चयन: आपको इस अनुसंधान में भाग लेने के लिए आमंत्रित किया जा रहा है क्योंकि आप अध्ययन के सभी समावेश मानकों को पूरा करते हैं और जेनेटिक डेटा के भविष्य के अनुसंधान में हमारे ज्ञान को बढ़ाने में सहायक हो सकते हैं।

स्वेच्छापूर्ण भागीदारी:

आपका इस अनुसंधान में भाग लेना पूर्णत: स्वेच्छित है। यह आपकी मर्ज़ी है कि आप भाग लें या न करें।

प्रक्रिया: हम आपसे जेनेटिक अनुसंधान और सैंपल या डेटा के भविष्य के अनुसंधान और उनकी नीतियों के बारे में अधिक समझने में हमारी मदद करने के लिए कह रहे हैं। ये सर्वेक्षण उपकरण प्राथमिक रूप से समाप्त प्रश्नों के साथ समाप्त होंगे और प्रतिस्पर्धियों को अपने धारणाओं, प्रथाओं और अनुभवों पर अतिरिक्त जानकारी प्रदान करने के लिए आवश्यकता होगी। सर्वेक्षण मद्दों को चार खंडों में व्यवस्थित किया जाएगा, जो जनसांख्यिकी, ज्ञान, धारणाएं और प्रथाओं के नाम से होंगे।

अवधि: अनुसंधान एक साल से अधिक के दौरान होगा। उस समय के दौरान, हम आपसे केएपी यात्रा/अनुसूचियाँ के पूर्व-पोस्ट मूल्यांकन के लिए और स्तेकहोल्डर्स के लिए एक दिन के प्रशिक्षण/शिक्षा कार्यक्रम के लिए पूछेंगे।

जोख

अवधि: अनुसंधान एक साल से अधिक के दौरान होगा। उस समय के दौरान, हम केएपी यात्रा/अनुसूचियों के पूर्व-पोस्ट मूल्यांकन के लिए और स्तेकहोल्डर्स के लिए एक दिन के प्रशिक्षण/शिक्षा कार्यक्रम के लिए पूछेंगे।

जोख:

इसमें कोई खतरा या हानि नहीं है।



लाभ:

आपके लिए कोई सीधा लाभ नहीं होगा, लेकिन आपका भागीदारी हमें व्यक्ति के केएपी के बारे में और अनुसंधान के लिए जेनेटिक संबंधित डेटा के नैतिक चुनौतियों के बारे में अधिक मूल्यांकन करने में मदद कर सकता है।

गोपनीयता:

क्लिनिकल अनुसंधान समुदाय में इस अनुसंधान का प्रदर्शन हो सकता है और यदि आप भाग लेते हैं तो आपसे अनुसंधानकर्ता द्वारा सवाल पूछे जा सकते हैं। हम आपके बारे में किसी भी जानकारी को अन्य किसी के साथ साझा नहीं करेंगे। हम इस अनुसंधान से जो जानकारी एकत्र करते हैं, वह निजी रूप से रखी जाएगी। आपके बारे में कोई भी जानकारी आपके नाम की जगह पर इनिशियल्स के साथ होगी।

आपके अधिकार और नैतिकता की जानकारी:

आपके पास निम्नलिखित के बारे में सवाल हो सकते हैं:

- आप एक अनुसंधान अध्ययन में भाग लेने वाले व्यक्ति के रूप में आपके अधिकार
- आपकी कैसे कैद जानकारी रखी जाती है
- स्व-अध्ययन- (चिंताएं और शिकायतें)

परिणाम साझा करना: आज आप हमें कुछ भी नहीं बताते हैं, जो अनुसंधान दल के बाहर किसी के साथ साझा नहीं किया जाएगा, और न किसी नाम के द्वारा आपके लिए समर्पित किया जाएगा। यह अनुसंधान से हमें प्राप्त ज्ञान को आपके और आपकी समुदाय के

साथ साझा किया जाएगा, जब तक कि यह सामान्य रूप से सार्वजनिक न हो जाए।

इनकार करने या वापस लेने का अधिकार: आपको इस अनुसंधान में भाग नहीं लेना है अगर आप इसे नहीं चाहते हैं, और भाग लेने का चयन करने से आपके काम या काम से संबंधित मूल्य.

परिणाम साझा करना: आज आप हमें कुछ भी नहीं बताते हैं, जो अनुसंधान दल के बाहर किसी के साथ साझा नहीं किया जाएगा, और न किसी नाम के द्वारा आपके लिए समर्पित किया जाएगा। यह अनुसंधान से हमें प्राप्त ज्ञान को आपके और आपकी समुदाय के साथ साझा किया जाएगा, जब तक कि यह सामान्य रूप से सार्वजनिक न हो जाए।

इनकार करने या वापस लेने का अधिकार: आपको इस अनुसंधान में भाग नहीं लेना है अगर आप इसे नहीं चाहते हैं, और भाग लेने का चयन करने से आपके काम या काम से संबंधित मूल्यों पर कोई असर नहीं पड़ेगा। आप चाहें तो अपनी नौकरी पर किसी प्रकार का प्रभाव न होने के साथ किसी भी समय [मूल्यांकन] में भाग लेना बंद कर सकते हैं।

संपर्क करने का तरीका: यदि आपके पास अब या बाद में कोई सवाल है, तो आप पूछ सकते हैं। यदि आप बाद में सवाल पूछना चाहते हैं, तो आप किसी भी संस्थानीय नैतिक समिति (आईईसी) के किसी सदस्य से संपर्क कर सकते हैं। यह अध्ययन केएएचईआर नैतिक समिति ने मानव विषयों पर अपने कार्य का किया है। आईईसी के बारे में अधिक जानकारी के लिए, आप संपर्क कर सकते हैं:

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अगर आपके पास किसी भी अनुसंधान के किसी भाग के बारे में कोई सवाल है, तो आप मुझसे पूछ सकते हैं। क्या आपके पास कोई सवाल है?

भाग II: सूचित सहमति प्रपत्र



मुझे चिकित्सा परीक्षण के स्टाकहोल्डर्स के केएपी का मूल्यांकन करने के लिए आनंदित होने के लिए अनुसंधान में भाग लेने के लिए आमंत्रित किया गया है जो भविष्य में जेनेटिक और इसके संबंधित डेटा के उपयोग के प्रति है। मैंने पूर्व दी गई जानकारी को पढ़ा है, या इसे मुझे पढ़ा गया है। मुझे इसके बारे में सवाल पूछने का मौका मिला है और मुझे सवालों के उत्तर मेरी संतुष्टि के लिए दिए गए हैं। मैं स्वेच्छा से इस अध्ययन में भाग लेने के लिए सहमत हूँ।

सहभागी का नाम प्रिंट करें_____

सहभागी का हस्ताक्षर _____

तारीख _____

दिन/महीना/वर्ष_____

अनुसंधानकर्ता द्वारा सहमति लेने का बयान: मैंने संभावित सहभागी को सूचना पत्र को सटीकता से पढ़ा है। मैं पुष्टि करता हूं कि सहभागी को अध्ययन के बारे में सवाल पूछने का अवसर दिया गया था, और सहभागी द्वारा पूछे गए सभी सवालों का सही और मेरी संभावना के अनुसार उत्तर दिया गया है। मैं पुष्टि करता हूं कि व्यक्ति को किसी भी दबाव में सहमति देने के लिए नहीं बाधित किया गया है, और सहमति स्वेच्छा से और स्वेच्छा से दी गई है।

अनुसंधानकर्ता / सहमति लेने वाले का हस्ताक्षर_____

तारीख _____

समय:_____

KANNADA INFORMED CONSENT DOCUMENT

KLE College of Pharmacy, Belagavi
KLE Academy of Higher Education and Research, Belagavi

ಮಾಹಿತಿ ಸಮ್ಮತಿ ಪತ್ರ

ಶೋಧನೆ ಶೀರ್ಷಿಕೆ: ಭವಿಷ್ಯದಲ್ಲಿ ಡೇಟಾ ಬಳಕೆಗಾಗಿ ಜನ್ಯುಮ ಸಂಶೋಧನೆ - ಕ್ಲಿನಿಕಲ್ ಟ್ರಯಲ್ ಹಿತರಕ್ಷಣಾಧಿಕಾರಿಗಳ ದೃಷ್ಟಿಕೋನಗಳ ಅನ್ವೇಷಣೆ
ಶೋಧಕನ ಹೆಸರು: ಶ್ರೀ. ರೇವಣ ಸಿ ದೇವರಿಂತಿ
ಮಾರ್ಗದರ್ಶಕರ ಹೆಸರು: ಪ್ರೊ.(ಡಾ.) ಎಮ್.ಎಸ್. ಗಣಾಚಾರಿ
ಸಂಸ್ಥೆಯ ಹೆಸರು: ಕೆಎಲ್ಇ ಫಾರ್ಮಸಿ ಕಾಲೇಜು-ಬೆಳಗಾವಿ
ಈ ಮಾಹಿತಿ ಸಂಗ್ರಹ ಫಾರ್ಮ್ ಎರಡು ಭಾಗಗಳನ್ನು ಹೊಂದಿದೆ:

I. ಭಾಗ I ಮಾಹಿತಿ ಹಾಳೆ (ಶೋಧನೆ ಬಗ್ಗೆ ಮಾಹಿತಿಯನ್ನು ನಿಮ್ಮೊಂದಿಗೆ ಹಂಚಲು)
II. ಒಪ್ಪಿಗೆಯ ಪ್ರಮಾಣಪತ್ರ (ನೀವು ಭಾಗವಹಿಸಲು ಆಯ್ಕೆ ಮಾಡಿದರೆ ಸಹಿ ಹಾಕಲು)



ಭಾಗ I: ಮಾಹಿತಿ ಹಾಳೆ

ಪರಿಚಯ: ನಾನು ಭವಿಷ್ಯದಲ್ಲಿ ಸಂಶೋಧನೆಗಾಗಿ ಜನ್ಯುಮ ಡೇಟಾ ಬಳಕೆಯ ಮೇಲೆ ಕೆಲಸ ಮಾಡುತ್ತಿದ್ದೇನೆ. ಬಹುಶಃ ಸಂಶೋಧಕರು ಮತ್ತು ಟ್ರಯಲ್ ಭಾಗವಹಿಸುವವರು ಜನ್ಯುಮ ಮಾದರಿಗಳು/ಡೇಟಾ ಮತ್ತು ಭವಿಷ್ಯದಲ್ಲಿ ಸಂಶೋಧನೆಗಾಗಿ ಅವುಗಳ ಬಳಕೆ ಇತ್ಯಾದಿ ಬಗ್ಗೆ ತಿಳಿದಿರುವುದಿಲ್ಲ. ಈ ಮೂಲಕ, ನಾವು ಕ್ಲಿನಿಕಲ್ ಟ್ರಯಲ್ ಹಿತರಕ್ಷಣಾಧಿಕಾರಿಗಳ (ಕ್ಲಿನಿಕಲ್ ಟ್ರಯಲ್ ತನಿಖಾಕಾರ, ಮಾನವ ನೈತಿಕ ಸಮಿತಿ ಸದಸ್ಯರು, ಔಷಧೀಯ ಪ್ರಾಯೋಜಕರು ಮತ್ತು ಕ್ಲಿನಿಕಲ್ ಟ್ರಯಲ್ ಭಾಗವಹಿಸುವವರು) ಜನ್ಯುಮ ಡೇಟಾ ಬಳಕೆಯ ಬಗ್ಗೆ ತಿಳಿದಿರುವ ಮಾಹಿತಿ, ದೃಷ್ಟಿಕೋನ ಮತ್ತು ದೃಷ್ಟಿಕೋನಗಳನ್ನು ಅಳೆಯಲು ಹೋಗುತ್ತಿದ್ದೇವೆ. ಈ ಅಧ್ಯಯನದ ಸಂಶೋಧಕರು ಜನ್ಯುಮ ಡೇಟಾ ಹಂಚಿಕೆ ನೀತಿಗಳ ಬಗ್ಗೆ ಟ್ರಯಲ್ ಹಿತರಕ್ಷಣಾಧಿಕಾರಿಗಳನ್ನು ತರಬೇತಿ ನೀಡುತ್ತಾರೆ/ಶಿಕ್ಷಣ ನೀಡುತ್ತಾರೆ.

ಶೋಧನೆಯ ಉದ್ದೇಶ: ಕ್ಲಿನಿಕಲ್ ಟ್ರಯಲ್‌ಗಳು ಹೇಗೆ ಜನ್ಯುಗಳು ರೋಗಗಳನ್ನು ಉಂಟುಮಾಡಬಹುದು ಅಥವಾ ಅವುಗಳ ಮೇಲೆ ಪ್ರಭಾವ ಬೀರುತ್ತವೆ ಎಂಬುದನ್ನು ಉತ್ತಮವಾಗಿ ಅರ್ಥಮಾಡಿಕೊಳ್ಳಲು ಸಹಾಯ ಮಾಡುತ್ತವೆ. ಈ ಮೂಲಕ, ಜಿನೋಮ್ ವಿಜ್ಞಾನವು ಶೀಘ್ರವಾಗಿ ಪ್ರಯೋಗಾಲಯ ಸಂಶೋಧನೆಯಿಂದ ಕ್ಲಿನಿಕಲ್ ಸೆಟ್ಟಿಂಗ್‌ಗೆ ಶಿಫ್ಟ್ ಆಗುತ್ತಿದೆ. ಮುಂದಿನ ದಶಕದಲ್ಲಿ, ಔಷಧೀಯ ಪ್ರಾಯೋಜಕರು ಅಥವಾ ಅವರ ಪ್ರತಿನಿಧಿಗಳು ನ್ಯೂಕ್ಲಿಕ್ ಆಮ್ಲದ ರೂಪಾಂತರಗಳನ್ನು ವೈಯಕ್ತಿಕ ಚಿಕಿತ್ಸೆಯ ಪ್ರತಿಕ್ರಿಯೆಗಳಿಗೆ ಸಂಬಂಧಿಸುವುದನ್ನು ಪ್ರಾರಂಭಿಸುತ್ತಾರೆ, ನಿರ್ದಿಷ್ಟ ರೋಗಿಗಳ ಉಪಸಮೂಹಗಳನ್ನು ಗುರುತಿಸುತ್ತಾರೆ ಮತ್ತು ಜನಸಮೂಹಗಳತ್ತ ಔಷಧಿ ಅಗತ್ಯವನ್ನು ಅಭಿವೃದ್ಧಿಪಡಿಸುತ್ತಾರೆ.

ಜನ್ಯುಮ ಮಾದರಿಗಳನ್ನು ವಿಭಿನ್ನ ವಿಶ್ಲೇಷಣೆಗಾಗಿ ಬಳಸಬಹುದು, ಅವುಗಳಲ್ಲಿ ಒಂದೇ ಜನ್ಯು, ಜನ್ಯುಗಳ ಸಮೂಹ, ಮತ್ತು ಸಂಪೂರ್ಣ ಜಿನೋಮ್ ಸೇರಬಹುದು, ಅದು ಸಂಗ್ರಹಣೆಯ ಸಮಯದಲ್ಲಿ ಕ್ಲಿನಿಕಲ್ ಟ್ರಯಲ್ ಗುರಿಯಲ್ಲಿಲ್ಲದಿರಬಹುದು. ಜನ್ಯುಮ ಅಧ್ಯಯನವನ್ನು ಪೂರ್ಣಗೊಳಿಸಲು ವಿವಿಧ ಮಾರ್ಗಗಳು ಇವೆ:

- ಜನ್ಯುಮ ಅಧ್ಯಯನ ಪ್ರೋಟೋಕಾಲ್‌ಗಳ ವಿಮರ್ಶೆ
- ಜನ್ಯುಮ ಅಧ್ಯಯನಗಳ ನಡೆಸುವುದು
- ಮಾನವ ಜೀವಶಾಸ್ತ್ರ/ಜನ್ಯುಮ ಮಾದರಿಗಳ ಮತ್ತು ಸಂಬಂಧಿತ ಡೇಟಾದ ಭವಿಷ್ಯದಲ್ಲಿ ಮರುಬಳಕೆ
- ಸಂಶೋಧನೆಯ ಪ್ರಗತಿಗೆ ಪ್ರತಿಕ್ರಿಯೆ

ಈ ರೀತಿಯ ನಿರೀಕ್ಷೆ/ಸವಾಲುಗಳನ್ನು ಸಂಶೋಧನಾ ವಿಶ್ಲೇಷಣೆ ನಡೆಸುವ ಮೂಲಕ ಮುಂಚೂಣಿಯಲ್ಲಿ ಇರಿಸಿಕೊಳ್ಳಬೇಕು.

ನಾವು ನೀವು ಜನ್ಯುಮ ಮಾದರಿಗಳು ಮತ್ತು ಡೇಟಾ ಬಗ್ಗೆ ಏನನ್ನು ತಿಳಿಯುತ್ತೀರಿ ಎಂಬುದನ್ನು ತಿಳಿಯಲು ಸಹಾಯ ಮಾಡುತ್ತೀರಿ ಎಂದು ನಂಬುತ್ತೇವೆ. ಜನ್ಯುಮ ಅಧ್ಯಯನಗಳಲ್ಲಿ ಭಾಗವಹಿಸುವ/ನಡೆಸುವ/ಪುನರ್ ವಿಮರ್ಶೆ ಮಾಡುವ ತೊಂದರೆಗಳನ್ನು ಕುರಿತು ನಾವು ತಿಳಿದುಕೊಳ್ಳುತ್ತೇವೆ. ಜನ್ಯುಮ ಸಂಶೋಧನೆಯಲ್ಲಿ ಭಾಗವಹಿಸುವ ನಿರೀಕ್ಷೆಯನ್ನು ಮುಂಚೂಣಿಯಲ್ಲಿ ಇರಿಸಿಕೊಳ್ಳುವುದು ಮತ್ತು ಭವಿಷ್ಯದ ಸಂಶೋಧನೆಗಾಗಿ ಜನ್ಯುಮ ಡೇಟಾ ಬಳಕೆ ನೀತಿಗಳನ್ನು ಕ್ಲಿನಿಕಲ್ ಟ್ರಯಲ್ ಹಿತರಕ್ಷಣಾಧಿಕಾರಿಗಳಿಗೆ ಅರ್ಥಮಾಡಿಸುವುದು ಈ ಅಧ್ಯಯನದ ಪ್ರಮುಖ ಉದ್ದೇಶವಾಗಿದೆ.

ಶೋಧನಾ ಹಸ್ತಕ್ಷೇಪದ ಪ್ರಕಾರ: ಈ ಸಂಶೋಧನೆ ನಿಮ್ಮ ಭಾಗವಹಿಸುವಿಕೆಯನ್ನು ಒಳಗೊಂಡಿರುತ್ತದೆ ಪ್ರೀ-ಪೋಸ್ಟ್ ಮೌಲ್ಯಮಾಪನದ KAP (ಜ್ಞಾನ, ಭಾವನೆಗಳು ಮತ್ತು ಅಭ್ಯಾಸಗಳು) ಮತ್ತು ಜನ್ಯುಮ ಡೇಟಾ ಹಂಚಿಕೆ ನೀತಿ ತರಬೇತಿ ಕಾರ್ಯಕ್ರಮವು ಒಂದು ದಿನ ಶೆಡ್ಯೂಲ್ ಮಾಡಲಾಗುವುದು.

ಭಾಗವಹಿಸುವಿಕೆ ಆಯ್ಕೆ:

ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ಭಾಗವಹಿಸಲು ನೀವು ಆಹ್ವಾನಿತರಾಗಿದ್ದೀರಿ ಏಕೆಂದರೆ ನೀವು ಅಧ್ಯಯನದ ಎಲ್ಲಾ ಒಳಗೊಂಡು ಮಾನದಂಡಗಳನ್ನು ಪೂರೈಸಿದ್ದೀರಿ ಮತ್ತು ಭವಿಷ್ಯದ ಸಂಶೋಧನೆಗಾಗಿ ಜನ್ಯುಮ ಡೇಟಾ ಬಳಕೆಯ ಮೇಲೆ ನಮ್ಮ ಅರ್ಥಮಾಡಿಕೊಳ್ಳಲು ನೀವು ಬಹಳಷ್ಟು ಸಹಾಯ ಮಾಡಬಹುದು.

ಸ್ವಯಂಸೇವಕ ಭಾಗವಹಿಸುವಿಕೆ: ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ನಿಮ್ಮ ಭಾಗವಹಿಸುವಿಕೆ ಸಂಪೂರ್ಣವಾಗಿ ಸ್ವಯಂಸೇವಕವಾಗಿದೆ. ಭಾಗವಹಿಸುವುದೋ ಇಲ್ಲವೋ ಎಂಬುದು ನಿಮ್ಮ ಆಯ್ಕೆಯಾಗಿದೆ.

ಪ್ರಕ್ರಿಯೆ: ನಾವು ನಿಮಗೆ ಜನ್ಯುಮ ಸಂಶೋಧನೆ ಮತ್ತು ಮಾದರಿಗಳು ಅಥವಾ ಡೇಟಾ ಭವಿಷ್ಯದ ಸಂಶೋಧನೆಗಾಗಿ ಅವುಗಳ ಬಳಕೆ ಮತ್ತು ಅವುಗಳ ನೀತಿಗಳನ್ನು ಬಗ್ಗೆ ಹೆಚ್ಚು ಅರ್ಥಮಾಡಿಕೊಳ್ಳಲು ಸಹಾಯ ಮಾಡಲು ಕೇಳುತ್ತೇವೆ.

ಈ ಸಮೀಕ್ಷೆಯ ಅಪ್ಲಿಕೇಶನ್‌ಗಳು ಪ್ರಾಥಮಿಕವಾಗಿ ಮುಚ್ಚಿದ ಪ್ರಶ್ನೆಗಳನ್ನು ಒಳಗೊಂಡಿರುತ್ತವೆ, ವಿಶೇಷವಾಗಿ ತೆರೆಯುವ

ಆಯ್ಕೆಗಳು ಸೇರಿಸಲ್ಪಡುತ್ತವೆ ಮತ್ತು ಉತ್ತರದಾರರು ತಮ್ಮ ಧಾರ್ಮಿಕತೆ, ಅಭ್ಯಾಸಗಳು ಮತ್ತು ಅನುಭವಗಳ ಬಗ್ಗೆ ಹೆಚ್ಚಿನ ಮಾಹಿತಿಯನ್ನು ಒದಗಿಸುತ್ತಾರೆ. ಸಮೀಕ್ಷಾ ಐಟಂಗಳನ್ನು ನಾಲ್ಕು ವಿಭಾಗಗಳಲ್ಲಿ ವ್ಯವಸ್ಥೆ ಮಾಡಲಾಗುತ್ತದೆ: ಜನಾಂಗೀಯತೆ, ಜ್ಞಾನ, ಭಾವನೆಗಳು ಮತ್ತು ಅಭ್ಯಾಸಗಳು.

ಅವಧಿ: ಅಧ್ಯಯನವು ಒಂದು ವರ್ಷಕ್ಕಿಂತ ಹೆಚ್ಚು ನಡೆಯುತ್ತದೆ. ಈ ಅವಧಿಯಲ್ಲಿ, ನಾವು KAP ಮೌಲ್ಯಮಾಪನ ಪೂರ್ವ-ಪೋಸ್ಟ್ ಭೇಟಿಗಳು/ವೇಳಾಪಟ್ಟಿಗಳನ್ನು ಕೇಳುತ್ತೇವೆ ಮತ್ತು ಹಿತರಕ್ಷಣಾಧಿಕಾರಿಗಳಿಗೆ ಒಂದು ದಿನದ ತರಬೇತಿ/ಶಿಕ್ಷಣ ಕಾರ್ಯಕ್ರಮವನ್ನು ಪ್ರಸ್ತುತಪಡಿಸುತ್ತೇವೆ.



ಅಪಾಯಗಳು: ಭಾಗವಹಿಸುವಿಕೆಯ ಯಾವುದೇ ಅಪಾಯ ಅಥವಾ ಹಾನಿ ಇಲ್ಲ.

ಲಾಭಗಳು: ನಿಮಗೆ ಯಾವುದೇ ನೇರ ಲಾಭವಿಲ್ಲ, ಆದರೆ ನಿಮ್ಮ ಭಾಗವಹಿಸುವಿಕೆ ನಮ್ಮಲ್ಲಿರುವ ವ್ಯಕ್ತಿಯ KAP ಮೌಲ್ಯಮಾಪನ ಮತ್ತು ಜನ್ಯಮ ಸಂಬಂಧಿತ ಡೇಟಾ ಬಳಕೆ ಸಂಶೋಧನೆಯಲ್ಲಿ ನೈತಿಕ ಸವಾಲುಗಳನ್ನು ಹೆಚ್ಚು ತಿಳಿಯಲು ಸಹಾಯ ಮಾಡುತ್ತದೆ.

ಗೋಪ್ಯತೆ: ಕ್ಲಿನಿಕಲ್ ಸಂಶೋಧನಾ ಸಮುದಾಯದಲ್ಲಿ ನಡೆಯುತ್ತಿರುವ ಸಂಶೋಧನೆ ಗಮನ ಸೆಳೆಯಬಹುದು ಮತ್ತು ನೀವು ಭಾಗವಹಿಸಿದರೆ ಸಂಶೋಧಕರಿಂದ ಪ್ರಶ್ನೆಗಳು ಕೇಳಬಹುದು. ನಾವು ಸಂಶೋಧನಾ ತಂಡದ ಹೊರಗೆ ಯಾರಿಗೂ ನಿಮ್ಮ ಬಗ್ಗೆ ಮಾಹಿತಿಯನ್ನು ಹಂಚಿಕೊಳ್ಳುವುದಿಲ್ಲ. ಈ ಸಂಶೋಧನೆಯಿಂದ ನಾವು ಸಂಗ್ರಹಿಸುವ ಯಾವುದೇ ಮಾಹಿತಿಯನ್ನು ಖಾಸಗಿ ಎಂದು ಇಡುತ್ತೇವೆ. ನಿಮ್ಮ ಬಗ್ಗೆ ಯಾವುದೇ ಮಾಹಿತಿಗೆ ನಿಮ್ಮ ಹೆಸರಿನ ಬದಲಿಗೆ ಆರಂಭಿಕ ಅಕ್ಷರ ಇರುತ್ತದೆ.

ನಿಮ್ಮ ಹಕ್ಕುಗಳು ಮತ್ತು ನೈತಿಕತೆ ಬಗ್ಗೆ ಮಾಹಿತಿ:

ನಿಮಗೆ ಈ ಕೆಳಗಿನ ವಿಷಯಗಳ ಬಗ್ಗೆ ಪ್ರಶ್ನೆಗಳು ಇರಬಹುದು:

• ಸಂಶೋಧನಾ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವ ವ್ಯಕ್ತಿಯಾಗಿ ನಿಮ್ಮ ಹಕ್ಕುಗಳು
• ನಿಮ್ಮ ವೈಯಕ್ತಿಕ ಮಾಹಿತಿಯನ್ನು ಹೇಗೆ ಇಡಲಾಗುತ್ತದೆ
• ಸ್ವಯಂ ಅಧ್ಯಯನ - (ಚಿಂತೆಗಳು ಮತ್ತು ದೂರುಗಳನ್ನು ಒಳಗೊಂಡಂತೆ)

ಫಲಿತಾಂಶಗಳನ್ನು ಹಂಚಿಕೆ: ನೀವು ಇಂದು ನಮ್ಮಿಗೆ ಹೇಳಿದ ಯಾವುದನ್ನೂ ಸಂಶೋಧನಾ ತಂಡದ ಹೊರಗೆ ಯಾರಿಗೂ ಹಂಚಲಾಗುವುದಿಲ್ಲ, ಮತ್ತು ಯಾವುದನ್ನೂ ನಿಮ್ಮ ಹೆಸರಿನಿಂದ ಸೂಚಿಸಲಾಗುವುದಿಲ್ಲ. ನಾವು ಈ ಸಂಶೋಧನೆಯಿಂದ ಪಡೆಯುವ ಜ್ಞಾನವನ್ನು ನಿಮ್ಮೊಂದಿಗೆ ಮತ್ತು ನಿಮ್ಮ ಸಮುದಾಯದೊಂದಿಗೆ ಹಂಚಿಕೊಳ್ಳುತ್ತೇವೆ.

ನಿರಾಕರಿಸುವ ಅಥವಾ ಹಿಂಪಡೆಯಲು ಹಕ್ಕು: ನೀವು ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ಭಾಗವಹಿಸಬೇಕೆಂದು ನೀವು ಇಚ್ಛಿಸದಿದ್ದರೆ, ನೀವು ಭಾಗವಹಿಸಬೇಕಾಗಿಲ್ಲ, ಮತ್ತು ಭಾಗವಹಿಸುವುದನ್ನು ಆಯ್ಕೆ ಮಾಡುವುದರಿಂದ ನಿಮ್ಮ ಕೆಲಸ ಅಥವಾ ಕೆಲಸ ಸಂಬಂಧಿತ ಮೌಲ್ಯಮಾಪನೆಗೆ ಯಾವುದೇ ರೀತಿಯ ಪರಿಣಾಮ ಬೀರುವುದಿಲ್ಲ. ನೀವು ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಭಾಗವಹಿಸುವಿಕೆಯನ್ನು ನಿಲ್ಲಿಸಬಹುದು.

ಯಾರನ್ನು ಸಂಪರ್ಕಿಸಬೇಕು: ನಿಮಗೆ ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳು ಇದ್ದರೆ, ನೀವು ಅವುಗಳನ್ನು ಈಗ ಅಥವಾ ನಂತರ ಕೇಳಬಹುದು. ನೀವು ನಂತರ ಪ್ರಶ್ನೆಗಳು ಕೇಳಲು ಇಚ್ಛಿಸಿದರೆ, ನೀವು ಈ ಕೆಳಗಿನ ಯಾರನ್ನಾದರೂ ಸಂಪರ್ಕಿಸಬಹುದು: IEC ಸದಸ್ಯರು

ಯಾರಿಂದ ಪರಿಶೀಲನೆ ಮತ್ತು ಅನುಮೋದನೆ ಪಡೆಯಲಾಗಿದೆ: ಈ ಪ್ರಸ್ತಾಪವನ್ನು ಮಾನವ ವಿಷಯಗಳಿಗಾಗಿ KAHER ನೈತಿಕ ಸಮಿತಿಯಿಂದ ಪರಿಶೀಲನೆ ಮತ್ತು ಅನು

ಭಾಗ ೧: ಸಂಶೋಧನಾ ಅಧ್ಯಯನದ ಮಾಹಿತಿ

ಯಾರನ್ನು ಸಂಪರ್ಕಿಸಬೇಕು: ನಿಮಗೆ ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳಿದ್ದರೆ, ಈಗ ಅಥವಾ ನಂತರ ನೀವು ಅವುಗಳನ್ನು ಕೇಳಬಹುದು. ನೀವು ನಂತರ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲು ಬಯಸಿದರೆ, ಈ ಕೆಳಗಿನವರಲ್ಲಿ ಯಾರನ್ನಾದರೂ ಸಂಪರ್ಕಿಸಬಹುದು: ಐಇಸಿ-ಸದಸ್ಯ

ಯಾರು ಅಧ್ಯಯನವನ್ನು ಪರಿಶೀಲಿಸಿ ಅನುಮೋದಿಸಿದ್ದಾರೆ: ಈ ಪ್ರಸ್ತಾವನೆಯನ್ನು ಡಾಕ್ಟರೇಟ್ ಪದವಿಗಾಗಿ KAHER ಮಾನವ ವಿಷಯಗಳ ನೀತಿ ಸಮಿತಿಯು ಪರಿಶೀಲಿಸಿ ಅನುಮೋದಿಸಿದೆ, ಇದು ಸಂಶೋಧನಾ ಪಾಲ್ಗಾರರನ್ನು ಹಾನಿಯಿಂದ ರಕ್ಷಿಸಲು ಸಮಿತಿಯ ಕಾರ್ಯವಾಗಿದೆ. ಐಇಸಿ ಕುರಿತು ಹೆಚ್ಚಿನ ಮಾಹಿತಿಯನ್ನು ಕಂಡುಹಿಡಿಯಲು ಬಯಸಿದರೆ, [ಹೆಸರು, ವಿಳಾಸ ಮತ್ತು ದೂರವಾಣಿ ಸಂಖ್ಯೆ] ಯನ್ನು ಸಂಪರ್ಕಿಸಿ.

ಸಂಪರ್ಕ ಮಾಹಿತಿ:

- ಹೆಸರು: ಡಾ. ಶೀತಲ್ ಹರ್ಕುಣಿ
- ಹುದ್ದೆ (Designation): ಸದಸ್ಯ ಕಾರ್ಯದರ್ಶಿ
- ಸಂಪರ್ಕ ಸಂಖ್ಯೆ: +91 98458-67527

ಸಂಶೋಧನಾ ಅಧ್ಯಯನದ ಯಾವುದೇ ಭಾಗದ ಬಗ್ಗೆ ನೀವು ನನ್ನನ್ನು ಇನ್ನಷ್ಟು ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಬಹುದು. ನಿಮಗೆ ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳಿವೆಯೇ?



ಭಾಗ II: ಮಾಹಿತಿ ಸಹಮತಿ ಫಾರ್ಮ್

ನಾನು ಜೀನತಾಂತ್ರಿಕ ಮತ್ತು ಅದರ ಸಂಬಂಧಿತ ಡೇಟಾ ಬಳಕೆಯನ್ನು ಭವಿಷ್ಯದ ಸಂಶೋಧನೆಗೆ ಬಳಸುವ ಹಕ್ಕಿಗೆ ಸಂಬಂಧಿಸಿದಂತೆ ಕ್ಲಿನಿಕಲ್ ಟ್ರಯಲ್ ಪಾಲುದಾರರ KAP ಅನ್ನು ಮೌಲ್ಯಮಾಪನ ಮಾಡಲು ಸಂಶೋಧನೆಯಲ್ಲಿ ಭಾಗವಹಿಸಲು ಆಹ್ವಾನಿಸಲ್ಪಟ್ಟಿದ್ದೇನೆ. ನಾನು ಮೇಲಿನ ಮಾಹಿತಿಯನ್ನು ಓದಿದ್ದೇನೆ ಅಥವಾ ಅದು ನನಗೆ ಓದಿಕೊಡಲಾಗಿದೆ. ನಾನು ಅದರ ಬಗ್ಗೆ ಪ್ರಶ್ನೆಗಳು ಕೇಳಲು ಅವಕಾಶವನ್ನು ಪಡೆದಿದ್ದೇನೆ ಮತ್ತು ನಾನು ಕೇಳಿದ ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳು ನನ್ನ ತೃಪ್ತಿಗೆ ಉತ್ತರಿಸಲ್ಪಟ್ಟಿವೆ. ನಾನು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಸ್ವತಃಸ್ಫೂರ್ತಿಯಿಂದ ಒಪ್ಪಿಗೆ ನೀಡುತ್ತೇನೆ.

ಭಾಗವಹಿಸುವವರ ಮುದ್ರಿತ ಹೆಸರು: _____

ಭಾಗವಹಿಸುವವರ ಸಹಿ: _____

ದಿನಾಂಕ: _____

ದಿನ/ತಿಂಗಳು/ವರ್ಷ: _____

ಸಹಮತಿ ಪಡೆಯುತ್ತಿರುವ ಸಂಶೋಧಕರ ಹೇಳಿಕೆ

ನಾನು ಮಾಹಿತಿ ಶೀಟನ್ನು ಭಾಗವಹಿಸುವವರಿಗೆ ನಿಖರವಾಗಿ ಓದಿಸಿದ್ದೇನೆ. ಅಧ್ಯಯನದ ಬಗ್ಗೆ ಪ್ರಶ್ನೆಗಳು ಕೇಳಲು ಭಾಗವಹಿಸುವವರಿಗೆ ಅವಕಾಶ ನೀಡಲಾಗಿದೆ ಎಂಬುದನ್ನು ನಾನು ದೃಢೀಕರಿಸುತ್ತೇನೆ ಮತ್ತು ಭಾಗವಹಿಸುವವರಿಂದ ಕೇಳಲಾದ ಎಲ್ಲಾ ಪ್ರಶ್ನೆಗಳು ಸರಿಯಾಗಿ ಮತ್ತು ನನ್ನ ಸಾಮರ್ಥ್ಯದಂತೆ ಉತ್ತರಿಸಲಾಗಿದೆ. ವ್ಯಕ್ತಿಗೆ ಒತ್ತಡಹುಟ್ಟು ಒಪ್ಪಿಗೆ ಪಡೆಯಲಾಗಿಲ್ಲ ಮತ್ತು ಒಪ್ಪಿಗೆಯನ್ನು ಸ್ವತಃಸ್ಫೂರ್ತಿಯಿಂದ ಮತ್ತು ಸ್ವಯಂ ಪ್ರೇರಿತವಾಗಿ ನೀಡಲಾಗಿದೆ ಎಂದು ನಾನು ದೃಢೀಕರಿಸುತ್ತೇನೆ.

ಸಹಮತಿ ಪಡೆಯುತ್ತಿರುವ ಸಂಶೋಧಕರ ಸಹಿ: _____

ದಿನಾಂಕ: _____ ಸಮಯ: _____

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"सूचित सहमति पत्र"

अनुसंधान शीर्षक: जेनेटिक अनुसंधान के बावजूद भविष्य के उपयोग के लिए चिकित्सा परीक्षण स्तेकहोल्डर्स के दृष्टिकोन का अन्वेषण

अनुसंधानकर्ता का नाम: श्री रेवाणा एस देवारिटि

मार्गदर्शक का नाम: प्रोफ़ेसर (डॉ.) एम एस गणाचारी

संस्थान का नाम: के.एल.इ. फार्मेसी कॉलेज-बेलगावी



यह सूचित सहमति पत्र दो भागों में है:

- सूचना पत्रिका (आपके साथ अध्ययन के बारे में जानकारी साझा करने के लिए)
- सहमति का प्रमाणपत्र (हस्ताक्षर यदि आप भाग लेने का चुनते हैं)

भाग I: सूचना पत्रिका

परिचय: मैं भविष्य के अनुसंधान के लिए जेनेटिक डेटा का उपयोग कर रहा हूँ, अधिकांश अनुसंधानकर्ता और परीक्षण सहभागियों को जेनेटिक सैंपल/डेटा और या भविष्य के अनुसंधान के लिए उपयोग आदि के बारे में पता नहीं है। इसके साथ, हम चिकित्सा परीक्षण स्तेकहोल्डर्स (क्लिनिकल ट्रायल जांचक, मानव नैतिक समिति के सदस्य, फार्मास्यूटिकल प्रायोजक और क्लिनिकल ट्रायल पार्टिसिपेंट्स) के जेनेटिक डेटा के भविष्य के अनुसंधान के लिए ज्ञान दृष्टिकोण और धारणाओं का मूल्यांकन करने जा रहे हैं। ये अध्ययन अनुसंधानकर्ताओं को भी जेनेटिक डेटा साझा करने की नीतियों और मार्गदर्शन का प्रशिक्षण देते हैं।

अनुसंधान का उद्देश्य: क्लिनिकल ट्रायल हमें यह बेहतर समझने में मदद करते हैं कि जेनेटिक्स कैसे बीमारियों का कारण या प्रभाव दे सकती है, इसके साथ ही, जीनोम विज्ञान अब गहरी बाधा से लैब अनुसंधान से लेकर क्लिनिकल सेटिंग में तेजी से बदल रहा है। अगले दशक के भीतर, फार्मास्यूटिकल प्रायोजक या उसके प्रतिनिधि व्यक्ति चिकित्सा उपचारों के व्यक्तिगत प्रतिस्पर्धा को न्यूक्लिक एसिड वेरिएंट्स के साथ जोड़ना शुरू करेंगे, विशेष उपग्रुप की पहचान करेंगे, प्रतिस्पर्धियों और जनसंख्याओं की ओर दवा की आवश्यकता विकसित करेंगे।

जेनेटिक सैंपल्स को विभिन्न विश्लेषणों के लिए उपयोग किया जा सकता है, जिसमें एकल जीन, जीन के सेट और पूरा जीनोम शामिल हो सकता है, जो परीक्षण के उद्देश्यों को साक्षात्कार करने के समय पूर्व-निर्धारित हो सकता है या नहीं। जेनेटिक अध्ययन को पूरा करने के विभिन्न तरीके हैं।

- जेनेटिक अध्ययन प्रोटोकॉल की समीक्षा
- जेनेटिक अध्ययन का आयोजन
- मानव जैविक/जेनेटिक सैंपल्स और संबंधित डेटा के भविष्य का पुनः उपयोग
- अनुसंधान की प्रगति के बारे में प्रतिपुष्टि

इन प्रकार की आशाएं/चुनौतियों को अनुसंधान विश्लेषण के माध्यम से पूर्वानुमानित किया जाना चाहिए। हम मानते हैं कि आप हमें जेनेटिक सैंपल्स और डेटा के बारे में जो जानते हैं, उसकी मदद कर सकते हैं। हमें जेनेटिक अध्ययनों में शामिल होने/आयोजित करने/समीक्षा करने में आने वाली समस्याओं/चुनौतियों के बारे में जानने की जरूरत है। जेनेटिक अनुसंधान में भागीदारी को

पूर्वानुमान करना और भविष्य के अनुसंधान के लिए जेनेटिक डेटा का नीतियों के बारे में चिकित्सा परीक्षण स्तेकहोल्डर्स को समझाना अध्ययन का प्रमुख उद्देश्य है।

अनुसंधान हस्तक्षेप का प्रकार: यह अनुसंधान आपके भागीदारी को पूर्वानुमानित ज्ञान, धारणा और प्रथाओं (केएपी) का पूर्व-पोस्ट मूल्यांकन में शामिल करेगा और एक दिन के लिए जेनेटिक डेटा साझा करने की नीति प्रशिक्षण कार्यक्रम को आयोजित करेगा।

भागीदारी चयन: आपको इस अनुसंधान में भाग लेने के लिए आमंत्रित किया जा रहा है क्योंकि आप अध्ययन के सभी समावेश मानकों को पूरा करते हैं और जेनेटिक डेटा के भविष्य के अनुसंधान में हमारे ज्ञान को बढ़ाने में सहायक हो सकते हैं।

स्वेच्छापूर्ण भागीदारी:

आपका इस अनुसंधान में भाग लेना पूर्णत: स्वेच्छित है। यह आपकी मर्ज़ी है कि आप भाग लें या न करें।

प्रक्रिया: हम आपसे जेनेटिक अनुसंधान और सैंपल या डेटा के भविष्य के अनुसंधान और उनकी नीतियों के बारे में अधिक समझने में हमारी मदद करने के लिए कह रहे हैं। ये सर्वेक्षण उपकरण प्राथमिक रूप से समाप्त प्रश्नों के साथ समाप्त होंगे और प्रतिस्पर्धियों को अपने धारणाओं, प्रथाओं और अनुभवों पर अतिरिक्त जानकारी प्रदान करने के लिए आवश्यकता होगी। सर्वेक्षण मद्दों को चार खंडों में व्यवस्थित किया जाएगा, जो जनसांख्यिकी, ज्ञान, धारणाएं और प्रथाओं के नाम से होंगे।

अवधि: अनुसंधान एक साल से अधिक के दौरान होगा। उस समय के दौरान, हम आपसे केएपी यात्रा/अनुसूचियाँ के पूर्व-पोस्ट मूल्यांकन के लिए और स्तेकहोल्डर्स के लिए एक दिन के प्रशिक्षण/शिक्षा कार्यक्रम के लिए पूछेंगे।

जोख

अवधि: अनुसंधान एक साल से अधिक के दौरान होगा। उस समय के दौरान, हम केएपी यात्रा/अनुसूचियों के पूर्व-पोस्ट मूल्यांकन के लिए और स्तेकहोल्डर्स के लिए एक दिन के प्रशिक्षण/शिक्षा कार्यक्रम के लिए पूछेंगे।

जोख:

इसमें कोई खतरा या हानि नहीं है।



लाभ:

आपके लिए कोई सीधा लाभ नहीं होगा, लेकिन आपका भागीदारी हमें व्यक्ति के केएपी के बारे में और अनुसंधान के लिए जेनेटिक संबंधित डेटा के नैतिक चुनौतियों के बारे में अधिक मूल्यांकन करने में मदद कर सकता है।

गोपनीयता:

क्लिनिकल अनुसंधान समुदाय में इस अनुसंधान का प्रदर्शन हो सकता है और यदि आप भाग लेते हैं तो आपसे अनुसंधानकर्ता द्वारा सवाल पूछे जा सकते हैं। हम आपके बारे में किसी भी जानकारी को अन्य किसी के साथ साझा नहीं करेंगे। हम इस अनुसंधान से जो जानकारी एकत्र करते हैं, वह निजी रूप से रखी जाएगी। आपके बारे में कोई भी जानकारी आपके नाम की जगह पर इनिशियल्स के साथ होगी।

आपके अधिकार और नैतिकता की जानकारी:

आपके पास निम्नलिखित के बारे में सवाल हो सकते हैं:

- आप एक अनुसंधान अध्ययन में भाग लेने वाले व्यक्ति के रूप में आपके अधिकार
- आपकी कैसे कैद जानकारी रखी जाती है
- स्व-अध्ययन- (चिंताएं और शिकायतें)

परिणाम साझा करना: आज आप हमें कुछ भी नहीं बताते हैं, जो अनुसंधान दल के बाहर किसी के साथ साझा नहीं किया जाएगा, और न किसी नाम के द्वारा आपके लिए समर्पित किया जाएगा। यह अनुसंधान से हमें प्राप्त ज्ञान को आपके और आपकी समुदाय के

साथ साझा किया जाएगा, जब तक कि यह सामान्य रूप से सार्वजनिक न हो जाए।

इनकार करने या वापस लेने का अधिकार: आपको इस अनुसंधान में भाग नहीं लेना है अगर आप इसे नहीं चाहते हैं, और भाग लेने का चयन करने से आपके काम या काम से संबंधित मूल्य.

परिणाम साझा करना: आज आप हमें कुछ भी नहीं बताते हैं, जो अनुसंधान दल के बाहर किसी के साथ साझा नहीं किया जाएगा, और न किसी नाम के द्वारा आपके लिए समर्पित किया जाएगा। यह अनुसंधान से हमें प्राप्त ज्ञान को आपके और आपकी समुदाय के साथ साझा किया जाएगा, जब तक कि यह सामान्य रूप से सार्वजनिक न हो जाए।

इनकार करने या वापस लेने का अधिकार: आपको इस अनुसंधान में भाग नहीं लेना है अगर आप इसे नहीं चाहते हैं, और भाग लेने का चयन करने से आपके काम या काम से संबंधित मूल्यों पर कोई असर नहीं पड़ेगा। आप चाहें तो अपनी नौकरी पर किसी प्रकार का प्रभाव न होने के साथ किसी भी समय [मूल्यांकन] में भाग लेना बंद कर सकते हैं।

संपर्क करने का तरीका: यदि आपके पास अब या बाद में कोई सवाल है, तो आप पूछ सकते हैं। यदि आप बाद में सवाल पूछना चाहते हैं, तो आप किसी भी संस्थानीय नैतिक समिति (आईईसी) के किसी सदस्य से संपर्क कर सकते हैं। यह अध्ययन केएएचईआर नैतिक समिति ने मानव विषयों पर अपने कार्य का किया है। आईईसी के बारे में अधिक जानकारी के लिए, आप संपर्क कर सकते हैं:

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अगर आपके पास किसी भी अनुसंधान के किसी भाग के बारे में कोई सवाल है, तो आप मुझसे पूछ सकते हैं। क्या आपके पास कोई सवाल है?

भाग II: सूचित सहमति प्रपत्र



मुझे चिकित्सा परीक्षण के स्ताकहोल्डर्स के केएपी का मूल्यांकन करने के लिए आनंदित होने के लिए अनुसंधान में भाग लेने के लिए आमंत्रित किया गया है जो भविष्य में जेनेटिक और इसके संबंधित डेटा के उपयोग के प्रति है। मैंने पूर्व दी गई जानकारी को पढ़ा है, या इसे मुझे पढ़ा गया है। मुझे इसके बारे में सवाल पूछने का मौका मिला है और मुझे सवालों के उत्तर मेरी संतुष्टि के लिए दिए गए हैं। मैं स्वेच्छा से इस अध्ययन में भाग लेने के लिए सहमत हूँ।

सहभागी का नाम प्रिंट करें_____

सहभागी का हस्ताक्षर _____

तारीख _____

दिन/महीना/वर्ष_____

अनुसंधानकर्ता द्वारा सहमति लेने का बयान: मैंने संभावित सहभागी को सूचना पत्र को सटीकता से पढ़ा है। मैं पुष्टि करता हूं कि सहभागी को अध्ययन के बारे में सवाल पूछने का अवसर दिया गया था, और सहभागी द्वारा पूछे गए सभी सवालों का सही और मेरी संभावना के अनुसार उत्तर दिया गया है। मैं पुष्टि करता हूं कि व्यक्ति को किसी भी दबाव में सहमति देने के लिए नहीं बाधित किया गया है, और सहमति स्वेच्छा से और स्वेच्छा से दी गई है।

अनुसंधानकर्ता / सहमति लेने वाले का हस्ताक्षर_____

तारीख _____

समय:_____

E. KAP QUESTIONNAIRE & DATA COLLECTION FORM

TITLE OF WORK: Clinical trial stakeholders Perception towards Genetic Research Data Re-Use for Future Research

ANNEXURE—KAP OF CLINICAL TRIAL STAKEHOLDERS

DATA COLLECTION FORM

If you have read and understood the above information choose the following	
Participant Initials [Eg: RAJ ANAND R-A]	
Role in the Committee-[Ethics committee members]	
Role in the Company –[Sponsors and CROs]	
Name of the Department [Clinical trials investigators]	
Preferred Language [Clinical trial participants]	
Date of Enrolment [Todays Date]	
Gender	
Age in Years	
Educational Background	
Marital status	

KNWOLEDGE RELATED QUESTIONNAIRES		
SL.NO	**QUESTIONS**	**OPTIONS**
1	Do you know about the clinical trials in genetics & their data reuse	Yes
		No
		Don't Know
2	What kind of sample analysis will be applied to genetic studies and trials?	Nucleic acid extracts
		Novel sources of tissue derived nucleic acid
		Don't Know
3	What does genetic research's secondary data entail?	Whole Exome/Genome Sequencing
		Personnel Health information
		Don't Know
4	What does optional consent mean in clinical trials and research?	Dummy Consent
		Informed consent for collection of biomarker samples
		Don't Know
5	Which forms of consent are used for gathering genetic data for clinical trials or research?	Blanket or broad consent
		Tiered consent
		Don't Know
6	What might happen if genetic data is shared?	Intentional Disclosure
		Misuses
		Don't Know
7	What are the advantages of sharing and reusing genetic information?	To explore a wide range of research questions
		To Validate of research results
		Don't Know
8	Do you anticipate any difficulties with the reuse of genomic data in the future?	Ethical and Legal
		Confidentiality
		Don't Know
9	Which of the following genetic data ICF material is being used for further research?	Data should be shared via unrestricted
		Controlled access repositories
		Don't Know
10	The following conditions apply to genetic consent forms.	Secondary Use of identified data and coded data
		Return of research results
		Don't Know

ATTITUDE RELATED QUESTIONNAIRES		
SL.NO	**QUESTIONS**	**OPTIONS**
1	Do you support the repurposing of genetic information in clinical trials?	Strongly Agree
		Agree
		Disagree
		Strongly Disagree
2	Do you concur that a separate consent is required for the reuse of data in study or research?	Strongly Agree
		Agree
		Disagree
		Strongly Disagree
3	Do you believe that the genetic data gleaned during clinical trials or research should have a separate consent	Strongly Agree
		Agree
		Disagree
		Strongly Disagree
4	Do you permit the return of findings from genomic research?	Strongly Agree
		Agree
		Disagree
		Strongly Disagree
5	Do you agree that sharing a single code will preserve patient privacy, especially when combined with other security measures?	Strongly Agree
		Agree
		Disagree
		Strongly Disagree
6	Do you believe that maintaining the safety and security of sensitive genetic information is a major challenge?	Strongly Agree
		Agree
		Disagree
		Strongly Disagree
7	Do you agree that disclosing genetic information to third parties could result in misuse?	Strongly Agree
		Agree
		Disagree
		Strongly Disagree
8	Do you agree that transferring samples to foreign countries requires correct knowledge?	Strongly Agree
		Agree
		Disagree
		Strongly Disagree
9	Do you think the biobanks are securely and safely storing participant data and sample data?	Strongly Agree
		Agree
		Disagree
		Strongly Disagree
10	Do you agree to the exchange or return of participant-specific genetic research data in encrypted form?	Strongly Agree
		Agree
		Disagree
		Strongly Disagree

PRACTICES RELATED QUESTIONNAIRES		
SL.NO	**QUESTIONS**	**OPTIONS**
1	What kinds of samples used in clinical trials and research for genetic analysis?	Blood samples
		Tissues
		Don't Know
2	Have you ever seen the genetic consent for the analysis of genomic data in any research protocols?	Yes
		No
		Don't Know
3	Is there a clinical study protocol that addresses the reuse of genetic sample data and their return?	Yes
		No
		Don't Know
4	Have you seen any instances of consent for the reuse of genetic data in clinical studies or trials?	Yes
		No
		Never
5	Choose any one of the alternatives in a multi-layered consent process.	Allow sample/bio specimen to be stored for future use for any biomedical
		The sample/bio specimen to be stored for future use for pre-specified health
		Don't Know
6	What types of issues might be encountered while requesting consent for genetic research?	Mention of Optional research on genomics in clinical trials
		Return of results to study participants in clinical trial
		Don't Know
7	Who has the authority to request the sponsors' return of study results or data?	Principal Investigator /Institute
		Study participant
		Don't Know
8	What ethical issues surround the sharing and reuse of genetic data?	Secondary or extended uses of stored samples/re-consent
		Ownership of the biological samples and its data
		Don't Know
9	Have you heard of any of the repositories and biobanks mentioned?	Cancer trial registry
		Any Pharmaceutical Biorepository
		Don't Know
10	Have any clinical trial genetic data results been returned to you in recent years?	Yes
		No
		Don't Know

F. GENETIC CONSNT MODEL

GENETIC CONSENT MODEL FOR CLINICAL TRIALS in Genetics-CTiG

PART-A: GENETIC RESEARCH STUDY INFORMATION

Research Title and No:

Protocol Version and date:

Name of the Sponsor/Contact Research Organization:

Name of the Government/External Funding Agencies: [Ex: NIH, ICMR, Bill Melinda gates etc]

Name of the bio-banking/ Genetic analysis Centre:

Dear Participants!

You have been invited to join this research study due to your specific medical condition. Your written consent is essential for your inclusion in the study. Prior to making a decision about your participation, you will receive detailed information about the study, encompassing the collection, storage, and utilization of your data and biological samples. Additionally, the process of sharing research findings with both participants and attenders will be explained. It is important to note that the study has undergone review by an institutional ethics committee or independent review board.

2 **Introduction:** We are conducting the study about the_____. We would like to understand the disease and related health problems in a better way as future perspectives

3.1. **Genetic research:** The primary emphasis is on understanding how genes contribute to various characteristics, particularly the development of diseases. This exploration

is crucial for Clinical trials investigators pointing potential therapeutic targets and gaining insights into genetic variations that influence responses to therapeutic interventions.

3.2. **Genetic Samples:** Samples of uncertain or unidentified origin collected from humans may encompass various biological materials. These include liquid blood or bloodstains, liquid saliva or saliva stains, and liquid semen, along with genital/vaginal/cervical samples collected on swabs and penile swabs. Additionally, tissue/skin can be part of these collected samples.

3.3. **Consent for future use:** Although it may be challenging to precisely outline the specifics of future research endeavours:

I-PWG Views:

- The research is scientifically sound
- Participants are informed of the scope of the intended future research
- Autonomy is respected by providing the option to consent separately for future research or by providing the option to terminate further use of samples upon request
- Good Clinical practices standards

4. **Return of Research Results**: Within pharmaceutical companies, policies regarding the disclosure of biomarker results to participants who request them involve numerous considerations. These considerations encompass various factors such as:

4.1. The conditions under which genetic results were generated

4.2. Whether results will have impact on medical care of the participant or on related person

4.3. Whether genetic counselling is recommended

4.4. The ability to accurately link the results to individual from whom the samples was collected

4.5. International and national, guidelines and policies regarding the participant's rights access the data to them

5. **<u>Collecting of bio-samples and its data</u>:** The study team will collect information related to your identity, such as your name, occupation, address, and contact number, along with data essential for assessing your health conditions and medical history as part of the study participant's information. The data obtained from the research will be handled as coded data.

   Biomarker Research, including research on pharmacogenomics biomarkers, serves as a valuable tool to enhance pharmaceutical development and deepen our understanding of diseases. This approach involves the analysis of biomolecules such as DNA, RNA, proteins, and lids, as well as other measurements, in relation to specific clinical endpoints of interest. Biomarker research can significantly influence all stages of drug development, spanning from drug discovery and preclinical evaluation to clinical development and post-marketing studies.



6 What do I need my data and bio-samples for?

6.1. Know how the study medications & same drugs work in the body

6.2. Know disease related health problems

6.3. To develop diagnostic tests for disease

6.4. To explore a wide range of research questions

6.5. To validate the research results

7 Who can Access my data and bio-samples?

7.1. The present study Investigator

7.2. Health authorities

7.3. IEC/IRB

7.4. Sponsors/CROs

The research site will share your data and bio-samples with the sponsors/CROs, but only after the data has been coded. In the context of drug discovery and development, the sponsor or their representatives may share your coded data and bio-samples with

third parties, facilitated by a Memorandum of Understanding (MOU) or a Material Transfer Agreement.

8 **Type of data coding:** Coding of your personnel data will be done as per the ICMR guidelines-2017

I.e. single coded anonymized data shall share with the study participants or relatives

9 **How long will my data and coded bio samples be retained?**

After completion of the study, as per the regulatory requirements study related data and document required keep for 25 Years. Your coded data will be deleted or anonymized, and your bio-samples returned to your study investigator.

10 **Benefits of data Sharing:**

10.1. The document should describe whether donors, their families, or communities would receive any financial or non-financial benefits by having access to the products, tests, or discoveries resulting from the research.



10.2. The benefits accrued, if any, should be returned to the communities from where the donors were drawn in community-based studies or from the research institutes.

10.3. To the maximum extent possible, benefits should be indirect or in kind

11 **Ownership of the biological samples and data:** The participant retains ownership of the biological samples and data collected from them. Consequently, the participant has the right to withdraw both the biological material contributed to the biobank and the associated data, unless the data is essential for outcome measurement and explicitly mentioned in the initial informed consent document. It is important to note that complete anonymization may lead to the practical loss of the original donor's ownership rights.

Biobanks or institutes function as custodians or trustees of the samples and data, overseen by their Ethics Committees (ECs). The present and future use of these materials are conducted under the supervision of the respective ECs. Researchers, in

turn, do not possess any claim to ownership or custodianship of the biological samples and data.

12 **Bio banking:** is a systematically curated repository of human biological materials, typically accompanied by associated datasets, preserved over an extended period in suitable facilities for research and potentially commercial purposes, incorporating transparent policies. As bio-banking involves the storage and future research utilization of biological materials, ethical considerations revolve around consent requirements for the collection, banking, and subsequent uses of tissue, DNA samples, and/or data.

13. **Any other optional tests and procedures:** Collecting of additional blood samples/tissues for genetic analysis may be done as part of this study.

14. **Contact details for the additional questions I might have.**



Name of the Researcher	
Phone Number	
Email	
Sub-Investigator-Research Coordinator	
Phone Number	
Name and address of the Medical Research Centre/Hospital	

Name and Address of the IEC/IRB	
Name of the Member Secretary/Chairperson	
Phone Number	
E Mail ID	

Name of the bio-banking/Genetic analysis Centre	
Name of the contact Person	
Address – India or Other country	
Phone Number	
E Mail ID	

PART-B: FUTURE RESEARCH INFORMATION

1. What is a Biomarker and what is Biomarker Research?

A biomarker is defined as a "characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention." Biomarker research, which includes the study of pharmacogenomics biomarkers, serves as a tool to enhance pharmaceutical development and deepen our understanding of diseases. This research involves the analysis of biomolecules such as DNA, RNA, proteins, and lipids, or other measurements like blood pressure or brain images, in relation to specific clinical endpoints of interest. Biomarker research plays a crucial role across all stages of drug development, ranging from initial drug discovery and preclinical evaluations to clinical development and post-marketing studies. The focus of this brochure is on biomarker research that involves the analysis of biomolecules from biological samples collected during clinical trials.



2. Why is Biomarker Research Important?

Biomarker research holds significant importance as it contributes to advancing our ability to predict, detect, and monitor diseases, while also enhancing our understanding of how individuals respond to medications. At its core, this research forms the basis of personalized medicine, an approach to patient treatment grounded in the molecular analysis of genes, proteins, and metabolites. The ultimate goal of biomarker research is to guide clinical decision-making toward safer and more effective treatment strategies, leading to improved patient outcomes and overall cost savings. Moreover, it facilitates the ongoing development and accessibility of medications that prove effective in specific sub-populations, overcoming limitations that might have hindered their creation based on broader population effectiveness alone.



4. How are Biomarkers Being Used in Drug/Vaccine Development?

Biomarker research is currently being used in drug/vaccine development to:

4.1. Explain variability in response among participants in clinical trials

4.2. Better understand the mechanism of action or metabolism of investigational drugs

4.3. Obtain evidence of Pharmacodynamic activity (i.e., how the drug affects the body) at the molecular level

4.4. Address emerging clinical issues such as unexpected adverse events

4.5. Determine eligibility for clinical trials to optimize trial design

4.6. Optimize dosing regimens to minimize adverse reactions and maximize efficacy

4.7. Develop drug-linked diagnostic tests to identify patients who are more likely or less likely to benefit from treatment or who may be at risk of experiencing adverse events

4.8. Provide better understanding of mechanisms of disease

4.9. Monitor clinical trial participant response to medical interventions

5. Biomarker Samples from Clinical Trials: An Invaluable Resource?

Biomarker samples collected from clinical trials represent an invaluable resource for advancing biomarker research. The robustness of clinical trials, characterized by adequate sample sizes and high-quality data obtained through rigorous control measures, is crucial for driving progress in this field. Clinical trials offer a unique opportunity for investigating biomarkers in relation to specific drugs, drug classes, and disease areas. As a result, clinical drug development programs serve as an unparalleled resource for conducting highly productive biomarker research.

6. Informed Consent for Collection & Banking of Biomarker Samples?

Collection of biological samples in clinical trials must be undertaken with voluntary informed consent of the participant (or legally acceptable representative). Policies and regulations for legally appropriate informed consent vary on national, state, and local levels, but are generally based on internationally recognized pillars of ethical conduct for research on human subjects

7. What is Optional vs. Required Subject Participation?

Depending on the relevance of biomarker research to a clinical development program at the time of protocol development, the biomarker research may be a core required component of a trial (e.g., key to elucidating the drug mechanism of action or confirming that the drug is interacting with the target) or may be optional (e.g., to gain valuable knowledge that enhances the understanding of diseases and drugs). Informed consent for the collection of biomarker samples may be presented either in the main clinical informed consent form or as a separate informed consent form, with approaches varying somewhat across pharmaceutical companies. The relevance of biomarker research to a clinical development program may change over time as the science evolves. The samples may therefore increase in value after a protocol is developed

8. Return of Research Results to Study Participants and Research institute?

Policies regarding the return of biomarker research results to study participants can vary among pharmaceutical companies, with several considerations influencing their decision-making process. These considerations include:

8.1. **Conditions of Result Generation:** This involves discerning whether biomarker research results were generated in an exploratory research laboratory or an

accredited diagnostic laboratory, influencing the reliability and interpretability of the findings.

8.2. **Impact on Medical Care**: Pharmaceutical companies assess whether the results will have a meaningful impact on the medical care of the participant or any related individuals, if applicable, as a key factor in determining the return policy.

8.3. **Genetic Counselling Recommendations**: In cases involving genetic results, considerations extend to whether genetic counselling is recommended. This emphasizes the importance of providing additional support and information for participants facing genetic implications.

8.4. **Linking Results to Individuals:** The ability to accurately link the biomarker research result to the individual from whom the sample was collected is another crucial factor. Ensuring precision in result attribution is vital for maintaining data integrity and participant trust.

By weighing these considerations, pharmaceutical companies formulate policies that aim to balance the interests of participants, ethical considerations, and the practicalities of biomarker research result disclosure**.**

9. **Privacy, Confidentiality, and Patient Rights?** are crucial aspects of ethical research practices:

Privacy: Protecting the privacy of study participants is fundamental. This involves safeguarding their personal information and ensuring that their identity remains confidential. Researchers must implement measures to prevent unauthorized access to participant data.

Confidentiality: Confidentiality pertains to the obligation to keep sensitive information obtained during the study confidential. Researchers, regulators, and all involved parties must take steps to prevent the unauthorized disclosure of participant data.

Patient Rights: Respecting and upholding the rights of patients is paramount. This includes providing clear and comprehensive information about the study, obtaining informed consent, and ensuring participants have the right to withdraw from the study at any time without facing negative consequences.

Maintaining a balance between collecting necessary data for research and protecting the rights and privacy of study participants is critical to ethical research conduct. Adhering to these principles, helps build trust between researchers and participants, fostering the integrity of the research process. In addition, maintaining the privacy of study participants and the confidentiality of information relating to them is of paramount concern to industry researchers, regulators, and patients

PART: C – GENETIC CONSENT FORM

Research Title and No:

Protocol Version and date:

Name & Contact details of the site:

I confirm that

1. I have engaged in discussions with the researcher, obtaining comprehensive answers to all my queries regarding the genetic research.
2. I comprehend the intended use of my personal information, data, and genetic samples, including the entities authorized to access them for future research. I acknowledge the version and date of the genetic research form.
3. I am aware that my participation in the genetic research is voluntary, and I retain the right to withdraw from the study at any point, without any adverse consequences.
4. I acknowledge the arrangement regarding the sharing of research results, whether with the researcher or with myself.
5. I commit to refraining from placing restrictions on the utilization of any genetic data or results arising from the research**.**

Consent Particular	**Date of signature**	**Time**
Signature or thumb Impression of the participant/LAR _____		
Name of the study participant or LAR who has signed _____		
Name of the Researcher and signature _____		

*If the study participant or their legally acceptable representative is unable to read or write, an impartial witness must be present throughout the entire informed consent process. This witness will then affix their signature to the consent form, indicating their presence and attesting to the participant's or representative is understanding and voluntary agreement to participate in the study.

Consent Particular	**Date of signature**	**Time**
Name and Signature Impartial witness _____		

REFERENCES:

1. Indian Council of Medical Research Guidelines-2017 Compiled & Edited by: Dr. Roli Mathur Head, ICMR Bioethics Unit NCDIR, Bengaluru
2. Understanding the Intent, Scope and Public Health Benefits of Exploratory Biomarker Research by IPWG

G. ORAL- PRESENTATION-01

5th NATIONAL PHARMD COLLOQUIUM (NPC-2024)

On 15th and 16th March, 2024

KLE College of Pharmacy, Belagavi

KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi-590010, Karnataka, India

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5th NATIONAL PHARM.D COLLOQUIUM (NPC-2024) organized by Dept. of Pharmacy Practice,

KLE College of Pharmacy, Belagavi on 15th & 16th March 2024.

Prof. (Dr). M. S. Ganachari
Programme Co-ordinator

Prof. (Dr). Sunil S. Jalalpure
Principal

POSTER- PRESENTATION-02



H. PUBLICATIONS

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Current Pharmacogenomics and Personalized Medicine, 2024, *21*, 28-37

RESEARCH ARTICLE

Clinical Trial Participant's Perspectives on Genetic Research Data Re-uses for Future Research

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ARTICLE HISTORY

Received: February 01, 2024
Revised: March 29, 2024
Accepted: April 04, 2024

DOI:
10.2174/0118756921305151240503075928

Abstract: ***Background*:** Clinical trial participants play a crucial role in advancing medical research, and the data generated from their participation can indeed be invaluable for future studies. However, the reuse of genetic or clinical research data comes with ethical challenges that need careful consideration. Here are some of the key ethical issues associated with the re-use of such data: Reusing data without clear informed consent raises issues of autonomy and respect for individuals' choices.

***Objective*:** The main aim of this study is to assess the understanding of individuals involved in clinical trials regarding the sharing of genetic research information. Moreover, it seeks to explore the ethical issues and benefits linked with the use of genetic research data for future research initiatives.

***Methods*:** A cross-sectional observational study was applied to assess Knowledge Attitude Practices of clinical trial participants on reuse of genetic research data.

***Results*:** The majority 70% of clinical trial participants were unsure about the difficulties that may arise in future regarding the re-use of genomic data, with concerns about confidentiality being the most common.

***Conclusion*:** The present study prioritized the involvement of clinical trial participants due to their critical role in both genetic and clinical research endeavors. There is a lack of awareness and understanding regarding the re-use of genetic research data and ethical issues among the trial participants. Researchers must take measures to de-identify or anonymize data to protect participants. There is a clear need for comprehensive awareness programs and guidelines aimed at all clinical trial stakeholders. These initiatives would ensure that researchers, participants, and other involved parties are well-informed and adhere to ethical standards when utilizing genetic data for subsequent research endeavors.

Keywords: Clinical trial participants, genetic data, clinical trials, optional research, genomic research, re-use of genomic data.

1. INTRODUCTION

Clinical trial participants are individuals who volunteer to take part in a clinical trial, which is a research study conducted to evaluate the safety and efficacy of new medical treatments, interventions, or devices. These trials are essential for advancing medical knowledge and developing new and improved methods of preventing, diagnosing, and treating various health conditions. Participation in clinical trials is voluntary. While the sharing of participant-level clinical trial data holds promise, apprehensions regarding potential harm to research participants have prompted caution from certain pharmaceutical sponsors and investigators. Yet, there remains a dearth of understanding regarding how clinical trial participants view the risks associated with data sharing [1]. Individuals choose to enroll in clinical research after receiving detailed information about the study, including its purpose, potential risks and benefits, and the procedures involved. The privacy and

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Current Pharmacogenomics and Personalized Medicine

confidentiality of participants are paramount in clinical trials. Personal information is kept confidential, and participants are identified by a code rather than their names in study records to protect their privacy. The sharing of participant-level clinical trial data holds significant potential benefits, yet concerns about potential harms to research participants have prompted caution among pharmaceutical sponsors and investigators. Considering their knowledge and experience, professionals involved in drug development trials weigh various factors when determining the return of results to participants. These considerations encompass the clinical significance of the data, the expertise of the laboratory involved, the robustness of informed consent procedures, the confidentiality safeguards for medical information, and the proficiency of individuals responsible for conveying results to participants [2]. Addressing participants' apprehensions about the potential use of their data for marketing purposes is crucial. To mitigate this concern, data repositories could implement measures such as requiring data requesters to confirm that no marketing use will occur. Additionally, consent documents could provide explicit assurances regarding this requirement, thereby fostering greater trust and transparency in data-sharing endeavors. The field of human genetics stands out among biomedical and health research areas for its heightened ethical considerations. This concern has intensified in recent years due to the emergence of direct-to-consumer testing and the potential for embryo manipulations. While recent advancements in DNA technology offer immense potential for understanding the human genome and its manipulation, they also raise significant concerns regarding scientists' capacity to manage information [3]. Sharing genomic data from clinical testing with researchers: public survey of expectations of clinical genomic data management in Queensland, Australia. Considerable investment and strategic planning have been dedicated to integrating genomic testing into Australia's public health system. As more patients' genomic data becomes stored in the public health system, researchers are increasingly seeking access to valuable information. It is crucial that public policy aligns with public expectations regarding the utilization of genomic data generated from clinical tests. To contribute to the formulation of public policy and discussions on genomic data sharing, gathered public opinions on the use of genomic data contained in medical records for research purposes in the Australian state of Queensland during February and May 2019, 1494 participants completed an online questionnaire. The majority expressed a desire to have the choice to permit the use of their genomic data from medical records in research. Their preferences on whether and how frequently they should be approached for permission depended on the identifiability of the data. Willingness to share data for research on factors such as the type of information shared, the nature of the research, and the entity conducting the research. Participants were primarily concerned about genomic data sharing that could result in discrimination (*e.g*., insurance and employment), data being used for marketing, data security, or commercial use. While most participants were open to sharing genomic data from medical records with researchers, they insisted that permission for use should be sought. However, existing policies in Queensland do not align with participant expectations, particularly concerning anonymous genomics data. Addressing this inconsistency may involve process changes, such as incorporating research consent into clinical consent or implementing general research data consent programs [4]. As per the Indian Council of Medical Research Participants retain ownership rights over the biological samples and data they provide, enabling them to withdraw both unless specified for outcome measurement in the initial informed consent. However, complete anonymization may forfeit the donor's ownership rights. Sharing clinical data is still in a nascent phase compared to genomics data, and there is a strong ethical imperative to protect data while balancing the need for research and health benefits. The proximity between routine genetic testing and research creates a delicate ethical landscape, giving rise to numerous issues encompassed by ethical, legal, and social considerations (ELSI). This necessitates continuous and vigilant oversight, coupled with thoughtful responses to the evolving ethical challenges [5]. Genomics data is rapidly accumulating in public repositories, propelled by the efforts of large consortia and individual labs exploring animal and plant tissues as well as cell cultures. These endeavors employ both established and cutting-edge technologies, resulting in vast datasets. The Human Genome Project marked the inception of the systems biology era, setting the stage for further advancements (Lander *et al.*, 2001; Gates *et al.*, 2021) [6]. Establishing a robust governance framework is essential to integrate these various components and ensure optimal protection for participants in genomics research and bio banking. Such a mechanism should offer oversight for sample reuse and data sharing, aligning with the principles and elements delineated in the framework. This approach aims to harmonize practices, enhance transparency, and uphold ethical standards throughout the research and bio-banking processes [7]. The groundbreaking Human Genome Project (HGP), spanning 13 years and concluding in 2003 with a cost of US$2.7 billion pioneered the sequencing of the entire human genome [8]. While predicting the specifics of future research poses challenges, the I-PWG advocates for the permissibility of utilizing samples collected for exploratory biomarker research in clinical trials under certain conditions. These conditions include ensuring that the future research is scientifically valid, inform-

ing participants about the general scope of intended future research, respecting autonomy by offering the option for separate consent for future sample use or the ability to request termination of sample use and adhering to industry standards for confidentiality protection as outlined in Good Clinical Practice guidelines [9, 10]. The global expansion of genetics in clinical research, along with the associated data repositories housed in biobanks, is underpinned by the aspiration that such research endeavors will ultimately yield improved approaches to disease prevention and treatment through innovative drug targeting, customized treatment protocols, and preemptive identification of disease risk factors [11, 12].

1.1. Risks of Genetic Research Data Sharing: Privacy Concerns

Genetic data is highly sensitive and can reveal intimate details about individuals and their families. Data sharing raises concerns about the potential misuse or unauthorized access to this information, leading to privacy breaches [13].

1.2. Informed Consent Challenges

Ensuring proper informed consent for data sharing can be challenging, especially when participants may not fully understand the potential implications or the extent to which their data will be shared.

1.3. Stigmatization and Discrimination

Genetic information can be used to stigmatize individuals or groups based on their predisposition to certain conditions. There is a risk of discrimination in areas such as employment, insurance, or social relationships.

1.4. Data Security

With the increasing threat of cyberattacks, maintaining the security of genetic data becomes crucial. Breaches in data security can lead to unauthorized access, data manipulation, or theft, posing risks to individuals and the integrity of research outcomes.

1.5. Misuse for Non-Research Purposes

There is a risk that genetic data shared for research purposes might be misused for non-scientific, commercial, or discriminatory purposes, leading to ethical concerns and potential harm to individuals.

1.6. Benefits of Genetic Research Data Sharing: Accelerated Scientific Discovery

Sharing genetic data facilitates collaboration among researchers, allowing them to pool resources and accelerate the pace of scientific discovery. This can lead to faster identification of disease causes, potential treatments, and preventive measures.

1.7. Validation and Reproducibility

Data sharing enables other researchers to validate and reproduce findings, enhancing the reliability of scientific research. This contributes to the robustness and credibility of the knowledge generated from genetic studies.

1.8. Precision Medicine Advancements

Genetic data sharing supports the development of personalized or precision medicine by identifying genetic variations associated with individual responses to treatments. This can lead to more targeted and effective healthcare interventions.

1.9. Improved Patient Outcomes

By sharing genetic data, researchers and clinicians can gain insights into the genetic basis of diseases, allowing for the development of better diagnostic tools, prognostic indicators, and therapeutic strategies. The Nuremberg Code recognizes the humanitarian benefit of human research [14, 15]. The utilization of genomic and health data for large-scale research and precision medicine offers significant potential. However, it is imperative to address concerns regarding social acceptability and the potential risks for individuals and their families. While there has been substantial public engagement regarding health data sharing in general and various aspects of genomic data reuse, there remains a gap in understanding public perspectives on models for accessing combined genomic and health data [16-18]. Sociodemographic factors and individual contexts continue to be significant influencers, while preferences for consent types vary widely among individuals. Establishing trusted environments and offering tailored consent options with active participant engagement is essential for enhancing research participation. These measures help to foster trust, respect individual preferences, and ensure that research practices are responsive to diverse participant needs and concerns [19].

2. MATERIALS AND METHODS

2.1. Study Participants

The participants in this study were individuals recruited from the Clinical Research Department, KLES Dr. Prabhakar Kore Hospital, who had voluntarily enrolled in an interventional clinical trial. Consent was obtained from participants using vernacular languages, including English (n=19), Kannada (n=12), Hindi (n=8), and Marathi (n=11). Informed consent forms were collected from all clinical trial participants.

2.2. Method

A cross-sectional observational study involving participants from a clinical trial conducted at KLE's Dr. Prabhakar Kore Hospital. Data collection was facilitated through Google Forms, integrating validated questionnaires that encompassed demographics, Knowledge Attitude Practices (KAP) assessments, and viewpoints regarding the re-use of genetic research data. Upon completion of data analysis, One-Way ANOVA and Chi-square Test were applied to examine the relationships and variations within the collected data.

3. EXPERIMENTAL

The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) guidelines serve as a globally acknowledged standard setting forth principles for the design, conduct, recording, and reporting of clinical trials involving human subjects [20]. The primary objective of ICH GCP is to uphold both ethical and scientific integrity, safeguarding the rights, safety, and well-being of trial participants. However, it is worth noting that while ICH GCP provides comprehensive guidance on conducting clinical trials, there is currently no universally established set of ethical guidelines specifically addressing the responsible use and sharing of genetic information in future research and clinical investigations. Given the rapid advancements in genetic research and the increasing availability of genetic data, there is a growing need for ethical frameworks tailored to the unique challenges and considerations posed by genetic information. Efforts are underway within the scientific and bioethics communities to address the gap. Various organizations, including governmental bodies, research institutions, and professional societies, are actively engaged in developing guidelines and policies to ensure the responsible collection, use, and sharing of genetic data. These initiatives aim to balance the potential benefits of genetic research with the protection of individual privacy, autonomy, and informed consent. The genetic research field continues to evolve, and ongoing dialogue and collaboration among stakeholders will be essential to establish robust ethical frameworks that promote responsible practices in genetic research and clinical research. These efforts will help uphold the principles of beneficence, non-maleficence, respect for autonomy, and justice, ensuring that genetic information is utilized ethically and responsibly to advance scientific knowledge and improve patient outcomes.

4. RESULTS

The demographic characteristics of the clinical trial participants (n=50) are outlined. The average age of participants is reported as 36.22 ± 13.41. Gender distribution is evenly split, with 50% male and 50% female participants. Regarding marital status, the majority (62%) are married, while 38% are unmarried. The table provides a concise overview of the key demographic features of the clinical trial participants (Table **1**). Knowledge-related questions (Table **2**, Attitude related Questions (Table **3**), and Practices Related Questions (Table **4**).

Table 1. Demographics of clinical trial participants.

Characteristics	Ct-Participants
	n=50
Age	36.22 ± 13.41
Gender	
Male	25 (50)
Female	25 (50)
Marital Status	
Married	31 (62)
Unmarried	19 (38)

5. DISCUSSION

The present study prioritized the involvement of clinical trial participants due to their critical role in both genetic and clinical research endeavors. While existing literature has explored public perspectives on genetic research, a notable gap exists in understanding the specific viewpoints of clinical trial participants. Our study thus aimed to fill this gap by investigating the perspectives of clinical trial participants regarding the re-use of genetic research data for future studies. Emphasizing three key dimensions—Knowledge, Attitude, and Practices (KAP).

5.1. Knowledge

Out of n=50 clinical trial participants, 26% were aware of clinical trial genetics and their data re-use, while 54% did not know about it. The majority 70% of clinical trial participants were unsure about the difficulties that may arise in the future regarding the re-use of genomic data, with concerns about confidentiality being the most common.

When the same participants were asked about the sample analysis applied to genetics and clinical trials, 92% of participants were unaware. There is a lack of understanding about the secondary data involved in the genetic research and 85% of clinical trial participants are unsure about the personnel health information and exome and genome sequencing. About 70 % of clinical trial participants do not know about the optional research or consent in the clinical trials. The majority of clinical trial participants supported the re-using of genetic information in clinical trials and they believed that a separate consent is required for genetic data re-use (As per statistical results mentioned in the Table **2**).

Table 2. Knowledge related questions.

Characteristics	CT-Participants n=50
1. Do you know about the clinical trials in genetics and their data reuse	
Yes	13 (26)
No	10 (20)
Don't know	27 (54)
2. Do you anticipate any difficulties with the reuse of genomic data in the future?	
Ethical and Legal	1 (2)
Confidentiality	14 (28)
Don't know	35 (70)
3. What kind of sample analysis will be applied to genetic studies and trials?	
Nucleic acid extracts (Blood cells, tissues, Buccal swab, Saliva, Bone marrow aspirate, Urine & feces)	4 (8)
Novel sources of tissue derived nucleic acids (*E.g*; Cell free DNA, Circulating tumor cells)	0
Don't know	46 (92)
4. What does genetic research's secondary data entail?	
Personnel Health information	7 (14)
Whole Exome/Genome Sequencing	0
Don't know	43 (86)
5. The following conditions apply to genetic consent forms.	
Secondary Use of identified data and coded data	0
Return of research results	0
Don't Know	50 (100)
6. What might happen if genetic data is shared?	
Intentional disclosure	0
Misuses	15 (30)
Don't Know	35 (70)
7. What are the advantages of sharing and reusing genetic information?	
To explore a wide range of research questions	2 (4)
To Validate of research results	0
Don't Know	48 (96)
8. What does optional consent mean in clinical trials and research?	
Informed consent for the collection of biomarker samples may be presented	15 (30)
Dummy Consent	0
Don't Know	35 (70)
9. Which of the following genetic data ICF material is being used for further research?	
Controlled access repositories	0
Data should be shared *via* unrestricted	0
Don't know	50 (100)
10. Which forms of consent are used for gathering genetic data for clinical trials or research?	
Blanket or broad consent	0
Tiered consent	2 (4)
Don't Know	48 (96)
Statistical applied: Chi-Square test	

Table 3. Attituded related questions.

Characteristics	CT-Participants
	n=50
1) Do you support the repurposing of genetic information in clinical trials?	
Agree	42 (84)
Disagree	4 (8)
Strongly Agree	4 (8)
Strongly Disagree	0
2) Do you concur that a separate consent is required for the reuse of data in study or research?	
Agree	34 (68)
Disagree	9 (18)
Strongly Agree	7 (14)
3) Do you believe that the genetic data gleaned during clinical trials or research should have a separate consent?	
Agree	30 (60)
Disagree	12 (24)
Strongly Agree	8 (16)
4) Do you permit the return of findings from genomic research?	
Agree	33 (66)
Disagree	11 (22)
Strongly Agree	5 (10)
Strongly Disagree	1 (2)
5) Do you agree to the exchange or return of participant-specific genetic research data in encrypted form?	
Agree	35 (70)
Disagree	11 (22)
Strongly Agree	4 (8)
Strongly Disagree	0
6) Do you agree that sharing a single code will preserve patient privacy, especially when combined with other security measures?	
Agree	34 (68)
Disagree	12 (24)
Strongly Agree	4 (8)
Strongly Disagree	0
7) Do you believe that maintaining the safety and security of sensitive genetic information is a major challenge?	
Agree	41 (82)
Disagree	4 (8)
Strongly Agree	5 (10)
Strongly Disagree	0
8) Do you agree that disclosing genetic information to third parties could result in misuse?	
Agree	41 (82)
Disagree	4 (8)
Strongly Agree	4 (8)
Strongly Disagree	1 (2)

(Table 3) contd….

Characteristics	CT-Participants
	n=50
9) Do you agree that transferring samples to foreign countries requires correct knowledge?	
Agree	41 (82)
Disagree	8 (16)
Strongly Agree	1 (2)
10) Do you think the biobanks are securely and safely storing participant data and sample data?	
Agree	41 (82)
Disagree	9 (18)
Strongly Agree	0
Strongly Disagree	0
Statistical applied: Mantel-Haenszel chi-square test	

Table 4. Practices related questions.

Characteristics	CT-Participants
	n=50
1) What kinds of samples were used in clinical trials and research for genetic analysis?	
Blood samples	41 (82)
Tissues	3 (6)
Don't Know	6 (12)
2) Have any clinical trial genetic data results been returned to you in recent years?	
Yes	1 (2)
No	49 (98)
3) Have you ever seen the genetic consent for the analysis of genomic data in any research protocols?	
Yes	0
No	50 (100)
4) Is there a clinical study protocol that addresses the reuse of genetic sample data and their return?	
Yes	0
No	50 (100)
5) Have you seen any instances of consent for the reuse of genetic data in clinical studies or trials?	
Yes	1 (2)
No	49 (98)
6) What types of issues might be encountered while requesting consent for genetic research?	
Mention of Optional research on genomics in clinical trials	0
Return of results to study participants in clinical trials	1 (2)
Don't Know	49 (98)
7) Who has the authority to request the sponsors' return of study results or data?	
Principal Investigator /Institute	17 (34)
Study Participants	1 (2)
Don't Know	32 (64)

(Table 4) contd….

Characteristics	CT-Participants n=50
8) What ethical issues surround the sharing and reuse of genetic data?	
Ownership of the biological samples and its data	0
Return of research results to individual/groups	0
Don't Know	50 (100)
9) Have you heard of any of the repositories and biobanks mentioned?	
Any Pharma industry biorepositories	1 (2)
Cancer trial registry	1 (2)
Don't Know	48 (96)
10) Choose any one of the alternatives in a multi-layered consent process.	
Allow sample/bio specimen to be stored for future use for any biomedical	0
The sample/bio specimen to be stored for future use for other prespecified health problems, such as diabetes, heart disease	1 (2)
Don't Know	49 (98)
Statistical applied: Chi-Square test	

5.2. Attitude

Most clinical trial participants agreed that a separate consent is required for the reuse of data in study or research, and that genetic data gleaned during clinical trials or research should have a separate consent. clinical participants also expressed concerns about the safety and security of sensitive genetic information and the potential misuse of disclosed genetic information to third parties (As per statistical results mentioned in the Table **3**).

5.3. Practices

In the present study, clinical trial participants n=50, blood samples were the most commonly used for genetic analysis in clinical trials. There is a lack of awareness and understanding regarding the re-use of genetic sample data and ethical issues surrounding the sharing and re-use of genetic data among the participants (As per statistical results mentioned in the Table **4**).

5.4. Ethical Challenges

The ethical challenges became apparent based on the feedback received from the participants in the present study.

- Confidentiality-28%.
- Separate consent for optional research-68%.
- Genetic Research data Missues-74%.

CONCLUSION

In conclusion, the findings from the study involving clinical trial participants revealed significant gaps in knowledge, attitudes, and practices related to the re-use of genetic data in clinical trials. In terms of knowledge, a substantial portion, 54%, were not aware of clinical trial genetics and data re-use. Concerns regarding future difficulties, particularly related to confidentiality, were prevalent among 70% of participants. Additionally, there was a lack of understanding about sample analysis applied to genetics and clinical trials, with 92% of participants being unaware. Regarding attitudes, the majority of clinical trial participants expressed the belief that separate consent is necessary for the re-use of genetic data in studies or research. The data also conveyed concerns about the safety and security of sensitive genetic information, emphasizing the need for separate consent for genetic data obtained during clinical trials. In terms of practices, the study revealed that blood samples were the most commonly used for genetic analysis in clinical trials. However, there was a notable lack of awareness and understanding among participants regarding the re-use of genetic sample data and ethical issues associated with sharing and re-using genetic information. Overall, these findings underscore the need for targeted educational interventions to improve the knowledge and awareness of clinical trial participants regarding genetic research and data re-use. Additionally, efforts should be directed towards addressing ethical concerns and ensuring proper consent procedures to enhance the responsible and transparent utilization of genetic data in clinical trials.

LIST OF ABBREVIATIONS

CT	=	Clinical Trial
EC	=	Ethics Committee
ELSI	=	Ethical, Legal, and Social Considerations
KAP	=	Knowledge Attitude Practices
GCP	=	Good Clinical Practice

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

IEC of KLE Academy of Higher Education and Research for Human Subjects for Research Project was held on June 7 and 8, 2021 and approved the study proposal with Ref: KAHER/EC/ 21-22-022 dated: 29-Jul-2021 as per national regulatory requirements.

HUMAN AND ANIMAL RIGHTS

All procedures performed in studies involving human participants were in accordance with the ethical standards of institutional and/or research committees and with the 1975 Declaration of Helsinki, as revised in 2013.

CONSENT FOR PUBLICATION

Informed consent form (KAP-Questionnaires) was obtained.

STANDARDS OF REPORTING

STROBE and Sager guidelines were followed.

AVAILABILITY OF DATA AND MATERIALS

The authors confirm that the data supporting the findings of this research are available within the article.

FUNDING

None.

CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

ACKNOWLEDGEMENTS

I would like to thank the clinical trial participants and Clinical Research Department staff from KLEs Dr. Prabhakar Kore Hospital and MRC, Belagavi-10.

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Original Article

Assessment of Knowledge, Attitude, and Practices on Genetic Research Data Reuse for Future Research: Clinical Trial Investigators Perspectives

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ABSTRACT

Introduction: According to the principle of good clinical practice, it is imperative that the personnel involved in the pharmaceutical or genetic research possess an educational background and comprehensive training. The clinical trial investigator must ensure the safeguard the privacy and confidentiality and prevent inadvertent reuse of research results of study participants. **Aim:** The objective of the current research is to assess the knowledge, attitude, and practices of clinical trial investigators concerning the reuse of genetic research data. **Settings and Design:** As a cross-sectional study, there was only one-time collection of knowledge, attitude, and practice on genetics and its data for future research from clinical trial investigators from the Tertiary Care Hospital and Clinical Research Centers in Belagavi Karnataka, India. **Subjects and Methods:** A study was conducted using validated knowledge, attitude, and practices questionnaire on the clinical trial investigators. **Statistical Analysis Used:** Data were analyzed using the SPSS software version 21one-way analysis of variance. **Results:** The present study was comprised n = 50 clinical trial investigators calculated by using the general formula for the calculation of sample size with a confidence of interval limit, of whom 64% exhibited awareness of genetic data reuse in clinical trials. Seventy-four percent of clinical trial investigators expressed concerns about confidentiality issues related to the reuse of genomic data. **Conclusions:** The lack of synchronized international conference on harmonization of technical requirements for pharmaceuticals for human use (ICH) guidelines directives concerning genomic sampling and data management in health-care research presents a formidable obstacle for pharmaceutical sponsors in achieving consistent and standardized genomic research samples and its data execution in pharmaceutical research on a global scale.

KEYWORDS: *Bioethics, biorepository, clinical trial investigators, genetic consent forms, genetic data coding, pharmaceutical and genetic research*

Received: 26-Oct-2023
Revised: 29-Jan-2024
Accepted: 31-Jan-2024
Published: 27-Mar-2024

INTRODUCTION

The field of human genetic research has been subject to a greater concern for ethical issues than any other area of biomedical and health research. This concern has increased in recent years due to the emergence of direct-to-consumer testing and the potential for embryo manipulations. While DNA technology has provided a powerful tool for uncovering the mysteries of the human genome and its manipulation, it has also raised concerns about scientists' ability to handle such information. In the current realm of clinical research, the majority of protocols and consent forms refer to

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Quick Response Code:

Website: www.ajprhc.com

DOI: 10.4103/ajprhc.ajprhc_138_23

How to cite this article: Devarinti R, Ganachari MS. Assessment of knowledge, attitude, and practices on genetic research data reuse for future research: Clinical trial investigators perspectives. Asian J Pharm Res Health Care 2024;16:58-66.

the inclusion of optional research or optional consent, as well as the potential reuse of genetic data. However, it is noteworthy that these elements are not explicitly articulated within the research objective or the research title. The preservation of an individual's privacy must be upheld in cases where their genomic data are utilized for research, clinical applications, or other purposes. Biospecimens obtained from medical settings, such as blood and tissue collected during biopsies, offer exceptional sources of samples and its data for genetic and genomic research. To illustrate, DNA extraction from residual deidentified blood spots obtained as part of the newborn screening public health program can facilitate a broad range of epidemiological, population based, or other studies on topics ranging from infectious disease to birth defects. As nonhuman subjects research, deidentified biospecimens are exempt from the informed consent requirements of the common rule. There is active participation from the principal investigator of clinical trials in the preservation of genetic material and its data during clinical trials. Furthermore, investigator perceive data sharing and reusing practices in genetic research in clinical trials with varying perspectives. The importance of data sharing is acknowledged, however, principal investigators express concerns regarding privacy and confidentiality. They seek clarity on the methods of sharing data, including the recipients of the data and their intended utilization. It is noteworthy that the individuals with whom data are shared, as well as the manner in which it is utilized influence attitudes toward donation.[1]

The clinical trial investigator is advised to elucidate the precise nature of the confidentiality of the data resulting from pharmaceutical or genetic research to the patient or participant. Divulgence of such information may result in psychosocial damage and therefore warrants meticulous handling. The objective of the current research is to juxtapose the knowledge, attitude, and practices of clinical trial investigators concerning the reutilization of genetic data. This analysis is significant in the sense that it can contribute to the creation of ethical protocols that will manage the return of research results to research participants, the process of obtaining consent, the encoding of genetic data, and the selection of voluntary research undertakings when utilizing the data for future research. Clinical trial investigators assume a vital function in the formulation of the protocol, implementation, screening, informed consent procedures, data collection, and the establishment of fundamental principles and values including trust, confidentiality, and privacy in nations that have instituted, or are on the verge of instituting, comprehensive nationwide genomic initiatives.

The global expansion of genetics in clinical research, along with the associated data repositories housed in biobanks, is underpinned by the aspiration that such research endeavors will ultimately yield improved approaches to disease prevention and treatment through innovative drug targeting, customized treatment protocols, and preemptive identification of disease risk factors.[2-4] However, it must also be acknowledged that the potential for improper use of archived genetic information, as well as its susceptibility to commercial exploitation, is a valid concern. Third-party entities play a vital role as stakeholders in the health-care industry. The prioritization of open permission standards for data access and usage is of utmost importance. It is imperative that patient benefits be given precedence over business interests.

The European populace has expressed their lack of confidence in the efficacy of data protection systems. Conversely, individuals' apprehensions regarding privacy concerns do not inevitably result in the repudiation of biobanks.[5-7] The lack of synchronized international conference on harmonization of technical requirements for pharmaceuticals for human use (ICH) guidelines directives about genomic sampling and data management in clinical investigations presents a formidable obstacle for sponsors and researchers in achieving consistent and standardized genomic sampling and research execution in clinical research on a global scale.

Subjects and Methods

Subjects

The present study has enrolled clinical trials investigators based on the inclusion and exclusion criteria of the study. The KAP questionnaires were validated by the Human Ethics Committee Members and Expertise from the Clinical Research has shared to more than 100 participants and received $n = 50$ responses through the Google Forms link. The $n = 50$ responses were included for the analysis through the research.

Methods

As a cross-sectional study, there was only one-time collection of knowledge, attitude, and practice on genetics and its data for future research from clinical trial investigators.

Step 1

A study using validated knowledge, attitude, and practices questionnaire and conducted the clinical trial investigators with 2 years of experience in a clinical trial setting from the Karnataka Lingayat Educational Society's Dr. Prabhakar Kore Hospital and Research Center Belgaum and Clinical Research Centers,

Karnataka, India. The study duration was 1 year from November, 2021 to November, 2022.

Step 2

The KLE Academy of Higher Education and Research Institutional Review Board on human subjects for PhD research project meeting held on June, 7–8, 2021. The ethics committee members were reviewed the submitted research proposals. IEC has approved the study and related documents letter dated: July 29, 2021.

Step 3

The later part was informed consent process and collection of data from the clinical trial investigators. Upon obtaining the ethical clearance from the ethics committee regarding human subjects, the research proposal was duly registered under the Clinical Trial Registry in India with CTRI/2021/11/038211 on November 23, 2021 [Figure 1].

Statistical analysis used

Employed one-way analysis of variance to investigate potential variations in age variables across distinct groups. In addition, utilized the Chi-square test to explore potential associations or differences between these categorical variables. Data are analyzed using SPSS software version 21 IBM, SPSS Version-26, USA and Excel.

Results

The present study was mainly focused on the clinical trial investigators (n = 50) knowledge, attitude, and practice on genetics and its data reuse for future research. The major concern of the genetic research is the storage and reuse of data but as per the present study.

Table 1 shows the characteristics of the clinical trial investigators. The mean age of the investigators in 44.90 years and the minimum age is 34 and the maximum is 67 years. In this case, there 40 male investigators and 10 females with a percentage are 80 and 20, respectively. The experience of principal investigators is 8.33 years. The most of clinical trial investigators are postgraduated, i.e., n = 40 (80%) [Figure 2]. Most of them are from the department of general medicine.

The present study comprised n = 50 clinical trial investigators, of whom 64% exhibited awareness of genetic data reuse in clinical trials. Of the same group, 74% expressed concerns about confidentiality issues related to the reuse of genomic data. In addition, 50% of participants saw advantages in sharing and reusing genetic information for a diverse range of research inquiries.

Table 1: Summary of Demographic data based on the clinical trial investigators department

Characteristics	Cardiology (n=3)	Community medicine (n=2)	Orthopedics (n=6)	ENT (n=2)	Pediatrics (n=2)	Endocrinology (n=2)	Plastic surgery (n=2)	General medicine (n=8)	Psychiatrics (n=2)	Nephrology (n=3)	Respiratory (n=2)	Neurology (n=1)	Neurosurgery (n=2)	Skin and dermatology (n=4)	OBG and gynecology (n=3)	Urology (n=2)	Oncology (n=3)	P
Age	45.33±1.15	41.50±2.12	47.33±11.91	40±2.83	47.50±0.71	39±1.41	47.50±10.61	44.50±7.07	42.50±9.19	46.33±5.86	38.50±2.12	-	38.50±6.36	41±1.41	52±12.17	53.50±12.02	41.33±3.21	0.685
Gender, n (%)																		
Male	3 (100)	2 (100)	5 (83.33)	0	2 (100)	2 (100)	2 (100)	6 (75)	2 (100)	3 (100)	1 (50)	1 (100)	2 (100)	3 (75)	1 (33.33)	2 (100)	3 (100)	0.232
Female	0	0	1 (16.67)	2 (100)	0	0	0	2 (25)	0	0	1 (50)	0	0	1 (25)	2 (66.67)	0	0	
Marital status, n (%)																		
Married	3 (100)	2 (100)	2 (100)	2 (100)	2 (100)	2 (100)	2 (100)	8 (100)	2 (100)	3 (100)	2 (100)	1 (100)	2 (100)	4 (100)	3 (100)	2 (100)	3 (100)	-
Unmarried	0	0	1 (100)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	

ENT: Ear nose tongue, OBG: Obstetrics and gynecology

Table 2: Knowledge-related questions

Knowledge	
Characteristics	**CT-investigators, *n* (%)**
1. Do you know about the clinical trials in genetics and their data reuse	
Yes	32 (64)
No	7 (14)
Don't know	11 (22)
2. Do you anticipate any difficulties with the reuse of genomic data in the future?	
Ethical and legal	11 (22)
Confidentiality	27 (24)
Don't know	12 (24)
3. What kind of sample analysis will be applied to genetic studies and trials?	
Nucleic acid extracts (blood cells, tissues, buccal swab, saliva, bone marrow aspirate, urine, and feces)	33 (66)
Novel sources of tissue-derived nucleic acids (Eg; cell-free DNA, circulating tumor cells)	1 (2)
Don't know	16 (32)
4. What does genetic research's secondary data entail?	
Personnel health information	24 (48)
Whole-exome/genome sequencing	6 (12)
Don't know	20 (40)
5. The following conditions apply to genetic consent forms	
Secondary use of identified data and coded data	9 (18)
Return of research results	11 (22)
Don't know	30 (60)
6. What might happen if genetic data is shared?	
Intentional disclosure	5 (10)
Misuses	37 (74)
Don't know	8 (16)
7. What are the advantages of sharing and reusing genetic information?	
To explore a wide range of research questions	24 (48)
To validate of research results	11 (22)
Don't know	15 (30)
8. What does optional consent mean in clinical trials and research?	
Informed consent for the collection of biomarker samples may be presented	22 (44)
Dummy consent	0
Don't know	28 (56)
9. Which of the following genetic data ICF material is being used for further research?	
Controlled access repositories	7 (14)
Data should be shared through unrestricted	1 (2)
Don't know	42 (84)
10. Which forms of consent are used for gathering genetic data for clinical trials or research?	
Blanket or broad consent	2 (4)
Tiered consent	11 (22)
Don't know	37 (74)

Analysis age: One-way ANOVA, Other variable's: Chi-square test. ICF: Informed consent form, CT: Clinical trial

What happen if the genetic data are shared

Eighteen individuals (36%) acknowledged intentional disclosure, 25 (50%) individuals reported instances of misuse, and 14% were uncertain of the outcome. These findings suggest that there are significant risks associated with the sharing of genetic data that must be taken into account [Table 2].

Any difficulties with the reuse of genomic data in the future

It has been identified that approximately 22% of individuals encountered ethical and legal issues. Meanwhile, the majority of respondents, consisting of 74%, did not report any difficulties. In addition, a smaller percentage, comprising 4%, indicated a lack of knowledge in relation to this matter.

Optional consent in clinical trials and research

In the realm of clinical trials, it has been observed that a considerable proportion of trial investigators, specifically 42%, has reported a lack of identification of informed consent in relation to the procurement of biomarker specimens. In addition, a noteworthy 58% of investigators have responded with an uncertainty regarding the matter [Table 2].

Table 3: Attitude-related questions

Characteristics	CT-investigators (n=50), n (%)
1) Do you support the repurposing of genetic information in clinical trials?	
Agree	26 (52)
Disagree	1 (2)
Strongly agree	23 (46)
Strongly disagree	0
2) Do you concur that a separate consent is required for the reuse of data in study or research?	
Agree	33 (66)
Disagree	1 (2)
Strongly agree	16 (32)
3) Do you believe that the genetic data gleaned during clinical trials or research should have a separate consent?	
Agree	28 (56)
Disagree	0
Strongly agree	22 (44)
4) Do you permit the return of findings from genomic research?	
Agree	35 (70)
Disagree	0
Strongly agree	15 (30)
Strongly disagree	0
5) Do you agree to the exchange or return of participant-specific genetic research data in encrypted form?	
Agree	35 (70)
Disagree	0
Strongly agree	15 (30)
Strongly disagree	0
6) Do you agree that sharing a single code will preserve patient privacy, especially when combined with other security measures?	
Agree	34 (68)
Disagree	2 (4)
Strongly agree	14 (28)
Strongly disagree	0
7) Do you believe that maintaining the safety and security of sensitive genetic information is a major challenge?	
Agree	24 (48)
Disagree	3 (6)
Strongly agree	23 (46)
Strongly disagree	0
8) Do you agree that disclosing genetic information to third parties could result in misuse?	
Agree	27 (54)
Disagree	0
Strongly agree	23 (46)
Strongly disagree	0
9) Do you agree that transferring samples to foreign countries requires correct knowledge?	
Agree	32 (64)
Disagree	0
Strongly agree	18 (36)
10) Do you think the biobanks are securely and safely storing participant data and sample data?	
Agree	31 (62)
Disagree	9 (18)
Strongly agree	9 (18)
Strongly disagree	1 (2)

All variable's: Mantel–Haenszel Chi-square test (we checking "Trend" rather than Association. Based on Trend we are comparing among group's. CT: Clinical trial

Table 4: Practices-related questions

Characteristics	CT-investigators (n=50), n (%)
1) What kinds of samples were used in clinical trials and research for genetic analysis?	
Blood samples	44 (88)
Tissues	1 (2)
Don't know	5 (10)
2) Have any clinical trial genetic data results been returned to you in recent years?	
Yes	2 (4)
No	48 (96)
3) Have you ever seen the genetic consent for the analysis of genomic data in any research protocols?	
Yes	8 (16)
No	42 (84)
4) Is there a clinical study protocol that addresses the reuse of genetic sample data and their return?	
Yes	2 (4)
No	48 (96)
5) Have you seen any instances of consent for the reuse of genetic data in clinical studies or trials?	
Yes	2 (4)
No	48 (96)
6) What types of issues might be encountered while requesting consent for genetic research?	
Mention of optional research on genomics in clinical trials	2 (4)
Return of results to study participants in clinical trials	20 (40)
Don't know	28 (56)
7) Who has the authority to request the sponsor's return of study results or data?	
Principal investigator/institute	27 (54)
Study participants	10 (20)
Don't know	13 (26)
8) What ethical issues surround the sharing and reuse of genetic data?	
Ownership of the biological samples and its data	30 (60)
Return of research results to individual/groups	10 (20)
Don't know	10 (20)
9) Have you heard of any of the repositories and biobanks mentioned?	
Any pharma industry biorepositories	1 (2)
Cancer trial registry	6 (12)
Don't know	43 (86)
10) Choose any one of the alternatives in a multi-layered consent process	
Allow sample/biospecimen to be stored for future use for any biomedical	4 (8)
The sample/biospecimen to be stored for future use for other prespecified health problems, such as diabetes, heart disease	3 (6)
Don't know	43 (86)

Analysis all variable's: Chi-square test. CT: Clinical trial

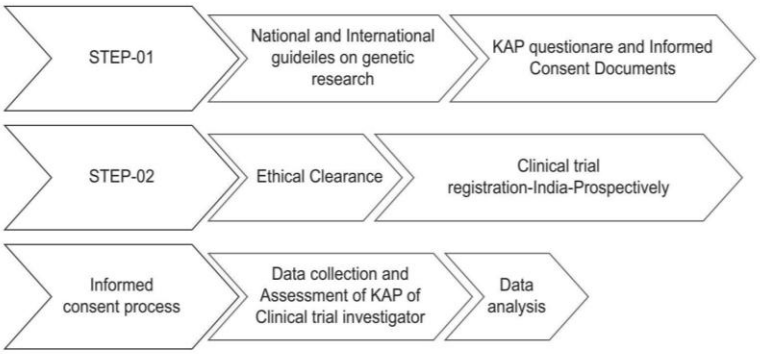


Figure 1: Study Procedure

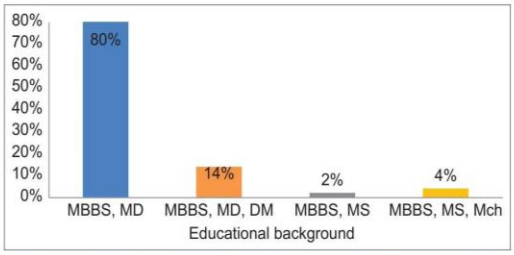


Figure 2: Distribution of subjects based on educational background

Types of consent used for gathering genetic data for clinical trials or research

A mere 4% of clinical trial investigators responded with a blanket or broad consent, whereas a significant 20% provided tired consent responses. Furthermore, it appears that the majority of clinical trial investigators are unaware of the type of consent utilized for the acquisition of genetic research and its subsequent data reuse [Table 3].

Support of reusing of genetic information in clinical trials

Specifically, 40% and 56% who strongly agree and agree, respectively, are in favor of this approach [Table 3].

A separate consent is required for the reuse of data in study or research

Thirty percent and 66% of clinical trial investigators expressed strong support for obtaining separate consent for the reuse of future research, according to the findings of the study [Table 3].

Permit the return of findings from genomic research

A consensus was reached by 84% of clinical trial investigators to authorize the transfer of research findings back to the research participants or subjects [Table 3].

Transferring of samples and its data to foreign countries requires correct knowledge

Thirty-six and 64% of the investigators in clinical trials strongly concurred that there is a pressing need for enhanced knowledge regarding the transfer of genetic data to foreign nations.

The biobanks are securely and safely storing participant genetic samples and its data

Eighteen percent hold the view that biobanks do not securely store genetic samples and their associated data, whereas 60% concur with this perspective.

Storage of genetic samples and its related data

Fifty-two percent of respondents concur that it is difficult to store genetic samples and their data in a secure manner. A paucity of information on sample use and export was observed by 62% [Table 4].

Ethical issues surround the sharing and reuse of genetic data

Forty percent of clinical trial investigators acknowledged the notion of possessing ownership over genetic samples or their corresponding data. In addition, a majority of clinical trial investigators, specifically 56%, affirmed the necessity of reconsent when utilizing secondary data [Table 4].

Heard of any biorepositories and biobanks

A staggering 84% of clinical trials lack knowledge regarding the biorepository or biobanking, whereas a mere 12% are aware of the cancer registry and a mere 4% of respondents possess knowledge regarding pharmaceutical biorepositories [Table 4].

Who has authority to request the sponsors' return of research results or its data

Forty-eight percent of the respondents indicated that the principal investigator or institute holds the responsibility of requesting the return of research results. On the other hand, 20% of the respondents identified the study participant as the authoritative data, moreover, it was identified that 32% of the respondents were unable to determine who has the rightful authority to request the return of the research results.

Discussion

The present study mainly focused to compare the clinical trial investigator's knowledge, practices, and attitudes on genetic data reuse for future research and includes types of optional research, use of genetic consent, and collected information or data coding. Most of the clinical trial protocols and consent forms mentioned about the collection of genetic samples and its data for future research but there is no mention of the type of research to be done on the genetic sample and their data for future purpose. In addition, optional research is not a part of their main research proposals. These are very common concerns in clinical research or biospecimen research in India. The sharing of data has been handled in the field of genetics in a special way. Only a small number of additional clinical study kinds are required to deposit data in open databases that may be accessed by anybody. Although this method may benefit the scientific community, several drawbacks for study participants need more consideration.[8]

As per ICMR policy[9]

The ownership of biological samples and data collected from the participants belongs to the participant themselves. As a result, participants have the option to withdraw both their biological material and related data, unless the latter is required for outcome measurement

and has been explicitly mentioned in the initial informed consent document. Complete anonymization of data would lead to the original donor losing their right of ownership. Biobanks and nonprofit organization act as custodians or trustees of the samples and data, with their ethics committees and clinical trial investigators responsible for overseeing their present and future use. Researchers have no claim for either ownership or custodianship.

The previous investigation of the global public perceptions of genomic data sharing topic has concluded that the optimization of societal benefits from genomic data necessitates the recognition and response to the factors that influence the decision to donate DNA in various social, cultural, and legal contexts. The provision of explicit, transparent, and genuine information is essential to ensure that the public can assess the importance of their participation in a collaborative effort with researchers, thereby enabling the delivery of public benefits and the protection of public interests. Nevertheless, there is a need to understand the perceptions of clinical trial investigators concerning of genetic research and its potential reuse for future research. The rate at which genomics data are accumulating in public repositories is steadily increasing. With both established and novel technologies, large consortia as well as individual laboratories is persistently exploring animal and plant tissue and cell cultures, resulting in immense amounts of data. It is worth noting that the era of systems biology was initiated by the human genome project.[10] The present statistics entailed that clinical trial investigators had significantly less knowledge practices on genetic data reuse for future purpose. Also were unaware of genetics and its data misuses and the coding used to identify the genetic samples for research data and return of study findings to whom, as well. There are no such uniform guidelines for the globe to conduct the genetic research and using of optional research in clinical trials to collect the samples or data for future research. There exists a necessity for education pertaining to genetics and its associated data for the reuse in clinical trials. This education is particularly crucial for clinical trial investigators, who are tasked with identifying, screening, and recruiting study subjects for research and genetic studies. Furthermore, these individuals hold the ethical responsibility of maintaining the confidentiality of study participant information.

The challenges facing these mechanisms could be technical, economic, legal, or political. Defining what data are and its type, therefore, is necessary to overcome these barriers because "the mechanisms to facilitate data sharing are often specific to data types." Unlike genomics data, which has established platforms, sharing clinical data "remains in a nascent phase." The article by Patrinos *et al.*[11]

The dissemination of information, encompassing genomic and health-related data, among the broader research community is fundamental to our comprehension of human health and well-being. Furthermore, this practice serves to promote scientific progress and its advantages, as evidenced by Knoppers *et al.*, and Evidently, data sharing is acknowledged as both an ethical and scientific necessity, as espoused by Bauchner.[12,13] However, it is frequently observed that minors are routinely omitted from data sharing initiatives, particularly when genomic data are concerned. The sensitive nature of genomic data, concerns related to obtaining consent, and the unpredictable likelihood of reidentification have all been cited as justifications for excluding minors from data sharing. Ethical guidelines for international research acknowledge the distinct vulnerability of minors as research subjects and the necessity for the implementation of specific safeguards for minors.[14,15] Most discussions about the samples have taken place in developed countries, where genetic manipulation techniques have greatly advanced in recent years. There is very little discussion in developing countries, although collaborative research with institutions from developed countries is on the increase.[16]

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Original Article

Pharmaceutical sponsors and contract research organization's perception toward genetic data reuse for future research

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Abstract

Background: Pharmaceutical sponsors and Contract research organization plays vital role in the preparation and implementation of clinical trials and give rise to ethical predicaments that pertain to various aspects such as general or genetic consent, optional research, storage and utilization of genetic data and specimens, as well as disclosure of research findings to study participants.

Objective: The current investigation is to assess the knowledge, attitudes, and practices of Clinical Research Organizations and Pharmaceutical Sponsors in relation to re-use of genetic research data for future research.

Study Participants and Methodology: A cross-sectional study conducted on pharmaceutical sponsor and their representatives from the metro cities, India.

Results: The present research encompassed $N=50$ of pharmaceutical sponsors and contract research organizations. Among these, 84% evinced cognizance regarding the re-use of genetic data in clinical trials. Furthermore, 62% of pharmaceutical sponsors and contract research organizations articulated apprehensions with respect to ethical and legal quandaries might arise due to the re-use of genomic data.

Discussion: A considerable proportion of participants are a willingness to share and reuse genetic data for future studies. However, it is observed that the perception towards practice is low, particularly in relation to the return of genetic results and ethical concerns while storing genetic samples.

Conclusion: There are presently no universally accepted international Conference on Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines in place for the management of genetic sampling and data at the global level. In India, however, ICMR regulations exist to provide direction for the use of biological materials and datasets in research.

Keywords: Clinical trial sponsor, Optional Research, Clinical Trials, Consent Forms, Data Re-use and Bioethics

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Received: 14-10-22, **Revised:** 06-02-23, **Accepted:** 11-03-23, **Published:** 15-11-23.

INTRODUCTION

Clinical research organizations and pharmaceutical sponsors play a significant part in the field of clinical trials. Starting with the planning and ending with their execution of clinical trials. The present study aims to evaluate pharmaceutical sponsor and their representative's knowledge, attitudes, and practices regarding the reuse

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Quick Response Code:	Website: www.picronline.org
	DOI: 10.4103/picr.picr_220_22

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How to cite this article: Devarinti R, Ganachari MS. Pharmaceutical sponsors and contract research organization's perception toward genetic data reuse for future research. Perspect Clin Res 0;0:0.

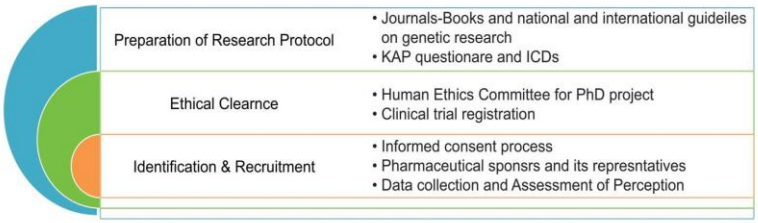


Figure 1: Methodology

of genetic data in future research. The clinical trials Give rise to ethical predicaments that pertain to various aspects such as general or genetic consent, optional research, storage and utilization of genetic data and specimens, as well as disclosure of research findings to study participants.

There are ICMR criteria for biology, materials, and datasets in India, but there are no comparable international recommendations to standardize or reduce concerns with ethics and consent on Genetic research.[1]

The people with whom data are shared and by whom they are most likely to be utilized have an impact on attitudes toward donation1. Studies indicate a preference for private healthcare in India over public healthcare, although in the USA, private healthcare is more commonly provided than public healthcare.[2]

Data sharing practices in genetic research and clinical trials seen differently by various clinical trial stakeholders. Given the significance of data sharing and their worries around privacy and confidentiality, they wanted to know how the data would be shared.[3]

The data re-use ought to investigate methods for the confidence of participants and the public with regard to potentially contentious matters, such as for-profit entities' access to data, the methods of Federal oversight and accountability, the dissemination of individual research findings to participants, and the circumstances in which researchers must request permission from participants for a new application of existing study data.[4]

To return or not to return the results of genomics research: that has been the question at the crux of an ongoing debate spawned by the increasingly rapid evolution of genomics. Many debates, one arises from conflicting perspectives on broader concerns: for example, the purported distinction between research and patient care, the relationship between health care institutions and the communities they serve, and the role of patient- and research-participant-engagement in such debates.[5] The population is rapidly growing; more

Table 1: Descriptive statistics for the demographic characteristics of respondents

Characteristics	Statistics
Age (years), mean (SD); minimum–maximum	29.94 (5.23); 23–49
Gender, *n* (%)	
Male	38 (76)
Female	12 (24)
Experience, mean (SD); minimum–maximum	4.70 (3.80); 1–20

SD=Standard deviation

Table 2: Distribution of responses to various knowledge-related questions

Questions	Response	*n* (%)
Do you know about the clinical trials in genetics and their data reuse?	Yes	42 (84)
	No	3 (6)
	Do not know	5 (10)
Do you foresee any challenges in the reuse of genomic data in the future?	Ethical and legal	31 (62)
	Confidentiality	17 (34)
	Do not know	2 (4)
What type of sample analysis is to be used for genetic research/trials?	Nucleic acid extracts	21 (42)
	Novel sources of tissue-derived nucleic acids	24 (48)
	Do not know	5 (10)
What is the secondary data in genetic research?	Whole exome/genome sequencing	28 (56)
	Personnel health information	1 (2)
	Whole genome sequencing	12 (24)
	Do not know	9 (18)
What are the following requirements for genetic consent forms?	Secondary use of identified data and coded data	39 (78)
	Return of research results	2 (4)
	Do not know	9 (18)
Sharing of genetic data may lead to?	Intentional disclosure	10 (20)
	Misuse	36 (72)
	Do not know	4 (8)
What are the benefits for sharing/reuse of genetic data?	To explore a wide range of research questions	33 (66)
	To validate of research results	6 (12)
	Do not know	4 (8)
What is optional consent in clinical research/trials?	Dummy consent	1 (2)
	Informed consent for the collection of biomarker samples may be presented	44 (88)
	Do not know	5 (10)
Which of the following ICF content for genomic data used for future research?	Data should be shared through unrestricted	3 (6)
	Controlled access repositories	39 (78)
	Do not know	8 (16)
What types of consent are used in the genomic data collection in clinical trials/research?	Blanket or broad consent	17 (34)
	Tiered consent	16 (32)
	Do not know	17 (34)
In which type of coding, traceability is possible?	Anonymized/anonymous	20 (40)
	Identified	19 (38)
	Do not know	11 (22)

ICF=Informed consent form

Table 3: Distribution of responses to various attitude-related questions

Questions	Response	*n* (%)
Do you agree to the reuse of genetic data in clinical trials?	Strongly disagree	2 (4)
	Disagree	4 (8)
	Agree	25 (50)
	Strongly agree	19 (38)
Do you agree the need of a separate consent for data reuse for future research?	Strongly disagree	0
	Disagree	1 (2)
	Agree	11 (22)
	Strongly agree	38 (76)
Do you agree the gaining a separate consent for the genetic data collected during clinical trials/research?	Strongly disagree	0
	Disagree	1 (2)
	Agree	19 (38)
	Strongly agree	30 (60)
Do you allow for the return of genomic research results?	Strongly disagree	0
	Disagree	6 (12)
	Agree	25 (50)
	Strongly agree	19 (38)
Do you agree with sharing/returning of genetic research-related data in coded to individual participant?	Strongly disagree	7 (14)
	Disagree	8 (16)
	Agree	21 (42)
	Strongly agree	14 (28)
Do you agree sharing of single code will provide protection for patient privacy, especially when combined with additional safeguards?	Strongly disagree	3 (6)
	Disagree	4 (8)
	Agree	19 (38)
	Strongly agree	24 (48)
Do you agree that storing sensitive genetic information safely and securely is a big challenge?	Strongly disagree	2 (4)
	Disagree	3 (6)
	Agree	26 (52)
	Strongly agree	19 (38)
Do you agree sharing genomic data with third parties may lead to misuse?	Strongly disagree	6 (12)
	Disagree	5 (10)
	Agree	15 (30)
	Strongly agree	24 (48)
Do you agree that adequate information is required regarding sample use and transferred to abroad?	Strongly disagree	0
	Disagree	5 (10)
	Agree	31 (62)
	Strongly agree	14 (28)
Do you agree participant information and samples stored in the biobanks are protected and securely?	Strongly disagree	0
	Disagree	3 (6)
	Agree	26 (52)
	Strongly agree	21 (42)
Do you think in some circumstances it may be acceptable to use archived samples in genomic research?	Strongly disagree	0
	Disagree	3 (6)
	Agree	32 (64)
	Strongly agree	15 (30)
Do you agree to share the data for future use?	Strongly disagree	5 (10)
	Disagree	5 (10)
	Agree	22 (44)
	Strongly agree	18 (36)

Table 4: Distribution of responses to various practice-related questions

Questions	Response	*n* (%)
What type of samples was collected for the genetic analysis in clinical trials/research?	Blood samples	30 (60)
	Tissue samples	20 (40)
In recent years have you seen any returned genetic data results from the clinical trials?	Yes	18 (36)
	No	26 (52)
	Do not know	6 (12)
In your experience have you observed the genetic consent for genomic data analysis in any trial protocols?	Yes	32 (64)
	No	13 (26)
	Do not know	5 (10)
Any clinical trial protocol mentioned on the return of genetic samples and its data reuse?	Yes	17 (34)
	No	16 (32)
	Do not know	17 (34)
Have you observed any genomic consent for data reuse in clinical research/trials?	Yes	23 (46)
	No	22 (44)
	Do not know	5 (10)
What type of issues may arise when seeking consent for genomic research?	Mention of optional research on genomics in clinical trials	27 (54)
	Return of results to study participants in clinical trials	13 (26)
	Do not know	10 (20)
Who has an authority to ask for the return of research results/ data from the sponsors?	Principal investigator/ institute	28 (56)
	Study participants	18 (36)
	Do not know	4 (8)
What are the ethical issues related to genomic data transfer/reuse?	Secondary or extended uses of stored samples/ re-consent	28 (56)
	Ownership of the biological samples and its data	16 (32)
	Return of research results to individual/groups	6 (12)
Have you heard any one of the mentioned repositories-Biobanks?	Cancer trial registry	18 (36)
	Any pharma industry biorepositories	16 (32)
	Do not know	16 (32)
Multiple options in a multilayered consent	Allow sample/biospecimen to be stored for future use for any biomedical	25 (50)
	Sample/biospecimen to be stored for future use for other prespecified health problems, such as diabetes and heart disease	18 (36)
	Do not know	1 (14)

thought should be given on how to involve this group in genomic research. If that were to be the case, it is imperative to understand the attitudes, preferences and concerns of this population group in relation to genomic data. Such an understanding is crucial for developing appropriate policies and practices in relation to recruitment, informed consent and privacy-setting options relevant to personal genomics.[6]

METHODS

The study was conducted in India's major megacities using a case series study and a self-administered, validated knowledge, attitude, and practices questionnaire. The research proposals were evaluated by the ethics committee (EC) members. Institutional EC has approved the study and study-related documents and later subsequently applied for the Clinical Trial Registry of India-CTRI/2021/11/038211. Figure 1 Methodology.

Study participants

Pharmaceutical sponsors and their representatives.

The survey was conducted during the period from July 29, 2021, to August 31, 2022. The present research has enrolled 50 pharmaceutical sponsors including CROs.

The questionnaire contains 5 parts

1. Demographics focused on the collection of age, sex, educational background, and years of experience
2. Pharmaceutical company – the profile the respondent about the company location and their position in the companies
3. Assessment of knowledge
4. Assessment of attitudes
5. Assessment of practices.

The study researcher maintained to kept confidentiality of the study participants' basic information. The responses were shared with more than 80 participants and received 50 responses through the Google Form link.

Statistical analysis

R-programming software was used to conduct the analysis for the present study.

RESULTS

The study's primary goal is to investigate how Pharmaceutical sponsor and Contract research organization's perceptions of the reuse of genetic data for subsequent research differ according to the subtypes of genetic consent, optional consent, and ethical concerns.

The demographics of pharmaceutical sponsors and contract research organizations are shown in Table 1.

The majority of respondents (72% and 20 % respectively) believed that exchanging genetic data could results in purposeful disclosure and misuse are shown in Table 2.

According to the findings of the present study, pharmaceutical sponsors and contract research organizations have a slight awareness of genetic research, sample types, and the advantages of sharing and reusing genetic data in clinical studies.

According to the Table 3 attitude statistics, the majority of participants were willing to share and re-use genetic data for future studies

Pharmaceutical sponsors' perception toward practice is very less as per Table 4, particularly in return for genetic results and ethical issues while storing genetic samples.

DISCUSSION

The present study mainly focused on the Pharmaceutical sponsor and Contract research organization's perception of genetic data reuse for future research. Most of the clinical trial protocol-related documents mentioned optional consent and genetic analysis for future, but there is no mention of the type of research to be done on genetic samples and their purpose. Furthermore, optional research is not a part of their main research proposals.

CONCLUSION

Most medical experts in the field of clinical trials are not very knowledgeable about the collecting of biological samples and the repurposing of their data for future studies.

In addition, there are no standardized International Conference on Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines for the handling of genetic sampling and data at the global level. There are the Indian Council of Medical Research rules in India to direct the use of biological, materials, and datasets in research, but there is little understanding of sample coding, ownership of research data, ethical considerations, and genetic data transfer.

Consent form

Yes.

Acknowledgments

The author would like to thank their supporting staff from the Department of Clinical Research and Pharmacy Practice, KLE College of Pharmacy, Belagavi.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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I. ONLINE TRAING & CERTICATION PROGRAMMES

Research Ethics Online Training by WHO on 16-Oct-2024



World Health Organization

Certificate of Achievement

This is to certify that

Revana Devarinti

successfully completed and received a passing grade in

Research Ethics Online Training

a course developed by the WHO ERC Secretariat, Global Health Ethics & Governance Unit offered on OpenWHO.org

Verified certificate issued on: October 16, 2024

Verify online: https://openwho.org/verify/xocez-difum-hamof-rilyl-lefuz

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Authoring Patient Narratives by ISCR on 23-Mar-2024



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SIDCER-FERCAP Research Ethics Training on 11-12-July -2022



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