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Fortis

Clinical Connect

Fostering a culture of innovation and excellence

Clinical Research Special

Synergizing Research with Clinical Excellence

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Leadership Message

Dr Ashutosh Raghuvanshi
MD & CEO - Fortis Healthcare

Clinical research is the foundation of medical progress. In a country as vast and diverse as India, it is not just an academic pursuit, it is a national responsibility. Research enables us to understand region-specific health challenges, tailor treatments, and contribute to global healthcare advancement. At Fortis Healthcare, we fully embrace this responsibility and are committed to fostering a research-driven culture that benefits patients, professionals, and society.

A key pillar of this culture is nurturing young professionals. The future of medicine lies with curious, committed, and ethically grounded individuals. Through structured research training, access to ethics committees, and mentorship, Fortis actively supports DNB scholars, residents, nurses, pharmacologists, and early-career clinicians. We are laying the foundation for the next generation of clinical leaders and innovators.

For research to drive meaningful change, it must be integrated into routine medical practice - not confined to academic institutions. Fortis encourages clinicians to initiate studies, participate in multi-centre trials, and contribute to real-world evidence. Our hospitals are equipped with established research departments and ethics boards to ensure scientific rigor and patient safety.

Sharing knowledge through scientific publications and conferences is vital. Fortis supports teams with training in data analysis, publication ethics, and manuscript preparation, ensuring every valuable clinical insight is shared with the wider medical community.

Modern research also focuses on patient-reported outcomes, how treatments impact patients' daily lives, functionality, and well-being. Through our clinical outcomes initiative, these insights are central to our research, ensuring our work reflects the real-world experiences of those we serve.

At every stage, from informed consent to follow-up, our research is guided by patient-centricity. We believe the most impactful research listens to the patient and responds to their lived reality.

As we look ahead, I envision Fortis Healthcare becoming a leading hub for clinical research in India. Our Fortis Medical Council (FMC) plays a vital role in setting research priorities, upholding ethical standards, and driving cross-disciplinary collaboration. Alongside this, the Fortis Research Advisory Committee continues to strengthen research across our network, aligned with national health priorities, and focused on generating high-quality, indigenous evidence for policymaking.

By investing in research infrastructure, academic and industry partnerships, and embedding innovation into clinical care, we are shaping a future where research and patient care go hand in hand. Together, let us nurture a culture of curiosity, collaboration, and integrity where every clinical question becomes an opportunity for discovery and better outcomes for our patients.

Dr Bishnu Panigrahi
Group Head - Medical Strategy & Operations
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As the Group Head of Medical Strategy and Operations (MSOG) and a Member of the Fortis Research Advisory Committee, I strongly believe that ethical integrity forms the cornerstone of all biomedical and health research involving human participants. While scientific innovation is essential for advancing healthcare, it must always be pursued with utmost respect for human dignity, protection of participant rights, and a commitment to building public trust. Our Institution is dedicated to fostering a research environment where ethical standards and scientific progress are seamlessly integrated.

Addressing general ethical concerns is the starting point for any research involving human subjects. Every study must be designed with a clear purpose and a balanced understanding of potential benefits and risks. Researchers must uphold principles such as respect for research participants, doing no harm, and fairness. These values guide every aspect of research, from participant selection to data handling and dissemination of results. Ethical awareness is not an additional task; it is central to responsible science.

A critical part of this commitment is ensuring the responsible conduct of research. Researchers are expected to maintain high standards of honesty, transparency, and accountability. This includes accurate data collection, objective analysis, and truthful reporting of results. Any form of scientific misconduct, including plagiarism or data manipulation, must be actively prevented through education, institutional oversight, and a culture of integrity. Research is not only about generating results but also about earning the trust of the scientific and public community.

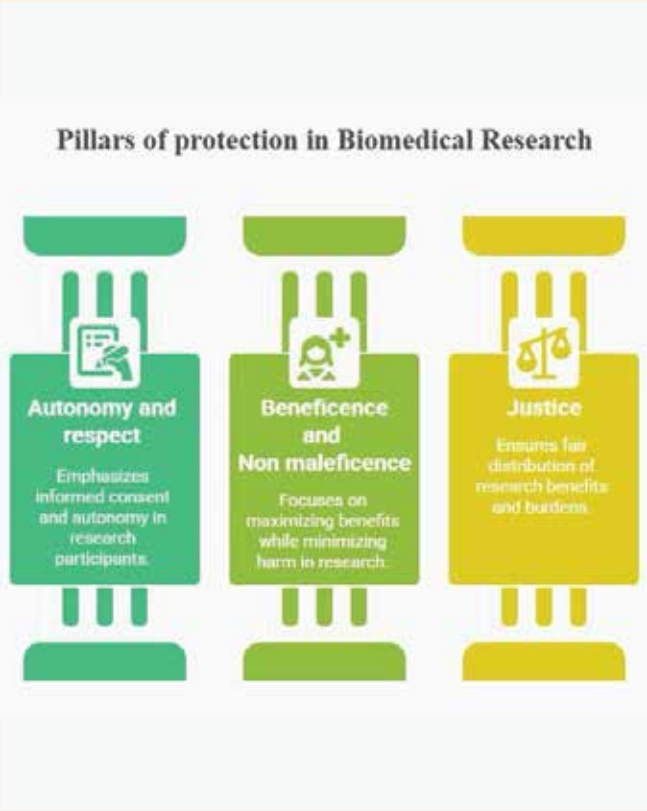
Equally important is the ethical review process. Before a study begins, it must be evaluated by a properly registered multidisciplinary and multisectoral institutional ethics committee. This review ensures that the research design is scientifically valid and that participants are adequately protected. Ethical review is not a one-time approval but a continuous process that involves monitoring for any deviations, adverse events, or ethical concerns during the course of the study.

The informed consent process is a key component of ethical research. Participants must be given clear, complete, and understandable information about the study. They should be fully aware of their rights, including the right to decline or withdraw at any time without consequence. Consent must be voluntary and free from any pressure. For those unable to give consent independently, such as minors or participants with cognitive challenges, appropriate legal and ethical procedures must be followed.

Research involving vulnerable populations requires additional safeguards. These groups may have limited capacity to protect their own interests and are at higher risk of exploitation. When including such participants, researchers must ensure that their inclusion is necessary, their participation is protected, and their welfare is prioritized at all times.

Finally, the importance of publishing research cannot be overstated. Ethical publication ensures that findings are shared with the scientific community and the public. Reports must be complete, accurate, and acknowledge all contributors. Publication plays a key role in validating research, guiding clinical practice, and informing policy decisions,

In conclusion, the pursuit of biomedical research must always be grounded in ethics. As an Institution, we remain committed to guiding our researchers toward excellence with a deep sense of responsibility to the people we serve and the knowledge we contribute to the world.



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Clinical research is a necessity and a service to the people and the country. Advances in health care and the prevention of diseases have contributed towards an increase in life expectancy at birth from 32 years at the time of independence to the present 71 years. Still, there are many clinical questions to which answers are not available.

Clinical research is necessary to find answers to these questions. But research requires time and money. Clinicains in India often express lack of time as well as funds for carrying out research. While this is largely true, it is also true that huge sums of money and lots of time is wasted on present-day research.

Waste of time and money in research is an area of major concern but remains poorly addressed. In 2014, Lancet published a series of five articles ("Increasing Value: Reducing Waste") running over 50 journal pages, with over 40 authors focused on the waste of time and money in the entire biomedical research spectrum (e.g. clinical health services, and basic science) It is estimated that nearly 85% of current research funding (approx. 170 billions) are wasted in biomedical research because of poor selection of research question, poor study design and execution, non-publication and poor reporting.

National Institute of Health Research (NIHR) in England established a working group to monitor and plan actions to ensure that NIHR funded research addresses questions relevant to clinicians, patients and the public; uses appropriate design and methods; is delivered efficiently, results in accessible full publication; and produces unbiased and usable reports.

Since 2013, NIHR has required that applicants, for support of new primary research, should reference an existing systematic review, or where no such systematic review exists, applicants should undertake to review relevant evidence to justify their clinical questions. For clinical trials, Medical Research Councils of UK and DF Germany also require that a systematic review of relevant evidence be presented in the proposal to justify conducting the trial.

However, the capacity to conduct a high-quality systematic review is limited among the clinical researchers. It is important to train clinical researchers in the methodology of conducting systematic reviews. This needs to be supported by the organisations in terms of free time and funding. This might well be the first step towards promoting clinical research while limiting the waste of time and money. This may help provide the best return on the time and money invested in clinical research.

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Medical research plays a critical role in advancing scientific understanding and enhancing the quality of healthcare. Clinical studies are essential for the development of new diagnostics, treatments, and preventive measures. However, the drive for innovation must be carefully balanced with an unwavering commitment to ethical principles. Upholding these standards is vital to protect the rights, dignity, and well-being of study participants who participate in research.

One of the most fundamental aspects of ethical research is informed consent. It is not merely a formal requirement but a manifestation of respect for individual autonomy. Every potential participant must be thoroughly informed about the nature and purpose of the research, the procedures involved, the potential risks and benefits, and their right to withdraw at any point without penalty. This process ensures that participation is both voluntary and based on a clear understanding, empowering individuals to make decisions that align with their personal values and circumstances.

Equally important are the ethical principles of

beneficence and non-maleficence, which require researchers to act in the best interest of participants by maximizing potential benefits while minimizing possible harm. Clinical studies must be designed with rigorous safety protocols and ethical oversight to protect participants from unnecessary risks. Researchers carry the moral responsibility to ensure that their work does not cause physical, psychological, or social harm to those involved.

The principle of justice also plays a crucial role in medical research ethics. It emphasizes fairness in the selection of research subjects and equitable distribution of the burdens and benefits of research. This principle protects vulnerable populations from exploitation and ensures that the outcomes of research contribute to the broader good rather than benefit only a privileged few.

Transparency and scientific integrity are additional pillars of ethical research conduct. Researchers must commit to full disclosure of their methodologies, results, funding sources, and any potential conflicts of interest. Honest reporting and open communication help build public trust and support reproducibility and validation within the scientific community.

As clinical research increasingly spans borders, ethical responsibilities must also extend to global equity and cultural sensitivity. Collaborating with local communities, respecting cultural norms, and addressing systemic health disparities are essential for conducting inclusive, respectful, and relevant research. Ethical global research fosters mutual respect and shared benefits, particularly for underserved populations.

Ultimately, ethical conduct in medical research is not only a legal or procedural requirement-it is a profound moral duty. By adhering to the core values of respect, beneficence, justice, and integrity, researchers contribute to meaningful scientific progress while safeguarding human dignity. This ethical foundation enhances the credibility of research, strengthens public trust, and leads to better health outcomes for all.

Ethical standards in clinical research are not merely regulatory checkpoints; they are the moral compass that guides responsible scientific inquiry. Upholding principles such as informed consent, beneficence, non-maleficence, justice, transparency, and integrity ensures that research is conducted with respect for human dignity and protection of participant rights. As research becomes increasingly global, it is also essential to consider cultural sensitivities and work collaboratively with local communities to ensure equitable inclusion and impact. Ethical lapses not only endanger participants but also compromise public trust and the credibility of the scientific community. Therefore, fostering an ethical research culture is critical, not just for compliance but for meaningful progress. By embedding ethics at every stage of research, from design to reporting, we promote trust, inclusivity, and real-world relevance. In doing so, we create a foundation for medical advancements that are not only innovative but also just, respectful, deeply rooted in human and values.

Dr Kuldeep Kumar
Associate General Manager - Clinical Research
Fortis Healthcare

Clinical research professionals are the unsung heroes of modern medicine, who are responsible for translating scientific innovation into real-world patient care. Their diligence ensures that investigational products (IPs), therapies, and medical devices are thoroughly evaluated for safety and efficacy before being made publicly available. Though their work happens largely behind the scenes, they play a critical role in driving healthcare forward. This piece offers an in-depth view into the daily life of these research professionals, highlighting their responsibilities, challenges, and the broader impact of their successful work.

Every successful clinical trial is rooted through careful and meticulous planning, much of which begins the day before the execution. For professionals juggling with multiple studies at various stages such as, recruitment, enrollment, dose administration, follow-up, or close-out—proactive preparation is the key. Tasks include verifying the availability of ethics committee approved informed consent forms in all vernacular languages, confirming stock of investigational products and laboratory kits, preparing source documents, and allocating resources based on the number and type of participant visits expected. This high-level detail helps to ensure seamless operation and protocol compliance.

On the day of conduct of clinical trials, research professionals start their day early. They review the visit schedules and reconfirm the communications from teams, participants, and sponsors. Morning coordination meetings with investigators, data

managers, research pharmacists, technicians, administrative support team and study coordinators are held which helps them to align the team for the day's tasks on priority. Before the first participant arrives, the eligibility criteria are reviewed, informed consent forms are rechecked, and all necessary calibrated equipment are functional, and the documents are made available. Attention to detail at this stage ensures that all interactions meet rigorous scientific and ethical standards.

By mid-morning, the focus shifts to participant visits. For new enrollers, professionals guide participants through the consent process, answer questions, and collect detailed medical histories. Baseline assessments and biological sample collections follow according to protocol. For ongoing participants, the day may involve administering investigational products, monitoring for adverse events, and documenting follow-up outcomes. As studies near closure, emphasis turns to resolving outstanding queries, finalizing data, and completing investigational products accountability logs. Throughout, meticulous documentation ensures data accuracy and supports regulatory compliance.

In the afternoon, the team transitions into data verification, internal quality checks, and administrative duties. Study binders are reviewed to confirm completeness and accuracy, and any discrepancies or deviations are promptly addressed. The team updates participant records, files signed Informed consent documents and ensures all study specific logs and laboratory reports are appropriately archived. Adverse events and protocol deviations are documented and reported to sponsors, regulatory authorities, and ethics committees as needed. These steps create a comprehensive audit trail that reflects the study's adherence to good clinical practice (GCP).

Evenings are often dedicated to continuous professional development. Clinical research professionals stay abreast of industry changes by attending webinars, completing training modules, and reading relevant literature. They reflect on challenges, share insights with peers, and explore new methodologies and research opportunities. This commitment to growth ensures they remain current and capable of delivering high-quality, ethical research.

Though the day-to-day work may seem routine, the cumulative impact of clinical research professionals is transformative. Their work facilitates the development of life-saving treatments, enhances patient safety, and strengthens public trust in the research process. They also serve as strong advocates for participant welfare, ensuring respect for patient rights and the integrity of each trial.

In essence, a day in the life of a clinical research professional is marked by thoughtful planning, detailed execution, and unwavering dedication. These individuals are the foundation upon which clinical innovation is built. Their commitment not only advances medical science but also ensures that every trial conducted is ethical, reliable, and meaningful. Through their behind-the-scenes efforts, they turn research into real-world progress, one patient and one protocol at a time.

THE EDITORIAL TEAM

Please send your comments, feedback and suggestions to clinical.connect@fortishealthcare.com

Robotic GI

A Retrospective Analysis of Short-Term Outcomes of Robotic and Laparoscopic Cholecystectomy: An Indian Tertiary Care Comparative Experience

Source: 10.7759/cureus.69295

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Background

There has been a gradual adoption of general surgery robotic programs in India. However, we still do not have a single comparative study reporting the initial experience of robotic cholecystectomy (RC) compared to laparoscopic cholecystectomy (LC). This retrospective study is aimed at addressing this clinical data gap.

Methods

This is a retrospective medical chart review where data related to patient demographics, and intraoperative and postoperative outcomes were collected. All patients underwent either RC or LC for gallstone disease, performed by a single surgeon from January 2020 to September 2023. The surgeon had passed the learning curve for RC and this data collection reflects his post-learning curve experience.

Results

A total of 100 cases (RC: 50; LC: 50) were collected. Baseline parameters such as age, sex, BMI, and comorbidities were comparable. There were no conversions from the planned procedure in either of the groups (0% vs 0%). There were no intraoperative complications such as bleeding or common bile duct injury (0% vs 0%). The rates of surgical site infections (SSIs) were numerically lower in the robotic group, 2% vs 6% ($p = 0.3099$). There were no postoperative complications in the robotic group, whereas one patient in the laparoscopic group experienced port side bleeding (0% vs 2%, $p = 0.3173$). The mean length of hospital stay was one day in both groups. The mean pain score 24- hours after the surgery was 1.78 ± 0.68 in the robotic group and 3.3 ± 1.2 in the laparoscopic group ($p = <0.001$). None of the patients required opioid analgesics in the robotic group, whereas 20% of patients in the laparoscopic group needed at least one dose of opioid analgesics ($p = 0.0009$). There were no reoperations reported in the robotic group, whereas the laparoscopic group reported 1 case. The 30-day mortality was nil in both groups.

Conclusion

RC is feasible in Indian settings. Compared to LC, it does not increase morbidity. The improvement in acute postoperative pain can potentially allow early ambulation and recovery. A larger multicentric study, comparing RC to LC in India will validate our initial experience.

Oncology and Haemato-Oncology

Effect of Patient and Diagnostic Intervals on The Risk of Advanced Stage in Indian Patients with Seven Types of Gastrointestinal Cancers: A Retrospective Cohort Study

Source: Jain S, Sharma SS, Gupta DK. Effect of patient and diagnostic intervals on the risk of advanced stage in Indian patients with seven types of gastrointestinal cancers: a retrospective cohort study. Cancer Epidemiology. 2024 Feb 1;88:102514.

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Objectives

Advanced stage is linked to prolonged patient and diagnostic interval for gastrointestinal (GI) cancers. However, objective evidence of this fact is not so forthcoming. Our aim was to study the effect of these intervals on the risk of advanced stage for GI cancers.

Methods

We performed this retrospective cohort study to analyse the effect of patient and diagnostic intervals on final stage in seven types of GI cancers, during 2013 and 2022. Two groups of stage: early (TNM- 0, I, II) and advanced (TNM- III, IV), were formed. Outcome studied was interdependence between patient and diagnostic intervals and incidence of advanced stage. Binary logistic regression was applied to calculate odds ratio of having an advanced versus early stage as a function of duration of these delays, in the whole cohort. We used restricted cubic splines with five knots to study flexible and non-monotonic pattern of association between these delays and stage.

Results

In whole cohort of 1859 patients, median patient and diagnostic intervals of early and advanced cancers were 21 and 26 days and 120 and 45 days, respectively. There was a positive association between patient interval and advanced stage (odds ratio [OR], 1.04, confidence interval [CI], 1.035 to 1.045; P < 0.001) and negative association between diagnostic interval and advanced stage (odds ratio, 0.98, CI, 0.976 to 0.998; P-0.017), among all gastrointestinal cancers combined. Increased risk of advanced stage started from day one of patient interval and for diagnostic interval there was an initial decrease followed by subsequent increase in the risk of advanced stage beyond 26 days of diagnostic interval.

Conclusions

Longer patient and diagnostic intervals increase the risk of advanced stage in gastrointestinal cancers.

Dynamic ctDNA Monitoring: A Primary Tool Predictive of Response in a Patient on CAR-T Cell Therapy

Source: https://doi.org/10.1111/ijlh.14503

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Introduction

Dynamic monitoring of circulating tumor DNA (ctDNA) offers a non-invasive method to track treatment response in malignancies. While well-established in solid tumors, its role in lymphomas, especially in predicting response to CAR-T cell therapy, remains underexplored—more so in the Indian context. This case highlights ctDNA as a potential predictive biomarker in relapsed/refractory DLBCL undergoing CAR-T therapy.

Case Report

A 48-year-old male with transformed follicular lymphoma to DLBCL, refractory to R-CHOP and BR, was treated with anti-CD19 CAR-T cell therapy. Baseline ctDNA profiling from plasma revealed a TP53 p.E286K mutation at 1.3% VAF. Serial monitoring showed a decline to 0.4% at four weeks and complete clearance at eight weeks post-infusion, correlating with metabolic complete response on PET-CT. No co-occurring mutations were observed.

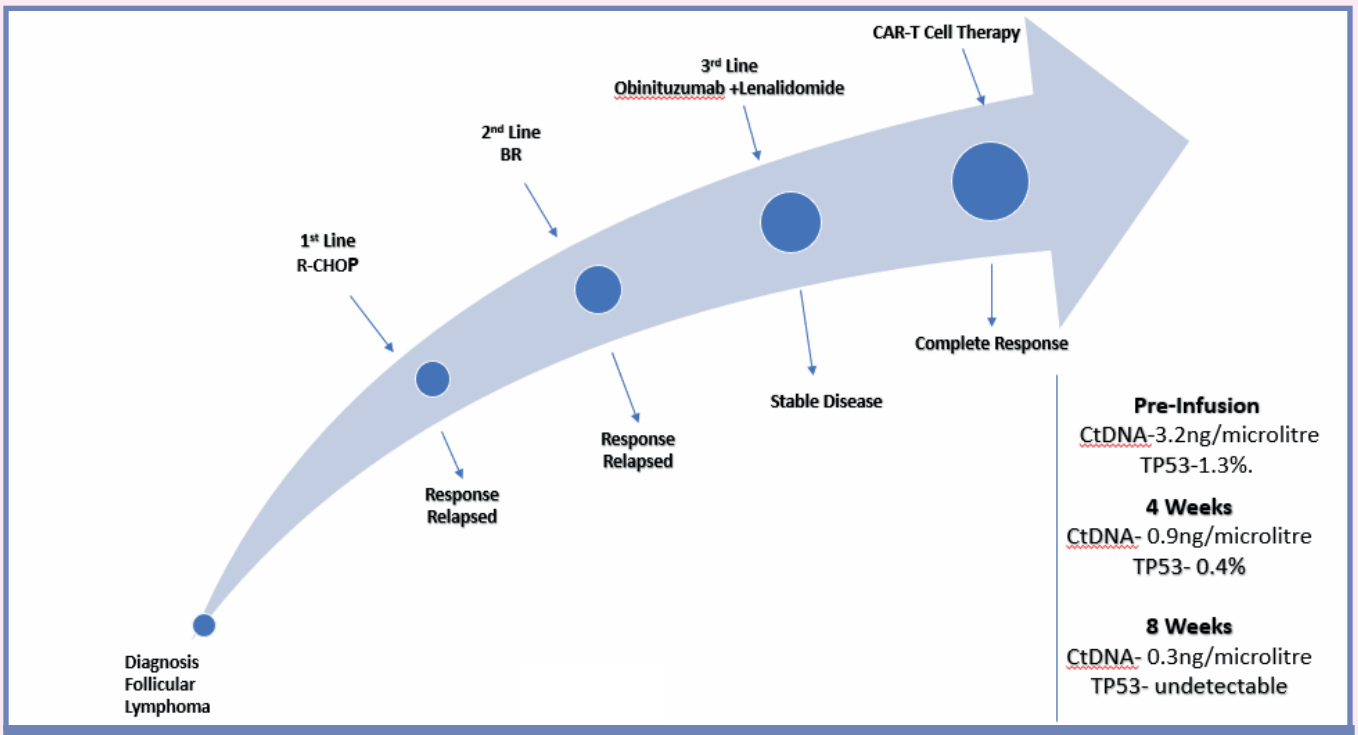

Figure 1: Disease Timeline of the Patient depicting different lines of therapy received and responses

Discussion

This case illustrates how dynamic ctDNA profiling can reflect early molecular response, preceding radiological confirmation. Existing literature suggests that early ctDNA negativity post-CAR-T correlates with improved outcomes. This is the first reported Indian case employing a validated, homebrew NGS-based ctDNA assay to longitudinally track CAR-T response. Incorporating ctDNA-guided surveillance may refine response assessment and reduce unnecessary imaging, optimizing outcomes in resource-constrained settings.

Figure 2 PET CT images from baseline, pre-CAR T infusion and post CART infusion.

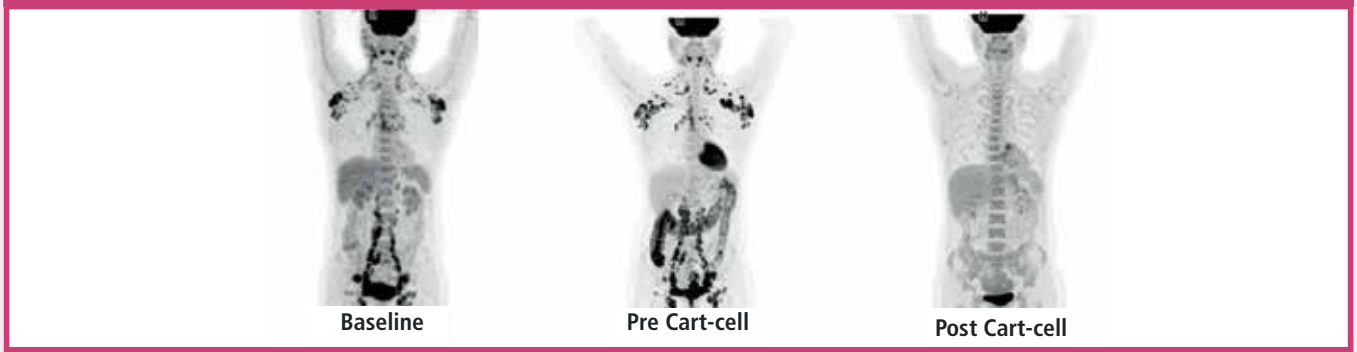

Figure 2(a): MIP (maximum intensity projection image) of baseline PET CT done in January 2023 shows hypermetabolic supra and infra diaphragmatic lymphadenopathy. There is no significant change seen post multiple lines of chemotherapy, however the MIP image of PET CT scan done post CAR T cell therapy demonstrates complete resolution (Deauville score 01).

Figure 2(b): Axial fused images of PET CT scan done at baseline and post multiple lines of chemotherapy show no significant change in size and metabolism of bilateral axillary lymph nodes, however complete metabolic and morphologic resolution of lymph nodes noted in PET CT scan done post CAR T cell therapy

Figure 2(c): Axial fused images of PET CT scan done at baseline and post multiple lines of chemotherapy show increase in size and metabolism of retroperitoneal lymphadenopathy, however complete metabolic and morphologic resolution of lymph nodes noted in PET CT scan done post CAR T cell therapy

Figure 2(d): Axial fused images of PET CT scan done at baseline and post multiple lines of chemotherapy show no significant change in size and metabolism of pelvic lymph nodes, the PET CT scan done post CAR T cell therapy demonstrates complete metabolic and morphologic resolution of lymphadenopathy

"HemeTEAM India: A Collaborative Leap Forward in Hematologic Care"

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HemeTEAM India: Together Everyone Achieves More

In a landmark publication titled "HemeTEAM India: Together Everyone Achieves More" (Int J Qual Health Care. 2025 Mar 10;37(1):mzaf016), a multidisciplinary team from Fortis Memorial Research Institute, Gurugram and affiliated centers presents a transformative approach to hematologic care in India. This initiative underscores the power of collaborative practice in enhancing patient outcomes, particularly in the complex field of haematology.

The HemeTEAM India project was conceived to address the multifaceted challenges inherent in hematologic malignancies, including diagnostic complexities, treatment nuances, and the need for coordinated care. By fostering a cohesive network of hematologists, oncologists, pathologists, and support staff, the initiative aimed to streamline patient management, reduce variability in care, and implement evidence-based protocols across participating centers.

Central to the success of HemeTEAM India was the establishment of standardized treatment pathways and the integration of multidisciplinary tumor boards. These boards facilitated real-time discussions on patient cases, allowing for collective decision-making that leveraged the diverse expertise within the team. Such an approach ensured that patients received personalized care plans tailored to their specific clinical scenarios.

The outcomes reported in the study are compelling. Patients managed under the HemeTEAM framework experienced improved diagnostic accuracy, timely initiation of therapy, and enhanced adherence to treatment protocols. Moreover, the collaborative model contributed to a notable increase in patient satisfaction, attributed to the comprehensive and coordinated care delivered by the team.

Beyond clinical metrics, HemeTEAM India also emphasized the importance of continuous education and capacity building. Regular workshops, training sessions, and knowledge-sharing platforms were instituted to keep the team abreast of the latest advancements in hematology. This commitment to professional development ensured that the care provided remained at the forefront of medical innovation.

The publication of this study serves as a testament to the efficacy of collaborative practice models in complex medical specialties. It highlights how structured teamwork, standardized protocols, and shared decision-making can collectively elevate the standard of care. As healthcare systems globally grapple with the challenges of delivering high-quality, patient-centered care, the HemeTEAM India initiative offers a replicable model that underscores the adage: Together Everyone Achieves More.

Dr Vikas Dua, Dr Sohini Chakraborty, Dr Neha Rastogi Panda, Dr Aastha Gupta, Dr Madhur Arora, Dr Nikhil M Kumar, Dr Anusha Swaminathan, Dr Akash Jaiswal, Dr Richa Soni, Dr Swati Bhayana, Dr Sunisha Arora, Dr Surbhi, Dr Prerna Mahajan, Dr Karthika Rudrakumar, Dr Paritosh Garg, Dr Aakriti Kothari, Dr Kanika Verma , Dr Manish Saini, Shikha Singh, Sukhdeep, Poonam, Veronica, Kiran

Neurology

Secondary Prevention with a Structured Semi-interactive Stroke Prevention Package in India (Sprint India): A Multicentre, Randomised Controlled Trial

Source: SPRINT INDIA trial collaborators. Secondary prevention with a structured semi-interactive stroke prevention package in INDIA (SPRINT INDIA): a multicentre, randomised controlled trial. Lancet Glob Health. 2023 Mar;11(3):e425-e435. doi: 10.1016/S2214-109X(22)00544-7. PMID: 36796986.

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Background

There is a high burden of stroke, including recurrent stroke, in India. We aimed to assess the effect of a structured semi-interactive stroke prevention package in patients with subacute stroke to reduce recurrent strokes, myocardial infarction, and death.

Methods

This was a multicenter, randomized, clinical trial conducted in 31 centers of the Indian Stroke Clinical Trial Network (INSTRuCT). Adult patients with first stroke and access to a mobile cellular device were randomly allocated (1:1) to intervention and control groups by the research coordinators at each centre using a central, in-house, web-based randomization system. The participants and research coordinators at each centre were not masked to group assignments. The intervention group received regular short SMS messages and videos that promoted risk factor control and medication adherence and an educational workbook, in one of 12 languages, and the control group received standard care. The primary outcome was a composite of recurrent stroke, high-risk transient ischemic attack, acute coronary syndrome, and death at 1 year. The outcome and safety analyses were done in the intention-to-treat population. The trial is registered with ClinicalTrials.gov, NCT03228979 and Clinical Trials Registry-India (CTRI/2017/09/009600) and was stopped for futility after interim analysis.

Findings

Between April 28, 2018, and Nov 30, 2021, 5640 patients were assessed for eligibility. 4298 patients were randomized to the intervention group (n=2148) or control group (n=2150). 620 patients were not followed up at 6 months and a further 595 patients were not followed up at 1 year because the trial was stopped for futility after interim analysis. 45 patients were lost to follow-up before 1 year. Acknowledgment of receipt of the SMS messages and videos by the intervention group patients was low (17%). The primary outcome occurred in 119 (5·5%) of 2148 patients in the intervention group and 106 (4·9%) of 2150 patients in the control group (adjusted odds ratio 1·12; 95% CI 0·85-1·47; p=0·370). Among the secondary outcome measures, alcohol cessation and smoking cessation were higher in the intervention group than in the control group (alcohol cessation 231 [85%] of 272 in the intervention group vs 255 [78%] of 326 in the control group; p=0·036; smoking cessation 202 [83%] vs 206 [75%]; p=0·035). Medication compliance was better in the intervention group than in the control group (1406 [93·6%] of 1502 vs 1379 [89·8%] of 1536; p<0·001). There was no significant difference between the two groups in other secondary outcome measures at 1 year: blood pressure, fasting blood sugar (mg/dL), low-density lipoprotein cholesterol (mg/dL), and triglycerides (mg/dL), BMI, modified Rankin Scale, and physical activity.

Interpretation

A structured semi-interactive stroke prevention package did not reduce vascular events when compared with

standard care. However, there was an improvement in some lifestyle behavioral factors, including adherence to medication, which might have long-term benefits. There was a possibility of type 2 errors owing to reduced power since there were fewer events, and a high number of patients could not be followed up.

Funding

Indian Council of Medical Research.

SPRINT INDIA: Regional Variations in Primary and Secondary Stroke Outcomes Based on Baseline Characteristics in North and South Indian Sites

Source: Kumaravelu S, Verma SJ, Arora R, Arora D, Devi KA, Dhasan A, Sylaja PN, Khurana D, Vijaya P, Ray B, Nambiar V. SPRINT INDIA: Regional Variations in Primary and Secondary Stroke Outcomes Based on Baseline Characteristics in North and South Indian Sites. Annals of Indian Academy of Neurology.:10-4103.

Dr Neetu Ramrakhiani

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Abstract

Background and Objectives

Regional differences in stroke prevalence and outcomes in India, driven by demographic and risk factors, are crucial for guiding effective prevention and management strategies. This sub analysis of Secondary prevention with a structured semi-interactive stroke prevention package in INDIA (SPRINT INDIA) randomized controlled trial compared the demographics, risk factors, and clinical outcomes of stroke patients from North and South India to identify regional differences and inform targeted interventions for stroke prevention.

Methods

The study analyzed data of 4298 participants from 31 stroke centers across India, focusing on demographics, stroke types, and risk factors. In this study, Mumbai, located at 19.07°N in western India, serves as the dividing line between North and South India. One year follow up data from 3038 patients were utilized to examine regional disparities between North and South India. Results: South Indian stroke patients were predominantly rural (60.1%) and less educated (58.2%), while North Indian patients were mostly urban (64.2%). South Indian patients had higher incidence of ischemic stroke (91.1% vs. 73.5%, P = 0.001) and higher rates of large artery atherosclerosis (33.6% vs. 19.7%, P = 0.001), hypertension, type 2 diabetes, smoking, and alcohol consumption, but better medication adherence. In contrast, North Indian patients had higher high-density lipoprotein, drug use, and tobacco use. At 1 year follow up, North Indian patients had more high risk transient ischemic attacks and poorer lifestyle related outcomes, despite South Indians having higher systolic blood pressure and fasting glucose levels.

Conclusion

Region specific strategies are crucial. Block randomization may help. South India needs better lifestyle modification programs, while North India requires improved health education and medication adherence strategies.

Trial registration: CTRI/2017/09/009600

Keywords

Stroke, regional variations, risk factors, prevention, cardiovascular events

Educational and Socioeconomic Correlates of Stroke Risk Behaviours: Findings from the SPRINT INDIA Trial

Verma SJ, Kaur G, Devi A, Arora D, Dhasan A, Sylaja PN, Khurana D, Pamidimukkala V, Ray BK, Nambiar V, Aaron S. Educational and Socioeconomic Correlates of Stroke Risk Behaviors: Findings from the SPRINT INDIA Trial. Annals of Indian Academy of Neurology.:10-4103.

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Abstract

Background and Objectives

Secondary Prevention by Structured Semi Interactive Stroke Prevention Package in India (SPRINT INDIA) trial was a randomized control trial that enrolled 4298 stroke patients and administered educational interventions at 31 centers across India, with the aim to reduce recurrent stroke through increased stroke knowledge. This SPRINT INDIA trial post hoc study aims to investigate the incidence of recurrent stroke, high-risk transient ischemic attack (TIA), acute coronary syndrome (ACS), death, and lifestyle behavioural factors at 1 year. In addition, it examines the relationship between patients' baseline characteristics and education levels, risk factors, and outcomes and performs subgroup analysis within the intervention and control groups.

Methods

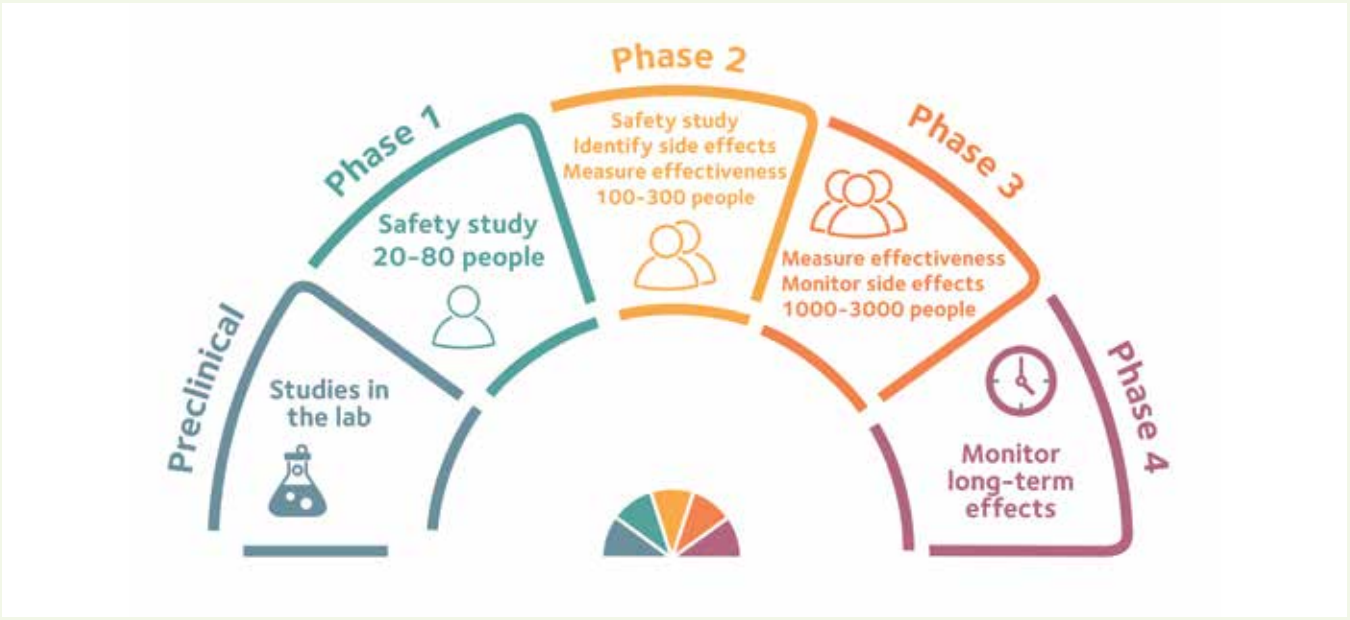
Participants were randomly assigned (1:1) to either intervention or control group through compute- based randomization on web. Intervention included stroke prevention Short Message Service messages, short duration videos, and printed workbooks. Baseline assessments captured demographic and educational data, classifying patients into three categories: no schooling, less than high school, and high school or above. Primary outcome was a composite of recurrent stroke, high risk TIA, ACS, and mortality at 1 year. Chi-square tests and analysis of variance were used to evaluate educational disparities across various variables .

Results

The intervention did not reduce primary outcomes at 1 year among patients with different educational levels. Higher educational group was associated with enhanced medication adherence (94.3% vs 85.4%; P < 0.001), increased physical activity (5497.91 ± 4117.7 vs 6169.91±4828.8; P < 0.001), lower triglyceride levels, and decreased engagement in behavioral risk factors like alcohol intake (5.1% vs 6.8%; P = 0.013) and tobacco use (smoked and chewed) (4% vs 7.9%; P < 0.001 and 5.8% vs 11.6%; P = 0.020).

Conclusions

Personalized secondary stroke prevention, tailored to educational levels, is crucial for effective stroke management.



Indian Trial of Tranexamic acid in Spontaneous Intracerebral Haemorrhage Study Protocol

Pandian JD, Phillips A, Verma SJ, Arora D, Dhasan A, Raju PS, Sylaja PN, Ray BK, Chakraborty U, Johnson J, Sharma PK. Indian Trial of Tranexamic acid in Spontaneous Intracerebral Hemorrhage study protocol. International Journal of Stroke. 2025:17474930241307933.

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Abstract

Rationale

Early mortality in intracerebral haemorrhage (ICH) is due to hematoma volume (HV) expansion, and there are no effective treatments available other than reduction in blood pressure. Tranexamic acid (TXA) a haemostatic drug that is widely available and safe can be a cost effective treatment for ICH, if proven efficacious

Hypothesis

Administration of TXA in ICH patients when given within 4.5 h of symptom onset will reduce early mortality at 30 days.

Design

Indian Trial of Tranexamic acid in Spontaneous Intracerebral Haemorrhage (INTRINSIC trial) is a multi-center, randomized, open-label, trial enrolling patients aged more than 18 years presenting with non-traumatic ICH within 4.5 h of symptom onset or when last seen well. Study participants received 2 g of TXA administered within 45 min while control group received standard of care. Intensive blood pressure reduction as per INTERACT 2 protocol is followed is done in both groups. Study plans to recruit 3400 patients. Primary outcome is mortality at day 30. Secondary outcomes are radiological reduction in HV at 24 h from baseline, neurological impairment at day 7 or earlier (if discharged), and assessments of dependency and quality of life at day 90.

Summary

If proven to be beneficial, TXA will have a major impact on medical management of ICH.

Keywords

Intracerebral haemorrhage, tranexamic acid, randomized clinical trial, hematoma, volume, management

Protocol and Statistical Analysis Plan for the Mega Randomised Registry Trial Comparing Conservative Vs. Liberal Oxygenation Targets in Adults with Nonhypoxic Ischaemic Acute Brain Injuries and Conditions in the Intensive Care Unit (Mega-ROX Brains)

Source: https://doi.org/10.1016/j.ccrj.2023.04.011

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Background

The effect of conservative vs. liberal oxygen therapy on 90-day in-hospital mortality in adults who have nonhypoxic ischaemic encephalopathy acute brain injuries and conditions and are receiving invasive mechanical ventilation in the intensive care unit (ICU) is uncertain.

Objective

The objective of this study was to summarise the protocol and statistical analysis plan for the Mega-ROX Brains trial.

Design, setting, and participants

Mega-ROX Brains is an international randomised clinical trial, which will be conducted within an overarching 40,000-participant, registry-embedded clinical trial comparing conservative and liberal ICU oxygen therapy regimens. We expect to enrol between 7500 and 9500 participants with nonhypoxic ischaemic encephalopathy acute brain injuries and conditions who are receiving unplanned invasive mechanical ventilation in the ICU.

Main outcome measures

The primary outcome is in-hospital all-cause mortality up to 90 d from the date of randomization. Secondary outcomes include duration of survival, duration of mechanical ventilation, ICU length of stay, hospital length of stay, and the proportion of participants discharged home.

Results and conclusions

Mega-ROX Brains will compare the effect of conservative vs. liberal oxygen therapy regimens on 90-day in-hospital mortality in adults in the ICU with acute brain injuries and conditions. The protocol and planned analyses are reported here to mitigate analysis bias.

Keywords

Oxygen Critical care Intensive care Oxygen therapy Hypoxemia, Hypoxemia Traumatic brain injury Subarachnoid hemorrhage.

Intervention Cardiology

Optical Coherence Tomography-Guided Percutaneous Intervention: A Comparative Study

Source: https://doi.org/10.22468/cvia.2023.00038

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Objective

Optical coherence tomography (OCT) is considered superior to coronary angiog- raphy (CA). However, OCT is not widely used, and data are limited in India. In the present study, the efficacy and safety of OCT for guiding percutaneous coronary intervention (PCI) in all-comer patients were evaluated and compared with those of CA.

Materials and Methods

In this retrospective study, the data associated with 434 patients who underwent PCI between December 2018 and June 2020 were analyzed. The primary endpoint was major adverse cardiac events (MACEs) at 6 months.

Results: The patients were divided into OCT-guided and angiography-guided PCI groups (217 in each group) after propensity matching. The OCT-guided PCI group had a significantly larger proportion of patients with unstable angina (55.7% vs. 43.3%, p=0.009) and non-ST-elevation myocardial infarction (NSTEMI; 17.5% vs. 10.0%, p=0.02) compared with the angiography-guided PCI group, and the proportion of patients with STEMI was significantly lower in the OCT-guided PCI group than in the angiography-guided PCI group (23.5% vs. 41.5%, p=0.00005). The OCT-guided PCI group had a lower incidence of MACEs at 6 months than the angiography-guided PCI group but without statistical significance (6.9% vs. 9.7%, p=0.296). Incidences of target lesion failure, target vessel myocardial infarction, in-stent restenosis, or stent thrombosis did not occur in either group. On post-PCI OCT, stent under-expansion, tis- sue prolapse, stent edge dissection, and stent malposition were observed in 28.5%, 10%, 4.1%, and 3.7% of the cases, respectively.

Conclusion

When comparing OCT-guided PCI with angiography-guided PCI, OCT-guided PCI showed slightly superior clinical outcomes at 6 months, although the differences were not statistically significant.

Keywords

Coronary angiography; Percutaneous coronary intervention; Optical coherence tomography; STEMI.

Drug-coated balloon in patients with in-stent restenosis: A prospective observational study

Source: Ray S, Bandyopadhyay S, Bhattacharjee P, Mukherjee P, Karmakar S, Bose P, Choudhury B, Paul D, Karak A. Drug-coated balloon in patients with in-stent restenosis: A prospective observational study. Indian Heart J. 2025 Mar-Apr;77(2):105-109. doi: 10.1016/j.ihj.2025.03.003. Epub 2025 Mar 3. PMID: 40043905; PMCID: PMC12138078.

Dr Shuvanan Ray

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Abstract

Aim

The aim of this study was to compare the safety and efficacy of paclitaxel-coated balloons (PCB) and sirolimus-coated balloons (SCB) in patients with in-stent restenosis (ISR).

Methods

This prospective, observational, single-centre pilot study enrolled 85 patients diagnosed with drug-eluting stent ISR. For all the eligible patients, various clinical baseline characteristics were collected, and angiography was performed to evaluate the lesion characteristics. After assessment, patients were treated with either PCB or SCB based on our center's time-based approach. Intravascular ultrasound (IVUS) imagining was used to assess the pre- and post-procedural minimal stent area (MSA). All the patients were followed up and major adverse cardiovascular events were documented for patients in both the groups.

Results

Of total 85 patients with ISR, 32 underwent treatment with PCB and 53 with SCB. A significant difference was noted in the post procedural MSA in both the groups (p = 0.005) and the values were 7.01 ± 1.11 mm2 and 8.01 ± 1.70 mm2 for PCB and SCB group, respectively. At median follow-up of 3.8 years, no cardiac death was noted in PCB group and one death was reported in SCB group (p = 0.459). In PCB group, target lesion revascularization (TLR) was noted in one (12.5 %) patient, while in SCB group TLR was noted in four (16.5 %) patients (p = 0.920).

Conclusion

Both PCB and SCB are found to be effective and safe in treating in patients with drug-eluting stents-ISR. Also, the use of DCB with imaging techniques like IVUS enhances treatment outcomes and optimizes patient care in ISR treatment.

Keywords

Coronary balloon angioplasty; Coronary restenosis; Death; Drug-eluting stents; Paclitaxel; Sirolimus.

Long-term Safety and Performance of The Biomime Morph Sirolimus-eluting Coronary Stent System for Very Long Coronary Lesions in Real-world Settings

Source: https://www.asiaintervention.org/doi/10.4244/AIJ-D-24-00008

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Background

Long stents reduce the risk for in-stent restenosis associated with percutaneous coronary interventions in long, tapered coronary lesions.

Aims: The Morph India study investigated the long-term safety and clinical performance of the BioMime Morph sirolimus-eluting stent (SES), a tapered stent used for treating long coronary lesions.

Methods

This is a prospective, multicentre, single-arm, real-world, post-marketing surveillance study conducted among patients with long coronary lesions (length >26 mm to ≤ 56 mm, reference vessel diameter 2.25-3.50 mm) implanted with the BioMime Morph SES. The primary endpoint was freedom from target lesion failure (TLF). The incidence of target vessel failure (TVF) – defined as a composite of cardiac death related to the target vessel, target vessel myocardial infarction (TVMI), and ischaemia-driven target vessel revascularisation (ID-TVR) – was the secondary endpoint. An angiographic follow-up was conducted at 9 months, and subjects were followed up for 3 years.

Results

Out of 448 enrolled patients, 420 patients completed the 3-year follow-up. The rate of freedom from TLF was 99.31% at 12 months and 98.80% at 3 years. In 3 years, there were 4 events each of TVMI, TVR (including ID-TVR) and ischaemia-driven target lesion revascularisation (all 0.95%). Quantitative coronary angiography analysis at a mean of 9.2 months revealed in-segment late lumen loss (LLL) of 0.29±0.23 mm and in-device LLL of 0.35±0.11 mm. The in-device minimal lumen diameter improved from 0.63±0.42 mm at preprocedure to 2.13±0.37 mm ($p<0.001$) at 9.2 months.

Conclusions

The 3-year safety and clinical outcomes of BioMime Morph SES for treating long coronary lesions were satisfactory. Further long-term comparative studies are necessary to validate these results.

Respiratory

Incidence and risk factors of weaning-induced Pulmonary Oedema: results from a multicenter, observational study

Source: Shi, R., Ayed, S., Beuzelin, M. et al. Incidence and risk factors of weaning-induced pulmonary oedema: results from a multicentre, observational study. Crit Care 29, 140 (2025). https://doi.org/10.1186/s13054-025-05350-6

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Abstract

Background

During the weaning process, the transition from positive to negative pressure ventilation may induce cardiac dysfunction, which may lead to pulmonary oedema. The incidence of weaning-induced pulmonary oedema (WIPO) is poorly documented and shows huge variations. Our study aims to investigate the incidence and risk factors for WIPO during weaning from mechanical ventilation in general critically ill patients.

Methods

This multicentre study was conducted in France, Italy, and India. Adult critically ill patients receiving invasive ventilation were included once a spontaneous breathing trial (SBT) was performed. The SBT technique could be either T-piece or pressure support mode with (PSV-PEEP) or without positive end expiratory pressure (PEEP) (PSV-ZEEP). A consensual diagnosis of WIPO was made a posteriori by five experts who analysed changes observed during the SBT that were retrospectively recorded.

Results

From July 2019 to February 2021, 634 SBTs were performed in 500 patients from 13 ICUs. Weaning success occurred in 417 patients (66%) and weaning failure in 217 (34%). Weaning was short in 414 (83%) of SBTs, difficult in 47 (9%) SBTs, and prolonged in 39 (8%) SBTs. WIPO was diagnosed in 79 (12%) cases, which accounted for 36% of the 217 weaning failures. WIPO occurred in 54/358 (15%) of T-piece SBT, in 7/84 (8%) of PSV-PEEP SBT (p = 0.072 vs. T-piece), and in 18/192 (9%) of PSV-ZEEP SBT (p = 0.002 vs. T-piece). In multilevel logistic regression analysis, 202 weaning failures from 149 different patients, COPD, and previous cardiomyopathy were identified as independent risk factors associated with WIPO.

Conclusion

In general ICU patients, WIPO accounts for 36% of weaning failure cases. Previous heart disease and COPD are two independent risk factors for developing WIPO during the weaning process.

ClinicalTrials.gov identifier (retrospectively registered on 2022-03-31): NCT05318261.

Achieving Clinical Remission in Asthma with Mepolizumab: A Sub-analysis on Vitamin D as a Predictor of Response

Dr Ravi Shekhar Jha
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Fortis Escorts, Faridabad

Abstract

Objective

Mepolizumab, an anti-IL-5 monoclonal antibody, has shown promise in reducing exacerbations and steroid dependency in severe eosinophilic asthma. This study aims to evaluate the effectiveness of mepolizumab in achieving clinical remission in asthma over 12 months and explore Vitamin D levels as a predictor of response.

Method

We assessed Asthma Control Questionnaire (ACQ) scores, spirometry, number of exacerbations, oral corticosteroid (OCS) use, and inhaled corticosteroid (ICS) use in 32 patients, observing significant clinical improvements. Data were collected 1 year prior to starting mepolizumab and one year after starting mepolizumab. Nasal polyps were not seen in all the patients, and computed tomography of para-nasal sinuses are not available for all the patients, so nasal polyps status are not evaluated to avoid any bias.

Result

Our results indicate that 12 patients achieved clinical remission after starting mepolizumab, with a strong correlation between higher Vitamin D levels and positive treatment outcomes. This suggests that optimizing Vitamin D levels could enhance the response to mepolizumab in asthma patients and help in achieving better asthma control.

Conclusion

Mepolizumab is an effective treatment for severe eosinophilic asthma, significantly improving clinical outcomes and reducing corticosteroid use. This study highlights the importance of Vitamin D as a predictor of response to mepolizumab, suggesting that higher Vitamin D levels may enhance treatment efficacy.

Risk Factors Associated with Mortality in Hypersensitivity Pneumonitis: Meta-analysis

Source: Risk factors associated with mortality in hypersensitivity pneumonitis: Meta-analysis

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Abstract

Background

Hypersensitivity pneumonitis (HP), an immune-mediated form of diffuse parenchymal lung disease (DPLD), is triggered by inhalation of a wide variety of allergens in susceptible individuals. Several studies suggest that the death rate associated with this disease has increased significantly in recent years. This meta-analysis investigates the significant clinico-radiological characteristics which may be appraised as potential risk factors associated with disease mortality.

Methods

Extensive literature search was conducted for original articles published between 1st January 2009 and 30th April 2021 through PubMed, Google Scholar, EMBASE, and Cochrane Library using the keywords: "hypersensitivity pneumonitis", "hazard ratio" and "mortality".

Results

A total of 21 independent studies related to mortality of HP subjects could be identified. The combined results of univariate and multivariate analysis suggest that older age [univariate odds ratio (OR): 1.038; multivariate OR: 1.036], male subjects [univariate OR: 1.508; multivariate OR: 1.396], honeycombing [univariate OR: 1.086; multivariate OR: 1.121] and traction bronchiectasis [univariate OR: 1.141; multivariate OR: 1.107] are significantly associated with mortality risk of HP subjects. Further, forced vital capacity, diffusing capacity for carbon monoxide, ground glass opacity and mosaic attenuation were associated with lower risk of all-cause mortality. Although smoking status correlated with mortality risk, the findings appeared to be insignificant.

Conclusion

Individual male subjects with older age and presence of extensive fibrosis, i.e., honeycombing and traction bronchiectasis experience an increased mortality risk. Additional observational and interventional studies are required to validate the findings and to identify extent of the risk factors and their association with disease mortality.

What's already known about this topic?

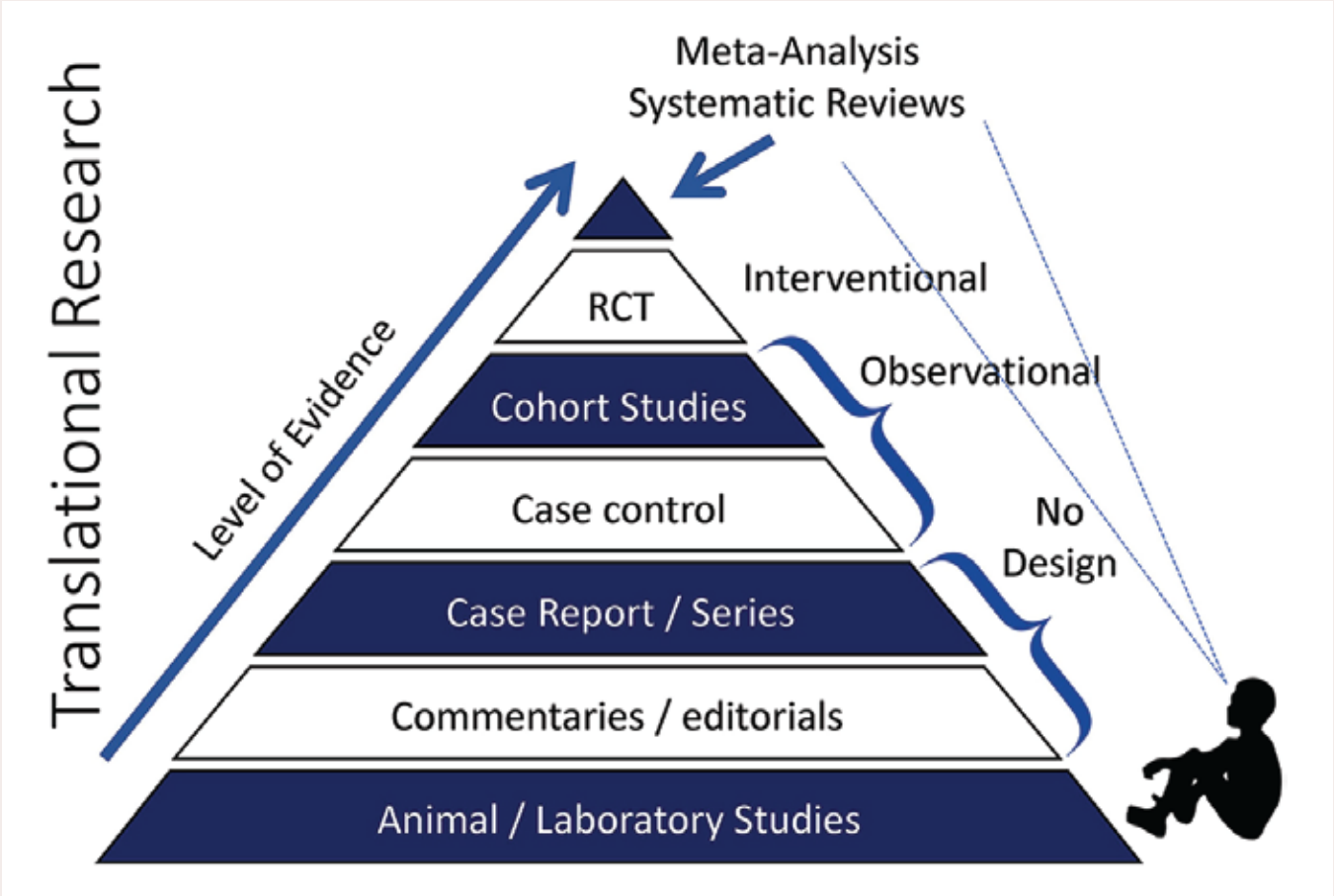
HP is triggered by inhalation of a wide variety of allergens in susceptible individuals and the death rate associated with this disease has increased significantly in recent years

Assessment of association between various risk factors and mortality of patients with HP has attracted considerable attention of clinicians from various countries

What does this article add?

This is the first attempt to investigate the significant clinico-radiological characteristics which may be appraised as potential risk factors associated with mortality of HP subjects by meta-analysis

Individual male subjects with older age and presence of extensive fibrosis, i.e., honeycombing and traction bronchiectasis experience an increased mortality risk.



Antimicrobial Stewardship

Effectiveness of Ceftazidime-Avibactam in Gram Negative Nosocomial Pneumonia: A Real-World Study in India

Source: Gupta N, Saseedharan S, Paliwal Y. Effectiveness of Ceftazidime-Avibactam in Gram-Negative Nosocomial Pneumonia: A Real-World Study in India. Cureus. 2024 Feb 19;16(2):e54443. doi: 10.7759/cureus.54443. PMID: 38510907; PMCID: PMC10951683.

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Director - Critical Care
SL Raheja Hospital - A Fortis Associate, Mumbai

Abstract

Background and Objective

The incidences of nosocomial pneumonia in intensive care units (ICUs) in India have been reported to range from 9% to 58% and are associated with a mortality rate of 30-70%. Ceftazidime-avibactam has activity against OXA-48-like carbapenem-resistant Enterobacterales (CRE) and has a safer adverse effect profile as compared to the nephrotoxic colistin. The current study aimed to assess the effectiveness and usage pattern of ceftazidime-avibactam in gram-negative hospital-acquired pneumonia (HAP) and ventilator-associated pneumonia (VAP) in real-world settings in India.

Methods

Electronic medical records of hospitalized patients in three prominent medical centers in India (Fortis Memorial Research Centre, Gurugram, S L Raheja Hospital, Mumbai, and Fortis Hospital, Anandapur, Kolkata) with nosocomial pneumonia and documented gram-negative Klebsiella pneumoniae (KP)-confirmed infection were collected. This study assessed the effectiveness, usage pattern of ceftazidime-avibactam, and clinical and microbiological cure rates.

Results

Among the 116 patients included, 78.45% (91/116) showed clinical cure. Microbiological cure was observed in nine out of 13 (69.23%) patients. In the subset analysis, a clinical cure rate of 84.85% (28/33) and microbiological recovery rate of 62.50% (5/8) were observed when ceftazidime-avibactam was initiated within 72 hours of diagnosis. Ceftazidime-avibactam was administered for a mean (±SD) duration of 7.79 ± 4.43 days, with improvement in signs and symptoms reported among 91.38% (106/116). Ceftazidime-avibactam showed a susceptibility of 56% (28/56) in the study.

Conclusion

The current study showed a better clinical and microbiological cure rate with a safer tolerability profile of ceftazidime-avibactam in carbapenem-resistant KP nosocomial pneumonia and VAP. This study has further demonstrated that ceftazidime-avibactam may be used as one of the viable treatment choices in carbapenem-resistant KP with favourable clinical outcomes.

Keywords

Ceftazidime-avibactam; clinical cure; hospital-acquired pneumonia; microbiological recovery; nosocomial pneumonia; ventilator-associated pneumonia.

A Prospective Study on Clinical Profile, Severity, Microbiology, and Outcome of Patients with Ventilator Associated Infective Complications Admitted in Intensive Care Unit of a Tertiary Care Hospital

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Background

Mechanical ventilation epitomizes intensive care medicine. Ventilator-associated complications are mainly Ventilator associated respiratory infections (VARI); These are a major cause of concern in the intensive care units (ICUs) worldwide, especially in developing countries. VARI includes patients with ventilator-associated tracheobronchitis (VAT) and ventilator-associated pneumonia (VAP). The clinical profile, severity, microbiology, and outcomes of such infections is not well described in Eastern India.

Objective: The primary objective of the study was to study the risk factors, severity scoring, microbiological profile and 28 days outcome of patients admitted in intensive care unit of our hospital. Secondary objective of our study was to find out any correlation between risk factors, severity scoring, microbiological profile, and outcome of patients with VAT and VAP admitted in intensive care unit of our hospital.

Materials and Methods

This was a prospective observational study done in the ICU of a tertiary care centre in eastern India. A total 50 patients of clinically, microbiologically and/or radiologically diagnosed case of VAP and VAT were included in the study. A structured data collection proforma was prepared and data collection was done. Raw data was tabulated and analysed.

Results

66% of our patients were male, Smoking was the commonest addiction (24%), VARI developed early with 17% on Day 3, 72% developed VARI within 5 days of ventilation. 16% had history of recent admission, Diabetes and hypertension were the commonest comorbidities. 58% of the patients developed VAP, the median SOFA score in VAP was 6 also similar in VAT. Patients with neurological diseases had the maximum number of VAT and VAP. Klebsiella pneumoniae was the commonest organism causing VAT (42%) while Acinetobacter Baumanii was commonest to cause VAP (44%). 51% of VAP patients were on volume control mode, while it was 52% of VAT patients. Most isolates are MDR pathogens with intermediate sensitivity to Polymyxin being most common (66%) 1 isolate was pan resistant. Mortality was 58% for VAP and 19% in VAT. Both Klebsiella and Acinetobacter accounts for 41% death in VAP group, in VAT group Klebsiella was commonest however no statistical significance with another organism.

Conclusion

Gram negative bacteria were the predominant cause of VAT and VAP, Acinetobacter and Klebsiella are the commonest organisms. Most Isolates are MDR with intermediate sensitivity to Polymyxins. Median SOFA scores were the same in both. Mortality was high in VAP group. Volume control mode was predominant mode of ventilation; Neurological causes was predominant cause that leads to ventilation and subsequent VARI

Nephrology

What is Wrong with the Blood Pressure Target Recommendation of Kdigo 2021 for Hypertension in Chronic Kidney Disease?

Source: https://doi.org/10.1159/000531029

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Context

Eighty-five percent of patients with chronic kidney disease (CKD) have hypertension, and blood pressure (BP) control is the cornerstone in the management of CKD. Although it is widely accepted that BP should be optimized, BP targets in CKD are not known.

Subject of Review

Kidney Disease Improving Global Outcomes (KDIGO) clinical practice guideline for the management of BP in CKD (Kidney Int. 2021 Mar 1;99(3S):S1–87) recommends targeting BP to less than 120 mm Hg systolic for patients with CKD.

Second Opinion

KDIGO BP target differs from all other hypertension guidelines. This is also a major change from the previous recommendation which was <140 systolic to all patients with CKD and <130 systolic for those with proteinuria. Targeting systolic BP to less than 120 mm Hg is hard to substantiate based on available data and is based primarily on subgroup analysis of a randomized control trial. Intensive BP lowering as suggested by the guidelines may lead to polypharmacy, added cost burden, and risk of serious harms.

Clinical Trials: From Investigational Science to Patient Outcomes

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Clinical trials are fundamental to medical advancement, driving innovations that enhance patient outcomes and quality of life. They serve as a critical connection between laboratory research and practical healthcare applications, relying on thorough testing, meticulous data analysis, and strict adherence to ethical guidelines. Clinical trials provide a systematic approach for assessing the safety and effectiveness of new therapies.

Those responsible for managing clinical trials, particularly principal investigators, bear substantial responsibility. From my perspective as an investigator, each clinical trial represents not merely a scientific endeavour but a commitment to advancing patient care through innovation, precision, and evidence-based practice. As an Interventional Cardiologist, my role in clinical trials is especially significant due to the complexity of procedures and device-related interventions involved. This role necessitates meticulous planning, comprehensive understanding of patient-specific hemodynamic parameters, and clearly defined clinical endpoints, thereby enabling precise and compassionate clinical decision-making.

Despite their importance, clinical trials encounter various challenges, including issues with patient recruitment, significant financial support, and regulatory complexities. Investigators must adeptly navigate ethical dilemmas, strive for diverse patient participation, and secure adequate funding. furthermore, patients do not understand the relevance and important implications of interventional trails for their benefits and think of trails as “experiments”, so enrollment becomes difficult. Moreover, retaining patients throughout the trial period poses additional challenges that can impact data integrity.

Clinical trials continue to evolve rapidly, driven by ongoing scientific discoveries, novel drug therapies, fascinating new technology all aimed at making treatment for diseases safer and more effective. These innovations continuously redefine benchmarks for successful clinical outcomes.

As an investigator, my responsibility is to ensure that research progresses in tandem with scientific breakthroughs, remains consistently focused on patient welfare, and effectively addresses real-world healthcare requirements. All newer advancement may not be effective or in the long term could be harmful. Hence pivotal large, powered, perspective, randomized trails are necessary, compering new therapies to the proven standard of care. As many trials exclude patients we commonly encounter in ‘real-life” practice, we must understand that the efficacy and safety of a drug or device can only be confidently attributed to the specific patient population enrolled in those trials. Extrapolation results to ‘all comers” or “real-world patients” has to be a combination of experience, large registry data and common sense, which is a major responsibility for the clinicians.

Looking ahead, I remain dedicated to advancing clinical research that integrates scientific rigor with practical applicability, while mentoring upcoming investigators committed to enhancing evidence-based patient care.

Concept to Compliance: The Value of Scientific Review Boards in Medical Research

Dr Vinod Raina

Chairman - Oncosciences
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A Scientific Review Committee (SRC), functioning as a subcommittee of the Institutional Ethics Committee (IEC), plays a critical role in academic and research institutions—particularly those engaged in intramural, investigator-initiated, or academic research. While the Ethics Committee is primarily responsible for ensuring ethical compliance in studies involving human participants, the SRC is tasked with evaluating the scientific validity and methodological soundness of research proposals. This article will help you understand the necessity, composition, and function of such a board, especially in ensuring that research is both ethically and scientifically robust.

The establishment of an SRC becomes especially important in academic and research settings where studies may not be sponsored by industry and thus lack the rigorous scientific review that commercial trials typically undergo. Ethical research cannot exist in isolation from scientific validity—a poorly designed study not only wastes resources but may also expose participants to unnecessary risks. The SRC ensures that proposals present clear objectives, robust methodology, sound statistical planning, and relevant scientific rationale—particularly in the local or national healthcare context.

SRCs are increasingly expected in institutions undertaking government-funded research or registered/planned for registration with regulatory bodies such as the Department of Scientific and Industrial Research (DSIR), as part of structured governance frameworks. The SRC typically comprises a Chairperson and domain experts—clinicians, researchers, statisticians, pharmacologists, and public health professionals. The Chairperson provides leadership and ensures impartial scientific evaluation, while committee members thoroughly review each proposal, focusing on hypothesis clarity, study design appropriateness, statistical validity, feasibility, and overall scientific merit.

This process not only supports the IEC in making informed ethical decisions but also elevates research quality, safeguards participant welfare, and strengthens institutional credibility. Structured scientific scrutiny is essential to prevent ethically approved yet scientifically flawed studies. Additionally, the SRC contributes to a research culture that fosters scientific inquiry, capacity building, and mentorship, particularly for emerging investigators and academic faculty.

In conclusion, the Scientific Review Board is a cornerstone of a responsible research ecosystem within academic institutions. Its role in upholding scientific integrity complements ethical oversight and enhances the quality, credibility, and impact of research outcomes. By following this structured approach, institutions can ensure compliance, gain public trust, and contribute significantly to evidence-based healthcare.

Fortis Healthcare has initiated and harmonized its academic and research activities through its dedicated not-for-profit research institute, Malar Stars, a registered Section 8 organization. Within this structured research framework, 14 registered Independent Ethics Committees (IECs) across various Fortis units in India have established dedicated subcommittees—Scientific Review Committees (SRCs) and Serious Adverse Event (SAE) Committees—to rigorously evaluate the scientific validity and safety of all proposed research activities.

With over three decades of experience as an investigator, and in my capacity as Chairperson of the Fortis Memorial Research Review Board and Member of the Fortis Research Advisory Committee, my unwavering priority is to promote and support scientifically sound, ethically governed research projects that address national healthcare priorities and contribute meaningfully to medical science.

Lean Diabetes in India: An Intriguing Entity

Dr Anoop Misra
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Type 2 diabetes (T2D) continues to be a major public health concern globally, with the International Diabetes Federation (2025) estimating that the number of people with diabetes will rise to 853 million by 2050. While the majority of research and prevention efforts have focused on obesity driven diabetes, a growing body of evidence points to an atypical form of a condition called lean diabetes that affects individuals with normal or even low body mass index (BMI). This phenomenon is particularly relevant to India and other low- and middle-income countries, where malnutrition and early life undernutrition intersect with increasing rates of metabolic disease.

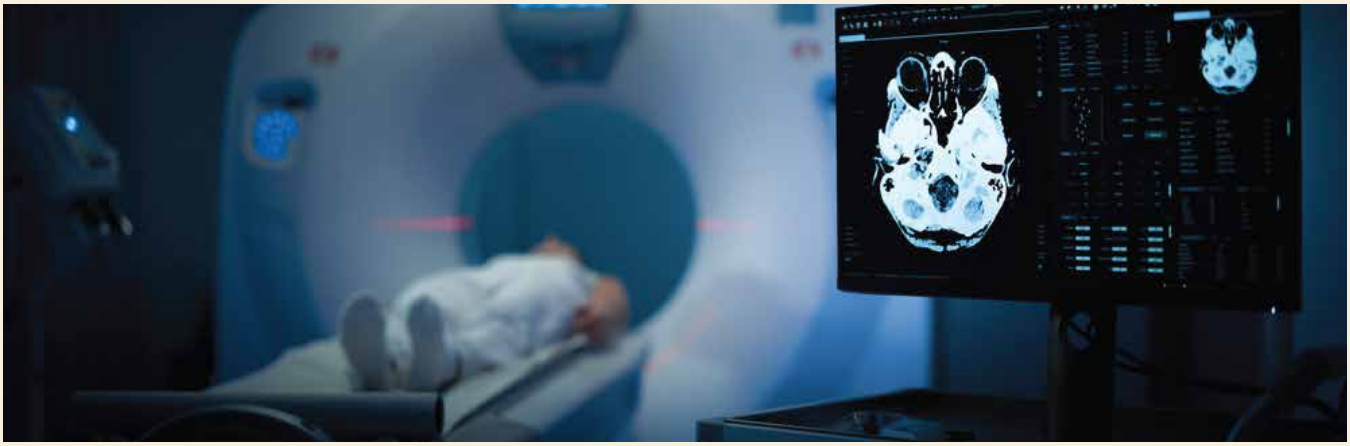
Lean diabetes challenges the conventional understanding of T2D, which is typically linked to obesity and insulin resistance. In contrast, lean individuals often exhibit severe insulin deficiency rather than insulin resistance. Emerging studies from India, including those conducted in the Northeast and among socially and economically marginalized populations, show that a substantial proportion of people with diabetes are underweight or stunted and often misclassified or mismanaged under standard treatment models. These individuals also face significantly higher risks of cardiovascular disease and all-cause mortality than their obese counterparts.

Furthermore, data from the Longitudinal Ageing Study in India (LASI) highlight the social inequities tied to lean diabetes, with higher prevalence seen in lower income groups. This suggests that lean diabetes is not just a biological anomaly but a manifestation of broader structural determinants, such as poverty, undernutrition, and limited access to early healthcare interventions.

Despite its growing significance, lean diabetes remains understudied and poorly understood. Most clinical guidelines and public health strategies are still modeled on western populations, where obesity predominates. This misalignment may result in delayed diagnosis, inappropriate treatment, and overlooked comorbidities in people with lean diabetes in India.

To bridge this critical gap, region specific research is urgently needed. A well designed, prospective, multicentric study focusing on lean adults with diabetes would offer invaluable insights into clinical presentation, risk factors, disease progression, and treatment responses. Such a study could also help differentiate lean diabetes from other forms such as latent autoimmune diabetes in adults (LADA), maturity-onset diabetes of the young (MODY), or malnutrition-related diabetes, allowing for more personalized and effective care.

In conclusion, lean diabetes represents a unique challenge in India. As a subject matter expert, I strongly advocate for dedicated research efforts to better characterize this population, inform national guidelines, and ultimately improve outcomes for the people who fall outside the conventional obesity diabetes paradigm.



Advocating FEES Based Swallowing Assessment in Post Extubated Cardiac Surgical Patients- A Call for Focused Indian Research

Dr Murali Chakravarthy

Director - Clinical Affairs,

Sr. Director - Anesthesia, Surgical ICU, and Pain Relief,

Chairman - Central Infection Prevention and Control Committee,

Fortis Healthcare

Post extubation dysphagia is a significant but underrecognized complication among critically ill patients, particularly those undergoing prolonged mechanical ventilation, as is common in cardiac surgical populations. While the international literature increasingly highlights the role of Fiberoptic Endoscopic Evaluation of Swallowing (FEES) in detecting aspiration risk post extubation, India lacks indigenous, procedure specific data in high risk groups such as post cardiac surgery patients. It is imperative that structured research in this area be initiated within Indian clinical settings.

Recent global studies underline a concerning prevalence of aspiration and penetration among post extubated ICU patients, ranging from 20% to over 40%, especially in those ventilated for more than 48 hours. These events are associated with serious outcomes, including aspiration pneumonia, malnutrition, prolonged ICU stay, and even mortality. Cardiac surgical patients are particularly vulnerable due to multiple factors such as sedation, disuse atrophy of swallowing muscles, suppressed cough reflex, and prolonged intubation durations.

FEES, a bedside, noninvasive, and cost effective tool, allows direct visualization of pharyngeal and laryngeal structures during swallowing. It has demonstrated high diagnostic accuracy in identifying silent aspiration, penetration, and residue all of which are frequently missed during clinical bedside swallow assessments. The technique is particularly valuable in settings with limited access to radiological swallowing assessments such as videofluoroscopic studies, making it ideal for Indian ICUs and cardiac care centers.

Given this background, a prospective observational study focused on cardiac surgical patients post extubation would be highly relevant. The study should aim to assess the incidence and severity of aspiration and penetration using the standardized 8 point Penetration Aspiration Scale (PAS) through FEES. Inclusion of patients extubated within 24 hours of cardiac surgery who were intubated for at least 12 hours will help identify early onset dysphagia patterns and guide timely interventions.

The findings from such a study can provide invaluable insights into the burden and nature of post extubation swallowing disorders in Indian cardiac ICUs. Moreover, it can inform clinical guidelines, leading to protocolized FEES screening in select high risk post surgical patients. This will not only enhance patient safety but also reduce risks of aspiration pneumonia, unplanned reintubation, and associated healthcare costs.

As an expert in critical care research, I strongly advocate for initiating this much needed research in Indian hospitals. It is essential that our clinical strategies for post extubation care evolve from reactive to proactive, rooted in robust evidence, tailored to our population, and enabled by simple, scalable tools like FEES.

Advancing Early Detection of Lung Cancer in India

Dr Niti Raizada

Principal Director – Medical Oncology & Hemato-Oncology & Member of Fortis Research Advisory Committee

Fortis Hospital, Bannerghatta Road, Bengaluru

Lung cancer remains a major global health challenge and is among the top five cancers in India. Alarmingly, it continues to be associated with one of the highest mortality rates, largely due to delayed diagnosis. In India, most lung cancer cases are detected at advanced stages when therapeutic interventions are less effective, contributing to poor survival outcomes with five-year survival rates rarely exceeding 15%. Despite its severity, India lacks a structured lung cancer screening framework, resulting in a missed opportunity for early detection and timely intervention.

Traditionally, smoking has been the most prominent risk factor for lung cancer. However, a growing number of non-smoking individuals, particularly women are being diagnosed with the disease. This shift in epidemiology underscores the need to broaden our understanding of risk beyond tobacco exposure. In India, other high-risk groups include individuals with chronic obstructive pulmonary disease (COPD), resistant tuberculosis, prolonged exposure to environmental and occupational carcinogens (e.g., radon, asbestos, mining), and those residing in polluted urban environments. Unfortunately, these individuals often remain undiagnosed or misdiagnosed due to non-specific symptoms and limited access to advanced imaging.

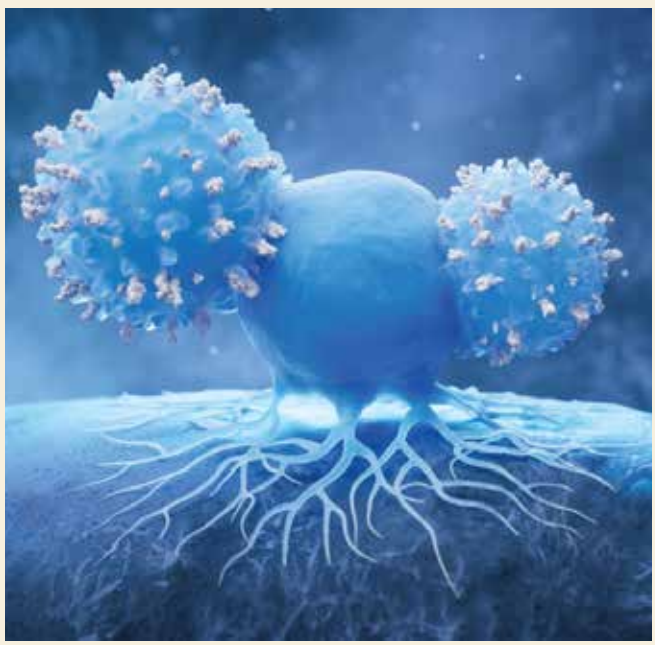
Recognizing this urgent need, a multicentric, prospective, hospital-based pilot study has been designed to evaluate the feasibility and impact of lung cancer screening in high-risk populations across India. The study will be conducted across eight Fortis oncology centers and will enroll individuals aged 50–80 years with well-defined risk factors, including chronic smoking, COPD, resistant TB, and occupational or environmental exposure.

Participants will undergo a structured risk assessment followed by low-dose computed tomography (LDCT), a globally accepted, non-invasive method for early lung cancer detection. This study will utilize paper-based case report forms (CRFs) for data collection, with follow-up of positive findings including diagnostic confirmation and referral for treatment.

The primary objective is to estimate the detection rate of early stage lung cancer in these populations while also evaluating the operational feasibility of implementing such screening in diverse healthcare settings. Insights gained from this study will be pivotal in shaping national policy for lung cancer screening in India, particularly in resource-constrained environments.

By addressing critical gaps in awareness, access, and diagnosis, this initiative represents a meaningful step toward reducing lung cancer-related mortality. Establishing cost-effective and scalable screening protocols tailored to Indian demographics could ultimately pave the way for a nationwide program that saves lives through early intervention.

As a subject matter expert, I strongly advocate for the implementation of such pilot studies in India, not just as academic exercises, but as transformative tools for public health advancement.



Early-Phase Clinical Research: Facility, Workforce, and Compliance Imperatives

Dr K P Singh
Director - Endocrinology
Fortis Hospital, Mohali

The conduct of early-phase clinical trials, particularly Phase I studies, represents a critical juncture in the drug development process, where investigational products are administered to human subjects—often for the first time. These trials primarily aim to evaluate the safety, tolerability, pharmacokinetic (PK), and pharmacodynamic (PD) profiles of new therapeutic agents. Given the inherent risk involved, early-phase studies must be conducted under strictly controlled and regulated conditions to ensure both the safety of participants and the integrity of the clinical data generated.

One of the fundamental requirements before initiating any clinical study in India is prospective registration with a recognized clinical trial registry such as the Clinical Trials Registry of India (CTRI). This process enhances transparency, aligns with ethical standards, and ensures regulatory compliance in accordance with ICMR and CDSCO guidelines. Beyond regulatory approval, the facility infrastructure where early-phase trials are conducted must meet rigorous standards. Essential areas include a dedicated informed consent room equipped with audio-visual recording capabilities to document the consent process as per regulatory mandates, a pharmacy room for investigational product storage and handling, a sample processing and bio-storage facility, a duty doctor's room for 24/7 medical supervision, and a secure archival room for managing and storing trial-related documents (both physical and electronic) in accordance with SOPs.

Participant safety is paramount. Therefore, alarm systems must be installed in all subject-occupied areas such as showers, toilets, wards, and recreational zones, with routine testing to ensure functionality. The clinical unit must have an up-to-date floor plan indicating the locations of all emergency exits, alarm points, subject areas, and emergency equipment. Emergency trolleys stocked with resuscitation equipment and emergency medications (for both adult and pediatric populations) should be readily accessible in each major zone and mobile for quick deployment. Continuous monitoring equipment such as ECG machines, pulse oximeters, and multiparameter monitors must be available to track vital signs including heart rate, blood pressure, temperature, and respiratory rate. Additionally, facilities for nebulization should be provided, including functional nebulizers with appropriately sized masks.

Maintaining calibration of all critical equipment is non-negotiable, with documented evidence of annual calibration to ensure precision in assessments and interventions. Equally important is the availability of a well-trained and adequately staffed clinical research team. At a minimum, this team should include a project lead, physician, clinical pharmacologist, research nurse, clinical research monitor, pharmacist, quality assurance officer, and archivist. Each team member must have clearly documented roles and responsibilities, supported by ongoing training and competency-based assessments. Special emphasis should be placed on emergency resuscitation training and documented staffing levels to guarantee full coverage during dosing, observation, and overnight stays.

In conclusion, the successful execution of early-phase clinical trials necessitates a confluence of robust infrastructure, stringent operational standards, and a highly skilled multidisciplinary team. Adherence to regulatory requirements, coupled with a commitment to participant safety and scientific rigor, ensures that these trials are ethically sound and scientifically valuable, setting a strong foundation for later-phase clinical development.

Landscape of Clinical Trials in India

Prabhat Kumar
Group General Counsel
Fortis Corporate office

India's engagement with clinical trial stretches back t the COVID-19 pandemic thrust the sector into the spotlight, accelerating vaccine and drug development like never before. Clinical trials—meticulously designed studies that test the safety and effectiveness of new treatments—are the lifeblood of medical progress. They help us understand how new drugs behave in the human body, their benefits, side effects, and, ultimately, whether they are safe and effective for widespread use.

Evolution of Legal Framework for Clinical Trials in India

The legal framework for clinical trials in India has undergone a remarkable transformation over the years. In the early days, the Drugs and Cosmetics Act of 1940 and its accompanying Rules of 1945 provided only a skeletal structure for clinical research. It wasn't until 1988, with the introduction of Schedule Y in the said Rules, that clinical trials received formal regulatory attention—though the provisions remained quite basic. Recognizing the need for stronger ethical standards, the Indian Council of Medical Research (ICMR) introduced its Good Clinical Practice (GCP) Guidelines in 2001, along with a series of ethical guidelines in 2000 and 2006. In 2017, ICMR expanded its oversight with the National Ethical Guidelines for Biomedical and Health Research, broadening the ethical net to cover public health and behavioral studies. Yet, participant safety and fair compensation continued to be areas of concern. This led to the introduction of the New Drugs and Clinical Trials Rules, 2019—a comprehensive overhaul that addressed these gaps and ushered in a new era of protection for trial participants.

Key Players in India's Clinical Trial Ecosystem

Central Drugs Standard Control Organization (CDSCO):

As India's national regulatory authority, CDSCO is the gatekeeper for drug approvals, clinical trial oversight, and quality control. Working alongside state regulators, it ensures that safety and ethical standards are upheld nationwide.

Drugs Controller General of India (DCGI)

The DCGI, a senior official within CDSCO, is the ultimate authority for clinical trial approvals. From granting trial permissions to inspecting sites and overseeing drug manufacturing, the DCGI's role is pivotal in maintaining the integrity of India's research environment.Indian Council of Medical Research (ICMR): As one of the world's oldest and most respected medical research organizations, ICMR shapes the direction of biomedical research in India. Guided by a governing body led by the Union Health Minister and supported by expert advisory groups, ICMR ensures that research priorities align with national health needs.

Rules and Guidelines that Shape Clinical Trials

The New Drugs and Clinical Trials Rules, 2019

These rules form the cornerstone of India's clinical trial regulations. They cast a wide net, defining "new drugs" to include everything from innovative molecules and vaccines to gene therapies and advanced drug delivery systems. The rules also clarify what constitutes an "adverse event"—any negative reaction during a trial—which triggers mandatory compensation protocols.A standout feature is the requirement for Ethics Committees. These diverse panels—comprising medical experts, legal professionals, laypersons, and independent voices—must review and approve every trial protocol, ensuring balanced and ethical oversight. The rules also introduce a four-phase trial system (Phases I-IV), mirroring global best practices.Applications for trial approval must follow a set format and include prescribed fees. Notably, if regulators do not respond within a stipulated period, the application receives "deemed approval" preventing bureaucratic delays. Compensation for trial-related injuries or deaths is calculated transparently, considering factors such as age, risk, and severity. The rules also set strict standards for the manufacture, labeling, and storage of trial drugs, safeguarding quality at every step.

Ethical Guidelines and Best Practices

ICMR's National Ethical Guidelines for Biomedical and Health Research (2017) provide a moral compass for all research involving human participants. They champion principles such as respect for individuals, informed consent, confidentiality, and fairness. Complementing these, the Good Clinical Practice (GCP) Guidelines set rigorous standards for trial design, monitoring, and documentation, ensuring both participant safety and data reliability. The Good Clinical Laboratory Practices, also from ICMR, guarantee that biological samples are handled with utmost precision, underpinning trustworthy results.

Mandatory Registration of Clinical Trials

All trials must be registered with the Clinical Trials Registry – India (CTRI), a publicly accessible database managed by ICMR. This allows anyone—from regulators to the general public—to track trial protocols, approvals, and outcomes, fostering trust and accountability.

Challenges and the Road Ahead

Despite this robust framework, challenges remain. Regulatory approvals can sometimes be sluggish, and consent processes may be cumbersome. Post-trial care for participants often remains inconsistent. To overcome these hurdles, India must continue to innovate: digitizing approval processes, refining consent procedures, standardizing Ethics Committee training, ensuring data privacy and guaranteeing post-trial support.

As the world's clinical trial industry expands at breakneck speed, India stands poised to become a global research powerhouse. However, this promise can only be realized through diligent enforcement of regulations, unwavering ethical standards, and a culture that places participant welfare above all. By weaving together strong laws, vigilant oversight, and a commitment to transparency, India can ensure its clinical trials not only meet but exceed global benchmarks—advancing healthcare innovation for the benefit of all.

Financial Aspects in Clinical Research: Ensuring Accountability and Sustainability

Mr Ravi Bhatia

National Finance Controller
Fortis Corporate office

Clinical research, while being the cornerstone of medical advancement, also demands meticulous financial planning and transparent management. A well-structured financial framework is critical to ensure that research activities are conducted efficiently, ethically, and in compliance with regulatory and institutional standards. Below are the key financial aspects that guide the successful execution of clinical trials and academic research projects.

1. Study and Evaluation of Budget Grid

The financial journey of any clinical research project begins with a comprehensive study of budget grid. This grid outlines the financial responsibilities of the sponsor and serves as the foundation for negotiations between the research institution and the study sponsor or funding body. It includes detailed cost elements such as investigator fees, patient reimbursement, laboratory tests, radiology, ethics committee submissions, administrative overheads, pharmacy charges, archiving, and documentation.

During the review phase, the clinical research team, in collaboration with finance personnel and investigators, must scrutinize the proposed budget grid to ensure that all required resources and activities are accurately captured. This step is crucial to avoid underfunding or unaccounted costs that can impact the project's feasibility and sustainability.

2. Budget Preparation and Negotiation

Once the budget grid is finalized, the next step is budget preparation. This involves translating the budget grid into a working financial proposal, tailored to the institution's policies, infrastructure, and resource utilization. Budget preparation must factor in both direct and indirect costs:

Direct costs: Study-related expenses such as tests,

procedures, staff time, participant recruitment, and monitoring.
Indirect costs (overheads): Institutional infrastructure, administrative support, electricity, IT, and facilities maintenance.
Institutions must negotiate effectively with sponsors to secure fair compensation for both components. Strong negotiation is especially important for investigator initiated studies or government-funded projects where funding may be limited. Transparency, justification of costs, and benchmarking with standard rates play a pivotal role in this phase.

3. Statement of Expenditure (SoE)

After the study begins, institutions are required to submit a Statement of Expenditure (SoE) at regular intervals to sponsors, funders, or regulatory bodies. The SoE details how funds are being utilized and reflects actual vs. planned expenditure. It provides accountability for each budget line item and helps track whether the research is progressing within its financial plan.
Accurate SoE reporting requires coordination between the clinical research coordinator, finance department, and principal investigator. It is often accompanied by supporting documents such as invoices, timesheets, patient visit logs, and trial master file documentation. Regular submission of SoEs also facilitates smoother fund disbursement from sponsors and funding agencies.

4. Utilization of Funds

Efficient fund utilization is key to maintaining financial integrity in research. Funds must be used strictly for approved project-related activities and in accordance with institutional and sponsor guidelines. Institutions should establish robust internal mechanisms for monitoring fund utilization, preventing misappropriation, and ensuring timely procurement of required services and materials.
Periodic internal audits are encouraged to ensure compliance and improve transparency. Funds should also be earmarked for key research quality drivers, including training, quality control, and publication support.

5. Budget Reconciliation

As the study progresses or nears completion, it is essential to undertake budget reconciliation. This process involves matching the expected budget with actual expenditure, resolving any discrepancies, and ensuring that all study-related financial obligations are met. It also includes the settlement of any pending investigator payments, sponsor reimbursements, and unused fund refunds if applicable.
Effective reconciliation helps build trust with stakeholders and paves the way for continued collaboration. It also provides insights for better planning of future studies, identifying areas where cost-saving or resource optimization is possible.

Conclusion

Sound financial planning and management in clinical research are vital to ensuring ethical, compliant, and sustainable study execution. From budget review and preparation to utilization and reconciliation, each step must be handled with diligence and accountability. As research institutions like Fortis expand their academic and clinical trial activities, adopting standardized financial protocols and fostering cross-functional collaboration between research and finance teams will be instrumental in supporting high-quality, impactful research.

Review on Clinical Research from Investigator's Perspective in the Field of Gastroenterology (GI) at Fortis Hospital, Anandapur, Kolkata

Dr Udipta Ray

Director - GI, Minimal Access & Bariatric Surgery
Fortis Hospital, Anandapur

Clinical Research is always an essential activity of any clinician to gather evidence on any procedure or medicine which can have far reaching consequences in patient care and outcome.

At Fortis Hospital Anandapur, Kolkata, my team and myself have recently been part of a nation-wide study which involves 11 Superspeciality hospitals on the topic of 'Robot Assisted Repair of Ventral Hernia'. In this multicentric study named "ASPIRE", data collection has been completed and submitted for statistical analysis.

Simultaneously there is another ongoing prospective study from my hospital on the topic of 'Robotic Surgery for Gall Bladder Disease'.

As the principal investigator my experience has been diverse and rich. The first abstract comes from the patient's consent where there is almost a universal skepticism regarding "study". The outlook of the patient towards research work comes with a mindset that it is a modified laboratory experiment of guinea pig. Myths needs to be busted. Communication is also a challenge, especially with questionnaire on pain and quality of life. Individual perceptions vary and so will the response. The data keeping and telephonic interactions require no less efforts and patience.

At Fortis Hospital Anandapur, Kolkata, I feel quite privileged of having an well-organized and progressive Clinical Research Team and Academics Department to support all these activities with at most sincerity. I would like to thank them all from the bottom of my heart to take part in these activities which will surely make a mark in surgical outcome and help people to go back with a smile.

Investigator's Perspective in Clinical Trials

Dr Ravi Shekhar Jha

Director and Head - Pulmonology
Fortis Hospital, Faridabad

As a Principal Investigator, clinical trials represent more than a research activity—they are a responsibility toward science and, more importantly, toward our patients. Every trial I undertake involves careful balancing of scientific protocol with real-world clinical realities.

The biggest challenge often lies in patient recruitment and retention, especially in specialized fields like pulmonology. It demands not just clinical eligibility, but time, trust, and clear communication. Educating patients about the trial, addressing their concerns, and ensuring ethical informed consent are central to my role.

Another key aspect is coordination—between site staff, sponsors, CROs, and ethics committees. As an Investigator, I serve as the anchor—ensuring compliance, safeguarding patient safety, and maintaining data quality, all while continuing routine care.

Today, with increasing digitization and complex protocols, the Investigator's role is evolving. But what remains constant is our commitment—to scientific rigor, ethical standards, and patient-centric care.

Clinical trials, when done right, are a powerful way to advance treatment and make a difference. And as an Investigator, that's both a privilege and a responsibility I carry with pride.

Thank you for the opportunity to share my perspective.

EMR and Clinical Research

Dr Narayan Pendse

Director - Electronic Medical Records
Senior Vice President - MSOG
Fortis Healthcare

Clinical research has always been at the core of modern medicine. From early documentation by Hippocrates to randomized controlled trials that define today's gold standards, it has underpinned how we move from observation to evidence to practice. This is the foundation of evidence-based medicine (EBM), our collective commitment to offer care that is not just experienced but proven.The journey of clinical research has not been without challenges. For decades, it was hindered by fragmented data, incomplete paper-based documentation, and inconsistencies in data capture across sites. Valuable insights were lost in illegible notes, misfiled and misplaced records, or inaccessible archives. Data—arguably the most vital ingredient of medical research—was too often unreliable, unstandardized, and difficult to recover.The past two decades have changed everything. With introduction of improved Electronic Medical Records (EMR) applications and adoption of digital health tools, healthcare began to digitize not only documentation but also decision-making. While EMRs were initially introduced to improve clinical workflows, they are now seen as powerful tools for generating real-world data (RWD) and supporting clinical trials.In the U.S., EMR usage among hospitals has surged from 30% in 2009 to over 95% by 2021, driven by regulatory and payor incentives. A 2023 review published in Clinical Trials Arena reported that using EMR-based patient identification increased the number of contactable trial participants by 63.7%, compared to traditional recruitment methods. Another study showed that 61.5% of participants were enrolled via EMR alerts, compared to only 25.4% through direct referrals [BMC Trials, 2016]. These numbers are not just statistics but are a signal of the shift toward data-embedded, digitally intelligent research.

How EMRs Enable Smarter Clinical Trials

1. Intelligent Patient Recruitment

EMRs enable researchers to scan databases for inclusion/exclusion criteria in seconds. Protocol-eligible patients can be flagged automatically, reducing screen failures and shortening recruitment timelines.

2. Data Quality and Compliance

Structured templates reduce human error. EMR-to-eCRF integration supports audit trails, timestamps, and GCP compliance—critical in regulatory audits.

3. Real-World Evidence and Longitudinal Tracking

EMRs allow us to track patients over months or years—enabling post-trial monitoring, safety surveillance, and real-world comparative effectiveness research.

4. Cost-Efficiency and Scalability

Automated data extraction from EMRs reduces the time and labor associated with traditional trial documentation, accelerating multi-center trials.India is the third-largest contributor to global clinical trials. Yet, the adoption of EMRs in research remains fragmented and under-leveraged. A 2023 scoping review of low- and middle-income countries (LMICs), including India, revealed: 40% of trials used EHRs for patient identification, 80% for capturing primary outcomes while only 7% extended EMR use to long-term follow-up [JMIR Medical Informatics, 2023]. Similarly, a survey of 13 Indian hospitals showed that only 8 had EMRs suitable for clinical research, with others relying primarily on administrative HIS modules [BioMed Research International, 2023].But clinician sentiment is changing. A study in Central India showed that 93% of clinicians wanted EMR systems implemented, recognizing their benefits in improving care quality, research access, and operational efficiency [BMC Health Services Research, 2025].At Fortis, we recognize that our EMR systems hold the potential to transform not just care but discovery. EMR implementation, though still in early stage, has already shown promise in supporting clinical research – clinicians are now able to search patient database for clinically relevant details at the click of a mouse and extract structured data reports for various clinical conditions and treatments without depending on paper-based records, and correlate with lab and other investigation and treatments etc. As EMR adoption improves across Fortis, it will herald a new chapter in our clinical research program.

The Pillar of Ethical Oversight: Recognizing the Vital Role of the Ethics Committee Member Secretary

Dr Supriya Amey
Director - Medical Operations
Fortis Hospitals, Mumbai

As the backbone of clinical research and academic projects, Ethics Committees (ECs) play a vital role in ensuring that studies are conducted with the highest ethical standards. Ethics Committees (ECs) serve as essential guardians of Integrity, Human Rights, and Scientific Responsibility. While many roles contribute to this complex Ecosystem, one often overlooked yet critical figure is the Member Secretary. Far from being a mere administrative function, the Member Secretary is the Operational and Ethical Key Person of Ethical Committee, ensuring that every Research Proposal upholds the highest standards of Ethics and Regulatory Compliance.

The Member Secretary: Fuelling Integrity in Ethical Review

The Member Secretary is not just a facilitator. They serve as Ethics Committee's strategic mind and moral anchor. Member Secretary of committee ensures that EC's processes run smoothly, transparently, and in strict adher-ence to National Ethical Guidelines.

Core Responsibilities and Daily Activities

The Member Secretary's contributions are both substan-tive and procedural, often spanning the follow-ing critical areas:

Protocol Management: Coordinates the submission, distri-bution, and tracking of research proposals for review.

Regulatory Compliance: Interprets and applies evolving guidelines from regulatory bodies like ICMR, CDSCO, and GCP.

Meeting Coordination: Plans and Manages EC meetings, drafts agendas, ensures quorum, and prepares minutes and decision letters.

Documentation & Recordkeeping: Maintains accurate, retrievable, and secure records of all EC activities, decisions, and correspondences.

Stakeholder Communication: Acts as the primary point of contact between investigators, committee members, institutional heads, and regulatory authorities.

Training & Capacity Building: Organizes ethics training programs and continuous education for committee mem-bers and researchers.

Monitoring and Follow-Up: Tracks ongoing studies, handles protocol amendments, reviews serious adverse events, and ensures post-approval compliance.

Meeting Challenges with Leadership

The Member Secretary must carefully handle difficult situations and make the right choices when things are confusing or involve tough ethical decisions.

Balancing Ethics with Scientific Innovation: Ensures Partic-ipant Safety while supporting Research that pushes Scien-tific Boundaries.

Managing Diverse Expectations: Mediates between Institutional Goals, Researchers' timelines, and Regulato-ry Scrutiny.

Maintaining Timeliness Without Compromising Quality: Delivers swift decisions while ensuring rigorous ethical review.

Upholding Confidentiality and Impartiality: Safeguards the sensitive nature of proposals and participant data.In all these areas, the Member Secretary brings resilience, integrity, and leadership, acting as the stabilizing force behind the committee's effectiveness.

A Lasting Impact on Research Culture

An effective Member Secretary is instrumental in shaping a culture of Ethics within the Institution. Their efforts lead to:

- Improved Quality and Credibility of research
- Enhanced Protection of Human participants
- Increased institutional reputation and compliance
- Strengthened Public Trust in Clinical Research

Far from being "behind-the-scenes," the Member Secre-tary's influence extends to every corner of the research enterprise from protocol design to post-study closure. Member Secretary role is not just administra-tive, it is strategic, ethical, and transformative. She is a custodian of research integrity, a mentor to investiga-tors, and a leader in ethical governance. Member Secre-tary in Ethics Committees ensures that every research endeavour is not only scientifically sound but ethically uncompromised.

The Indispensable Role of Clinical Research Nurses in Elevating Trial Integrity

Capt. Sandhya Shankar Pandey
Chief of Nursing
Fortis Healthcare

Clinical trials are the cornerstone of modern medicine, yet their success depends not just on protocols or molecules but on the people who implement them. Among these, the Clinical Research Nurse (CRN) plays a pivotal role in ensuring trials are safe, credible, and patient-centered.

When CRNs are included from the earliest stages of a study, the benefits are profound. They bring pragmatic insights into patient flow, feasibility, and safety monitoring—helping prevent costly protocol amendments. Their ability to build trust improves recruitment and retention, while their ethical vigilance safeguards informed consent and protects participants' rights. Beyond logistics, they enhance authenticity, ensuring that the lived patient experience is faithfully translated into reliable data.

At Fortis Healthcare, we have actively enabled nurses to step into this research journey. Nursing is no longer confined to bedside care is now deeply connected with data, analysis, and evidence-based practices. Nurse educators, infection control nurses (ICNs), nurse managers, and unit nursing heads are increasingly attuned to the power of evidence. They do not merely collect information; they analyze trends, interpret outcomes, and translate findings into practice. This shift has strengthened their ability to lead quality improvement, drive safer care, and contribute to research at both local and national levels.

To support this transformation, Fortis has invested in capacity building—training nurses in research methodology, Good Clinical Practice, and the principles of evidence-based care. We have built a repository of nurse-led initiatives and evidence-based practices, ensuring that learning is captured, disseminated, and applied across the system. With mentorship and recognition mechanisms in place, our nurses are evolving into knowledge producers and evidence custodians.

This ongoing effort has fostered a stronger culture of inquiry within Fortis. Nurse educators are integrating data into teaching, ICNs are applying evidence to strengthen infection prevention, nurse managers are using outcomes to guide decisions, and nursing heads are encouraging research-informed practice. Collectively, these steps help enhance both the credibility of clinical research and the quality of everyday patient care.

In essence, embedding CRNs and research-minded nurses from the beginning does not just add value—it multiplies integrity, efficiency, and patient safety. At Fortis, we believe this is not optional. It is fundamental to advancing authentic, patient-centered research and to securing the future of nursing as a true partner in science.

Clinical Research Vision and Process

Fortis Healthcare: Strengthening India's Clinical Research Landscape

Dr Kuldeep K Chauhan
Associate General Manager – Clinical Research MSOG
Fortis Corporate Office

Overview of Clinical Research in India

India's clinical research sector has seen significant evolution over the past decade. Despite initial fluctuations, the introduction of the New Drugs and Clinical Trial Rules (NDCT), 2019 has placed the country on a renewed path of progress. These regulations have brought greater transparency, ethics, and efficiency to the clinical trial ecosystem. By mandating processes such as audio-visual consent, strict SAE (Serious Adverse Events) reporting timelines, and structured compensation for trial-related injuries, the NDCT rules have aligned India's clinical trial practices with global standards. The emphasis on patient rights, regulatory clarity, and streamlined approvals has helped rebuild trust and attract new research investments.

Vision of Fortis Research Department

Guided by its vision "Promoting Education and Research for the Benefit of Humanity"—the Fortis Healthcare Research Department is playing a leading role in India's clinical research resurgence. Positioned as a trusted research partner, Fortis bridges the gap between science, clinical care, and education with a focus on integrity, quality, and ethical standards.

Current Strengths and Capabilities

Fortis has amassed extensive experience, having conducted over 1800 research projects, including 600+ global clinical trials across all phases (I–IV), post-marketing surveillance (PMS), observational studies, real-world evidence (RWE) studies, and investigator-initiated studies (IIS). Operating through 17 research sites, each with GCP-trained investigators and access to a multispecialty patient base, Fortis has established itself as a trusted research site network for both global pharmaceutical companies and clinical research organizations (CROs). Support systems across Fortis hospitals further strengthen research capabilities. These include NABL-accredited laboratories, advanced radiology services (including MRI, CT, and radiation therapy), robust hospital information systems (HIS), archival facilities, 24x7 power backup, and comprehensive IT infrastructure. The research infrastructure also includes AV consenting tools, calibrated equipment, laptops, scanners, and electronic trial master file (e-TMF) systems—all of which ensure precision and compliance.

Research Categories and Project Distribution

Fortis engages in a wide range of research types, including sponsored research, academic/intramural projects, unfunded research, government-funded initiatives (ICMR, etc.), and education-driven studies. The overall research portfolio currently includes 364 biomedical projects and 111 industry-sponsored trials, with 21 projects under legal review and 52 more in the pipeline.

Among industry-sponsored trials, Fortis is actively contributing to Phase 1 (1 study), Phase 2 (3), Phase 3 (69), and Phase 4 (38) research. Therapeutic areas span a broad spectrum including Cardiology (32 projects), Gastroenterology (21), Oncology & Hematology (15), Neurology (11), Endocrinology (9), Pulmonology (8), Rheumatology (4), and Nephrology/Others (11).

Research Governance and Team Structure

The research operations at Fortis are guided by the Fortis Research Advisory Committee (FRAC), which includes 60% internal and 40% external experts. The clinical research team, functioning under the guidance of the Dean of Research, Head of MSOG and AGM Clinical research supervises operations across all 17 research sites through a centralized, dedicated support team. This ensures standardized processes, centralized communication, and effective oversight of study activities.

Quality Assurance through R-QMS

To maintain the highest standards in research delivery, Fortis has implemented a Research Quality Management System (R-QMS). This system oversees critical areas such as consent process audits, data privacy, protocol adherence, and data completeness. Regular training on GCP and NDCT rules, SOP implementation, and internal audits (planned and surprise spot checks) help enforce compliance and improve overall study performance. Patient enrolment trends, repeated non-compliance, and site performance are closely monitored to ensure accountability and excellence.

Educational and Capacity-Building Initiatives: The CREATIVE Program

Fortis Healthcare strongly advocates for continuous learning, capacity-building, and strengthening the bridge between academia and industry through its flagship CREATIVE (Continuous Research Education and Training Initiatives) program. This initiative fosters a culture of knowledge exchange and skill development within the clinical research ecosystem. One of the key highlights is the "Ask the Expert" series, which has successfully conducted 12 interactive sessions in last six months. These sessions serve as a platform for DNB students, clinical investigators, ethics committee members, and research professionals to engage with subject matter experts, gaining practical insights into evolving trends and challenges in medical research.

Furthering its commitment to academic integration, the TABI (Talent Alignment Between Industry & Academia) program is actively working to bridge the gap between academia and the research industry. In the financial year 2024–25 alone, 38 students were trained under this initiative, equipping them with real-world exposure and industry-relevant research skills. Additionally, Fortis offers PhD support, with three students currently benefitting from institutional guidance and resources for their doctoral research.

In collaboration with leading universities and educational institutions, Fortis has established strong industry-academic partnerships. These collaborations aim to promote interdisciplinary research, enhance academic curricula, and prepare students for evidence-based clinical practice.

To nurture internal talent, Fortis has also introduced investigator profiling and mentorship programs, designed to guide clinicians through a structured transition into active clinical research roles. This "Clinician to Investigator" model emphasizes mentorship, training, and hands-on experience to build a robust pool of physician-researchers.

Moreover, the FOCUS (Fortis Clinical Data Understanding for Research) program encourages research publication and data utilization by providing support to investigators for analyzing and publishing insights derived from Fortis's clinical data. This initiative not only enhances the visibility of Fortis's contributions to medical research but also reinforces its position as a data-driven, evidence-based healthcare leader.

Expanding the Horizon: Current Collaborations and Strategic Vision

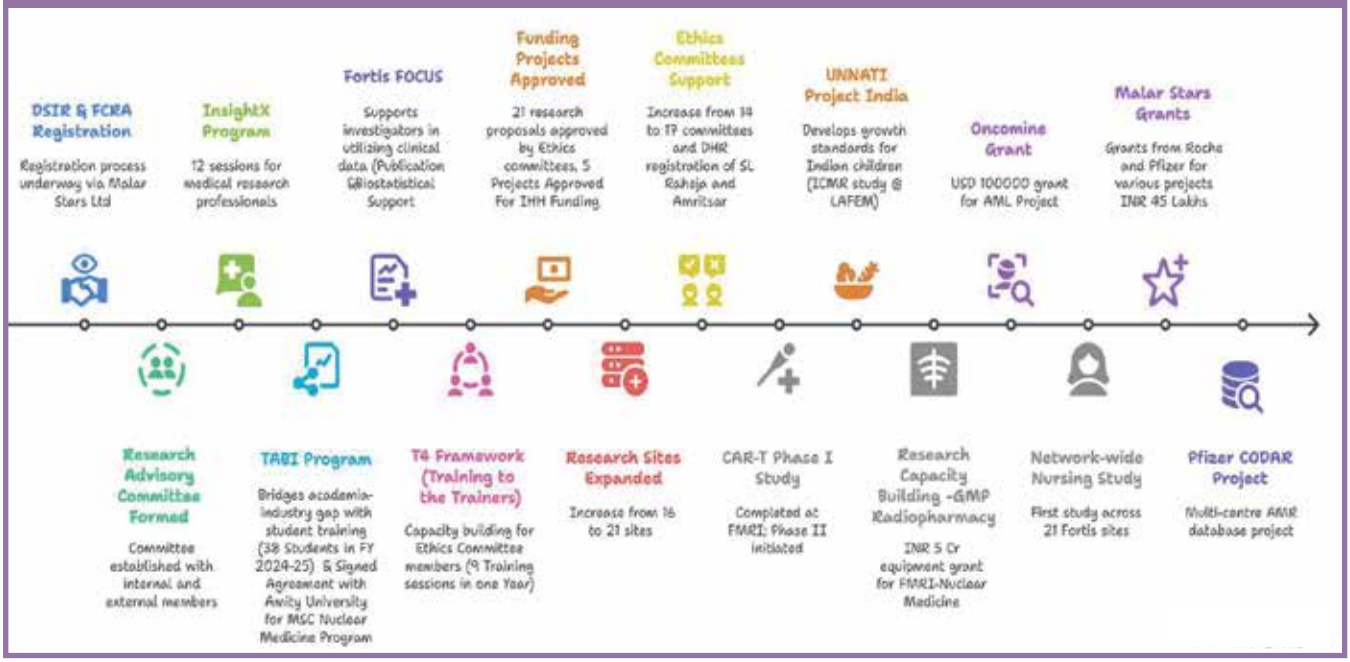
Fortis is preparing to step into the spotlight of collaborative research, maximizing its internal strengths and network potential. A collaboration with Oncoshot is currently under final discussion, with 6 new multi-site studies planned across Fortis hospitals. This effort aims to scale research impact, enhance data quality, and increase Fortis's contribution to meaningful medical evidence—especially in real-world, non-RCT settings.

Fortis Healthcare has laid out a clear and progressive roadmap to strengthen its clinical research capabilities, focusing on both immediate advancements and long-term transformation. In the short term, key priorities include the implementation of a Digital Clinical Research Management System (CRMS) to streamline operational workflows, enhance data management, and ensure regulatory compliance across its 17 research sites. Simultaneously, Fortis is committed to strengthening the CREATIVE Program, which aims to bridge the gap between clinicians and researchers through continuous education and structured investigator profiling, encouraging more clinicians to transition into active research roles. Another significant milestone in the near future is securing registration under the Department of Scientific and Industrial Research (DSIR), which will position Fortis to access various government-backed research benefits. Additionally, the establishment of three Centers of Excellence (CoEs) in key therapeutic areas is underway, designed to nurture focused research, innovation, and high-impact collaborations.

Looking ahead, Fortis's long-term vision centers around digital transformation and infrastructure enhancement. A major initiative is the complete digitalization of Ethics Committee operations, aimed at bringing transparency, efficiency, and compliance to research governance. Plans are also in place for the installation of 21 CFR Part 11-compliant temperature monitoring systems to ensure the safe and compliant storage of investigational products and biological samples. Another important goal is the creation of a centralized tissue repository or biobank, which will support future research in genomics, precision medicine, and

biomarker discovery. In line with its expanding capabilities, Fortis also aims to formally register as a Contract Research Organization (CRO), enabling it to offer end-to-end research services to the broader industry. Finally, Fortis is working toward making its digital clinical data "research-ready", by standardizing and curating datasets for retrospective analysis, real-world evidence generation, and AI-driven insights. Together, these initiatives reflect Fortis's strategic intent to emerge as a leading research-driven healthcare institution, deeply rooted in ethical practices and scientific excellence. Through visionary leadership, robust infrastructure, and an unrelenting commitment to quality and ethics, Fortis Healthcare is redefining clinical research in India. As the research landscape becomes more data-driven and patient-centric, Fortis is well-positioned to lead impactful change—locally and globally.

Research Initiatives2024-2026



Quality Management System (QMS)

Dr Rehan Abdur Rub
Quality Assurance - Clinical Research, MSOG,
Fortis Corporate

The rapid growth of clinical research activities across Fortis Hospitals Pan India, necessitates a robust and standardized Quality Management System (QMS) to ensure compliance, consistency, and patient safety. QMS, guided by the principles of ISO 9001:2015, the International Council for Harmonisation Good Clinical Practice (ICH-GCP E6 (R3) and NDCT Rules, 2019, plays a pivotal role in aligning organizational processes with regulatory requirements, facilitating efficient study conduct, and promoting continual improvement.

Introduction to QMS in Clinical Research

QMS in clinical research encompasses all coordinated activities aimed at ensuring the quality of clinical trial processes and data. The implementation of a centralized and harmonized QMS framework helps streamline operations and ensure consistent adherence to ethical and scientific standards.

Key Components of QMS

A. Leadership Commitment (ISO 9001:2015 - Clause 5) - active support, hospital-wide quality policy and allocate adequate resources

B. Scope Definition and Planning (ISO 9001:2015 - Clause 4) – Clear Scope and definition, involves stakeholder identification and process mapping

C. Document Control and SOPs (ISO 9001:2015 - Clauses 6 & 7) - standardized SOP's across all sites to ensure uniform practices

D. Risk-Based Quality Management (ICH-GCP E6(R2), ISO 31000) - Implement risk-based approach. Risk assessment tools help identify critical-to-quality factors and allocate resources efficiently.

E. Training and Competency Development (ISO 9001:2015 - Clause 7.2) - role-specific training in GCP, ethics, protocol adherence, and data integrity. Effectiveness through assessments and continuous improvement plan

F. Clinical Trial Conduct and Monitoring – Regular Internal Monitoring to ensure GCP compliance. Each site within the hospital chain must follow consistent procedures.

G. Internal Audits and Compliance Monitoring (ISO 9001:2015 - Clause 9.2) - Regular internal audits across all sites help evaluate QMS implementation, detect deviations, and drive corrective actions.

H. Data Integrity and Management (ALCOA+ Principles) - ensuring that data is Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, and Available. Centralized data systems can facilitate standardization.

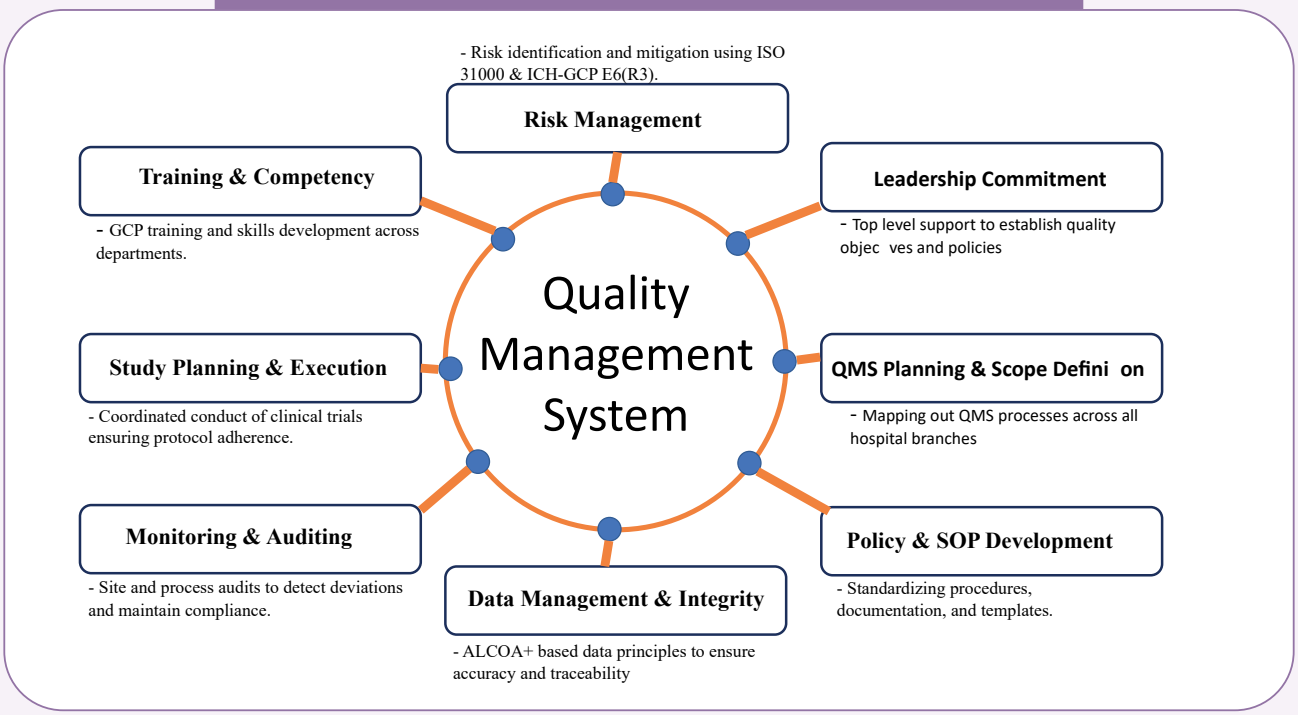
I. Nonconformance and CAPA (ISO 9001:2015 - Clause 10.2) - All nonconformities must be recorded, investigated, and resolved with appropriate Corrective and Preventive Actions (CAPA). Root cause analysis tools such as the "5 Whys" or Fishbone Diagram can support effective CAPA development.

J. Management Review and Continual Improvement (Clause 9.3, 10.3) – periodic review of the effectiveness of QMS, set new quality objectives, and implement continual improvement initiatives based on data from audits, CAPAs, and feedback mechanisms.

Benefits of QMS at site in Clinical Research

- Standardization Across Sites
- Improved Regulatory Compliance
- Data Integrity and Reliability
- Stakeholder Confidence

QMS Workflow Diagram for Clinical Research in Multi-Chain Hospitals



Conclusion

Establishing a QMS based on ISO 9001:2015 in a hospital for clinical research ensures that the processes are reliable, compliant, and efficient across all sites. The integration of GCP guidelines with the principles of risk-based quality management allows organizations to maintain high standards of patient safety and data integrity. Commitment from top leadership, consistent training, effective risk management, and continual monitoring are essential to the successful application of QMS in clinical research.

On-Site Monitoring and Governance Mechanism

Ms Shweta Rai
Clinical Research Associate
MSOG, Fortis Corporate

At each site visit, the CRA systematically reviews all critical trial components. Typical on-site monitoring tasks include:

Investigational Product Accountability

Verify drug receipt, storage conditions, dispensing and inventory logs match documentation.

Informed Consent Documentation

Check that consent forms are Ethics Committee approved, properly signed and dated by subjects/Legally Authorized Representative and Investigator.

Regulatory Binder Review

Ensure the Investigator Site File contains all essential documents (e.g. Ethics Committee approvals, protocol amendments, delegation logs) as required by ICH-GCP and Local regulations.

Source Data Verification (SDV)

Cross-check Case Report Forms against source records (charts, lab reports, etc.) to confirm accuracy and completeness of data.

Protocol Compliance

Confirm enrolled subjects meet eligibility criteria and that visit procedures, dosing, and assessments are conducted per protocol.

Safety Reporting

Review documentation of adverse events (AEs) and serious AEs to verify timely, complete reporting to the sponsor and IRB.

Staff Training and Delegation

Check that all personnel are trained on the protocol and that a current Delegation of Authority Log is in place.

Data Documentation and Queries

Identify and document any discrepancies (illegible entries, missing data, wrong calculations) and ensure queries are resolved or appropriately explained. Data Integrity: All trial data must be ALCOA ("Attributable, Legible, Contemporaneous, Original, Accurate"). This means entries are traceable (name/initials and date), legible, and faithfully recorded when generated. Monitors enforce this by source verification and checking that corrections are properly dated and initiated.

Feedback and Reporting

Discuss findings with the site team, clarify action items, and prepare a formal monitoring report. All findings and correspondence (including CAPAs) are logged in the Trial Master File (TMF) and site records.

For any business development queries, information on new molecules under trial, or concept notes related to network-based research studies, you are kindly requested to direct them to cl.researchfehi8@fortishealthcare or Shweta.rai@fortishealthcare.com .

Happenings @ Fortis

Insight X – A Capacity Building Initiative by Fortis Healthcare Research Department

InsightX is a capacity-building initiative launched by the Fortis Research Foundation and Fortis Healthcare Limited, aimed at strengthening the research ecosystem across our 21 sites. The platform brings together subject matter experts from the industry to share valuable insights with a wide audience of Fortis research professionals including young investigators, Ethics Committee members, research associates, DNB students, trainee research associates, the medical writing team, data management staff, research nurses, phlebotomists, students and administrative staff involved in day-to-day research operations. The experts can share in-depth information, answer questions, share tips and tricks on the topic, and provide ideas how to prepare better to enable the Researchers successful in their endeavours.

WEBINAR SPEAKERS AND TOPICS

Dr Vishnu Vardhan Rao- National Chair - Medical Statistics, ICMR-NIN, Hyderabad

Dr (prof) Tulsi Adhikari (Scientist F, ICMR, Faculty of Medical Research, AcSIR, Coordinator CTRI)

Dr Vishal Deo - Scientist, ICMR-NIRRCHDS, New Delhi

Ms Sneha Gupta Associate Director - Regulatory Affairs, IQVIA limited.

Ms Gupta delivered a focused session on the key updates in ICH-GCP E6 (R3) guidelines, highlighting critical changes and their practical implications for ongoing and upcoming clinical trials.

Dr Sumit Anand, Associate Director, Clinical Operations, Abbott India

Dr Anand provided an insightful overview of Medical Device Rules in clinical trials, emphasizing regulatory considerations and operational nuances that impact study execution.

Dr Nilanjan Saha – Adjunct Faculty at ICMR, Prof and Head at Department of CTCR- Jamia Hamdard

Dr Gunjan Kumar – Scientist D, ICMR, Delhi

Dr M K Sudarshan – Chairman – Institutional Ethics Committee – Fortis Hospital, BG Road, Bangalore (WHO expert advisory panel (2012-16) and consultations on rabies (2004, 2009 & 2012) & Global Alliance for Vaccines and Immunization (GAVI, 2015) Geneva, Switzerland and Government of India expert committee member (2007 & 2013) on rabies and founder secretary of Karnataka Association of Community Health (KACH, Estd.1985).

CONCLUSION

Initiatives like InsightX continue to play a vital role in fostering research excellence, regulatory awareness, and cross-functional learning. The Fortis Research Department remains committed to empowering teams with knowledge and industry alignment to ensure quality and compliance in all clinical research activities.

Fortis Organised the Biomedical Research National Conference





5th April 2025 | Fortis Hospital, Okhla, New Delhi

Fortis Healthcare successfully organised the Biomedical Research National Conference 2025, a full-day event that brought together clinicians, research scholars, regulatory leaders, and students for a power-packed exchange of ideas on the evolving world of clinical research in India. With the theme "Research to Reality: Navigating Methodology, Ethics, and Publication in Medical Research," the conference highlighted the urgent need to balance scientific rigor with ethical integrity and global visibility.

Leadership Perspectives

Dr Kameshwar Prasad (Dean – Clinical Research) and Dr Vikram Aggarwal (Facility Director – FEHI) opened the discussions by underscoring Fortis's commitment to ethical, patient-centered, and innovation-driven practices. Their address focused on the importance of well-designed trials—particularly the role of placebo-controlled studies, ethical interim analyses, and strict adherence to protocols.

Regulatory Insights

Delivering the regulator's perspective, DCGI Dr Rajeev Singh Raghuvanshi emphasized the need for Indian research to transition from "quantity to quality." Drawing on his experience in both industry and regulatory leadership, he highlighted how robust regulations ensure safety, reliability, and international credibility for clinical trials.

Call for Global Collaboration

Dr Z.S. Meharwal reflected on his three decades of research, reminding participants that "research is only impactful when the world knows about it." He stressed the importance of publishing, presenting, and forging global partnerships while reiterating India's growing trust in multi-institutional research based on strong ethical frameworks.

Fortis Research Department

Dr Kuldeep K. Chauhan provided an overview of the scope and achievements of Fortis Healthcare's Clinical Research Department. Currently active across 17 hospitals with more than 367 projects underway, the department ensures compliance with DCGI, NABH, and DHR standards. Key initiatives include the CREATIVE Program for training researchers, development of centralized data systems, and plans to digitize ethics processes, promote decentralized trials, and establish dedicated Centers of Excellence.

Academic & Practical Insights

A series of expert-led sessions enriched the learning experience:

Prof. Bikash Medhi (PGIMER) highlighted India's comparatively low contribution to global research and urged greater output from leading institutions.

Dr Bireshwar Sinha shared practical guidance on scientific writing, aligning manuscripts with globally

accepted standards.

Dr Parloop Bhatt outlined the entire research process, from topic selection and literature review to data analysis, interpretation, and recommendations.

Dr Vishal Deo (ICMR) emphasized the role of biostatistics in ensuring data reliability and introduced a new Statistician Helpdesk.

Dr Charu Paliwal delivered an interactive session on literature reviews, systematic reviews, and meta-analysis, keeping participants highly engaged.

Panel Discussion

The day concluded with a panel discussion featuring Dr Ishita B Sen, Dr Vishal Deo, Advocate Pawan Kumar, and Ms. Priyanka Kapoor. The panel offered multi-dimensional insights into the practical challenges and ethical considerations of conducting research in today's healthcare landscape.

Event Snapshot

- Venue: Board Room, Fortis Hospital, Okhla
- Timings: 09:00 – 17:30 hrs
- Participants: 112 in person, 254 online
- Audience: DNB students, research scholars, clinicians, ethics committee members

The event successfully reinforced Fortis Healthcare's vision of shaping research that is scientifically robust, ethically sound, and globally relevant.

Fortis Marks National Biostatistics Day with Focus on Data Reliability and Research Rigor

Fortis research Foundation and Fortis Healthcare proudly celebrated National Biostatistics Day 2025 on June 27th, commemorating the birth anniversary of Prof. P.C. Mahalanobis, the Father of Indian Statistics. The event was held virtually under the theme "Building Clinical Research Excellence with Statistical Foundations", highlighting the indispensable role of biostatistics in strengthening clinical research and healthcare outcomes.

The event witnessed enthusiastic participation from researchers, clinicians, academicians, and healthcare professionals across India. Esteemed speakers shared their insights on various facets of biostatistics in clinical research, enriching the learning experience for all attendees.

The knowledge sessions began with Dr Kameshwar Prasad, Dean – Clinical Research, Fortis Healthcare, who provided an enlightening perspective on the evolving role of statistics in biomedical research. This was followed by an in-depth session by Dr M. Vishnu Vardhana Rao, National Chair - Medical Statistics, ICMR-NIN, Hyderabad, who addressed Statistics Made Simple: Understanding the Basics for Better Research.

Further advancing the discussion, Dr Vishal Deo, Scientist, ICMR-NIRRCHDS, New Delhi, elaborated on Fundamental Statistical Considerations in clinical research-Effect Size, Sample size, and analysis. Dr Tulsi Adhikari, Scientist F & Coordinator CTRI, ICMR-Data Center, New Delhi, delivered an insightful talk on Testing of hypothesis and Sample sizes and Estimation.

A significant highlight of the event was the Panel Discussion on "Statistical Stewardship and Registry Integration: A Translational Arc from Protocol Development to Publication Excellence." The session was moderated by Dr Kuldeep K. Chauhan, an expert in Clinical Research & Medical Affairs, who led a thought-provoking dialogue with panelists Dr M. Vishnu Vardhana Rao and Dr Vishal Deo.

Key Conference Message:

In today's era of evidence-based medicine, statistics is the backbone of credible biomedical research. From study design to publication, statistical principles uphold scientific integrity, ethical standards, and practical relevance.

Robust study design starts with statistical input—choosing the right model (e.g., RCTs or cohort studies), calculating adequate sample sizes, and ensuring unbiased randomization for valid, generalizable results.

Formulating clear hypotheses from clinical questions also relies on statistical guidance, helping researchers define measurable outcomes and generate actionable insights.

Ethical oversight committees depend on sound statistical planning to assess scientific validity and minimize risks, particularly by avoiding underpowered or poorly structured studies.

Clinician-statistician collaboration enriches protocol development, balancing real-world clinical challenges with methodological rigor. This synergy enhances research feasibility and quality.

When it comes to data interpretation, statistics ensures transparency and accuracy, transforming raw data into meaningful, unbiased conclusions that readers can trust.

High-quality statistical reporting is a key requirement for publication, improving reproducibility and credibility, and facilitating acceptance in reputed journals.

In the realm of real-world evidence (RWE), statistics plays a vital role in adjusting for bias and confounders, enabling researchers to draw valid conclusions from observational or post-marketing studies.

Funding bodies and regulators now demand statistically sound protocols, making early statistical planning essential for approval and support.

Statistical literacy among clinicians is equally important—it empowers them to appraise literature critically, adopt data-informed practices, and contribute meaningfully to research.

By embedding statistics in medical education, we nurture a research-aware culture where future clinicians can lead high-impact, ethically sound investigations.

The event concluded with deep appreciation for all speakers, panelists, and attendees.

E-certificates were distributed as a token of participation, marking a successful knowledge-sharing initiative.

National Biostatistics Day 2025 served as an engaging platform to reaffirm the significance of biostatistics in driving research integrity, clinical advancements, and data-driven decision-making in healthcare. This conference underscored the critical importance of statistics in biomedical research, not just as a technical function, but as a strategic enabler of ethical, impactful, and sustainable scientific advancement.

Fortis celebrates International Clinical Trials Day

Theme: "The Other Half of Ethics Committee Oversight: Recognising the Impact of Non-Scientific Members in Ethics Committees"

Session Highlight
200+ Registrations
100+ Active Participants

Key Highlights

Welcome Address: Ms Maithili Janye (Research Team, Fortis Mulund) highlighted the importance of clinical trials and the crucial role of non-scientific Ethics Committee members.

Non-Scientific Members' Role: Emphasized their human-centric perspective in ensuring ethics, participant safety, and clarity in communication.

Dr Kameshwar Prasad: Stressed methodologically rigorous trials, GCP compliance, and data integrity.
Dr Kuldeep K Chauhan: Spoke on evolving Ethics Committees, contributions of non-scientific members, and Fortis Healthcare's initiatives in training and safety.

Breakout Sessions: Focused on laypersons/social scientists, legal experts, and EC coordinators with expert-led discussions.
Panel Discussion: Experts (Dr Neeraj Pandit, Ms. Ashima Sawhney, Dr Vijay Kumar Gawali, Mr. Parag Goyal) discussed strengthening non-scientific members' role in ECs.

Legal Insights (Mr. Parag Goyal): Importance of indemnification, arbitration clauses, and clear protocols for trial termination.

Legal Review (Ms. Ashima Sawhney): Common dossier deficiencies, consent clarity, SOP adherence, and insurance validity.

NABH Observations (Dr Neeraj Pandit): Need for SOP awareness and active EC member involvement.

Best Practices (Dr Vijay Kumar Gawali): Complete dossier submissions, CRC role in consent customization, monitoring visit responsibilities.

Closing
Panelists thanked for valuable insights.
Participants appreciated for active engagement and 90% retention till event end.

T4 Framework for Ethical Excellence

(Strengthening ECs through Rotational Peer Training)

The T4 Research Framework, which stands for Training to the Trainers, is a strategic initiative launched by the Fortis Research Foundation to strengthen the capacity, knowledge, and effectiveness of Ethics Committees (ECs) across the Fortis Healthcare network. The program is designed to standardize training practices and promote peer-leading learning to ensure ethical and regulatory compliance across all aspects of clinical research.

Ethics Committees at Fortis are multisectoral and multidimensional bodies, composed of technical and nontechnical, scientific and nonscientific members. Their core responsibility is to safeguard the rights, safety, and well-being of research participants by ethically reviewing clinical research proposals. Supporting this function, each EC includes a Scientific Review Board (SRB), a subcommittee tasked with evaluating the scientific integrity of proposals prior to EC review.

Under the T4 model, one member from any of the Ethics Committees is identified as a trainer, responsible for providing training to members of all 15 Ethics Committees across Fortis. For each session, a different member from a different committee is selected in rotation. The selected trainer designs and conducts the training session based on their role within the Ethics Committee and their domain expertise in ethics committee operations. The objective is to enhance understanding of ethical frameworks, regulatory requirements, and research governance, while encouraging peer learning, experience sharing, and collaborative problem solving.

What distinguishes the T4 initiative is its hands-on, experience-based approach. Trainers share real time challenges and practical case studies, helping committee members engage with evolving issues in clinical research ethics. These interactive sessions foster deeper understanding of responsibilities and strengthen the decision-making capabilities of both ECs and SRBs.

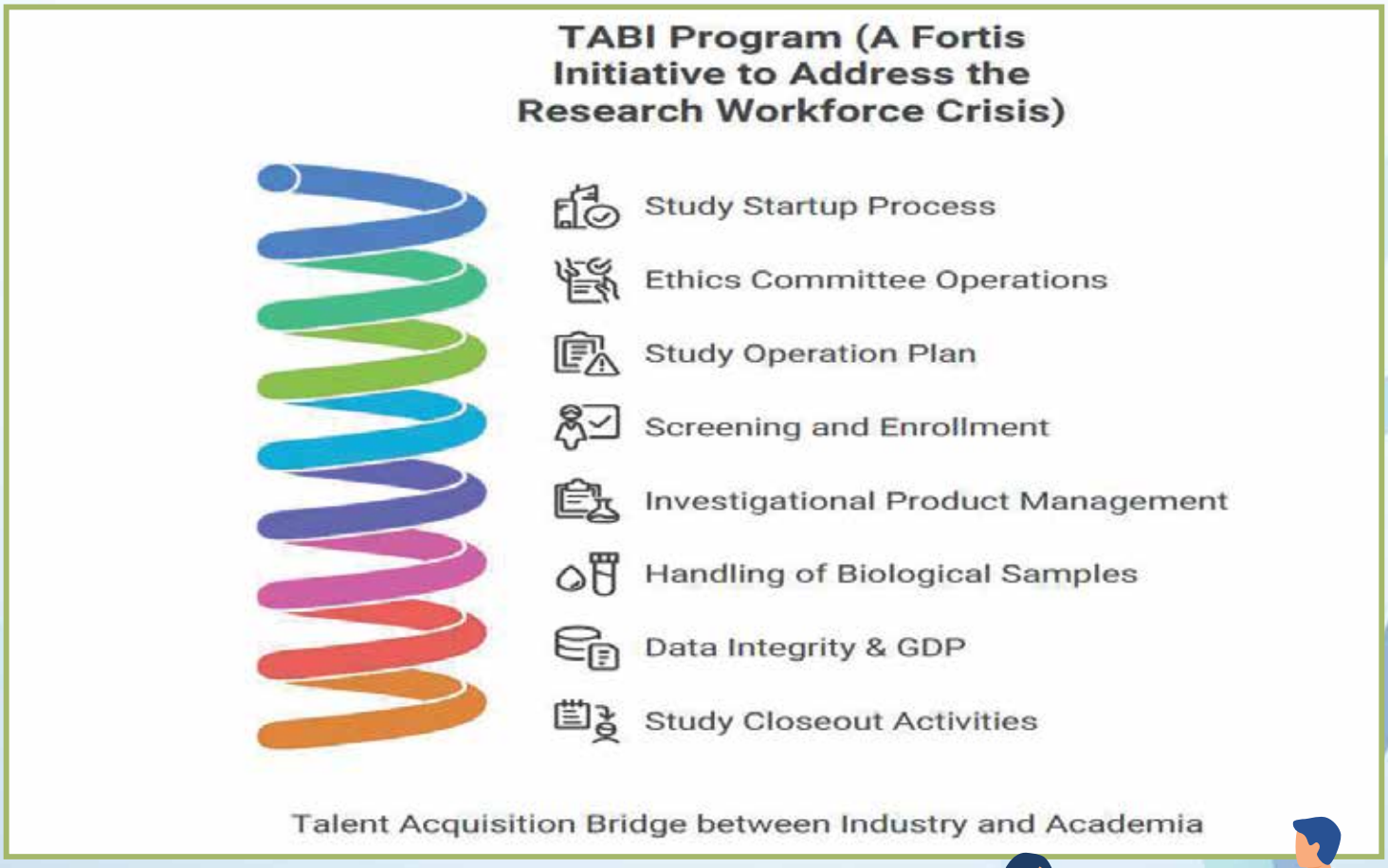
The T4 Framework reflects the Fortis Research Foundation's strong commitment to institutional capacity building, ethical excellence, and consistency in review practices. By investing in internal trainers and promoting continuous education, Fortis is developing a sustainable, scalable, and high-quality model for research oversight.

In essence, T4 is more than just a training initiative. It is a culture building platform that nurtures leadership, reinforces accountability, and advances ethical research practices across Fortis Healthcare.

TABI Program
(Talent Acquisition Bridge between Industry and Academia)

The Fortis Research team has identified several critical workforce challenges affecting the clinical research industry. These include a shortage of trained clinical research professionals to meet the growing demand, high attrition rates due to overburdened staff and burnout, and increasing competition for skilled professionals, where smaller research sites often lose staff to larger CROs and pharmaceutical companies offering better pay and career growth opportunities. These issues have a direct impact on the quality of research, with staff shortages compromising Good Clinical Practice (GCP) compliance and data integrity. Ultimately, these challenges lead to delays in research progress, slowing the pace of medical advancement.

In response to these pressing concerns, and in alignment with its commitment to academic integration, the Fortis Clinical Research Department launched the TABI Program (Talent Acquisition Bridge between Industry and Academia). This initiative aims to bridge the gap between academic training and the practical demands of the research industry. Through TABI, students are provided with real-world exposure and hands-on experience in clinical research operations. In the financial year 2024–25 alone, 38 students were trained under this program, acquiring valuable skills aligned with current industry needs.



Digital Transformation in Clinical Research: Evolution, Impact, and Future Directions

Dr Kameshwar Prasad
Principal Director - Neurology
Dean - Clinical Research
Fortis Hospital, Vasant Kunj

Over the past 15 years, clinical research has transitioned from paper-based practices to a digitally advanced, patient-centric model. In the early years (2000–2012), trials were heavily dependent on manual processes. Clinical Research Associates (CRAs) verified data on paper case report forms (CRFs), informed consent was obtained using a single paper form, and investigational products were stored on-site using basic thermometers. Though simple, this model was slow, resource-intensive, and prone to human error. Data queries took weeks to resolve, and site visits were the only mode of verification and monitoring.

From 2013 to 2018, the adoption of digital tools gained momentum. Electronic Data Capture (EDC), electronic consent (eConsent), and electronic clinical outcome assessments (eCOA) became standard. This period also saw the introduction of risk-based monitoring, where CRAs used centralized systems to assess site performance and data trends, reducing the need for frequent on-site visits. The delegation of authority logs and protocols became more complex, reflecting the growing sophistication of research processes. Importantly, the shift to electronic platforms accelerated data review and minimized manual discrepancies.

The COVID-19 pandemic from 2019 onwards catalyzed the implementation of Decentralized Clinical Trials (DCTs). With lockdowns and restricted travel, digital tools allowed remote patient participation, telemedicine-based consultations, and virtual monitoring. Data could be collected through wearable devices, mobile apps, and electronic patient-reported outcomes (ePROs), making clinical trials more accessible and inclusive. However, this transition brought challenges such as the need for technical support, tool costs, and training requirements for both staff and participants.

To align with these changes, the International Council for Harmonisation (ICH) introduced the E6(R3) Good Clinical Practice (GCP) guideline. This updated version promotes a quality-by-design approach and encourages the integration of digital technologies and risk-based methodologies. It emphasizes participant protection, data integrity, and efficient trial conduct while supporting real-time data review, centralized oversight, and electronic documentation. The ICH-GCP R3 framework ensures that evolving practices remain scientifically sound and ethically robust.

Conclusion and Recommendations:

The digitalization of clinical research has significantly enhanced efficiency, data accuracy, and patient engagement. However, successful implementation depends on equipping research teams with the skills to navigate digital platforms effectively. Institutions should prioritize structured training programs on EDC systems, eConsent platforms, remote monitoring tools, and data security protocols. Continuous education will ensure compliance with ICH-GCP R3 standards and empower teams to conduct high-quality, technology-enabled clinical research that is both future-ready and ethically aligned.

Role Spotlights

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Expansion of Clinical Research Sites

Fortis Hospital, Kalyan, Mumbai
Fortis Hospital, Greater Noida, Uttar Pradesh
Fortis Hospital, Manesar, Haryana
Fortis La-Femme, Delhi
Fortis Hospital, C-Doc, Delhi
Fortis Shrimann Hospital, Ludhiana, Punjab
O.P. Jindal, Raigarh

Amazing Facts About Clinical Research in India

DID YOU KNOW?

India Has Over 500 Active Clinical Trial Sites

- India hosts over 500 DCGI-registered clinical trial sites across multispecialty hospitals, research centers, and academic institutions.
- These include top hospitals like Fortis, AIIMS, Apollo, PGI Chandigarh, and more.

Second-Largest English-Speaking Workforce in Healthcare

- India's large pool of GCP-trained investigators and clinical research professionals gives it an edge in global trials.
- Estimated 70,000+ professionals trained in ICH-GCP and regulatory practices.

Over 20,000 Trials Registered in CTRI

- India's Clinical Trials Registry (CTRI) has recorded 20,000+ registered trials since inception in 2007.
- CTRI registration is mandatory for all interventional trials since 2009.

Huge Cost Advantage – 30%–50% Lower Trial Costs

- India offers significantly lower costs for conducting trials (up to 50% lower than in the US/EU), making it attractive for global pharma and biotech firms.

New Drugs and Clinical Trials Rules (NDCTR) – 2019

- The 2019 reform brought faster approvals, more ethical protections, and AV consent mandates—rebuilding India's image as a safe and regulated trial destination.

Strong Patient Pool for Diverse Therapeutic Areas

- With its large, genetically diverse population, India is ideal for studies in oncology, neurology, cardiology, infectious diseases, and rare diseases.

India Is a Rising Hub for Decentralized Trials (DCTs)

- Telemedicine, e-consent, wearable integration, and remote monitoring are now being piloted across top Indian hospitals to support hybrid and DCT models.

Growing Role in Vaccine and Biologic Trials

- India played a key role in COVID-19 vaccine development (e.g., Covaxin, Covishield trials), and continues to be a leader in vaccine and biosimilar trials.

Top CROs Have Set Up Operations in India

- Global CROs like IQVIA, Parexel, ICON, and Labcorp have large-scale offices in India.
- Indian CROs like Syngene, CliniRx, Lambda, and Veeda are expanding globally.

Government Is Actively Supporting R&D & Trials

- Supportive schemes like Biotechnology Industry Research Assistance Council (BIRAC), Startup India, and Make in India are boosting clinical innovation.
- The DSIR recognition enables tax incentives for clinical research organizations.
- India's Digital Health Mission, e-Hospital, and Ayushman Bharat programs are expected to digitally link research, hospitals, and health records—transforming data-driven trials.

- APPRECIATION -

KUDOS TO THE TEAMS

FOR PUTTING THEIR BEST FOOT FORWARD

Ms Nungshijungla (Operations Manager)

Mr Mayank Yadav (Clinical Trial Administrator – Contracts and Budget)

Ms Maithili Janye (Medical Writing Support Lead)

Ms Himani Malik (Biostatistician)

Ms Bishnu Priya (Ethics Committee Lead)

Fortis News

Fortis Hospital, Gurugram, Secures Prestigious JCI Re-accreditation with 98% Compliance

Fortis Hospital, Gurugram, has successfully concluded the 4-day JCI audit, held from September 9-12, 2025, securing the prestigious JCI re-accreditation for the second time. This year's JCI assessment was one of the toughest so far, conducted under the 8th edition revised format, which allows only two outcomes — 'Met' or 'Not Met' — with no provision for 'Partially Met.' Out of 1,073 measurable criteria, Fortis Gurugram achieved an outstanding 98% compliance rate. This milestone has been made possible through the dedication and splendid efforts of the Quality, Medical, Nursing, Admin, HR, Emergency, Biomedical, ICUs, Housekeeping, Engineering, Security and F&B teams, and every supporting department. The prestigious re-accreditation was achieved under the guidance of Mr Yash Rawat, VP & Facility Director, Fortis Hospital Gurugram, and Dr Jyoti Mishra, Medical Director, Fortis Hospital, Gurugram.

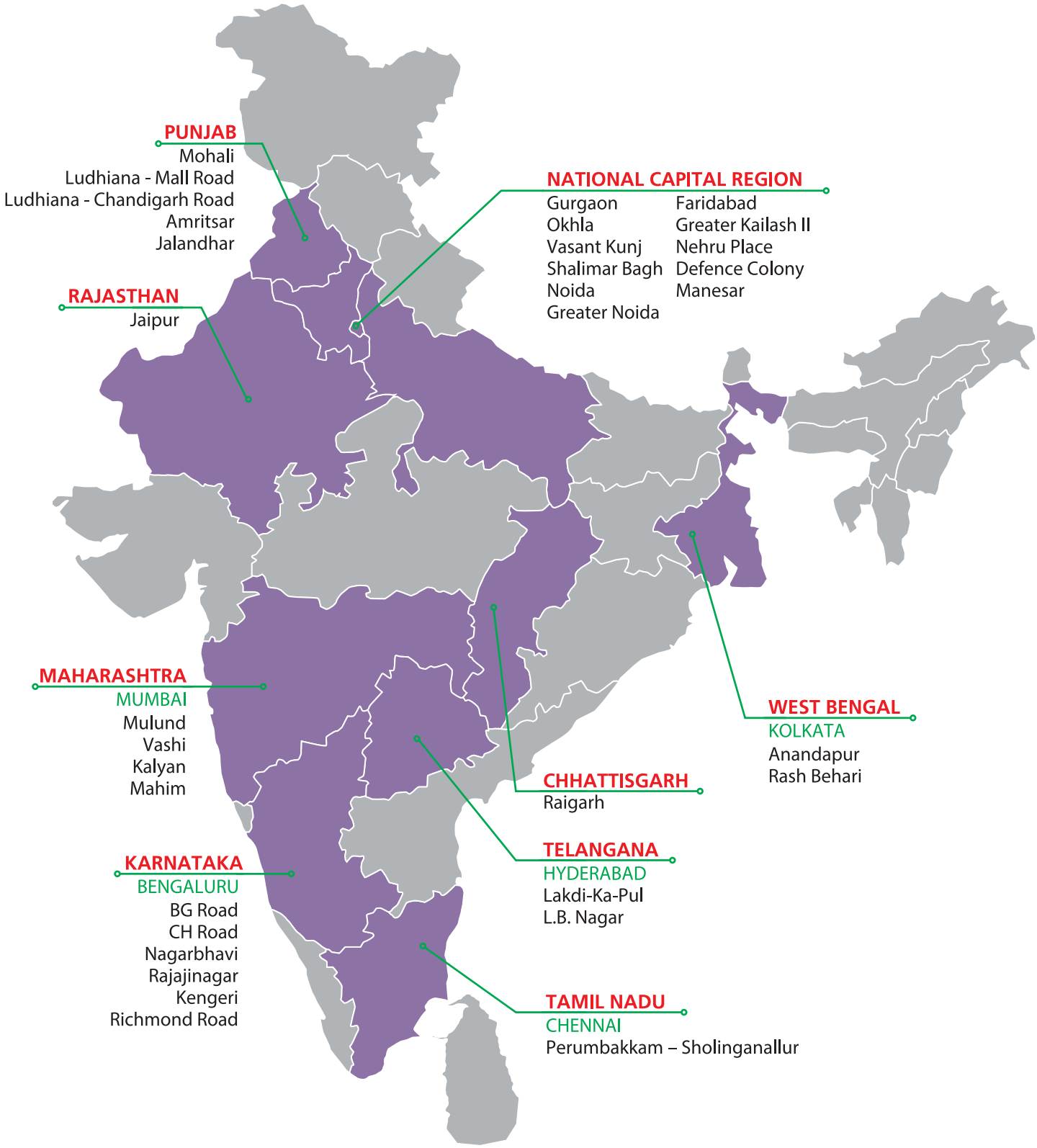
Congratulations, Team Gurugram!

Fortis Launches its First Information Centre in Gulf Cooperation Council Region at Salalah, Oman

Fortis has further strengthened its global footprint with the successful inauguration of an Information Centre in Gulf Cooperation Council (GCC) at Salalah, Oman. This is the 11th overseas Fortis Information Centre and sixth to be inaugurated this year. The inauguration was held on September 29, 2025, and was attended by key officials, former patients and their family members, social media influencers and members of the local media. Fortis was represented by Ms Renu Vij, Head – International Sales, and Mr Shubham Dhankar, Territory Lead – Middle East. The centre will bridge the information gap for patients from Oman seeking treatment at Fortis, by sharing the right information.

Congratulations, Team International Sales!

The Fortis Hospital
Network* Across India



*Including JVs and O&M facilities

To book an appointment
Scan the QR code and
download the **myFortis app**.

or 9205 010 100

Fortis

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