

Lupin's Commitment to Clinical Trial

- Transparency, Standards and Programme



Lupin's Commitment to Research Transparency and Data Sharing

At Lupin, we uphold the principles of transparency and responsible information sharing as the foundation of our research practices. We are committed to disseminating clinical trial outcomes, post-launch assessments to relevant stakeholders, including:

- Regulators
- Healthcare professionals
- Researchers
- Clinical trial participants and
- Others acting in the best interest of patients

We actively share this data with the scientific community and healthcare ecosystem because we believe that collaborative knowledge exchange accelerates innovation, advances scientific research, and ultimately improves access to quality healthcare worldwide.

Commitment to Trial Data Transparency

Lupin is committed to ensuring transparency in clinical research through timely disclosure, prior registration, comprehensive publication of results, and responsible data sharing. These practices uphold ethical standards, foster scientific integrity, and strengthen trust among stakeholders.

Lupin is committed to maintaining transparency across all clinical trial activities through a robust governance framework. We ensure timely disclosure of trial results in accordance with regulatory requirements and update public registries as mandated. All clinical trials are registered in credible, publicly accessible databases prior to participant enrollment—such as the Clinical Trials Registry-India (CTRI) for studies conducted in India, ClinicalTrials.gov for the United States, and the EU Clinical Trial Registry or EU Clinical Trial Information System (CTIS) for the European Union.

Results are disclosed in public registries irrespective of study outcomes, and select findings are published in peer-reviewed journals based on strategic considerations. For trials that are terminated, results are reported in compliance with applicable regulations. Additionally, Lupin facilitates data sharing by providing raw data to third parties upon request, subject to regulatory requirements and confidentiality agreements.

Through these measures, Lupin reinforces its dedication to ethical research practices, scientific integrity, and patient trust. We believe that transparency in clinical trial data is essential for advancing healthcare and improving patient outcomes globally.



Clinical Trial Standards

Lupin is committed to ensuring that all clinical trials, whether conducted in-house, offshore, or through outsourced partners, adhere to the highest standards of quality, ethics, and compliance. Our approach is guided by international best practice guidelines, globally recognized codes, and principles to safeguard the rights, safety, and well-being of trial participants while ensuring scientific integrity and transparency.

Lupin is committed to conducting clinical trials in accordance with globally recognized standards and ethical principles. All trials adhere to:

- ICH E6 Good Clinical Practice (GCP) Guidelines
- Declaration of Helsinki
- Applicable local regulatory frameworks

We commit to upholding ethical principles outlined in internationally recognized codes to ensure respect for human rights and dignity in all clinical trials.

Our Quality Management System (QMS) is aligned with international standards and codes that govern Standard Operating Procedures (SOPs) for trial conduct. Key practices include:

- Trials are initiated only after review and approval by regulatory authorities and Institutional Ethics Committees (IEC) or Institutional Review Boards (IRB).
- Continuous monitoring ensures compliance with protocols and regulatory requirements.
- SOPs are implemented for oversight of trials outsourced to Contract Research Organizations (CROs).

Lupin ensures regular monitoring of offshore and outsourced studies as part of its clinical research governance framework which involves periodic oversight visits, remote monitoring, performance metrics review, risk-based monitoring, audit and quality checks.

Lupin upholds international codes and principles that ensure ethical conduct, scientific integrity, and patient safety throughout the clinical research process.

Through these measures, Lupin is committed to continuously evolving its clinical research practices to meet emerging global standards and ethical expectations. We will leverage innovation, advanced monitoring technologies, and collaborative partnerships to enhance transparency, participant safety, and data integrity. As we look ahead, our focus remains on setting benchmarks in responsible clinical research, ensuring that every trial we conduct contributes to a healthier, more sustainable future for patients and communities worldwide.



Clinical Trial Programme

Lupin's clinical trial program is built on the principles of participant safety, ethical conduct, and regulatory compliance. Our clinical trial program is guided by international best practices and unwavering commitment to scientific integrity.

Key commitments include:

- **Senior Management Accountability:** Leadership ensures adherence to ethical standards throughout trial conduct.
- **Ethical Oversight:** Independent Ethics Committees (IEC) have full authority to approve, modify, or terminate trials.
- **Risk & Impact Assessment:** Comprehensive risk and impact assessments are conducted prior to trial commencement to identify and mitigate potential adverse effects on participants and communities.
- **Free, Prior and Informed Consent:** Participants' consent is obtained through a transparent process that ensures they fully understand the trial's purpose, risks, and benefits before enrollment.
- **Training & Awareness:** Employees involved in trials undergo regular training programs.
- **Market Relevance:** We ensure that clinical trials are conducted exclusively in regions where the investigational product is intended for future marketing, aligning with local healthcare needs and accessibility.
- **Post-Trial Access:** Medicines are provided post-trial where applicable.
- **Grievance Redressal:** Lupin provides robust grievance redressal channels for trial participants, ensuring timely resolution of concerns and maintaining trust throughout the trial process. The Informed Consent Document clearly states that participants can contact the Investigator/Doctor or the Ethics Committee for any study-related, health-related, or participant-rights concerns.
- **Transparency:** Monitoring outcomes, violations, and corrective actions are publicly reported where required.
- **Continuous Monitoring:** Continuous monitoring mechanisms are in place to ensure compliance with protocols, ethical standards, and participant safety throughout the trial duration.

Lupin remains committed to advancing ethical and patient-centric clinical research practices in alignment with our Purpose of catalyzing treatments that transform hope into healing. This commitment reflects our strategy of conducting trials responsibly, guided by integrity, scientific rigor, and respect for human dignity.