LAMBDA
Research Accelerated

Novum
PHARMACEUTICAL RESEARCH SERVICES

Audit & Inspection Readiness:

A Comprehensive Approach

At Lambda Therapeutic Research, we not only acknowledge but deeply embrace the paramount importance of inspection readiness within the clinical research industry. In an environment governed by rigorous regulations, readiness isn't just commendable; it's an absolute necessity.

To attain this level of preparedness, we leverage cutting-edge digital solutions and industry best practices, meticulously crafting the foundation for precision, security, and the relentless pursuit of excellence.

Regulatory Success:
A Testament to Our Commitment

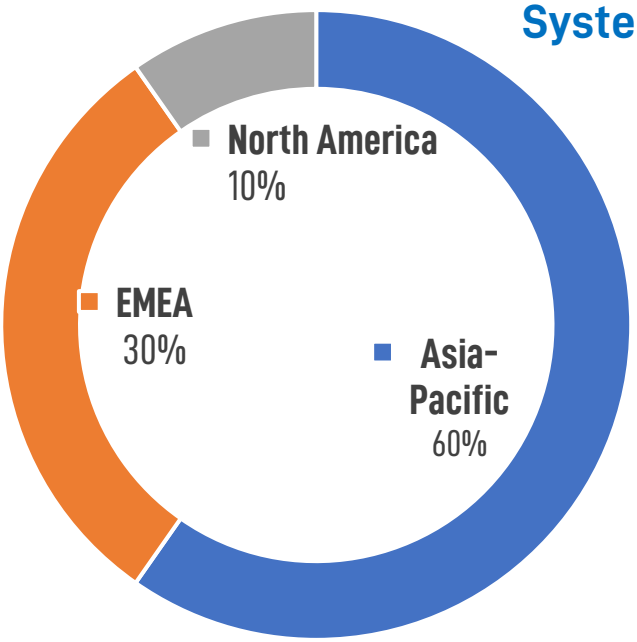
Lambda has successfully navigated a significant number of international inspections and audits, including international inspections, sponsor audits, and monitoring visits. Lambda has been recently honored with the 'Regulatory Excellence' Award at the CPHI Awards 2023 for the exceptional work in 'Enhancing Compliance & Data Generation in Clinical Trials through Advanced Software Solutions and EDC Platform.'

100+
International Inspections/Audits

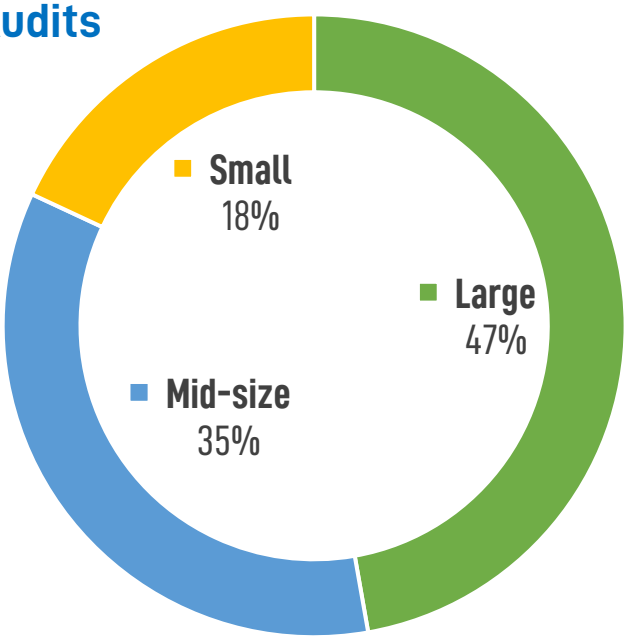
200+
Sponsor Audits

2000+
Monitoring Visits

System Audits



Country of Sponsor Origin



Size of Company

Leveraging Digital Solutions for Precision & Preparedness

Utilizing EDC Technology: We employ BizNET EDC technology to maintain the highest accuracy and quality in clinical study data, ensuring a strong foundation for inspection readiness.

Empowering Data Retrieval: We've adopted IMPTrack, KnowledgeNET, and Biolyte software to enhance data retrieval. This enables us to accurately reconstruct study events, allowing us to respond swiftly during inspections.

- **IMPTrack**: Inventory tracking of investigational medicinal products (IMPs).
- **KnowledgeNET**: Electronic trial master file (eTMF) management & document retrieval.
- **Biolyte**: Streamlined organization of chromatographic data.

Lambda utilizes **Gateway**, a cloud-based suite for late-phase clinical trial operations, with dynamic dashboards for project, investigator, and site management, facilitating global remote audits with real-time user data access.

Quality Management Software: To simplify audit and inspection processes, we've transitioned from paper records to quality management software. This transition allows us to manage SOPs, Change Controls, Deviations, CAPAs, Incidents, User's access management, and e-logbooks with ease. This digitization reinforces our commitment to process excellence and compliance.

Continuous Preparedness and Vigilance

At Lambda, we don't stop at being ready just when inspections are on the horizon. We maintain a state of continuous preparedness & vigilance through the following practices:

Ongoing Verification and Quality Assurance: Regular QC and QA audits ensure constant facility preparedness and adherence to SOP and protocol specifications.

Holistic Quality Monitoring: Regular Quality Review Board meetings with management ensure holistic quality system monitoring & trend analysis for continuous enhancement.

Skilled Workforce and Training: We invest in our team by providing thorough training, ensuring a highly skilled and knowledgeable staff committed to maintaining compliance.

Advancing Data Precision and Security

Our focus on data precision and security is unwavering. We integrate advanced functionalities like barcode scanning and retina-based validation to enhance data collection precision from the outset. Real-time data capture aligns with ALCOA+++ principles for data integrity and compliance. Moreover, digitization eradicates manual errors, ensuring precise data capture and security through access controls, audit trails, and encryption.

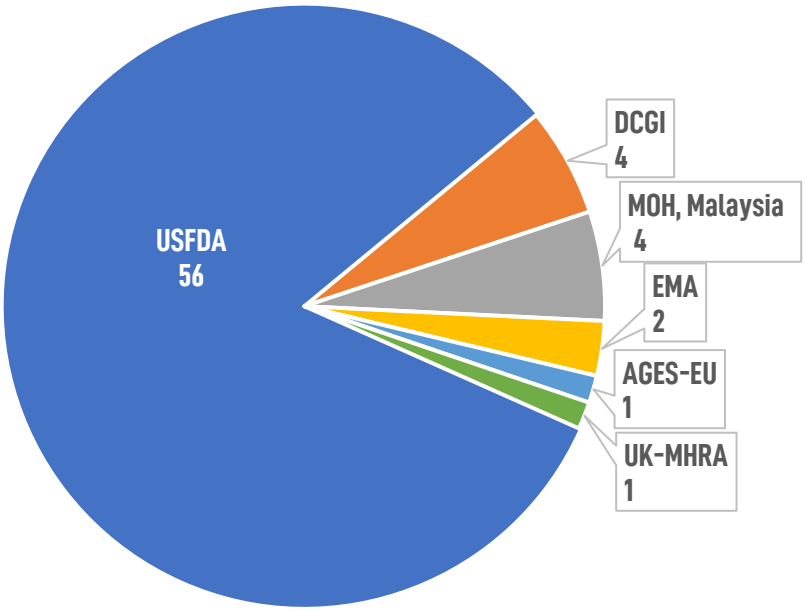
Empowering Investigator Sites for Inspection Success

We understand that preparation for inspections starts long before they are announced. For investigator sites, inspection readiness is embedded within our processes from the very beginning and strategic Site Selection. Our approach includes:

- **Early Preparation:** Inspection readiness at trial sites commences at the outset of a trial, identifying critical data and processes early on.
- **Risk Assessment and Mitigation:** We conduct rigorous risk assessments and implement robust mitigation strategies to effectively address potential risks.
- **Goal-Oriented Checklist:** Our onsite monitoring process integrates a meticulously compiled checklist that aligns with the ultimate objective of being inspection-ready.
- **Ongoing Monitoring:** A dedicated group continuously reviews critical checkpoints, ensuring perpetual preparedness.
- **Empowering Site Staff:** Comprehensive training is provided to empower site staff, enabling them to confidently face inspections.
- **Thorough Site Close-Out:** Upon trial completion, our comprehensive Inspection Readiness checklist ensures that the site is fully prepared for inspections.

Our track record of successful trial site inspections speaks volumes about our commitment to the highest standards of regulatory compliance.

With over **65 successful inspections from global regulatory authorities** such as US FDA, MHRA, EMA, AGES, we've consistently demonstrated our dedication to upholding the highest standards.



Impeccable Regulatory Track Record

INDIA | WHO | EU | UK | US

CANADA | NGCMA - INDIA | AUSTRIA | BELGIUM | BRAZIL

CANADA | CZECH REPUBLIC | FRANCE | GERMANY | GULF COOPERATION COUNCIL

HUNGARY | IRELAND | ITALY | KAZAKHSTAN | LATVIA

MALAYSIA | NETHERLANDS | POLAND | PORTUGAL | SLOVAKIA

SPAIN | THAILAND | TURKEY | NABL INDIA | US

Leverage our extensive experience & proven track record to accelerate your clinical trials.

✉ **BD@lambda-cro.com**