



A Full-service Global CRO

India | USA | Canada | UK | Poland

Comprehensive End-to-End Services



Awards & Accolades

**REGULATORY
& COMPLIANCE
EXCELLENCE**

CPHI Pharma
Awards 2023



**INDUSTRY
PARTNER
OF THE YEAR**

Global Generics &
Biosimilars Awards
2023



Global Presence



Impeccable Regulatory Track Record



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



CAP

Research Accelerated



- Multicontinental presence
- End-to-end clinical research service offerings
- Robust digital platforms across business verticals
- Hub & Spoke, flexible business models



- Global Revenues of USD 90 million in FY 23-24
- Growing at 29% CAGR YoY
- Best credit rating in the CRO industry



- Strong Leadership with 35+ years of experience
- Multicultural workforce
- 1200+ employees



- Impeccable regulatory track record
- Independent Quality Assurance
- Stringent GXP Compliance

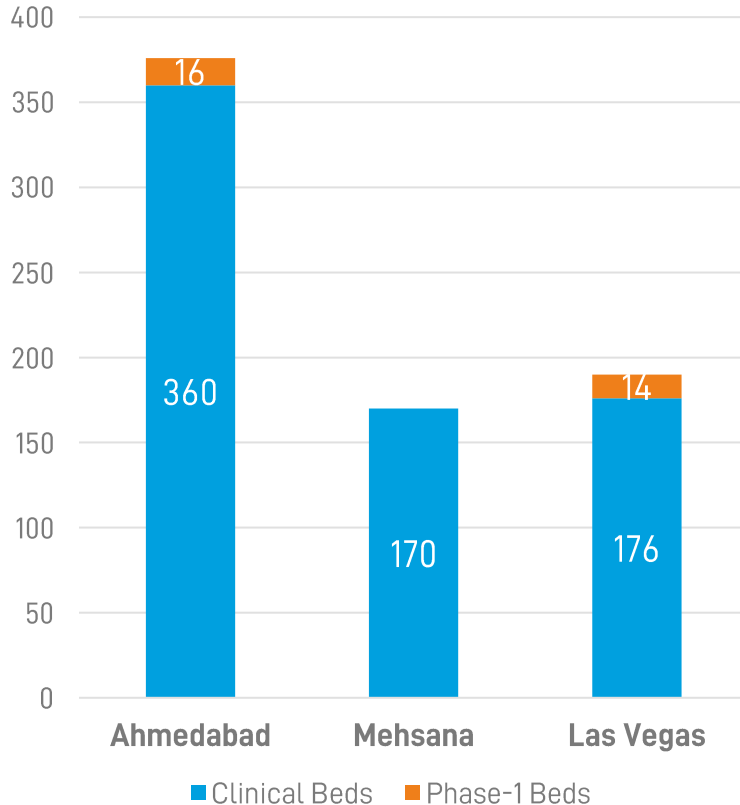


Early Development & Innovation

Navigate the complex landscape of early-stage drug development

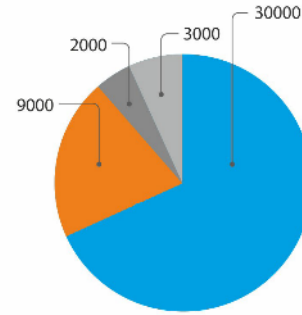
Global Bed Capacity & Volunteer Database

700+ Beds Globally

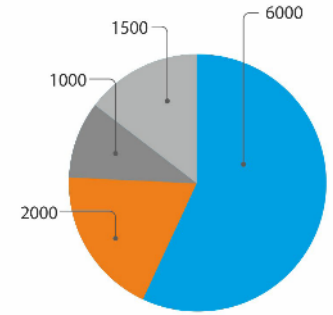


Volunteer Database

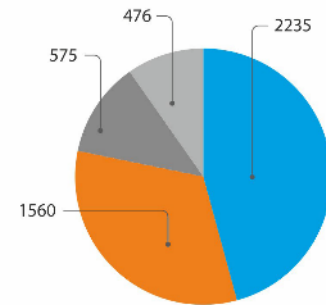
LAMBDA - AHMEDABAD



LAMBDA - MEHSANA



NOVUM - USA



HEALTHY MALE HEALTHY FEMALES PM & SURGICALLY STERILE WOMEN ELDERLY

Phase-1 Studies

Executed over

40

Phase-I Studies

- ✓ Single / Multiple Ascending Dose (SAD/MAD)
- ✓ First-in-human (FIH)
- ✓ Biosimilars
- ✓ Drug-Drug Interaction
- ✓ Food-Drug Interaction
- ✓ Drug-Device Combinations
- ✓ PK-PD
- ✓ Proof-of-Concept
- ✓ Food effect studies
- ✓ Cardiac Safety studies
- ✓ Inhalation studies
- ✓ Dermatology Studies
- ✓ Human Factor Studies

CPUs in
Ahmedabad (India)
& Las Vegas (USA)

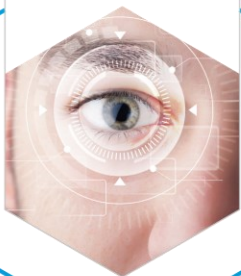


7500+ Studies with diverse formulation experience



PK/PD Studies

First in the Industry to Implement IRIS registration facility



Experience of conducting 7500+ PK/PD studies



24/7 Medical coverage



Advanced ICU facilities



Negative pressure inhalation chambers



Real-time data capture



Controlled substance studies



Safety & Bioanalytical lab with Sample Management System



Mixed population studies





**Over The Counter
(OTC) Products**



**Hair Re-growth
Products**



**Skin & Personal
Hygiene products**



**De-Addiction
Products**



**Multivitamins &
Nutritional
supplements**



**Fortified Food
Products**

Edible Oil, Flours, Fruit Extracts,
Milk products, Rice extracts

132 Total Study
experience

9 Nutraceutical
Products

82 Oral Care
Products

41 Skin & Personal
Hygiene Products















Phase II-IV Clinical Trials

Vast Therapeutic Expertise, Global Reach, and Seamless Execution

Experience the Lambda Advantage



Late Phase Clinical Studies

	Therapeutic Area	Studies	Patients
	Dermatology	105	40916
	Oncology	66	5151
	Neuroscience	30	4184
	Pulmonology	21	18116
	Musculoskeletal	15	6490
	Women's Health	15	5661
	Gastroenterology	7	1874
	Infectious Disease	7	2139
	Ophthalmology	5	1768
	Cardiology	5	452
	Nephrology	2	351
	Diabetology	2	120



280+
Multi-Centric Studies

85000+
Patients

3000+
Sites

Extensive Experience in
Oncology & Dermatology

Proven Expertise in
Biosimilars

Patient-based PK Studies

Indication/ Therapy	Studies	Patients	Sites
Schizophrenia and/or Bipolar I Disorder	12	1529	123
Ovarian Cancer	10	570	136
Metastatic Breast Cancer & Colorectal Cancer	05	199	34
Metastatic Breast Cancer (MBC)	04	170	44
Malignant Gliomas	04	124	45
Chronic Myeloid Leukemia	02	68	19
Pancreatic Cancer-	02	96	14
Hypertension	01	16	03
Type 2 Diabetes Mellitus	01	60	05
Idiopathic Thrombocytopenic Purpura (ITP)	01	20	06
Rheumatoid Arthritis / Psoriasis	01	42	03



40+
Studies

3000+
Patients

425+
Sites

Global Site Network | Investigator Sites





Labs - Central Clinical Lab, Bioanalytical & Biosimilars

Experience Laboratory Excellence with Lambda – Where Precision Meets Innovation

Comprehensive Services for all phases of Clinical Trial Testing

- Biomarkers
- Assay Development
- Safety Testing
- Hematology
- Cytology
- Biochemistry
- Immunology & Serology
- Molecular Biology
- Microbiology
- Coagulation study

Over **25** validated
Biomarkers

Validated **LIMS**
System

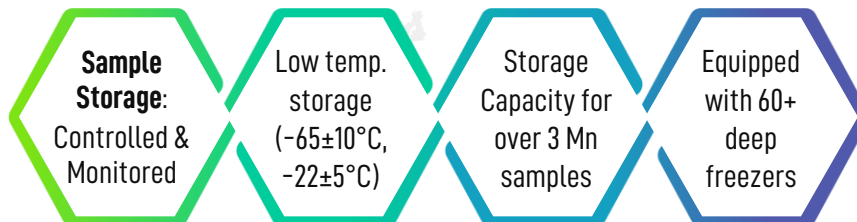
Pan-India capabilities for
seamless **Sample Logistics**

Microbiological testing for
Healthcare **Hygiene products**



1400+ Validated Bioanalytical Assays

- **GLP Certified** Lab with **Automated** Sample Inventory Management System and Liquid Handling System.
- Capacity to analyze **1,10,000+ Samples** per month.
- Specializing in method development, method validation and study sample analysis of complex molecules.
- Expertise in NCE molecules having quick turnaround time and pre-clinical studies having extremely low matrix volume.
- Expertise in molecules like Colesevelam, Sucralfate, and others requiring in-vitro studies for Bioequivalence.
- Fat estimation in fecal and food samples using FT-IR platform.
- TAT < 10 days for 8000+ samples in support of 505(b)(2)/F2F studies dossier filings.



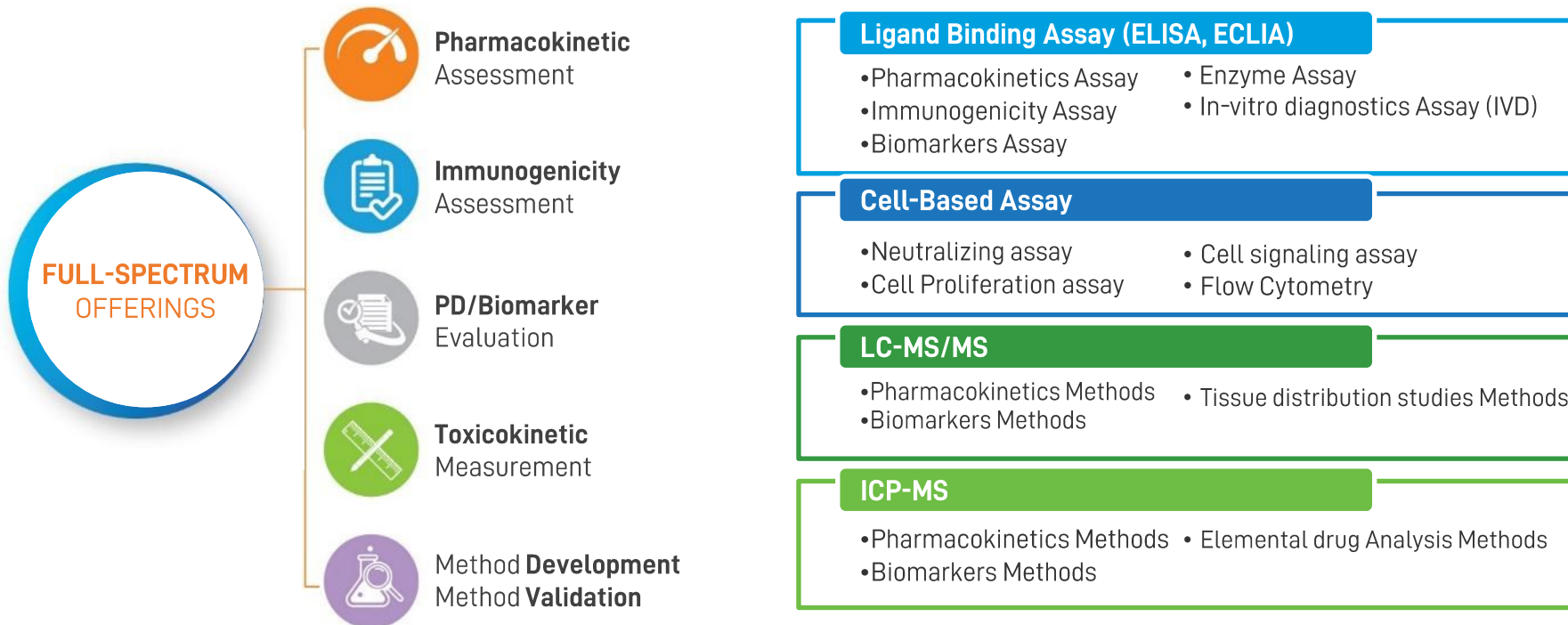
Extensive experience in MD/MV for generic, complex & NCE molecules

- Ultra-trace detection assay
- Endogenous assay
- Protein-bound & unbound assay
- Conjugated & unconjugated assay
- Liposomal-encapsulated & un-encapsulated assay
- Vitamin product assay
- Fat analysis in food and feces
- Light-sensitive assay
- Chiral assay
- Hormonal product assay
- Assay for highly unstable molecules
- Biphosphonate assay

	LC-MS/MS	FTIR	LHS	ICP-MS
Lambda	42	03	04	01
Novum	14	-	-	-

8-10 New method development per month

Biosimilars & Large Molecule Analysis



Biosimilars & Large Molecule Services



Molecule	Methods
Denosumab	PK Immunogenicity (ADA and NAb), Biomarkers (P1NP, CTx, NTx)
Pertuzumab	PK, Immunogenicity (ADA and NAb)
Vedolizumab	Immunogenicity (ADA)
Trastuzumab emtansine (T-DM1)	Immunogenicity (ADA)
Trastuzumab (IV and SC)	PK, Immunogenicity (ADA and NAb)
Ranibizumab	PK, Immunogenicity (ADA and NAb)
Pegfilgrastim	PK, Biomarkers (ANC), Immunogenicity(ADA and NAb)
Teriparatide	PK, Biomarkers (serum Calcium), Immunogenicity (ADA and NAb)
Filgrastim	PK, Biomarkers (CD34+), Immunogenicity (ADA and NAb)
Bevacizumab	PK, Immunogenicity (ADA and NAb)
r-hFSH	PK, Biomarkers (β – Estradiol), Immunogenicity (ADA)
Adalimumab	PK, Immunogenicity (ADA and NAb)
Romiplostim	PK, Immunogenicity (ADA)
Enoxaparin	Biomarkers (Anti Factor Xa, Anti Factor IIa, TFPI)
Rituximab	PK, Biomarkers (CD 19), Immunogenicity (ADA)

A blue-tinted photograph of a medical team in a control room. Two large monitors at the top show chest and skull X-rays. A hand on the right points at the skull X-ray. A tablet in the center also displays a skull X-ray. The scene is overlaid with a semi-transparent blue filter.

Medical Imaging

Centralized imaging services to provide high quality data to support key clinical endpoints

- Panel of Board-certified Radiologists
- Centralized Reading and Reporting
- Automated & paperless processes.
- 21 CFR Part 11 Compliant Digital Solutions
- Specializes in a wide range of imaging modalities:
OCT, FA, CFP, DXA, CT, PET scan, MRI
- **DiSoft (Diagnostic Imaging Software)**, a customized web-based global imaging application, which enables the secure uploading, analysis, and storage of images for the evaluation of clinical trial endpoints.

Worked with **600+ clinical sites** for imaging,
5000+ Images Reviewed

Extensive Capabilities:



Oncology



Musculoskeletal



Ophthalmology

Future Expansion Planning:

- iRECIST evaluation method
- Gastrointestinal (GI) imaging
- PCWG3 evaluation method

A hand in a white glove points towards a large, semi-transparent circular data visualization. The visualization consists of a central hub with several smaller circular nodes connected by thin lines. Each node contains a different icon: a brain with a Wi-Fi signal, a computer monitor with a double-headed arrow, three interlocking gears, a microchip with a checkmark, a bar chart with an upward arrow, and a flowchart with arrows. The background is a solid blue color with a faint, larger-scale version of the same circular data visualization pattern.

Biostatistics & Data Management

Ensuring High Data Quality, Integrity & Accurate Results

- End-to-end Data Management services
- Quick & expandable DM resource model
- 21 CFR compliant in-house EDC systems
- CDASH (SEND) & CDISC (SDTM & ADaM) standards
- Visual Data Analytics
- Study design, sample size estimation
- Randomisation Generation & Management
- SAP, TLFs, SAR development
- PK/PD & Immunogenicity Data Analysis
- Population PK modelling & reporting

Close-knit team of Data Managers, Programmers and Biostatisticians



A hand holding several white, oval-shaped pills. A large, semi-transparent checkmark icon is overlaid on the hand. The background is a blurred pharmacy shelf with various medicine bottles. A network of white dots and lines is overlaid on the image, suggesting a digital or data-driven theme.

Clinical Safety & Pharmacovigilance

Empowering drug safety through end-to-end pharmacovigilance services

Clinical Safety & Pharmacovigilance

Experience & expertise in major Therapeutic Areas & Products

- **Drugs**
- **Vaccines**
- **Medical Devices**
- **Biologics & Biosimilars**
- **Combination Products**
- **Advanced therapy medicinal products**



Clinical Safety & Pharmacovigilance

Operational Services

- ICSR Case Processing & Electronic Submissions of ICSRs
- Aggregate Reports (ARs) & Risk Management Plan (RMP / REMS)
- Literature Monitoring
- Signal Detection, Evaluation, & Management
- xEVMPD Compliance Solution & Services

PV Systems

- QPPV Services in UK & EU
- LRPVs across Europe
- Global Safety Database (PvEDGE)
- Smart EV Triage Solution (PvDcode)

Support Services

- PV consulting & Training
- PV Gap Analysis
- Quality Management System
- Global Compliance Monitoring
- Audits and Inspections Management

Year **2023** at a Glance

571,586

Literature Screening

89669

Cases

747

Aggregate Reports

165

RMP

1470

Signal Management Reports





Medical & Scientific Writing

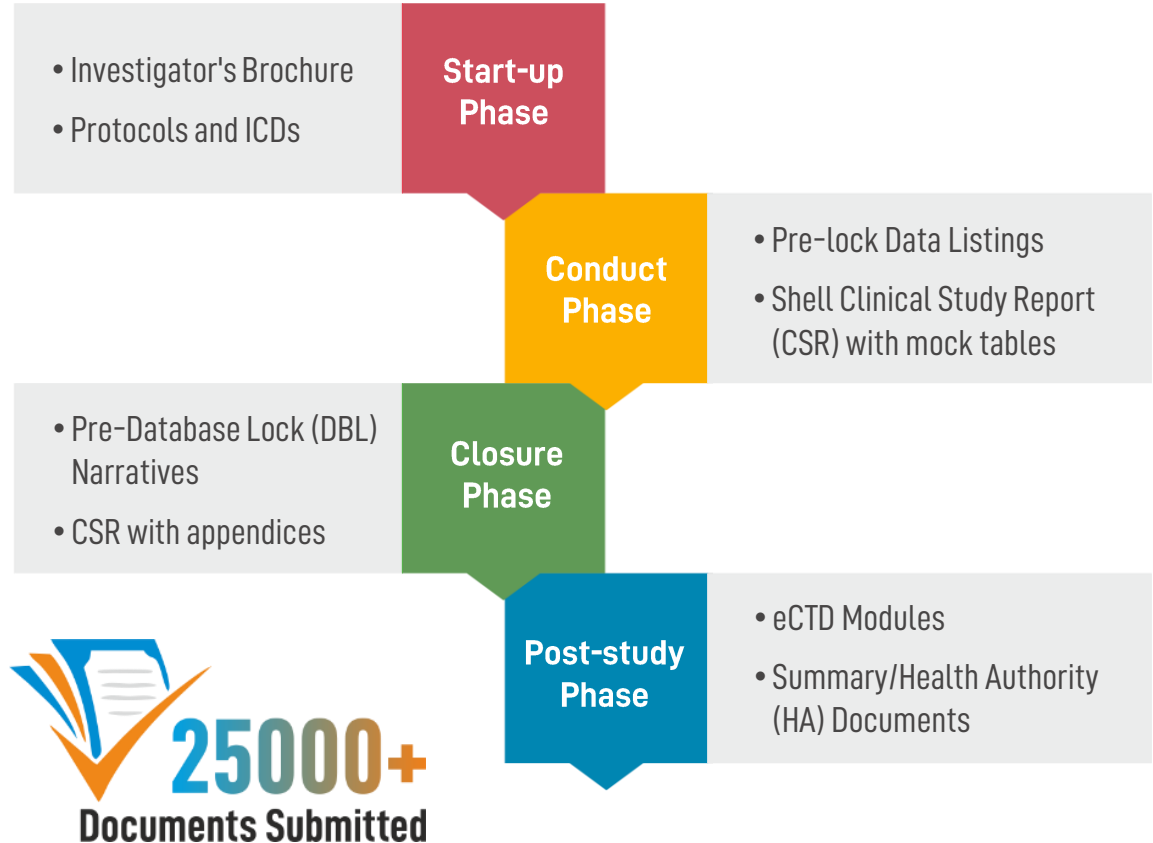
Fully-integrated Solutions with expertise in diverse therapeutic areas.

Medical & Scientific Writing

Support for Diverse Document Types:

- **Clinical Study Protocols**
- **Clinical Study Reports (CSR)**
- **Investigator's Brochure (IB)**
- **Regulatory Documents**
- **Drug Safety & Risk Management**
 - Aggregate reports (DSUR/PBRER/PSUR/PADER/SUSAR LL)
 - Risk management plans (EU/Core)

Expertise in **eCTD** submissions package for **USFDA, EMA, DCGI, TGA, ANVISA, HC** etc.

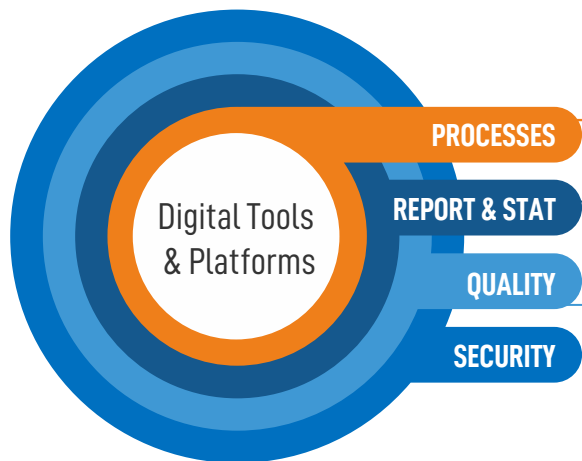


A hand is shown holding a glowing digital interface. The interface consists of a central circular node with a circular arrow icon, from which numerous lines radiate outwards to various icons representing different technologies and concepts. These icons include a document, a bar chart, a magnifying glass, a location pin, a double-headed arrow, a gear, a server rack, a laptop, a Wi-Fi symbol, a globe, a cloud, a microchip, a signal tower, a bar chart with a line, a document with a checkmark, and another gear. The background is a blurred image of a person's hand holding a tablet, overlaid with a blue tint and a network of white lines and dots.

Technologies

Innovating for Clinical Excellence

Digital Infrastructure & Automation



- Clinical Trial Management System (CTMS)
- Patient Data Management System (PDMS)
- Interactive Web Response System (IWRS)
- Clinical Trial Supply Management (IMPTrack-WHS)
- Medical Imaging Software (Di-Soft)
- Electronic IRB (EC Approval)
- Sample Information Management System (SIMS)

PROCESSES

- EDC – BizNet, Medidata, TrialMaster
- Electronic Lab Notebook platform (ELN)
- Comprehensive Bioanalytical Solutions (BioLyte)
- Laboratory Information Management System (LIMS)
- Pharmacy Supply Management (IMPTrack)
- PV & Drug Safety Database (PvEdge)
- Medical Information Management (PrITR)

REPORT & STAT

- eTMF
- Realtime Monitoring Dashboards

- SAS
- Phoenix WinNonlin

QUALITY

- Quality Management System (QMS)
- Training Management System (TMS)
- Secure eSignature Solution (DocStack)

- Document Management System
- HRMS – SAP SuccessFactors
- Data Archival Solution (StackTrack)

SECURITY

- Multi-factor authentication (MFA)
- Vulnerability Assessment & Penetration Testing
- Extended Detection and Response (XDR)
- Backups/Disaster Recovery

- Firewalls
- Encryptions
- Secured VPNs



Services

- Global Footprint
- World-class Infrastructure
- One-stop solution for your drug development journey
- Hub & Spoke, flexible business model
- Strong financials offering stability and flexibility for upscaling



People

- Team of Industry-leading domain experts
- Experience in conducting 7500+ PK studies
- 280+ multicentric studies
- Flexible, amiable, and adaptable culture fostered by 1200+ Professionals



Quality

- Proven Regulatory Track Record
- QMS-backed Strong Governance Structure
- "Quality by Design"-driven decision making
- GDPR Compliance
- Transparency at each step

Let's Connect



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