
LAMBDA
Research Accelerated
Novum
PHARMACEUTICAL RESEARCH SERVICES
A Full-service Global CRO
India | USA | Canada | UK | Poland

Comprehensive End-to-End Services

Awards & Accolades

Global Presence

Impeccable Regulatory Track Record

Lambda

- 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

Novum

- U.S. FOOD & DRUG ADMINISTRATION
- MHRA
- Health Canada
- AGES

Research Accelerated

- Multicontinental presence
- End-to-end clinical research services
- 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

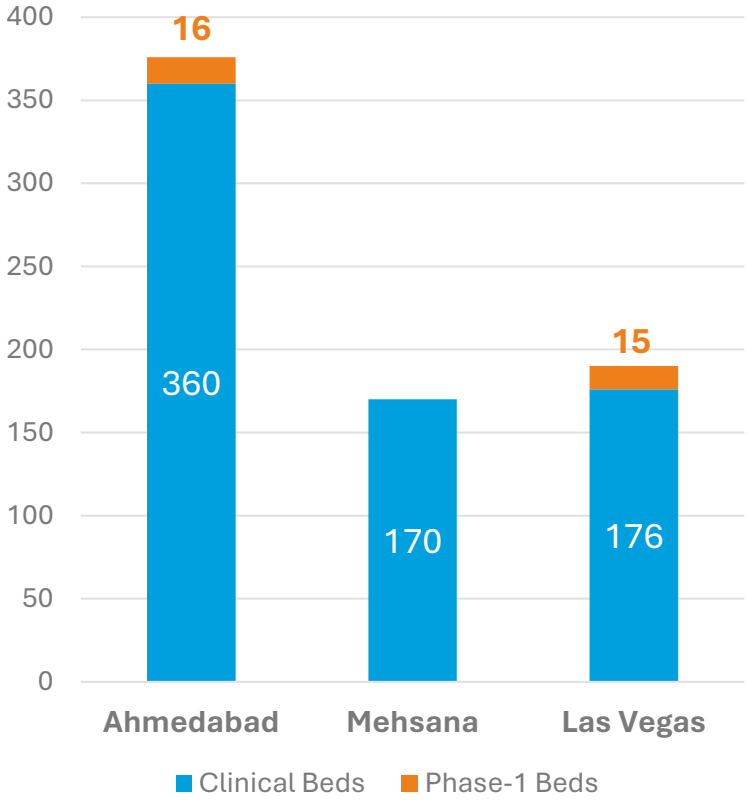
- Impeccable regulatory track record
- Independent Quality Assurance
- Stringent GXP Compliance

Early Development & Innovation

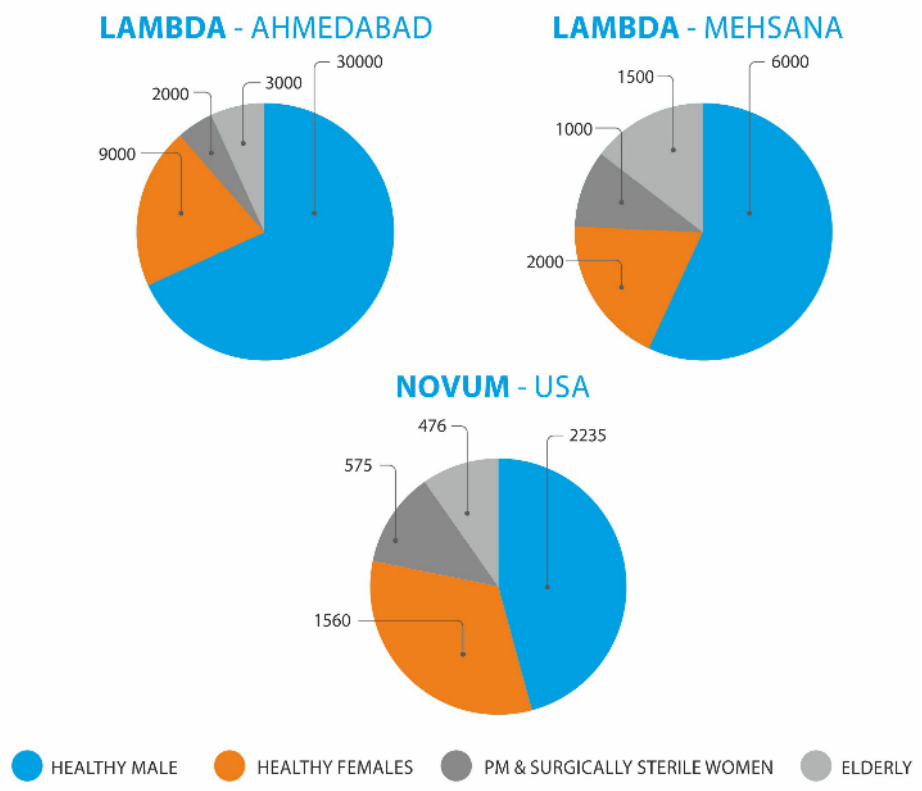
Navigate the complex landscape of early-stage drug development

Global Bed Capacity & Volunteer Database

700+ Beds Globally



Volunteer Database



Phase-1 Studies

Extensive Capabilities

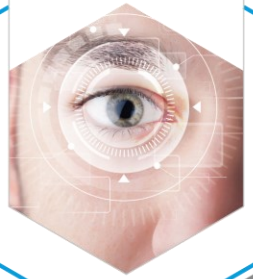
- ✓ Single / Multiple Ascending Dose (SAD/MAD)
- ✓ First-in-human (FIH)
- ✓ Biosimilars
- ✓ Drug-Drug Interaction
- ✓ Food-Drug Interaction
- ✓ Drug-Device Combinations
- ✓ PK-PD Proof-of-Concept
- ✓ Food effect studies
- ✓ Cardiac Safety studies
- ✓ Inhalation studies
- ✓ Dermatology Studies
- ✓ Human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

PK/PD Studies

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

Nutraceuticals & Consumer Products Studies

Over The Counter (OTC) Products

Skin & Personal Hygiene products

Multivitamins & Nutritional supplements

Hair Re-growth Products

De-Addiction Products

Fortified Food Products

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

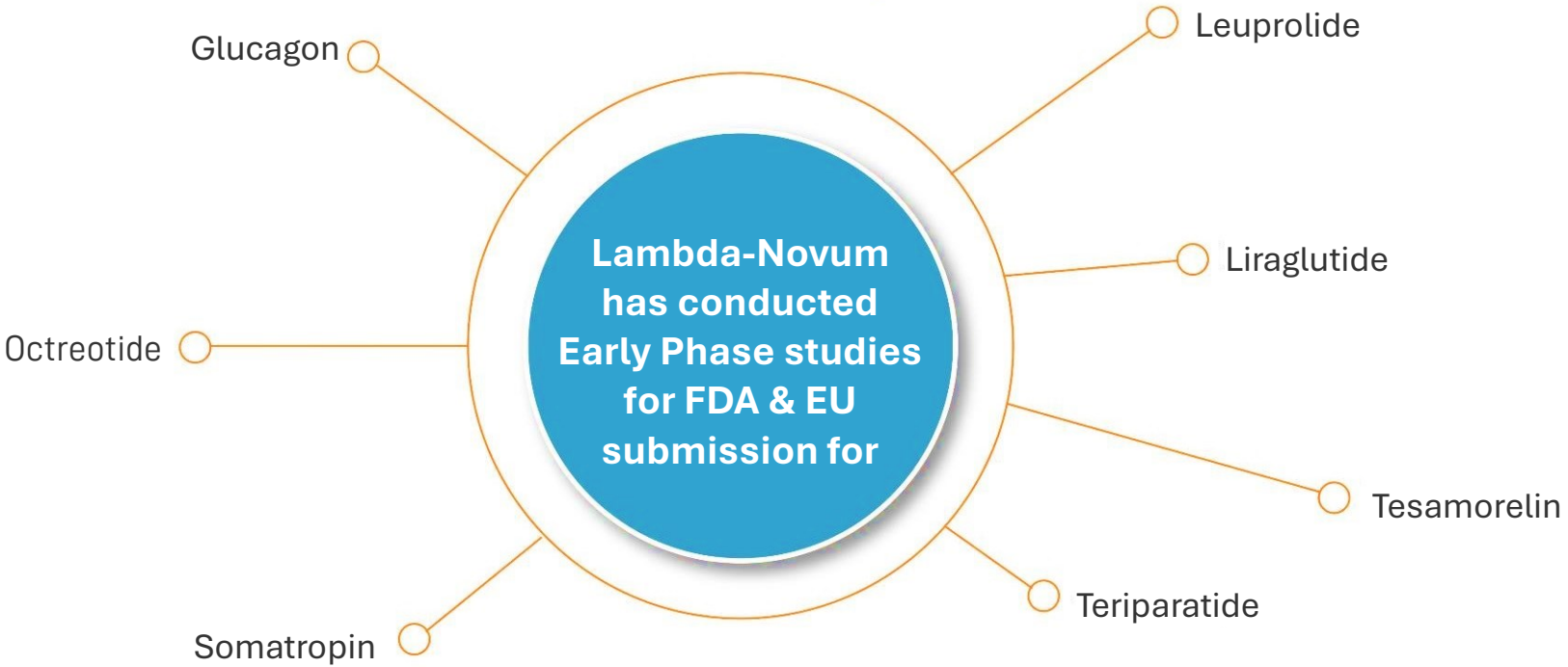
132 Total Study experience

9 Nutraceutical Products

82 Oral Care Products

41 Skin & Personal Hygiene Products

Proteins and Peptides Experience



Controlled Substances Experience

Extensive Experience in conducting Controlled substance studies

- Qualified by FDA to conduct Schedule II - V products
- Vast experience with products requiring a DEA 222 form
- Extensive opioid experience for products that require the co-administration of naltrexone

New Chemical Entity Experience

Vast Experience in conducting studies for NCEs

- Extensive experience in SAD/MAD studies.
- Experience Encompasses Small Molecules & Large Molecules for Pharma and Biotech Clients
- Scientific Expertise & Operational Expertise: Collaborative Environment (Partnership) for Successful Study Conduct:

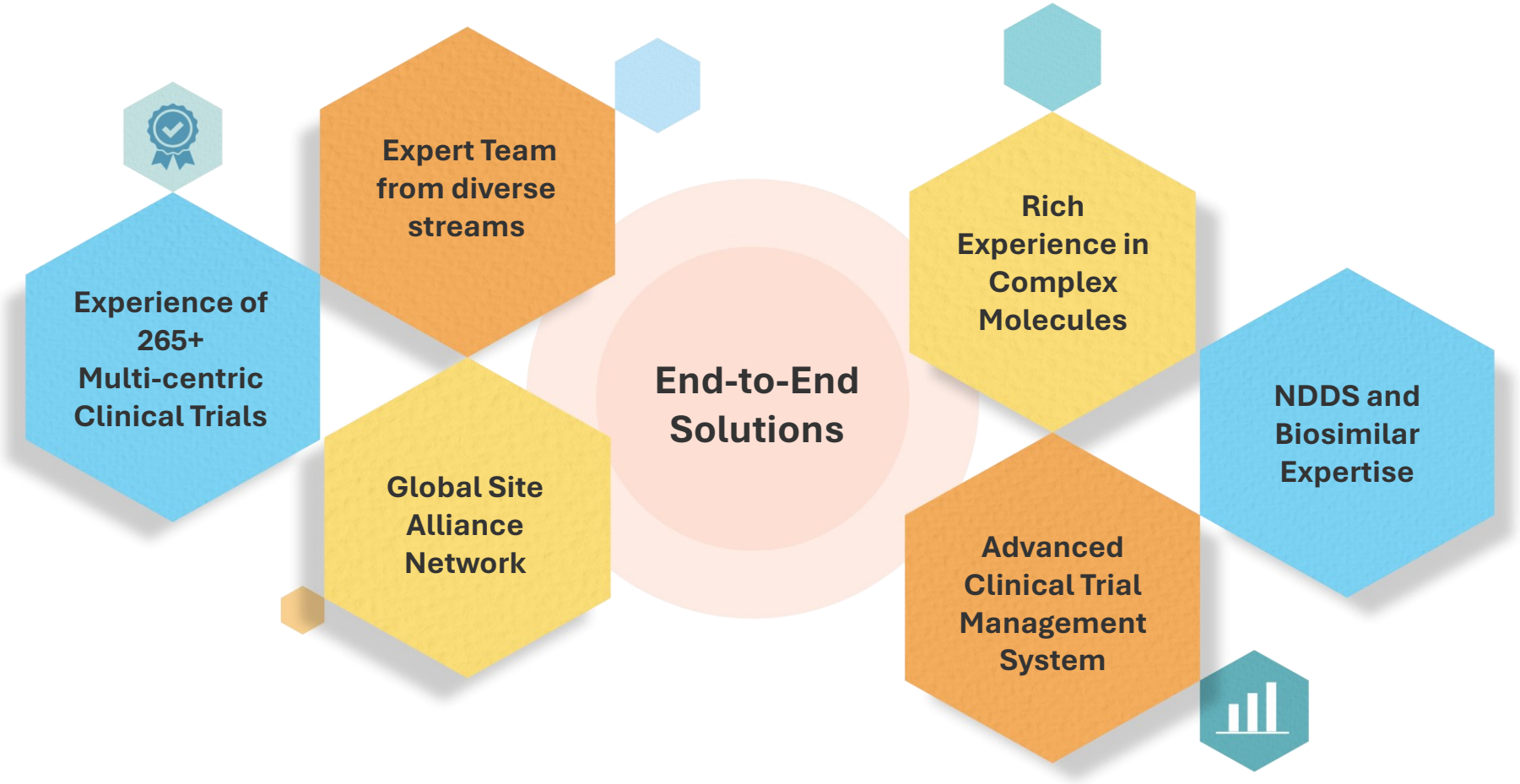
Pharmacodynamic Staff Training

- Adhesion Scoring
- C-SSRS
- Dermal Response Scoring
- Intense Blood Pressure Monitoring
- Intense ECG Measurements
- Standard 12-lead, Holter Monitors and Telemetry
- Ophthalmology Testing
- Skin Biopsies
- Symptom Score Questionnaires
- Taste / Palatability / Dose Acceptance
- Visual Analog Score

Phase II-IV Clinical Trials

Vast Therapeutic Expertise, Global Reach, and Seamless Execution

Experience the Lambda Advantage



Late Phase Clinical Studies

Therapeutic Areas	Studies	Patients
Dermatology	105	41695
Oncology	67	5128
Neuropsychiatry	23	4332
Pulmonology	19	17212
Women's Health	15	5516
Musculoskeletal	12	4721
Gastroenterology	7	1861
Infectious Diseases	7	2156
Metabolic Disorders	6	660
Ophthalmology	4	758
Cardiology	2	224
General Medicine	1	369

268
Multi-centric Studies

3000+
Sites

80000+
Patients Enrolled

Extensive Experience in
Oncology & **Dermatology**

Proven Expertise in
Biosimilars

Patient-based PK Studies

Indications / Therapy	Studies	Patients
Schizophrenia	13	1775
Ovarian Cancer	9	490
Metastatic Breast Cancer and Colorectal Cancer	4	167
Breast Cancer, Advanced Breast Cancer, Metastatic Breast Cancer	4	170
Solid Tumor, Advanced solid malignancies	3	68
Advanced Ovarian Cancer or Metastatic Breast Cancer	2	144
Pancreatic or Ovarian Cancer	2	110
Chronic Refractory Immune (Idiopathic) Thrombocytopenic Purpura	2	32
Iron Deficiency Anemia	2	150
Rheumatoid Arthritis / Psoriasis, Knee Osteoarthritis	2	86
Acute Myeloid Leukemia in Remission Phase	1	60
Chronic Myeloid Leukemia	1	26
Malignant Gliomas	1	14
Philadelphia chromosome positive Chronic Myeloid Leukemia	1	42
Glioblastoma Multiforme or Anaplastic Astrocytoma	1	40
Breast cancer or Colorectal Cancer	1	39
Moderate to Severe Atopic Dermatitis	1	72

50
Studies

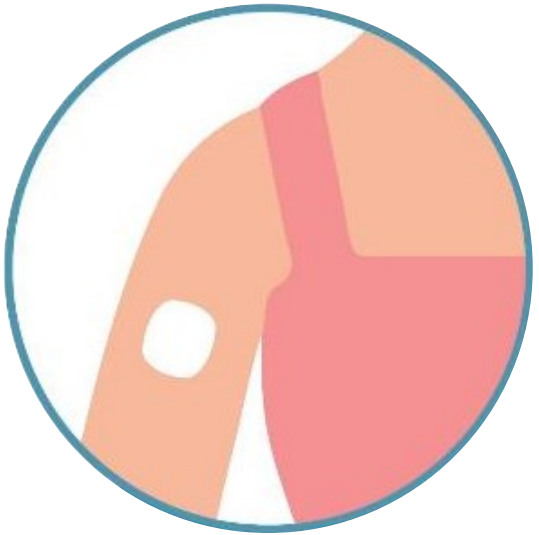
480
Sites

3485
Patients

Transdermal Experience

Over 200 transdermal patch studies

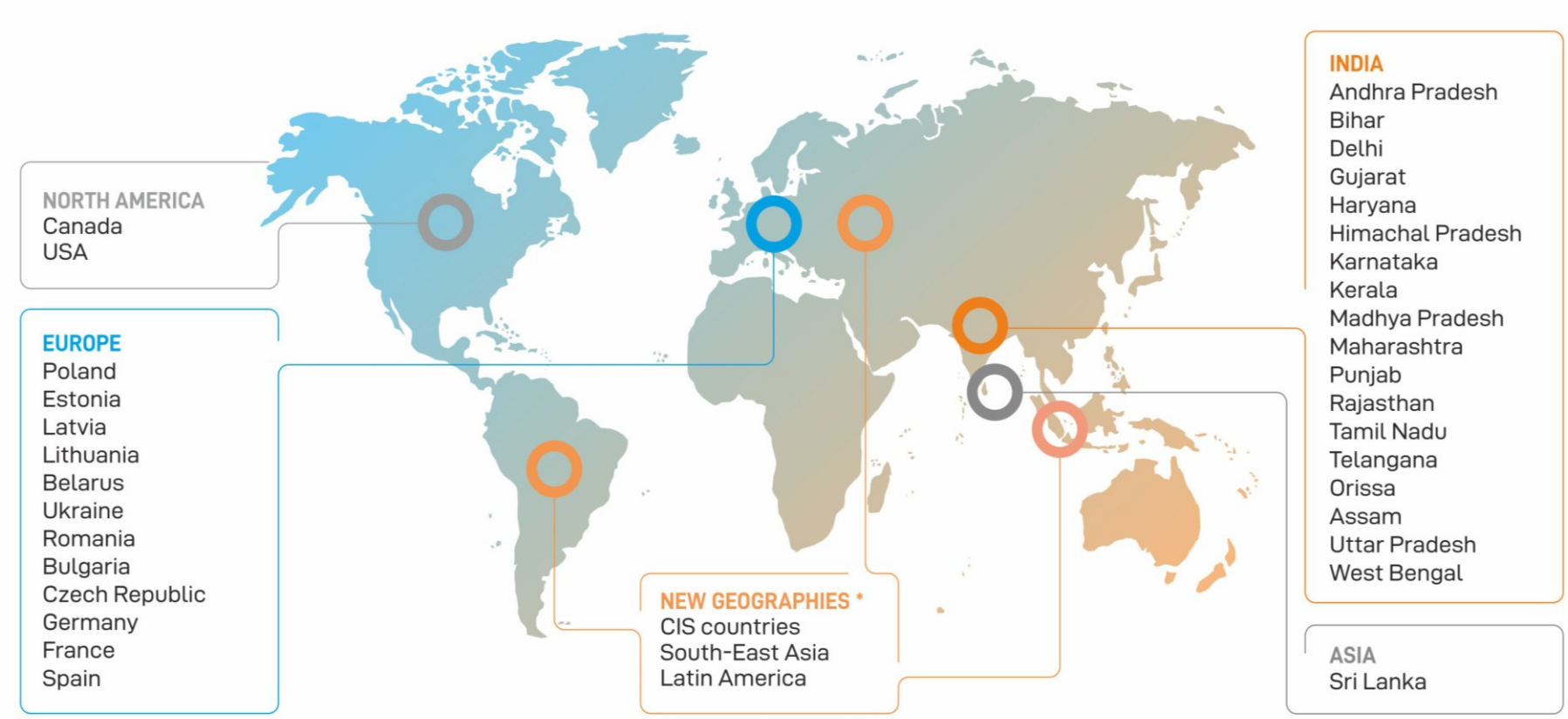
- PK, Adhesion, and Irritation/Sensitization
- ANDA and NDA applications
- Strong training and validation program
- Complex statistical analysis
- All pivotal studies include cross-rater and cross-site validation as part of the study and reporting



Nasal/Inhalation Experience

- Negative Pressure Dosing Chamber in Las Vegas clinic: Specifically designed to prevent cross-contamination on MDI, DPI, and Nasal Spray Studies.
  - Minimizes the potential for small air-borne drug particle cross-contamination.
  - All PK samples are collected/subjects are housed in separate areas from dosing and sample processing.
  - All PK samples are processed in a separate lab away from subjects and the dosing chamber.
- Experience in evaluating prototype (novel) actuators and prototype breath actuators.
- SOPs developed specifically for Orally Inhaled and Nasal Spray studies to help prevent cross-contamination of airborne particles.
- Respiratory therapist on-site for screening and dosing, upon request.
- Complex statistical analysis for in vitro population BE studies.

Global Site Network | Investigator Sites



Labs - Central Clinical Lab, Bioanalytical & Biosimilars

Experience Laboratory Excellence with Lambda – Where Precision Meets Innovation

Central Clinical Lab

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**
- **Pan-India** capabilities for seamless **Sample Logistics**
- Validated **LIMS** System
- **Microbiological testing** for Healthcare **Hygiene products**

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

NABL

Bioanalytical

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.

Sample Storage: Controlled & Monitored

Low temp. storage (-65±10°C, -22±5°C)

Storage Capacity for over 3 Mn samples

Equipped with 60+ deep freezers

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	**39**	03	04	01
Novum	**14**	-	-	-

8-10 New method development per month

Biosimilars & Large Molecule Analysis

LAMBDA Research Accelerated | Novum Pharmaceutical Research Services

FULL-SPECTRUM OFFERINGS

- **Pharmacokinetic** Assessment
- **Immunogenicity** Assessment
- **PD/Biomarker** Evaluation
- **Toxicokinetic** Measurement
- Method **Development**
  Method **Validation**
- **Quick turnaround** Bioanalysis

Ligand Binding Assay (ELISA, ECLIA)

- Pharmacokinetics Assay
- Immunogenicity Assay
- Biomarkers Assay
- Enzyme Assay
- In-vitro diagnostics Assay (IVD)

Cell-Based Assay

- Neutralizing assay
- Cell Proliferation assay
- Cell signaling assay
- Flow Cytometry

LC-MS/MS

- Pharmacokinetics Methods
- Biomarkers Methods
- Tissue distribution studies Methods

ICP-MS

- Pharmacokinetics Methods
- Biomarkers Methods
- Elemental drug Analysis Methods

OECD GLP Certified

Excellence Validated

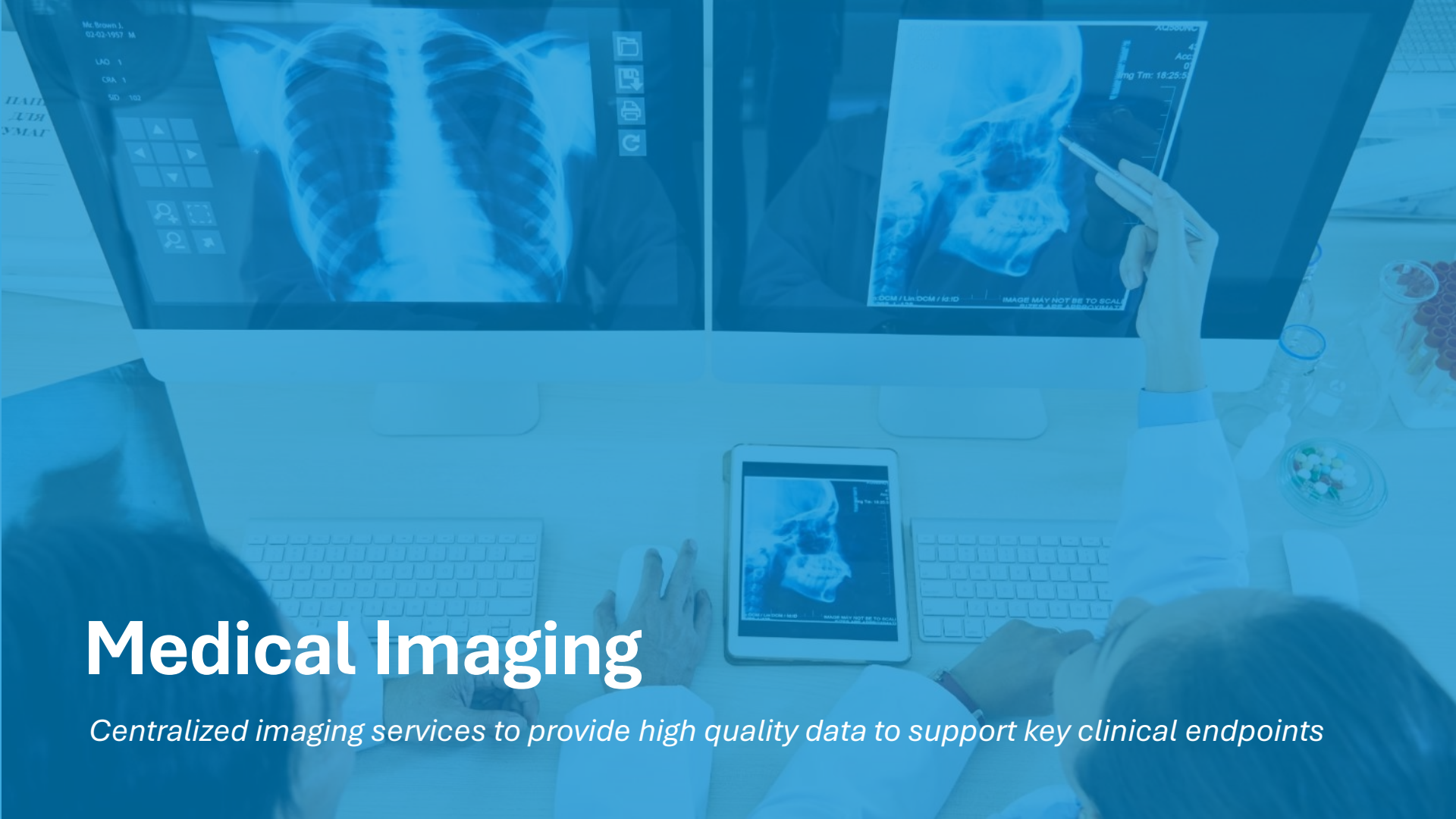
Successfully cleared **MHRA** & **FDA** Inspections for Biosimilar Studies.

FDA U.S. FOOD & DRUG ADMINISTRATION

MHRA Regulating Medicines and Medical Devices

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)



Medical Imaging

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

Medical Imaging

- 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

Biostatistics & Data Management

Ensuring High Data Quality, Integrity & Accurate Results

Biostatistics & Data Management

- 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

Clinical Safety & Pharmacovigilance

Empowering drug safety through end-to-end pharmacovigilance services

Clinical Safety & Pharmacovigilance

Experience & expertise in major Therapeutic Areas & Products

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

Offices in UK (Harrow), Warsaw (Poland), India(Ahmedabad) & Canada (Toronto)

Cost-effective, customizable, user-friendly, regulatory-compliant Safety database

Expert team of Physicians, Pharmacists, and PV Specialists with broad therapeutic expertise (400+ active molecules.)

Successfully underwent 30+ regulatory Inspections of PV Functionality.

U.S. FOOD & DRUG ADMINISTRATION | AIFA | MHRA | Health Canada | Ministerstwo Zdrowia

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	89669	747	165	1470
Literature Screening	Cases	Aggregate Reports	RMP	Signal Management Reports

Medical & Scientific Writing

Fully-integrated Solutions with expertise in diverse therapeutic areas.

Medical & Scientific Writing

LAMBDA Research Accelerated | Novum Pharmaceutical Research Services

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.

Start-up Phase
- Investigator's Brochure
- Protocols and ICDs

Conduct Phase
- Pre-lock Data Listings
- Shell Clinical Study Report (CSR) with mock tables

Closure Phase
- Pre-Database Lock (DBL) Narratives
- CSR with appendices

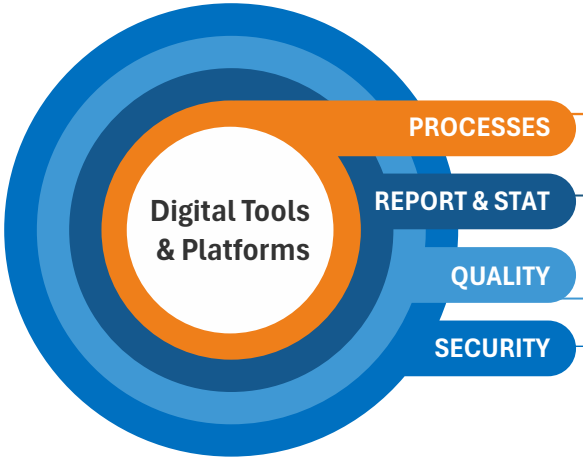
Post-study Phase
- eCTD Modules
- Summary/Health Authority (HA) Documents

25000+
Documents Submitted

Technologies

Innovating for Clinical Excellence

Digital Infrastructure & Automation



- Clinical Trial Management System (CTMS)
- Protocol Deviation 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)

- 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)

- eTMF
- Realtime Monitoring Dashboards

- SAS
- Phoenix WinNonlin

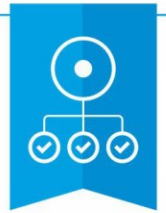
- Quality Management System (QMS)
- Training Management System (TMS)
- Secure eSignature Solution (DocStack)

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

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

- Firewalls
- Encryptions
- Secured VPNs

Value Proposition



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

Experience

- Team of Industry-leading domain experts
- Experience in conducting 7500+ PK studies
- 265+ 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

LAMBDA
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Novum
PHARMACEUTICAL RESEARCH SERVICES

Let's Connect

✉ BD@lambda-cro.com