



# Global Full-service CRO

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INDIA | USA | CANADA | UK | SPAIN | POLAND



**LAMBDA**  
Research Accelerated



**Novum**  
PHARMACEUTICAL RESEARCH SERVICES





**8,000+**  
PK/PD Studies

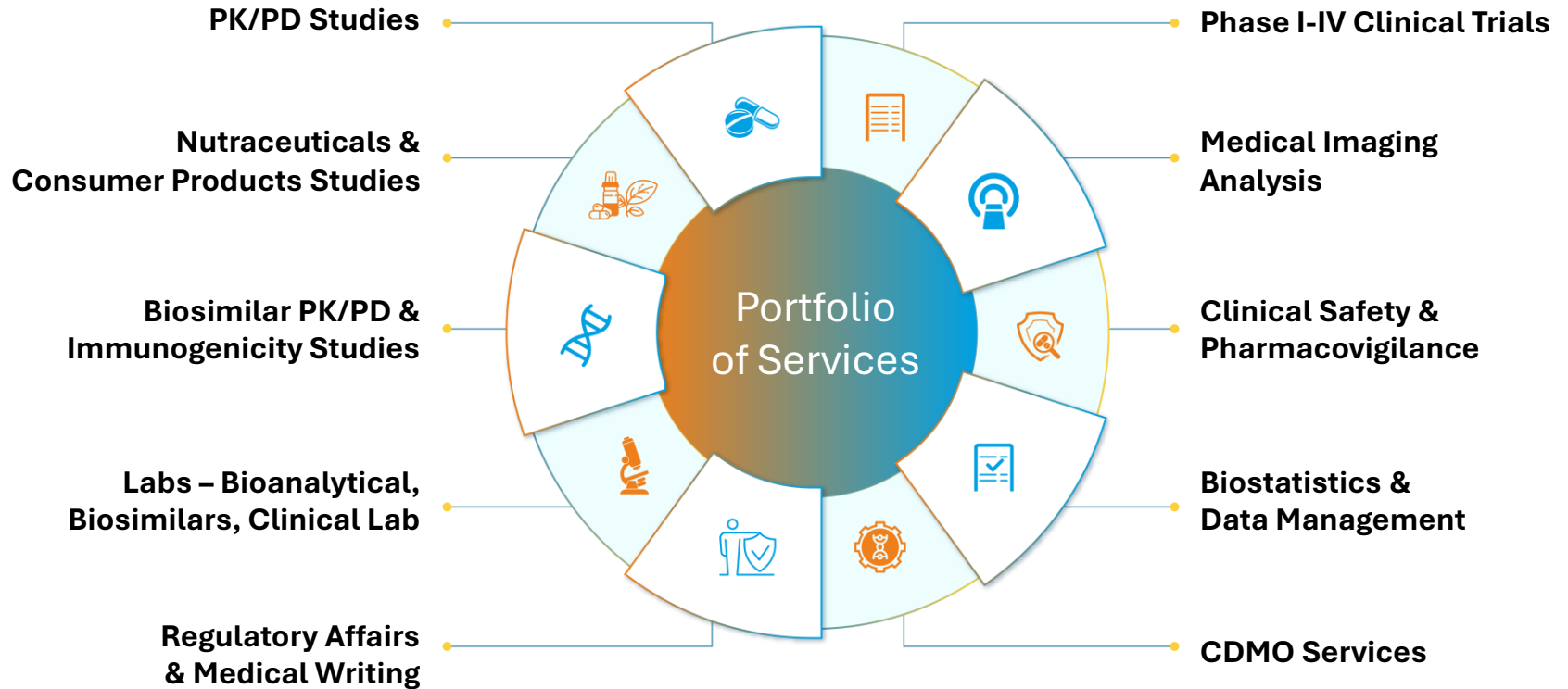
**290+**  
Late Phase Trials

**1,600+**  
Bioanalytical Methods

Lambda HQ - Ahmedabad Facility

# 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



NABL



CAP

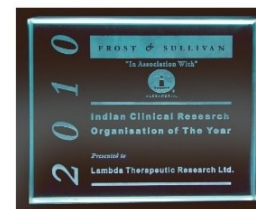
## Novum



# Recent Regulatory Inspection Success

Regulatory Agency	Month-Year of Inspection	Facility	Scope BA/BE
 <b>MHRA</b> Regulating Medicines and Medical Devices	March 2025	Ahmedabad, India	Clinical & Bioanalytical
 <b>U.S. FOOD &amp; DRUG</b> ADMINISTRATION	October 2025	Mehsana, India	Clinical
	October 2025	Ahmedabad, India	Clinical

# Awards & Accolades





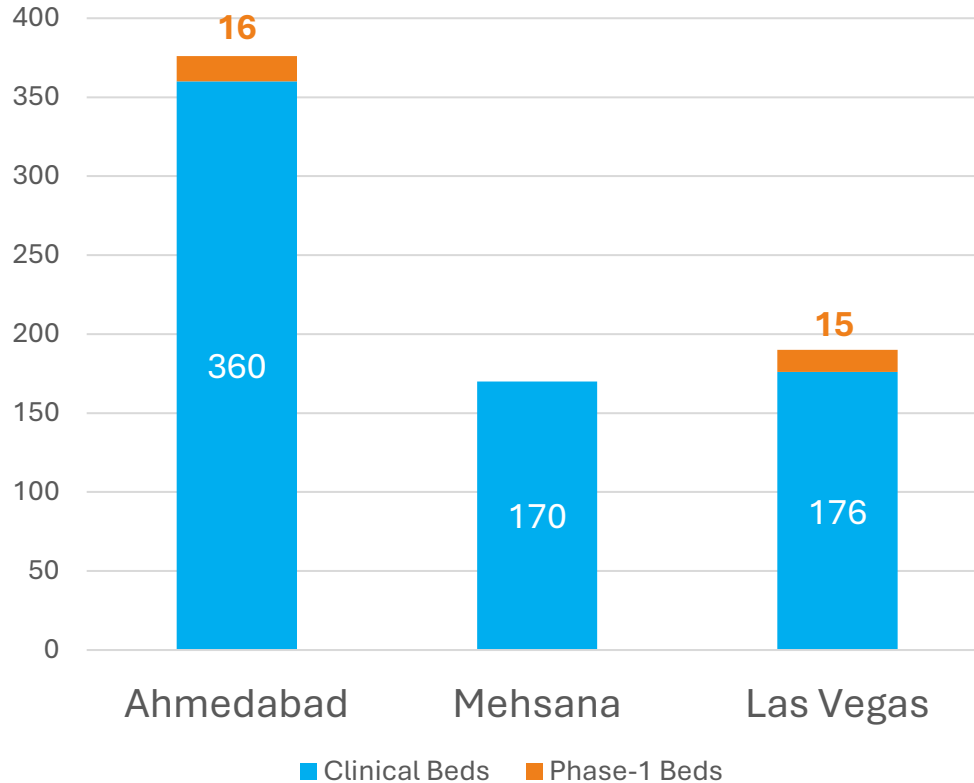


# Early Development & Innovation

*Navigate the complex landscape of early-stage drug development*

# Global Bed Capacity

700+ Beds Globally



Extensive & Diverse  
**Volunteer Database**  
Across Global Units



Healthy Volunteers  
(Males & Females)



PM & Surgically Sterile  
Females



Elderly

## Extensive Capabilities

- ✓ Single / Multiple Ascending Dose (SAD/MAD)
- ✓ First-in-human (FIH)
- ✓ Biosimilars
- ✓ Drug-Drug Interaction
- ✓ Food effect studies
- ✓ Drug-Device Combinations - e.g. studies involving AI (Autoinjector) devices, multiple-dose pen devices
- ✓ PK-PD Proof-of-Concept
- ✓ Cardiac Safety studies
- ✓ Inhalation studies
- ✓ Dermatology Studies
- ✓ Human Factor Studies
- ✓ Self-administration Studies
- ✓ Oral contrast agents
- ✓ Special population - e.g., Post-menopausal female, Japanese origin



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

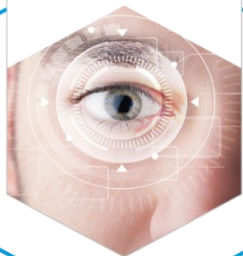
## 8,000+ Studies

with diverse formulation experience



# Advanced PK/PD Capabilities & Expertise

**First in the Industry**  
to Implement  
IRIS registration  
facility



Experience of  
conducting  
**8000+**  
PK/PD studies



**24/7**  
Medical  
coverage



Advanced  
**ICU**  
facilities



Negative  
pressure  
**inhalation**  
chambers



**Real-time**  
data capture



**Controlled**  
Substance  
studies



**Bioanalytical &**  
**Safety 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

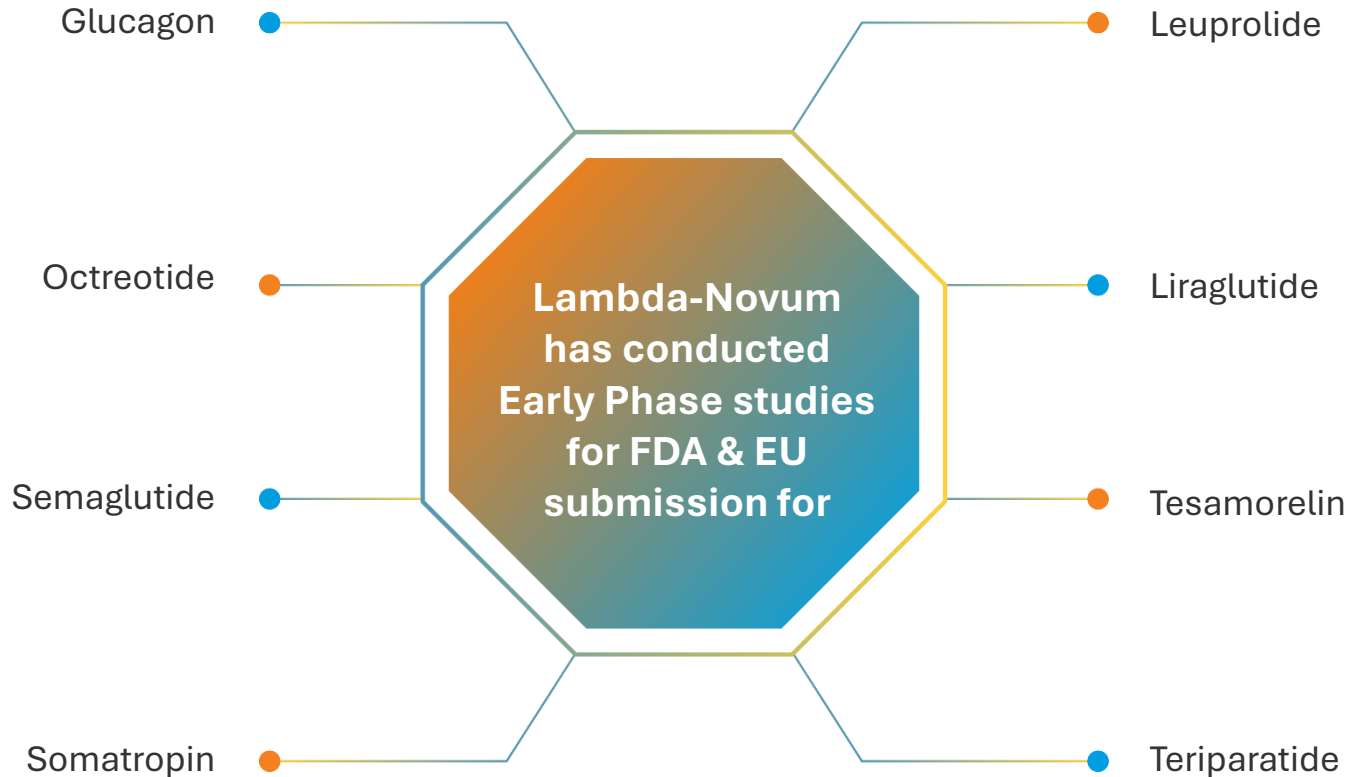
**9** Nutraceutical  
Products

**82** Oral Care  
Products

**41** Skin & Personal  
Hygiene Products



# Proteins and Peptides Experience

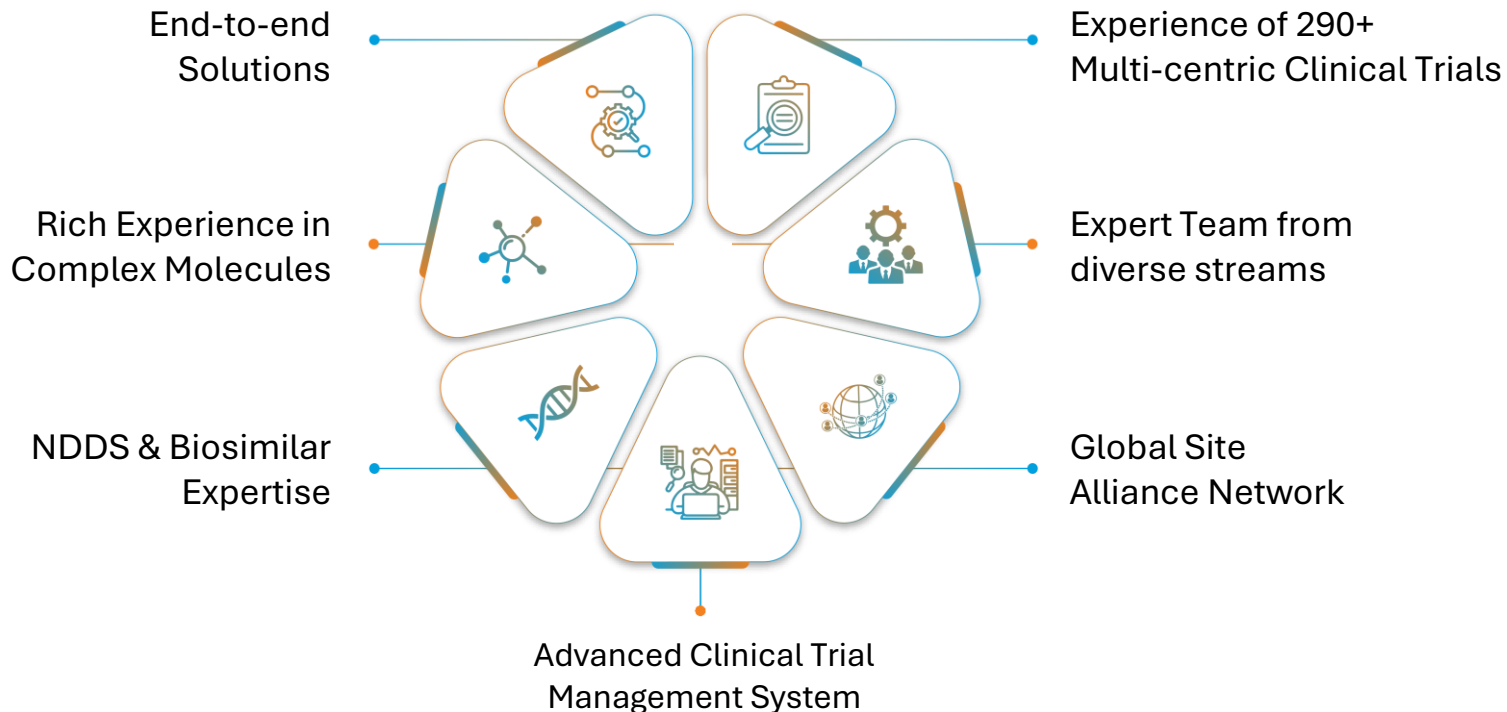
















# Phase II-IV Clinical Trials

*Vast Therapeutic Expertise, Global Reach, and Seamless Execution*

# Experience the Lambda-Novum Advantage



# Late Phase Clinical Trials

Therapeutic Areas	Studies	Patients
 Dermatology	107	42255
 Oncology & Hematology	84	8220
 Neuro-psychiatry	21	4332
 Pulmonology	21	17332
 Women's Health	15	5596
 Musculoskeletal	15	5021
 Ophthalmology	9	2295
 Gastroenterology	8	2011
 Infectious Disease	7	2156
 Endocrinology & Metabolic Disorders	5	760
 Cardiology	2	224
 General Medicine	1	369



**290+**

Multi-centric Trials

**3000+**

Sites

**90000+**

Patients Enrolled

Extensive Experience in

**Oncology & Dermatology**

Proven Expertise in

**Biosimilars**

# Patient-based PK Trials

Indications / Therapy	Studies	Patients
Schizophrenia	17	1911
Ovarian Cancer	10	548
Breast Cancer	6	650
Metastatic Breast Cancer and Colorectal Cancer	4	167
Advanced Ovarian Cancer or Metastatic Breast Cancer	3	212
Chronic Myeloid Leukemia	3	100
Iron Deficiency Anemia	3	330
Chronic Refractory Immune (Idiopathic) Thrombocytopenic Purpura	2	32
Pancreatic or Ovarian Cancer	2	110
Solid Tumor	2	36
Acute Myeloid Leukemia in Remission Phase	1	60
Advanced solid malignancies	1	32
Breast or Colorectal Cancer	1	39
Glioblastoma Multiforme or Anaplastic Astrocytoma	1	40
Hypertension	1	16
IBD & Dysmenorrhea	1	0
Malignant Gliomas	1	14
Metastatic Small Cell Lung Cancer (SCLC)	1	50
Moderate to Severe Atopic Dermatitis	1	72
Rheumatoid Arthritis / Psoriasis	1	42
Knee Osteoarthritis	1	44

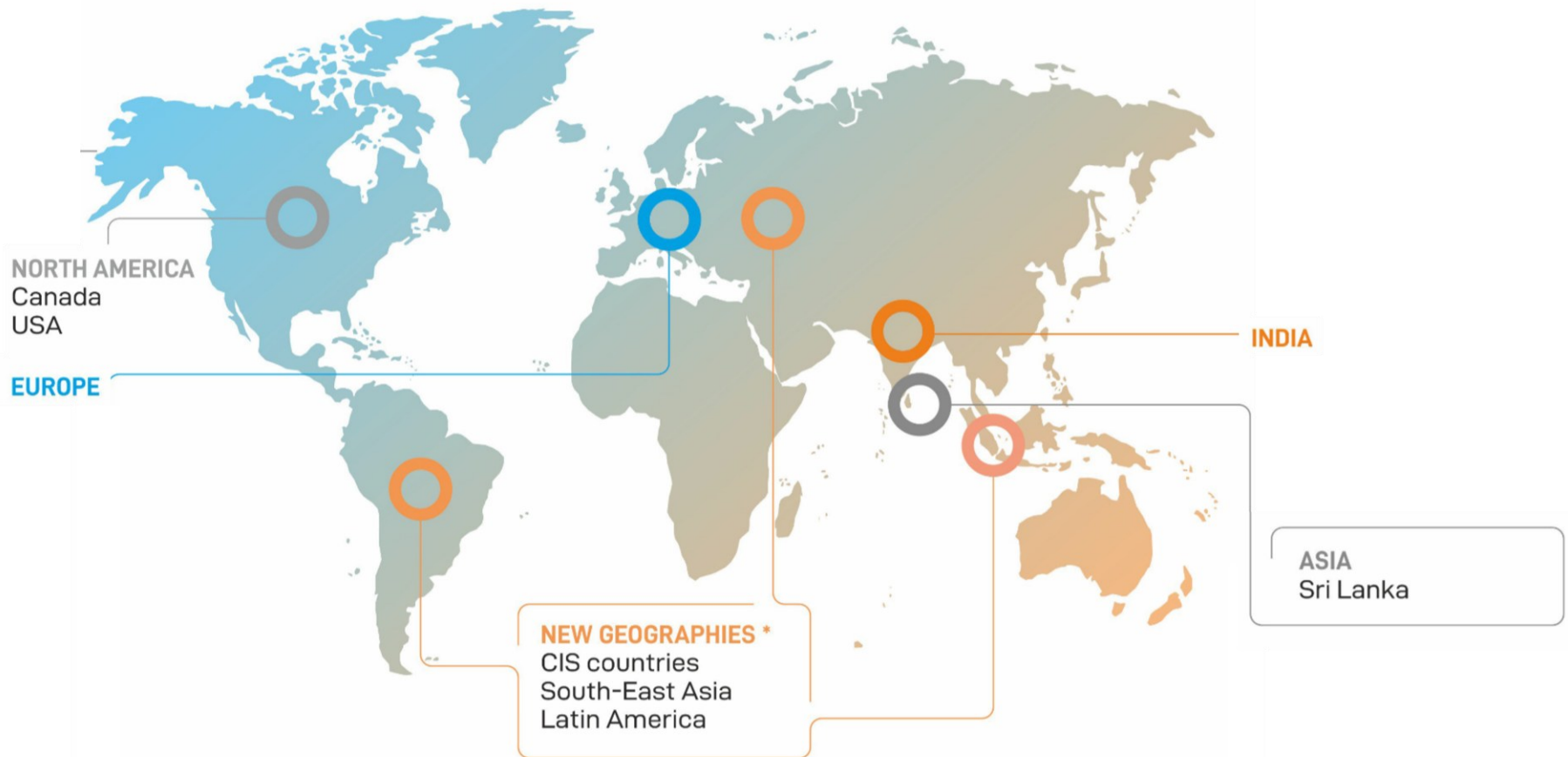


**60+**  
Studies

**480**  
Sites

**4500+**  
Patients

# Global Site Network | Investigator Sites





- 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**
- **MI-LP** a customized web-based global imaging application, which enables the secure uploading, query management, analysis, and storage of images for the evaluation of clinical trial endpoints.

Worked with **600+ clinical sites** for imaging,  
**9500+ Images** Reviewed

## Extensive Capabilities:



**Oncology**




**Musculoskeletal**



**Ophthalmology**

## Future Expansion Planning:

- iRECIST evaluation method
- Gastrointestinal (GI) imaging



# **Labs** - Central Clinical Lab, Bioanalytical & Biosimilars

*Experience Laboratory Excellence – 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

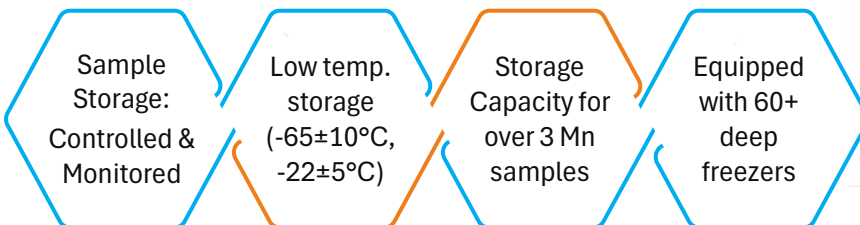
**Pan-India** capabilities for  
seamless **Sample Logistics**

**Microbiological testing** for  
Healthcare **Hygiene products**



## 1600+ Validated Bioanalytical Assays

- **GLP Certified** Lab with **Automated** Sample Inventory Management System and Liquid Handling System.
- Capacity to analyze **110,000+ 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.

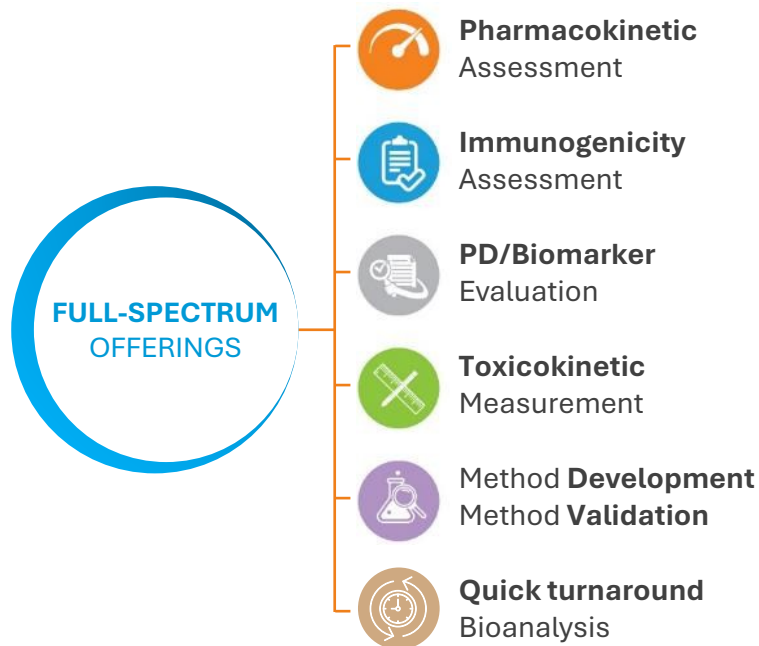


## Extensive experience in MD/MV for generic, complex & NCE molecules

- 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
- Bisphosphonate assay

	LC-MS/MS	FTIR	LHS	ICP-MS
Lambda	39	3	4	1
Novum	6	-	1	-

8-10 New method development per month



## 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

Molecules	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 ( $\beta$ – 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 hand holding several small, light-colored pills. A large, semi-transparent checkmark icon is overlaid on the hand. The background is a blurred pharmacy shelf with various bottles and boxes. A network of dots and lines is overlaid on the image, suggesting a digital or interconnected theme.

# 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**



## 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 **2024** at a Glance

**544,313**

Literature Screening

**110700**

Cases

**790**

Aggregate Reports

**235**

RMP

**1463**

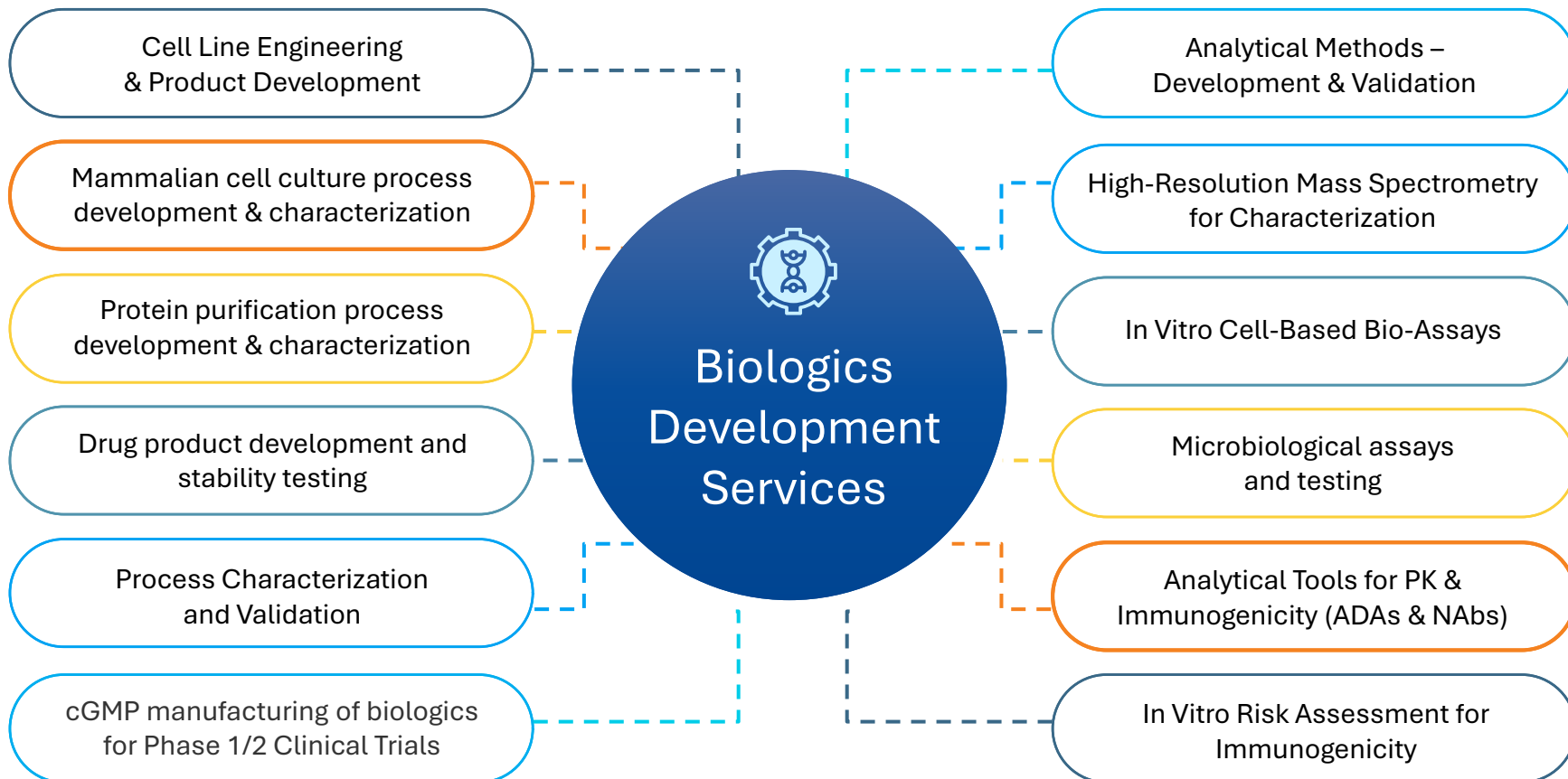
Signal Management Reports





# CDMO

*End-to-End Biosimilar Development*



## Technical Prowess

- Expertise in Process and Analytical Sciences
- Accelerated biologics development
- End-to-end support from gene to launch
- Inward and outward technology transfer
- Process and analytical expertise for US & EU filings

## State-of-the-art technologies

- Multiple clone platforms
- Fed batch and perfusion-based cell culture
- Continuous chromatography options
- Formulation of drug product and controlled nucleation expertise for lyophilization
- Batch release, stability & extended analytical characterization capabilities

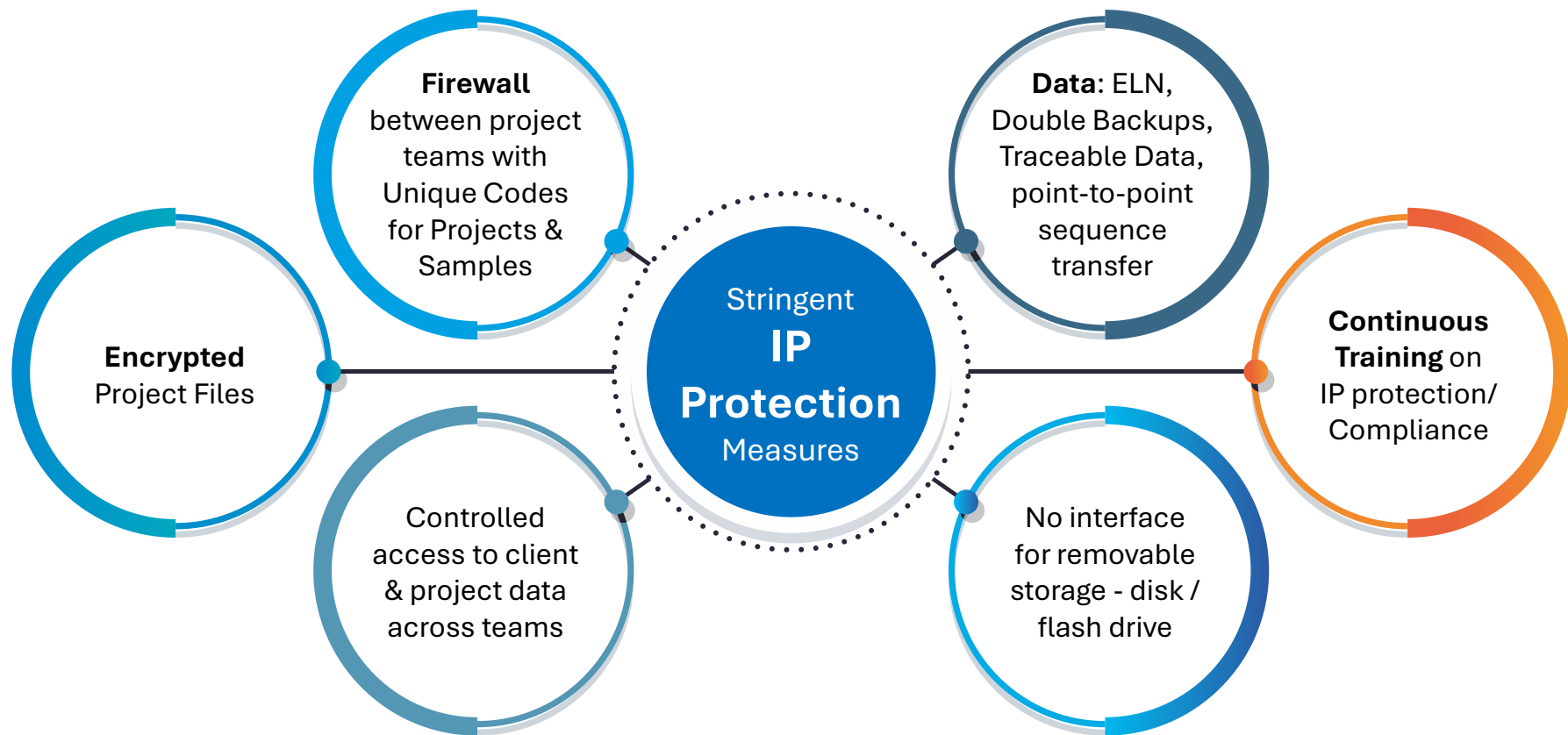
## Facility Compliance

- DS and DP facilities aligned with FDA & EMA regulations.
- Robust cGMP workflows and sufficient capacity for reliable long-term supply.
- Strong quality systems for data integrity
- QMS designed for early-phase acceleration

## Project Management

- Customized Documentation templates for client review & collaboration
- Transparent and timely communication
- Regular progress updates
- Competitive pricing with on-time delivery

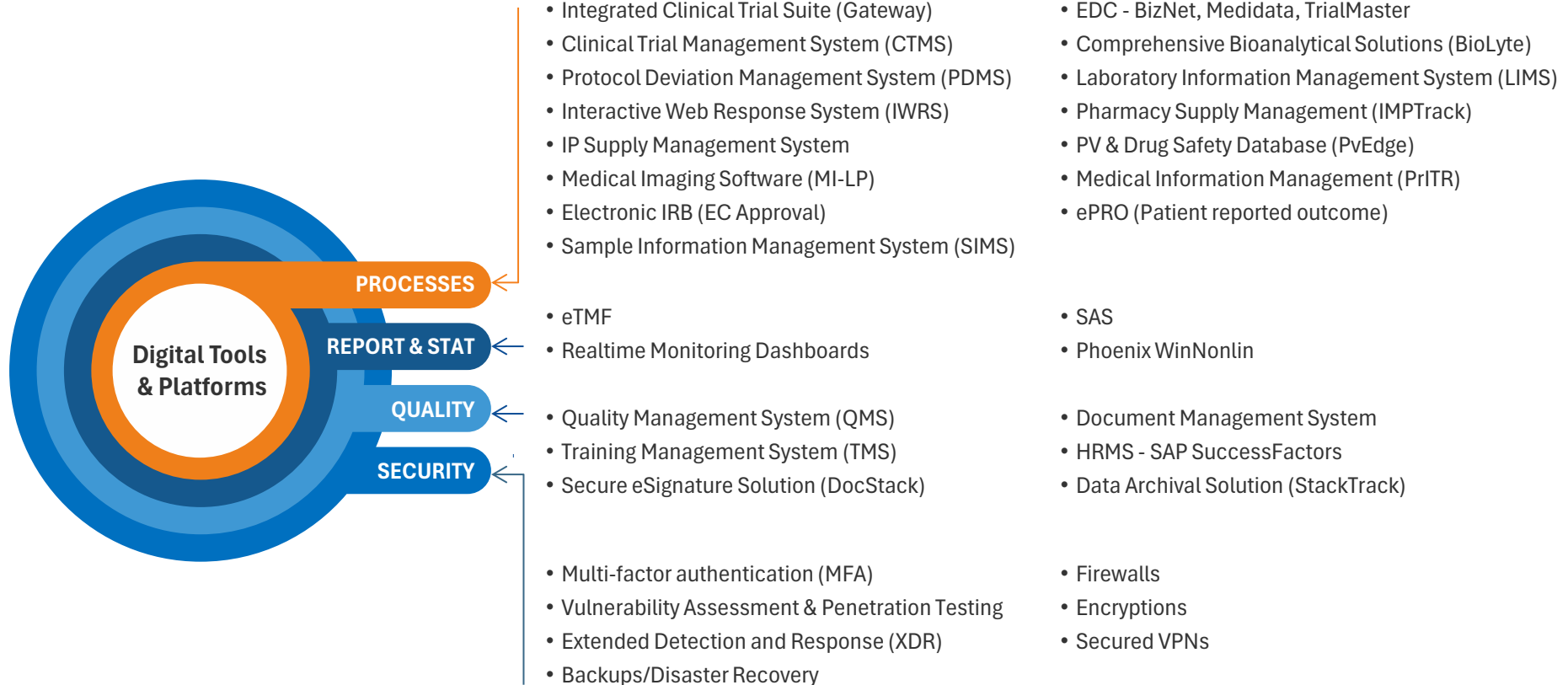




A hand is shown holding a glowing digital interface. The interface features a central circular node with two arrows forming a loop, from which numerous lines radiate outwards to various circular icons. These icons represent different technological concepts: a document, a server rack, a gear, a magnifying glass, a bar chart, a location pin, a double-headed arrow, a laptop, a cloud, a microchip, a Wi-Fi symbol, a globe, a signal tower, a monitor, a bar chart, a document, a server rack, and a gear. The background is a solid blue color with a faint image of a person's hand holding a device.

# Technologies

*Innovating for Clinical Excellence*





## GLOBAL OPERATIONS

- Multicontinental presence
- End-to-end clinical research services
- Integrated digital tools and platforms for streamlined operations
- Hub & Spoke, flexible business models



## STRONG PERFORMANCE

- Legacy of Excellence: 25+ years with Lambda & 50+ years with Novum
- Best credit rating in the CRO industry
- Proven regulatory track record



## EXPERTISE & EXPERIENCE

- Experience in conducting 8000+ PK/PD studies & 290+ multicentric studies
- Broad therapeutic expertise
- Expert team with deep domain knowledge
- 1200+ professionals in a multicultural workforce



## QUALITY & COMPLIANCE

- QMS-backed Strong Governance Structure
- “Quality by Design”-driven decision making
- GDPR compliance
- Transparency at every stage



# Thank you

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