RESEARCH ACCELERATED

- Multicontinental presence
- End-to-end clinical research service offerings
- Robust digital platforms across business verticals
- Awarded ‘Best Indian CRO’ by Frost & Sullivan (USA) and ‘Great Indian Workplace’ by UBS Transformance

- Global Revenues of USD 80 million in FY 21-22
- Growing at 28% CAGR YoY
- Best credit rating in the CRO industry

- Strong Leadership with 35+ years of experience
- Multicultural workforce
- 1500+ employees

- Impeccable regulatory track record
- Independent Quality Assurance
- Stringent GXP Compliance
- Hub & Spoke, flexible business models
GLOBAL PRESENCE

- Toronto, Canada
- Las Vegas, USA
- Pittsburgh, USA
- London, UK
- Warsaw, Poland
- Ahmedabad & Mehsana, India
# IMPECCABLE REGULATORY TRACK RECORD

<table>
<thead>
<tr>
<th>Country</th>
<th>Regulatory Body</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>Indian Council for Product Quality Assurance (ICPQA)</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization (WHO)</td>
</tr>
<tr>
<td>EU</td>
<td>European Medicines Agency (EMA)</td>
</tr>
<tr>
<td>UK</td>
<td>Medicines and Healthcare Products Regulatory Agency (MHRA)</td>
</tr>
<tr>
<td>US</td>
<td>U.S. Food &amp; Drug Administration (FDA)</td>
</tr>
<tr>
<td>Canada</td>
<td>Health Canada</td>
</tr>
<tr>
<td>Austria</td>
<td>Austrian Agency for Health Security (AGES)</td>
</tr>
<tr>
<td>Belgium</td>
<td>Federal Agency for Medicines and Health Products (FAMHP)</td>
</tr>
<tr>
<td>Brazil</td>
<td>Brazilian National Health Surveillance Agency (ANVISA)</td>
</tr>
<tr>
<td>Canada</td>
<td>Health Products and Food Branch (HPFB)</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>Czech Institute for Drugs and Medical devices (ÚZVÚ)</td>
</tr>
<tr>
<td>France</td>
<td>French National Agency for Health Products (ANSM)</td>
</tr>
<tr>
<td>Germany</td>
<td>German Federal Institute for Drugs and Medical Devices (BfArM)</td>
</tr>
<tr>
<td>GCC</td>
<td>Gulf Cooperation Council</td>
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<tr>
<td>Hungary</td>
<td>Hungarian National Institute of Pharmacy (OGYEI)</td>
</tr>
<tr>
<td>Ireland</td>
<td>Irish Pharmacy Council (HPRA)</td>
</tr>
<tr>
<td>Italy</td>
<td>Instituto Nazionale dell’Assicurazione Malattie (INAM)</td>
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<tr>
<td>Kazakhstan</td>
<td>Kazakh Ministry of Health and Social Development</td>
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<tr>
<td>Latvia</td>
<td>Latvian National Health Service (LNNŪ)</td>
</tr>
<tr>
<td>Malaysia</td>
<td>Malaysian Health Department (MOH)</td>
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<tr>
<td>Netherlands</td>
<td>Dutch Medicine and Health Products Agency (OMD)</td>
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<tr>
<td>Poland</td>
<td>Polish Agency for Health Protection (PAHP)</td>
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<tr>
<td>Portugal</td>
<td>Portuguese National Institute for Quality in Health Care (IPA)</td>
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<tr>
<td>Slovakia</td>
<td>Slovak Health and Social Care Inspectorate (TÚZH)</td>
</tr>
<tr>
<td>Spain</td>
<td>Spanish Agency for Medicines and Health Products (AEMPS)</td>
</tr>
<tr>
<td>Thailand</td>
<td>Thailand Food and Drug Administration (TFDA)</td>
</tr>
<tr>
<td>Turkey</td>
<td>Turkish Agency for Medicines and Medical Devices (TGA)</td>
</tr>
</tbody>
</table>

CAP: Certification and Accreditation Program
EARLY PHASE CLINIC CAPABILITIES
PHASE-I OVERVIEW

- Single Ascending Dose/Multiple Ascending Dose
- BA/BE Bio comparison
- Drug – Drug Interaction
- Food – Drug Interaction
- Drug – Device Combinations
- PK - PD Proof-of-Concept
- Food effect studies
- Vasoconstrictor and Cardiac Safety studies
- Inhalation studies
- Derma studies

EXECUTED OVER 40+ PHASE-I STUDIES
GLOBAL CLINICAL BED CAPACITY AND VOLUNTEER DATABASE

700+ BEDS GLOBALLY

AHMEDABAD
MEHSANA
NOVUM - USA

LAMBDA - AHMEDABAD
LAMBDA - MEHSANA
NOVUM - USA

BA/BE Beds
Phase 1 Beds

HEALTHY MALE
HEALTHY FEMALES
PM & SURGICALLY STERILE WOMEN
ELDERLY
BA/BE CAPABILITIES

- First in Industry to Implement IRIS registration facility
- Experience of conducting 7000+ BE studies
- 24/7 Medical coverage
- Advanced ICU facilities
- Negative pressure inhalation chambers
- Real time data capture
- Controlled substance studies
- Safety and bioanalytical Lab with Sample Management System
- Capability to handle mixed population studies
DIVERSE FORMULATION EXPERIENCE

- All Oral Dosage Forms
- Injectables
- Inhalation Products
- Topical Products
- Nasal Sprays
- Transdermal Products
- Vaginal Products
- Ointments & Creams
- Suppositories
- Rectal Products
LATE PHASE CLINICAL STUDIES
LATE PHASE CLINICAL STUDIES: OVERVIEW

- Team of experts from diverse streams like medicine, pharmacy, biotechnology and life sciences
- One stop shop for end-to-end clinical studies
- Teams with rich experience of handling complex molecules in various therapeutic areas
- Strong NDDS and Biosimilar Expertise
- 20+ years of Clinical operations experience
- Global site alliance network

CONDUCTED 160+ MULTICENTRIC STUDIES
## EXPERIENCE | LATE PHASE STUDIES

<table>
<thead>
<tr>
<th>Therapeutic Area</th>
<th>Studies</th>
<th>Patients</th>
<th>Sites</th>
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</thead>
<tbody>
<tr>
<td>Cardio Vascular &amp; Metabolic disorder</td>
<td>8</td>
<td>722</td>
<td>72</td>
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<tr>
<td>Dermatology</td>
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<td>Infectious Disease</td>
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<td>Nephrology</td>
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<td>Oncology</td>
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<td>Orthopedics</td>
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<tr>
<td>Rheumatology</td>
<td>4</td>
<td>761</td>
<td>57</td>
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<tr>
<td>Pulmonology</td>
<td>19</td>
<td>15083</td>
<td>379</td>
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</tbody>
</table>

Extensive experience in **DERMATOLOGY** and **ONCOLOGY**

Expertise in **BIOSIMILARS**

Enrolled **52000+ PATIENTS** across 1800+ sites
<table>
<thead>
<tr>
<th>Indication/Therapy</th>
<th>Studies</th>
<th>Patients</th>
<th>Sites</th>
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<tbody>
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<td>Type 2 Diabetes Mellitus</td>
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<tr>
<td>Metastatic Breast Cancer (MBC)</td>
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<tr>
<td>Ovarian Cancer</td>
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<tr>
<td>Chronic Myeloid Leukemia</td>
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<td>Idiopathic Thrombocytopenic Purpura (ITP)</td>
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<tr>
<td>Malignant Gliomas</td>
<td>4</td>
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<tr>
<td>Metastatic Breast Cancer and Colorectal Cancer</td>
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<tr>
<td>Pancreatic Cancer</td>
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<tr>
<td>Rheumatoid Arthritis / Psoriasis</td>
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<td>42</td>
<td>3</td>
</tr>
</tbody>
</table>
DATA MANAGEMENT AND BIOSTATISTICS

- End-to-end DM services
- Quick & expandable DM resource model
- CDASH Compliant
- 21 CFR compliant in-house EDC systems
- Visual Data Analytics

- Study design, sample size estimation
- PD specs, SAP, TLFs, SAR Development
- CDISC Standards
- Immunogenicity and PK Data Analysis
- Population PK modelling

CLOSE KNIT TEAM OF DATA MANAGERS, PROGRAMMERS AND BIOSTATISTICIANS
Teams with experience of handling global regulatory requirements

Expertise in eCTD submissions package for USFDA, EMA, DCGI, TGA, ANVISA, HC etc.
DRUG SAFETY & PHARMACOVIGILANCE
**PHARMACOVIGILANCE: OVERVIEW**

- **Offices in UK (Harrow), Warsaw (Poland), India (Ahmedabad) and Canada (Toronto)**
- **Team comprising of Physicians, Pharmacists and PV specialists with broad therapeutic expertise (400+ active molecules)**
- **Cost effective, customizable, user-friendly, regulatory compliant safety database**
- **Successfully underwent 20+ Regulatory Inspections for PV functionality**

Logos of FDA, U.S. Food & Drug Administration, AIFF, MHRA, Health Canada, and Novum.
PHARMACOVIGILANCE: SERVICES

OPERATIONAL SERVICES
- ICSRs
- Aggregate reports (PSUR/PADER/DSUR)
- Literature screening
- MICC
- xEVMPD entries (Art 57 database)

SPECIALIZED SERVICES
- QPPV services in UK and EU
- LRPVs across Europe
- Signal Detection
- Risk management
- Risk benefit analysis
- PSMFs

SUPPORT SERVICES
- Audits/Inspection handling and support
- Trainings / Consultancy
- Pharmacovigilance gap analysis.
Panel of Board-certified radiologists

Centralised Reading and reporting

Expertise in Oncology, Ophthalmic studies

Automated, Paperless processes

21 CFR Part 11 compliant digital solutions
BIOANALYTICAL: OVERVIEW

TEAM AND INFRASTRUCTURE

GLP CERTIFIED
Bioanalytical lab

1100+
Validated Bioanalytical Assays

150+
Qualified Scientists

Capacity to Analyse
1,100,000+ samples per month

8-10 NEW METHOD
developments per month

EXPERTISE in
MD/MV of Complex Molecules and NCEs

AUTOMATED Sample
Inventory Management System and Liquid Handling System

SAMPLE STORAGE

CONTROLLED AND MONITORED
low temperature storage
(-22±5°C, -65±10°C)

CAPACITY to store more than 3 million samples

60+ Deep freezers

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>LC-MS/MS</th>
<th>FTIR</th>
<th>LHS</th>
<th>ICP-MS</th>
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</thead>
<tbody>
<tr>
<td>INDIA</td>
<td>42</td>
<td>03</td>
<td>03</td>
<td>01</td>
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<tr>
<td>CANADA</td>
<td>14</td>
<td>-</td>
<td>1</td>
<td>-</td>
</tr>
</tbody>
</table>
BIOSIMILARS & LARGE MOLECULES SERVICES

FULL SPECTRUM OFFERINGS

Pharmacokinetic Assessment
Immunogenicity Assessment
PD/Biomarker Evaluation
Toxicokinetic Measurement
MD/MV

ANALYTICAL PLATFORMS

- Enzyme Linked Immunosorbent Assays (ELISA)
- Electrochemiluminescent Assays (ECLIA / MSD)
- Cell Based Assays (for neutralizing antibody assays)
- In-vitro diagnostics (for Biomarkers)
- Fluorometric Assays
- Flow Cytometry

VALUE ADDITIONS

- Antibody sourcing and Antigen Affinity based purification
- Conjugations: Biotin, Digoxigenin, HRP, Ruthenium

Successfully cleared MHRA and U.S. FOOD & DRUG ADMINISTRATION inspections for Biosimilar studies
CENTRAL LABORATORY: OVERVIEW

- CAP & NABL accredited State of the art facility
- Team of Clinical Pathologists, Microbiologists & Biotechnologists
- 25+ validated Biomarkers
- Biomarkers/Pharmacodynamic testing
- Microbiological Testing for hygiene products
- Validated LIMS
- Pan-India capabilities for sample logistics
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 to upscaling

PEOPLE
- Team of Industry-leading domain experts
- Experience of conducting 7000+ PK studies
- 160+ multicentric studies
- Flexible, amiable and adaptable culture

QUALITY
- QMS-backed Strong governance structure
- QBD-driven decision making
- GDPR Compliance
- Transparency at each step
LET’S CONNECT

✉️ BD@lambda-cro.com

Follow us on:  LinkedIn  Twitter  Instagram  |  www.lambda-cro.com  |  www.novumprs.com