RESEARCH ACCELERATED

- A Global CRO with Comprehensive Clinical Research service offerings
- Front runner in Medical Imaging with Robust Digital Platforms
- Awarded "Best Indian CRO" by Frost & Sullivan US
- Global Revenues of USD 90 million in FY 18-19
- Company growing at a CAGR of 20%
- Best Credit rating in CRO industry
- Strong Leadership with 20+ years of Experience
- Multi-continental presence
- 1500+ employees
- Impeccable regulatory track record
- Quality management framework
- Independent Quality Assurance
GLOBAL PRESENCE

- Ahmedabad, India 1999
- Mumbai, India 2003
- Mehsana, India 2017
- Warsaw, Poland 2007
- Fargo, USA 2019
- London, UK 2008
- Las Vegas, USA 2019
- New Delhi, India 2009
- Hyderabad, India 2009
- Toronto, Canada 2010
OUR JOURNEY

LAMBDA

1999
Lambda Clinical Research Ltd. was founded in Ahmedabad, Gujarat, India

2000-2005
- Establishment of Clinical Lab
- Started Operations in Mumbai, Maharashtra
- Establishment of Clinical Trial Management Division

2006-2010
- Started Operations in London, UK
- Started Operations in Warsaw, Poland
- Establishment of Pharmacovigilance Division

2011-2018
- Started Operations in Toronto, Canada
- Started Operations in Mehsana, Gujarat
- Establishment of Medical Writing / Medical Imaging Division

NOVUM

1972
Novum Pharmaceutical Research Services was founded in Pittsburgh, US

1975-2000
- Started Operations in Pittsburgh, US
- Started Operations in Houston, US

2001-2005
- Started Operations in Las Vegas, US
- Establishment of Data Management Division
- Establishment of Clinical Trial Management Division

2006-2019
- Started Operations in Fargo, US
- US Headquarters Re-located to Pittsburgh Downtown
- Expansion of Las Vegas Facility
- Integrated into Lambda

Together
Creating
Greater Capabilities
Across
A Global Footprint
EMBLEM OF OUR QUALITY COMMITMENT
LAMBDA SERVICE PORTFOLIO

- Phase I (First in Man)
- Bioanalytical
- Bioavailability & Bioequivalence
- Late Phase Clinical Trials (Phase II-IV)
- Data Services (BSP, CDM)
- Central Laboratory
- Medical Imaging
- Pharmacovigilance
PHASE-1 : OVERVIEW

- CAPABILITIES
  - Strong technical expertise in conducting studies such as:
    - Single Ascending Dose (SAD) - First in Man
    - Multiple Ascending Dose (MAD)
    - BA/BE Bio comparison
    - Drug – Drug Interaction
    - Food – Drug Interaction
    - PK -PD Proof-of-concept
    - Irritation Sensitization Adhesion
    - Cardiac Safety
    - Vasoconstrictor Studies for Topical Corticosteroids
    - Special Patient Populations
    - Potency Ranking Studies
    - Drug – Device Combinations
    - Food Effect Studies PK IPD studies
  - Executed over 43 phase-1 studies in the last 5 years for various formulations including Oral, Parenteral, Inhalers, Topical, Transdermal, Nasal Sprays, Injectables, Vaginal, Rectal etc.
PHASE–1 : VALUE PROPOSITION

NORTH AMERICA

• FiH Or SAD study in Canada & US
• Faster regulatory approval
• Parallel submission for MAD study in India
• Study starts with healthy subjects followed by patient cohorts
• Controlled substance for FDA submission

INDIA

• Cost effective option for subsequent Phase -I studies
• Easier Access for Renal and Liver impaired subjects study

VALUE PROPOSITION

• Cost effective business model (Hybrid)
• Faster turnaround time
• Global scientific overview
• Flexible Operational approach
Current total bed capacity is 1100+ beds globally
BIOAVAILABILITY/BIOEQUIVALENCE STUDIES

OVERVIEW

Qualified doctors around the clock
Dedicated “state of the art” ICUs
Capacity to handle 3200 new dosings in a month

Paperless technology right from screening until clinic completion
Stringent subject compliance
First In Industry to Implement IRIS registration

Experience of conducting over 7000+ BE studies
Inhalation Chambers
**BIOANALYTICAL : OVERVIEW (INDIA & CANADA)**

**CAPABILITIES**

- Scientists with 10+ years of experience
- Capacity to analyze 100,000+ samples/month
- 1000+ validated methods incl. methods as low as 0.5 pg / mL
- Approx. 8-10 new methods in development every month
- Expertise to develop sensitive methods for NCEs in different species like Rat, Mice, Dog and Monkey using low sample volume
- Knowledge of various chemical derivatization techniques
  - MS signal enhancement
  - Better HPLC redundant
- Handling non-traditional HPLC approaches, like HILIC separation
- Better HPLC redundant and selectivity for polar compounds
- Good experience in chiral separations

**INFRASTRUCTURE**

<table>
<thead>
<tr>
<th>Country</th>
<th>LC-MS/MS</th>
<th>FTIR</th>
<th>LHS</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>46</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Canada</td>
<td>14</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>3</td>
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</tbody>
</table>

**SAMPLE STORAGE**

- Controlled and monitored low temperature storage
  - (-22±5°C, -65±10°C)
- Capacity to store 3 million samples
<table>
<thead>
<tr>
<th>THERAPEUTIC AREA</th>
<th>STUDIES</th>
<th>PATIENTS</th>
<th>SITES</th>
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<tbody>
<tr>
<td>Dermatology</td>
<td>80</td>
<td>33195</td>
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<tr>
<td>Oncology</td>
<td>33</td>
<td>2477</td>
<td>353</td>
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<tr>
<td>Pulmonology</td>
<td>19</td>
<td>15083</td>
<td>379</td>
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<tr>
<td>Psychiatry</td>
<td>11</td>
<td>869</td>
<td>83</td>
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<tr>
<td>Women's Health</td>
<td>7</td>
<td>2969</td>
<td>203</td>
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<tr>
<td>Orthopaedic</td>
<td>6</td>
<td>4150</td>
<td>206</td>
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<tr>
<td>Gastroenterology</td>
<td>5</td>
<td>2389</td>
<td>167</td>
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<tr>
<td>Ophthalmology</td>
<td>4</td>
<td>1016</td>
<td>77</td>
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<tr>
<td>Rheumatology</td>
<td>4</td>
<td>761</td>
<td>57</td>
</tr>
<tr>
<td>Cardiology</td>
<td>1</td>
<td>22</td>
<td>3</td>
</tr>
<tr>
<td>Nephrology</td>
<td>1</td>
<td>175</td>
<td>24</td>
</tr>
</tbody>
</table>

Conducted over 160 multicentric trials across different geographies

Enrolled 50000+ patients in various therapeutic categories

Team with expertise in managing multi-country trials
<table>
<thead>
<tr>
<th>INDICATION/THERAPY</th>
<th>STUDIES</th>
<th>PATIENTS</th>
<th>SITES</th>
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</thead>
<tbody>
<tr>
<td>Schizophrenia / Borderline Personality Disorder</td>
<td>10</td>
<td>769</td>
<td>82</td>
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<tr>
<td>Ovarian</td>
<td>10</td>
<td>585</td>
<td>112</td>
</tr>
<tr>
<td>Metastatic Breast Cancer &amp; Metastatic Colorectal Cancer</td>
<td>9</td>
<td>797</td>
<td>82</td>
</tr>
<tr>
<td>Malignant Glioma</td>
<td>4</td>
<td>184</td>
<td>46</td>
</tr>
<tr>
<td>Atopic Dermatitis</td>
<td>4</td>
<td>1100</td>
<td>65</td>
</tr>
<tr>
<td>Metastatic Breast Cancer</td>
<td>3</td>
<td>109</td>
<td>24</td>
</tr>
<tr>
<td>Rheumatoid Arthritis</td>
<td>3</td>
<td>406</td>
<td>26</td>
</tr>
<tr>
<td>Advanced Solid Tumor</td>
<td>2</td>
<td>473</td>
<td>18</td>
</tr>
<tr>
<td>Acute Lymphoblastic Leukemia</td>
<td>1</td>
<td>66</td>
<td>4</td>
</tr>
<tr>
<td>Pancreatic</td>
<td>1</td>
<td>32</td>
<td>8</td>
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</tbody>
</table>
SCIENTIFIC AFFAIRS

BIOSTATISTICS & PROGRAMMING
- Two Stage Study Design
- In Vitro & Biosimilars immunogenicity Data Analysis
- PK/PD Analysis, Population PK & MVC modelling
- Randomization Management
- SAP & SAR Development, TLG Production
- ADRG, SDRG & define.xml file Preparation
- CDISC

BIOMETRIC SERVICES SOFTWARE
- MedDRA®
- WHO-DD
- Phoenix® (WiNonlin®)
- Phoenix® (NLME®)
- SAS® Server

CLINICAL DATA MANAGEMENT
- Global COM standards.
- COASH Modules.
- Visual Data Analytics – Real Time Updates
- End to End COM collaborations.
- Double layered data validation process.
- Quick & expandable OM resource model

REPORT WRITING
- REGIONAL ADMIN INFORMATION
- Quality overall summary
- Quality (Module 3)
- Non Clinical Study Reports (Module 4)
- Clinical Study Reports (Module 5)
HIGHLIGHTS

- CAP & NABL accredited
- Validated LIMS
- 1st Indian Lab to offer Immunogenicity testing
- PK of Biosimilars testing
- 25+ validated Biomarkers
- Microbiological Testing for hygiene products
- Pan-India capabilities for sample logistics

CENTRAL & LARGE MOLECULE LAB : OVERVIEW

TESTING EXPERTISE

- Biosimilars
- Biomarkers
- Immunogenicity
- Assay Development
- Safety Testing

OUR TEAM

- Clinical Pathologist
- Microbiologist
- Biotechnologist
- Medical Technologists
BIOSIMILARS & LARGE MOLECULE EXPERIENCE

PK – Pharmacokinetics, PD – Pharmacodynamics, IM – Immunogenicity, ADA - Anti drug antibody, nAb - Neutralizing antibody
Study Start-up & Consultation
Protocol & Study Design, Assessment Criteria Consultation etc.

Project Management
Site Support & Management

Image Management
Image Collection: MRI, CT Scan and X-ray
Project Management & Archival

Independent Review
Training, Testing & Quality monitoring

Conducted 8 studies in last 2 years
covering more than 1000 patients
PHARMACOVIGILANCE: OVERVIEW

Offices in UK (London), Warsaw (Poland), India (Ahmedabad) and Canada (Toronto)

Global safety team comprising Physicians, Pharmacists and PV specialists with broad therapeutic expertise (300+ active molecules)

Cost effective, customizable, user friendly, regulatory compliant safety database

Successfully underwent 15+ Regulatory Inspections for PV functionality
<table>
<thead>
<tr>
<th>OPERATIONAL SERVICES</th>
<th>SPECIALISED SERVICES</th>
<th>SUPPORT SERVICES</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Processing and submission of individual case safety reports</td>
<td>• Risk management planning</td>
<td>• Audits/Inspection handling and support</td>
</tr>
<tr>
<td>• Aggregate reports handling (PSUR/PBRER/PADER/DSUR)</td>
<td>• Signal management activities</td>
<td>• Trainings/Consultancy</td>
</tr>
<tr>
<td>• Literature screening and medical enquiry handling</td>
<td>• Risk benefit analysis</td>
<td>• CAPAs execution</td>
</tr>
<tr>
<td>• xEVMPD entries (Art 57 database)</td>
<td>• Qualified person responsible for pharmacovigilance and network of local responsible persons</td>
<td>• Pharmacovigilance gap analysis</td>
</tr>
<tr>
<td></td>
<td>• Pharmacovigilance system master file and safety agreements</td>
<td></td>
</tr>
</tbody>
</table>
GET THE LAMBDA/NOVUM EDGE

- Global Footprint
  - NA/EU/APAC
  - World-class Infrastructure
  - Customized Business Model

- Impeccable Regulatory Track Records
  - 7000+ PK studies
  - Carried out more than 160 multi-centric trials across different geographies

- Strong Leadership
  - Phase I – IV
  - One-stop Solution for all Support Services

- Financial Stability
  - (Credit Rating AA-)
  - CAGR ~20%
  - High end quality at optimal cost