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- Global Presence
- The Lambda Journey

Our Quality Promise (Regulatory Inspections)

Knowledge Bank

Project Process Flow

Customized Business Models

Accelerated Molecule to Market Timeline

Service Portfolio
- Phase I (First in Man)
- Bioavailability & Bioequivalence
- Bioanalytical
- Late Phase Clinical Trials (Phase II-IV)
- Data Services (BSP, CDM)
- Medical Writing
- Central Laboratory
- Medical Imaging
- Pharmacovigilance

Why Lambda?

Contact Us
Lambda: 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 50 million in FY 17-18
- Company growing at a CAGR of ~20%
- A ‘AA’ CRO in long term and highest possible in short term ‘A1+’ in CARE

- Strong Leadership with 20+ years of Experience
- Multi-continental presence
- 700+ employees

- Impeccable regulatory track record
- Quality management framework
- Independent Quality Assurance
GLOBAL PRESENCE

Operational Capabilities:

Asia Pacific
- India
- Sri Lanka
- Thailand
- Bangladesh

Europe
- UK
- Germany
- France
- Spain
- Turkey
- Poland
- Estonia
- Belarus
- Czech Republic
- Ukraine
- Romania
- Latvia
- Lithuania
- Bulgaria

Other Geographies
- North America
- Latin America
- CIS Countries
- South East Asia

- Warsaw, Poland 2007
- London, UK 2008
- Mumbai, India 2003
- Toronto, Canada 2010
- New Delhi, India 2009
- Istanbul, Turkey 2011
- Hyderabad, India 2009
- Bangkok, Thailand 2011
- Mehsana, India 2017
THE LAMDBA JOURNEY: ACCELERATED GROWTH STORY

1999
- Incepted in Ahmedabad, Gujarat, India
- Initiated BA/BE & Bio-analytical services

2000-2005
- Initiated Late Phase Studies
- Started Clinical Lab (CAP)
- Launch of Mumbai Operations

2006-2010
- Acquired CRO in London, UK for PV services
- Acquired CRO in Warsaw, Poland for Late Phase Trials
- Cleared US-FDA, ANVISA, DCGI etc inspections for BA/BE & CT studies
- Expansion of Ahmedabad facility with a capacity of 360 beds and a dedicated 16 bedded for Phase-1
- Awarded Best “Indian CRO “ in 2010 by Frost & Sullivan, US

2011-2018
- Acquired one of the oldest CROs in Canada for Early Phase Trials
- Established collaboration with Government Pharmaceutical Organization (GPO) in Thailand
- Established Medical Writing / Medical imaging services
- Clinical operations go paperless by extending EDC globally
- Won Great Indian Workplace Award 2017
- Launch of Mehsana clinical facility
QUALITY – EVERY STEP OF THE WAY

QUALITY MANAGEMENT SYSTEM

- Incidence /Investigation Reporting and Management
- Deviations and CAPA management
- Case identification and Issue escalation
- Quality Issue Handling : Process / System Correction

QUALITY INDICATORS TRENDING

- Critical / Major / Minor Categorization and Trend Analysis
- Quality Review Board Meeting
- Continuous CAPA and Training

QUALITY REVIEW AND RISK MANAGEMENT

- Interim and final review of project data and reports.
- Compliance with sponsor requirements and regulations.
- Site audit management on risk based matrix
- Rugged review process with timeline compliance
- Development of quality documents with risk mitigation.
PROGRESSIVE PROJECT MGMT APPROACH

Project Inquiry followed by Feasibility Assessment

Signing Agreement

Protocol Preparation

Client approval of protocol

Sample Analysis

Clinical Phase: Subject Housing, Dosing, Sampling, Discharge, ambulatory sample

Subject Screening

IEC/ DCGI approval of protocol

CMD, PK & Statistical analysis

Draft Report to Client

Final Report to Client

Archiving
## Accelerated Molecule to Market Timeline

### Day 0-7

<table>
<thead>
<tr>
<th>Week</th>
<th>W1</th>
<th>W2</th>
<th>W3</th>
<th>W4</th>
<th>W5</th>
<th>W6</th>
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### Day 8-14

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<th>W2</th>
<th>W3</th>
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<th>W5</th>
<th>W6</th>
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<tr>
<td>Protocol Finalization &amp; EC Approval</td>
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### Day 15-21

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<td>BE NOC/ T-License</td>
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### Day 22-28

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<th>W4</th>
<th>W5</th>
<th>W6</th>
<th>W7</th>
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<tbody>
<tr>
<td>MD/MV (If Applicable)</td>
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### Day 29-35

### Day 36-42

### Day 43-49

### Day 50-56

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<th>W9</th>
<th>W10</th>
<th>W11</th>
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<tr>
<td>Clinical Phase completion</td>
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### Day 57-63

### Day 64-70

### Day 71-77

### Day 78-84

### Day 85-91

<table>
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<th>Week</th>
<th>W10</th>
<th>W11</th>
<th>W12</th>
<th>W13</th>
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<td>Bio-analysis</td>
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<table>
<thead>
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<th>W11</th>
<th>W12</th>
<th>W13</th>
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</thead>
<tbody>
<tr>
<td>PK/Statistics</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Week</th>
<th>W12</th>
<th>W13</th>
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</thead>
<tbody>
<tr>
<td>Draft Report</td>
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</table>
LAMBDASERVICES
PHASE-1: OVERVIEW

**Capabilities**
- Strong technical expertise in handling studies like:
  - Single Ascending Dose (SAD) - First in Man
  - Multiple Ascending Dose (MAD)
- PK Studies
- Drug - Drug Interaction
- Food Effect Studies
- PK/PD studies
- Executed over 25 phase-I studies in the last 5 years for various formulations including Oral, Parenteral, Inhalers etc.
- Developed Skin Vasoconstrictor study capabilities for topical steroids.

**Set-up:**
- Dedicated state-of-the-art ICUs
  - Central Cardiac Monitoring System
  - Cardiac Telemetry/Holters/IV Infusion Pumps
- X-ray & Ultrasound facilities
- TET studies
  - GE MUSE system for ECG processing and management
  - GE Apex Pro Telemetry System / DASH 4000 Cardiac Monitors
  - Multilevel ECG reading by Cardiologists
  - Internet access to ECG data through ECG web portal
- Pulmonary Function Testing (PFT)
- Cognitive testing (CDR)
- Gastroesophageal monitoring
PHASE-1: VALUE PROPOSITION

Canada

- FiH Or SAD study in Canada
- Faster regulatory approval: ~35 days
- Parallel submission for MAD study in India
- Study starts with healthy subjects followed by patient cohorts

India

- Cost effective option for subsequent Phase -1 studies
- Easier Access for Renal and Liver impaired subjects study

Value Proposition

- Cost effective business model (Hybrid)
- Faster turn around time
- Global scientific overview
- Flexible Operational approach
Lambda’s current total bed capacity is 700+ beds globally.
Overview

- Qualified doctors round the clock
- Dedicated state of the art ICUs
- Capacity to handle 2500 fresh dosing in a month

- Paperless technology right from screening till clinic completion
- Stringent subject compliance
- First in industry to implement IRIS registration

- Experience of conducting over 6000+ BE studies
BIOAVAILABILITY / BIOEQUIVALENCE STUDIES

Capability

**Oral Dosage Forms:**
- Tablets and Capsules
- Suspensions
- Buccal
- Sublingual
- Lozenges

**Injectables:**
- IV, IM, SC

**Inhalers**

**Nasal Sprays**

**Suppositories**

**Ointments & Creams**

**Intravaginal tabs**

**Transdermal Patches**
BIOANALYTICAL: OVERVIEW (INDIA & CANADA)

Capabilities
- Scientists with 10+ years of experience
- Capacity to analyse 1,00,000+ 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
- Robust system for failure investigation
- GLP certified Bioanalytical lab in India and Canada.

Sample Storage
- Controlled and monitored low temperature storage (22±5°C, -65±10°C)
- Capacity to store 3 million samples

Infrastructure

<table>
<thead>
<tr>
<th>Country</th>
<th>LC-MS/MS</th>
<th>FTIR *</th>
<th>LHS #</th>
</tr>
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<tbody>
<tr>
<td>India</td>
<td>42</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Canada</td>
<td>10</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Total</td>
<td>52</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Indication</td>
<td># Studies</td>
<td># Sites</td>
<td>Regulatory</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------</td>
<td>---------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>CNS Tumor</td>
<td>4</td>
<td>46</td>
<td>USFDA, EMEA</td>
</tr>
<tr>
<td>ALL</td>
<td>1</td>
<td>6</td>
<td>Health CANADA</td>
</tr>
<tr>
<td>CML</td>
<td>3</td>
<td>26</td>
<td>USFDA, EMEA, DCGI</td>
</tr>
<tr>
<td>MBC</td>
<td>14</td>
<td>140</td>
<td>DCGI, USFDA, EMEA, ANVISA</td>
</tr>
<tr>
<td>MCC*</td>
<td>6</td>
<td>62</td>
<td>USFDA, EMEA, ANVISA</td>
</tr>
<tr>
<td>Pancreatic #</td>
<td>6</td>
<td>53</td>
<td>USFDA, EMEA, DCGI</td>
</tr>
<tr>
<td>Solid Tumor</td>
<td>1</td>
<td>4</td>
<td>DCGI</td>
</tr>
<tr>
<td>NSCLC</td>
<td>2</td>
<td>39</td>
<td>DCGI</td>
</tr>
<tr>
<td>ITP</td>
<td>1</td>
<td>6</td>
<td>DCGI</td>
</tr>
</tbody>
</table>

**Lambda is committed to being a beacon of hope for cancer patients, globally.**

**By providing advanced Late Phase Clinical Trials focused on Oncology, we are getting one step closer to cancer cure, everyday.**

Note: * Includes MBC patients. # Includes Ovarian cancer patients.
## CLINICAL TRIAL EXPERIENCE

<table>
<thead>
<tr>
<th>Therapeutic Area</th>
<th>Studies</th>
<th>Patients</th>
<th>Sites</th>
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<tbody>
<tr>
<td>Oncology</td>
<td>33</td>
<td>2477</td>
<td>353</td>
</tr>
<tr>
<td>Psychiatry</td>
<td>11</td>
<td>869</td>
<td>83</td>
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<tr>
<td>Dermatology</td>
<td>8</td>
<td>1048</td>
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<tr>
<td>Orthopaedic</td>
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<tr>
<td>Gastroenterology</td>
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<td>Cardiology</td>
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<td>22</td>
<td>3</td>
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<tr>
<td>Nephrology</td>
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<tr>
<td>Others</td>
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<td>14</td>
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<tr>
<td>Pulmonology</td>
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<td>678</td>
<td>27</td>
</tr>
<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>
</tbody>
</table>

- Carried out more than 50 multi-centric trials across different geographies
- Enrolled 8000+ patients in last 7 years 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>
<th>Submissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schizophrenia /BPD</td>
<td>10</td>
<td>641</td>
<td>63</td>
<td>5 FDA, 2 EMEA, 2 DCGi</td>
</tr>
<tr>
<td>Malignant Glioma</td>
<td>4</td>
<td>156</td>
<td>45</td>
<td>1 FDA, 2 EMEA, 1 ANVISA</td>
</tr>
<tr>
<td>MBC, MCC</td>
<td>8</td>
<td>584</td>
<td>82</td>
<td>1 CANADA, 4 FDA, 2 EMEA, 1 ANVISA</td>
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<tr>
<td>Advanced solid tumor</td>
<td>2</td>
<td>473</td>
<td>18</td>
<td>1 DCGi, 1 EMEA</td>
</tr>
<tr>
<td>MBC</td>
<td>8</td>
<td>16</td>
<td>80</td>
<td>7 DCGi, 1 EU</td>
</tr>
<tr>
<td>ALL</td>
<td>1</td>
<td>66</td>
<td>4</td>
<td>Canada</td>
</tr>
<tr>
<td>Ovarian /Pancreatic</td>
<td>1</td>
<td>688</td>
<td>8</td>
<td>USFDA</td>
</tr>
<tr>
<td>Atopic Dermatitis</td>
<td>4</td>
<td>287</td>
<td>54</td>
<td>2 EMEA 2 USFDA</td>
</tr>
<tr>
<td>Rheumatoid Arthritis</td>
<td>2</td>
<td>131</td>
<td>26</td>
<td>2 DCGi</td>
</tr>
<tr>
<td>Ovarian</td>
<td>7</td>
<td>425</td>
<td>89</td>
<td>5 USFDA, 3 EU</td>
</tr>
</tbody>
</table>

Total 33 Regulatory inspections at various sites: USFDA (28), MoH-Malaysia (4) & MHRA (1).
GLOBAL NETWORK OF SITES

Investigator Sites

**India**
- Andhra Pradesh
- Bihar
- Delhi
- Gujarat
- Haryana
- Himachal Pradesh
- Karnataka
- Kerala
- Madhya Pradesh
- Maharashtra
- Punjab
- Rajasthan
- Tamil Nadu
- Telangana
- Uttar Pradesh
- West Bengal

**Asia**
- Sri Lanka
- Bangladesh

**Europe**
- Poland
- Estonia
- Latvia
- Lithuania
- Belarus
- Ukraine
- Romania
- Bulgaria
- Czech Republic
- Germany
- France
- Spain

**North America**
- Canada
- USA

**New geographies**
- CIS countries
- South East Asia
- Latin America

*covered through partner CRO*
• Two Stage Study Design (Adaptive study or Group Sequential approach)

• In Vitro Data Analysis, Biosimilars Immunogenicity Data Analysis

• PK/PD Analysis, Population PK & IVIVC modelling

• Statistical Inputs for Study Protocols

• Sample Size Calculation, Randomization Management

• SAP & SAR Development, TLG Production

• Data Analysis & Real Time Data Analytics

• ADRG, SDRG & define.xml file Preparation

• CDISC Compliant SDTM, ADaM, SEND Datasets Programming
- Global CDM standards to ensure quality & compliance
- CDASH Modules to support CDISC data standards
- Seamless Software implementation
- Flexible, Efficient & Service Focused DM Team
- Visual Data Analytics - Real Time Updates
- End to End CDM collaborations on 50+ CT projects
- Integration with MedDRA & WHO-DD coding dictionaries
- Double layered data validation process - Manual & Programmatic review
- Quick & expandable DM resource model - 24x7 global software support
<table>
<thead>
<tr>
<th>Software</th>
<th>Version</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>BizNET® (CTM &amp; BABE)</td>
<td>6.0</td>
<td>SAS® Server</td>
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<tr>
<td>MedDRA®</td>
<td>21.0</td>
<td>Medical Coding Dictionary</td>
</tr>
<tr>
<td>WHO-DD®</td>
<td>2016</td>
<td>Drug Coding Dictionary</td>
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<tr>
<td>Phoenix® (WinNonlin®)</td>
<td>6.4</td>
<td>PK/PD Analysis Software</td>
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<tr>
<td>Phoenix® (NLME®)</td>
<td>7</td>
<td>Non-linear Mixed Effect Modeling</td>
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<tr>
<td>SAS®  Server</td>
<td>9.4</td>
<td>Statistical Analysis Software + CDISC Datasets</td>
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</tbody>
</table>
Compliance with all applicable regulatory requirements

Therapeutic Experience:
- Oncology
- Dermatology
- Musculoskeletal
- Cardiology
- Gastrointestinal
- Diabetology
- Respiratory
MEDSCI/MEDICAL WRITING: OVERVIEW

**PUBLICATION WRITING**
- Abstracts
- Posters
- ePosters
- Oral Presentations
- Manuscripts
- Review Articles
- Case Reports
- Drug Compendiums
- White Papers
- AdBoards

**REGULATORY WRITING**
- IB
- Protocols
- CSRs
- Narratives
- Literature Reviews
- Summary Documents

**INVESTIGATOR INITIATED STUDIES**
- Protocols
- ICFs
- CRF/eCRF
- Data Collection
- Data Entry
- Data Analysis
- Target Journal Identification
- Publication
CENTRAL LABORATORY: OVERVIEW

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

TESTING EXPERTISE

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

TEAM

- Clinical Pathologist
- Microbiologist
- Biotechnologist
- Medical Technologists
FULL SPECTRUM OFFERINGS

- Pharmacokinetic Measurement
- Method Validation
- Immunogenicity Assessment
- Method Development
- Pharmacodynamics / Biomarker Evaluation
- Toxicokinetics Measurement
CAPABILITIES

**Ligand Binding Assays**
- State of the art laboratory
- 21 CFR part 11 compliance
- Synergy Multimode Plate Reader (Biotek)
- M-Plex Multi Mode Reader (Tecan)
- QuickPlex SQ 120 Reader (MSD)
- Dynex, USA - Fully Automated ELISA Processors

**Cell Based Assays**
- Fully equipped cell culture laboratory
- Development and Validation of cell based neutralizing assays

**PD parameter & Biomarker analysis**
- COBAS e411 (ElectroChemiluminescence)
- VITROS ECI from J&J (Chemiluminescence)
- CBC (Fully automated Sysmex, XT-2000i)
- Immunophenotyping (BD, FACS-Canto)
- Coagulation studies (STA-Compact, Stago)
- Commercial ELISA kits for biomarker analysis
## BIOSIMILARS EXPERIENCE

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>PK, PD (ANC, CD34), IM (ADA + nAb)</th>
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</thead>
<tbody>
<tr>
<td>PEG-GCSF</td>
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<tr>
<td>PTH (1-34)</td>
<td>PK, PD (serum Calcium), IM (ADA + nAb)</td>
</tr>
<tr>
<td>Darbepoeitin alfa</td>
<td>PK, PD (Reticulocyte counts), IM (ADA)</td>
</tr>
<tr>
<td>Denosumab</td>
<td>PK, IM (ADA)</td>
</tr>
<tr>
<td>Bevacizumab</td>
<td>PK, IM (ADA)</td>
</tr>
<tr>
<td>r-FSH</td>
<td>PK, PD (β – Estradiol), IM (ADA)</td>
</tr>
<tr>
<td>Romiplostim</td>
<td>PK, IM (ADA)</td>
</tr>
<tr>
<td>Rituximab</td>
<td>PK, PD (CD 19), IM (ADA)</td>
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<tr>
<td>Trastuzumab</td>
<td>IM (ADA)</td>
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<tr>
<td>Ranibizumab</td>
<td>IM (ADA)</td>
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<tr>
<td>INFα 2b</td>
<td>PD (β-2 macroglobulin)</td>
</tr>
<tr>
<td>Human Insulin</td>
<td>PD (Glucose)</td>
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<tr>
<td>Iron Sucrose</td>
<td>PK, TK</td>
</tr>
<tr>
<td>Enoxaparin</td>
<td>PD (Anti Factor Xa, Anti Factor IIa, TFPI)</td>
</tr>
</tbody>
</table>

PK – Pharmacokinetics  
PD – Pharmacodynamics  
IM – Immunogenicity  
ADA – Anti drug antibody  
nAb – Neutralizing antibody
MEDICAL IMAGING: OVERVIEW

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
## Medical Imaging: Experience

<table>
<thead>
<tr>
<th>Indication</th>
<th>No. of studies</th>
<th>No. of patients</th>
<th>Imaging Criteria</th>
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<tbody>
<tr>
<td>Metastatic Breast Cancer</td>
<td>5</td>
<td>552</td>
<td>RECIST 1.1</td>
</tr>
<tr>
<td>Non-Hodgkin’s Lymphoma</td>
<td>1</td>
<td>144</td>
<td>IWG</td>
</tr>
<tr>
<td>Fracture of distal radius (Colles’)</td>
<td>1</td>
<td>120</td>
<td>Fracture Healing Assessment Criteria</td>
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<tr>
<td>Unresectable or Metastatic Non-squamous Non-small cell Lung Cancer</td>
<td>1</td>
<td>129</td>
<td>RECIST 1.1</td>
</tr>
</tbody>
</table>

**PACS:** 21 CFR part-II Compliant

- Board Certified Radiologist
- Customizable Evaluation Guidelines
- Fully Automated with built-in QC system
PHARMACOVIGILANCE: OVERVIEW

- Offices in UK (London), India (Ahmedabad) and Canada (Toronto)
- Global safety team comprising Physicians, Pharmacists and PV specialists with broad therapeutic expertise providing proficient services for client’s products (300 plus active moieties)
- Cost effective, customizable, user friendly, regulatory compliant safety database
- Successfully underwent 15+ Regulatory audits for PV functionality
PHARMA COVIGILANCE: SERVICES & CAPABILITIES

OPERATIONAL SERVICES
- Processing and submission of individual case safety reports
- Aggregate reports handling (PSUR/PBRER/PADER/DSUR)
- Literature screening and medical enquiry handling
- xEVMPD entries (Art 57 database)

SPECIALISED SERVICES
- Risk management planning
- Signal management activities
- Risk benefit analysis
- Qualified person responsible for pharmacovigilance and network of local responsible persons.
- Pharmacovigilance system master file and safety agreements

SUPPORT SERVICES
- Audits/Inspection handling and support
- Trainings/Consultancy
- CAPAs execution
- Pharmacovigilance gap analysis.
PROPRIETARY SAFETY DATABASE

- Product Inquiry Trail & Response
- Literature Automation Module
- ICSR Processing
- Clinical Trial / Vaccine Module
- Medical Device Module
- Signal Detection Module
- xEvmpd MODULE
GET THE LAMBDA EDGE

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

- Impeccable regulatory track records
- > 6000 Pk studies
- Scientific Approach

- Strong Leadership
- Phase-I to IV
- One-stop solution for all support services

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

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