

# Exploring Science, Evolving Healthcare



**LAMBDA**  
Research Accelerated



**Novum**  
PHARMACEUTICAL RESEARCH SERVICES

## A Full-Service Global CRO

SCIENCE

HEALTHCARE



## COMPANY OVERVIEW

Lambda Therapeutic Research & Novum Pharmaceutical Research Services is a full-service Clinical Research Organization (CRO) having a robust global footprint with facilities & operations in India (Ahmedabad & Mehsana), USA (Pittsburgh & Las Vegas), Canada (Toronto), UK (London) & Poland (Warsaw). With a rich legacy spanning two decades, we offer comprehensive end-to-end clinical research services to the global innovator, biotech, and generic pharmaceutical industries.

Our unwavering focus on timely project delivery is ensured through experienced teams comprising over 1500 employees, rigorous processes, and strict adherence to global regulatory standards. We prioritize cutting-edge digital platforms, secure IT infrastructure, and automation across all systems and processes.

Guided by a proficient management team comprised of highly qualified and experienced industry leaders, we leverage innovative technologies, therapeutic expertise, and an unwavering commitment to quality to empower our clients to develop products safely, effectively, and efficiently.



- **Multi-continental Presence**

- **Impeccable Regulatory Track Record**

- **Best credit rating in the CRO Industry**

- **Strong leadership with 35+ years of experience**

- **Independent Quality Assurance**

- **Robust Digital Platforms across Business Verticals**

- **Stringent GXP Compliance**



## IMPECCABLE REGULATORY TRACK RECORD



INDIA



WHO



EU



UK



US



CANADA



NGCMA - INDIA



AUSTRIA



BELGIUM



BRAZIL



CANADA



CZECH REPUBLIC



FRANCE



GERMANY



GULF COOPERATION COUNCIL



HUNGARY



IRELAND



ITALY



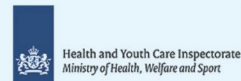
KAZAKHSTAN



LATVIA



MALAYSIA



NETHERLANDS



POLAND



PORTUGAL



SLOVAKIA



SPAIN



THAILAND



TURKEY

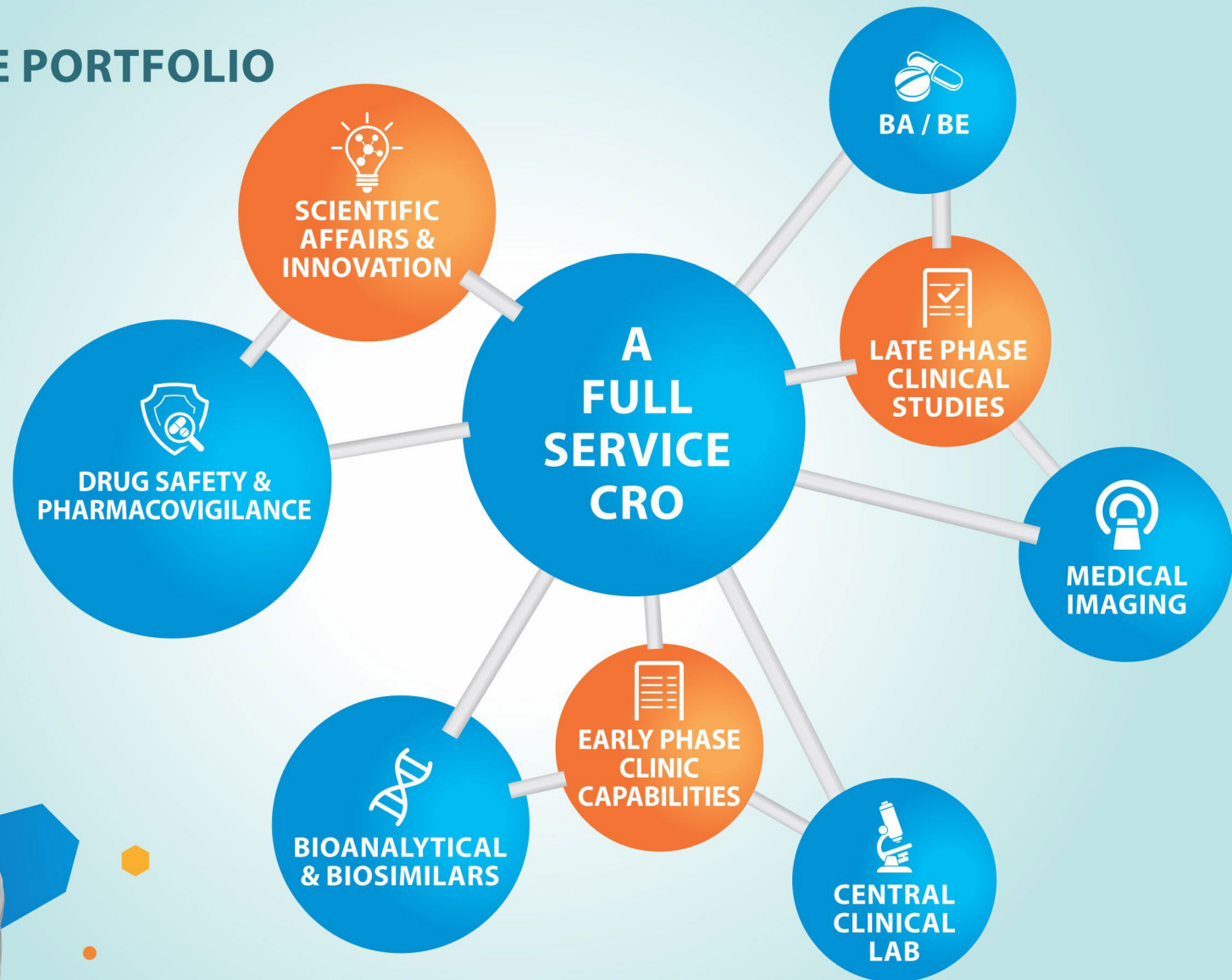


INDIA



US

## SERVICE PORTFOLIO



## PHASE-I OVERVIEW

- Single Ascending Dose/  
Multiple Ascending Dose
- BA/BE Biocomparison
- 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

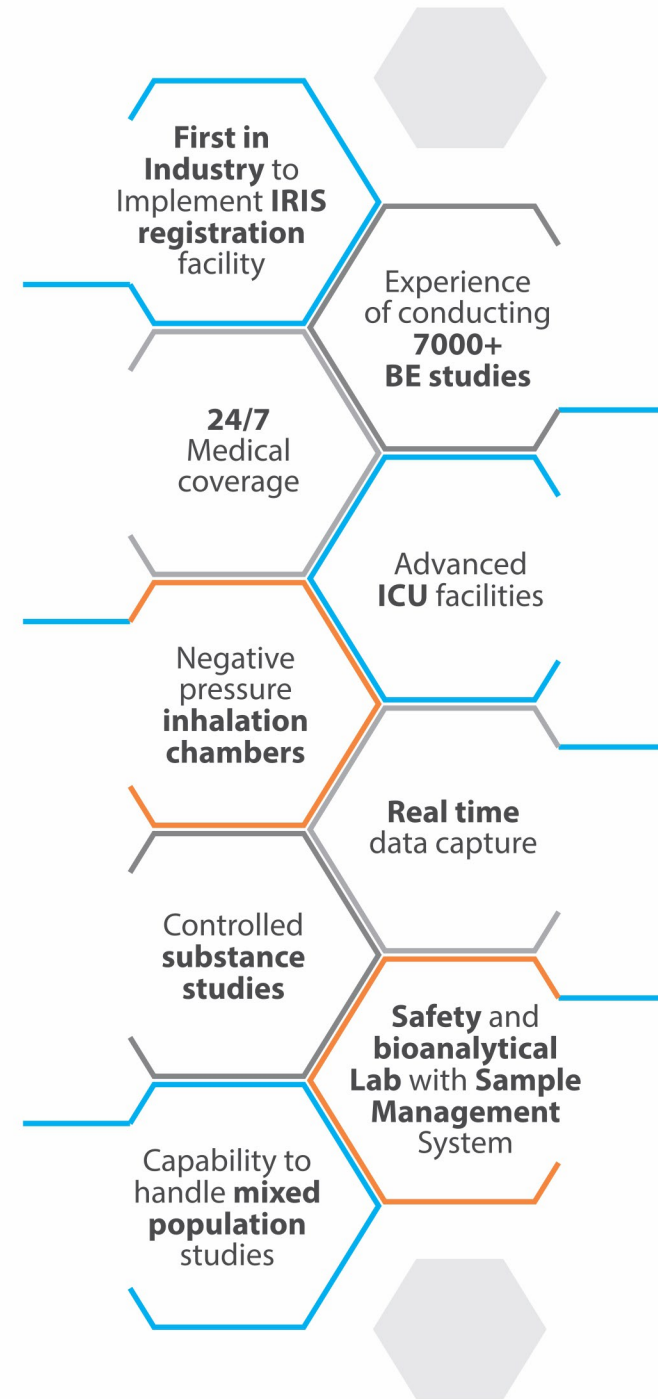
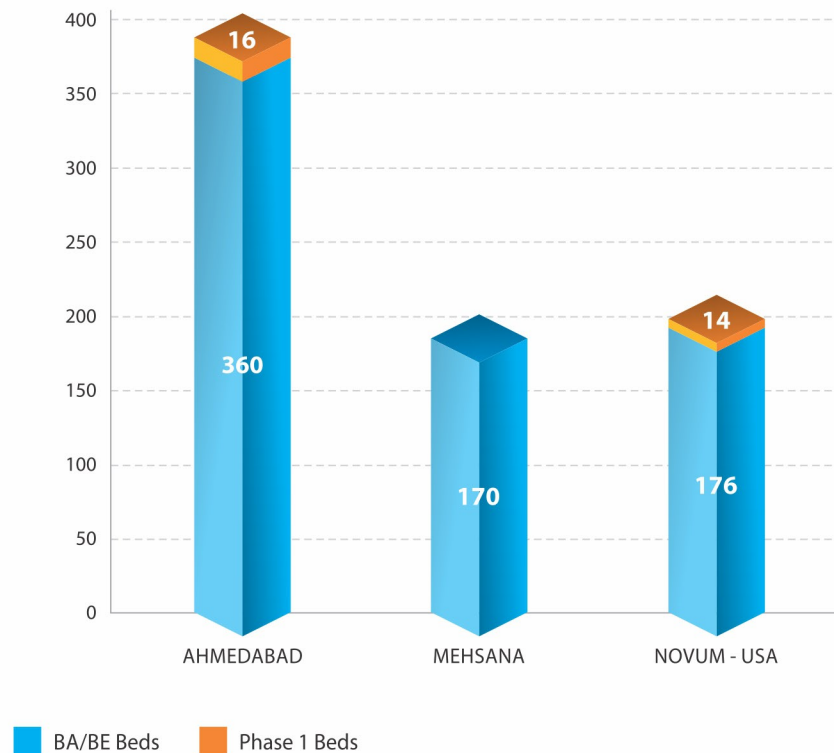
EXECUTED  
**40+**  
PHASE-I  
STUDIES



## BA/BE OVERVIEW

## GLOBAL CLINICAL BED CAPACITY

### 700+ BEDS GLOBALLY



## 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**



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

Expertise in  
**BIOSIMILARS**

Enrolled  
**52,000+ PATIENTS**  
across 1800+ sites

## LATE PHASE CLINICAL STUDIES EXPERIENCE

Therapeutic Area	Studies	Patients	Sites
Cardio Vascular & Metabolic disorder	8	722	272
Dermatology	80	33195	1412
Gastroenterology	6	2389	167
Women's Health	7	2969	203
Infectious Disease	3	231	34
Nephrology	1	193	24
Neurology	1	332	19
Oncology	59	4238	876
Ophthalmology	4	1016	77
Orthopedics	6	4150	206
Psychiatry	17	2535	201
Rheumatology	4	761	57
Pulmonology	19	15083	379



## PATIENT PK STUDIES EXPERIENCE

Indication/ Therapy	Studies	Patients	Sites
Hypertension	1	16	3
Type 2 Diabetes Mellitus	1	60	5
Metastatic Breast Cancer (MBC)	4	170	44
Ovarian Cancer	10	570	136
Chronic Myeloid Leukemia	2	68	19
Idiopathic Thrombocytopenic Purpura (ITP)	1	20	6
Malignant Gliomas	4	124	45
Metastatic Breast Cancer and Colorectal Cancer	5	199	34
Pancreatic Cancer	2	96	14
Schizophrenia and / or Bipolar I Disorder	12	1529	123
Rheumatoid Arthritis / Psoriasis	1	42	3

GRAND  
TOTAL

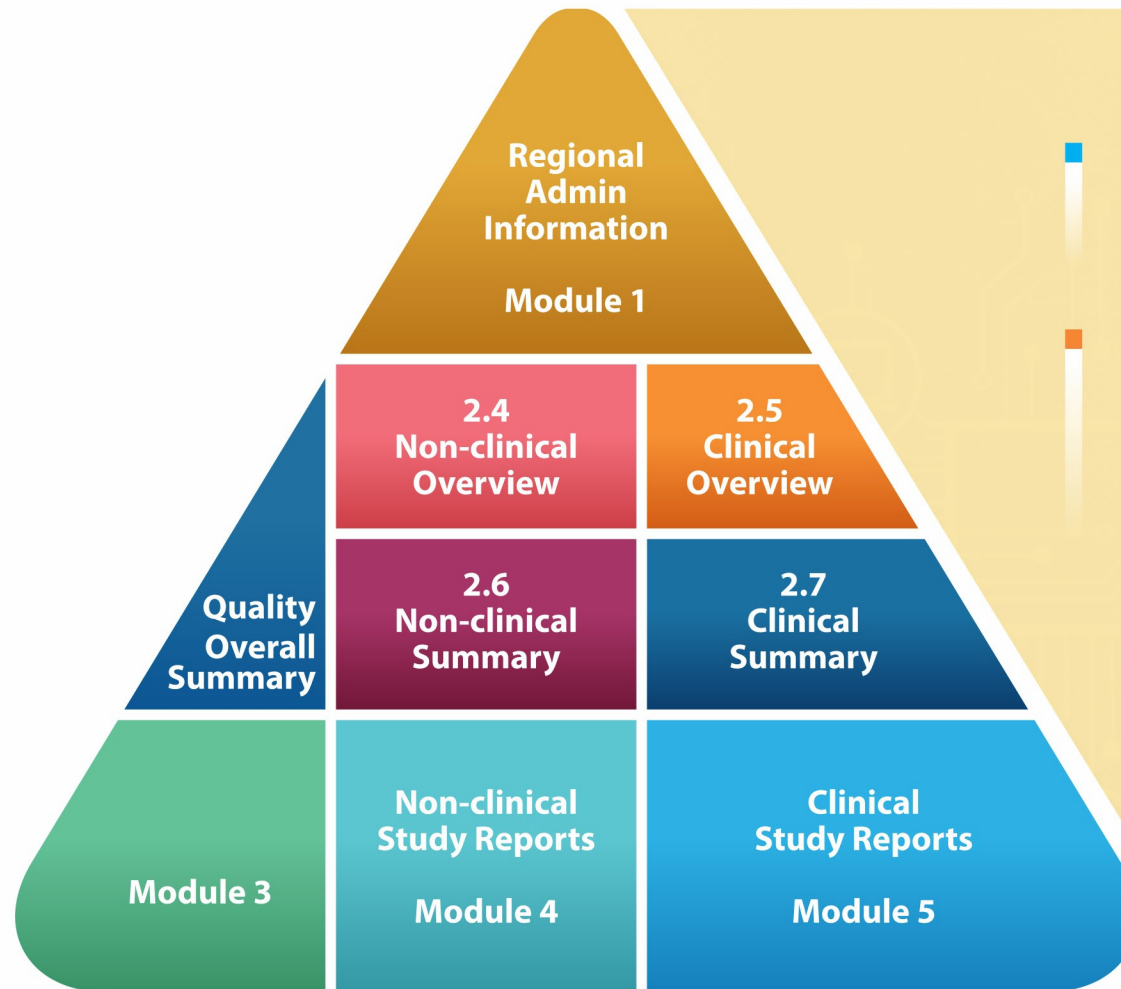
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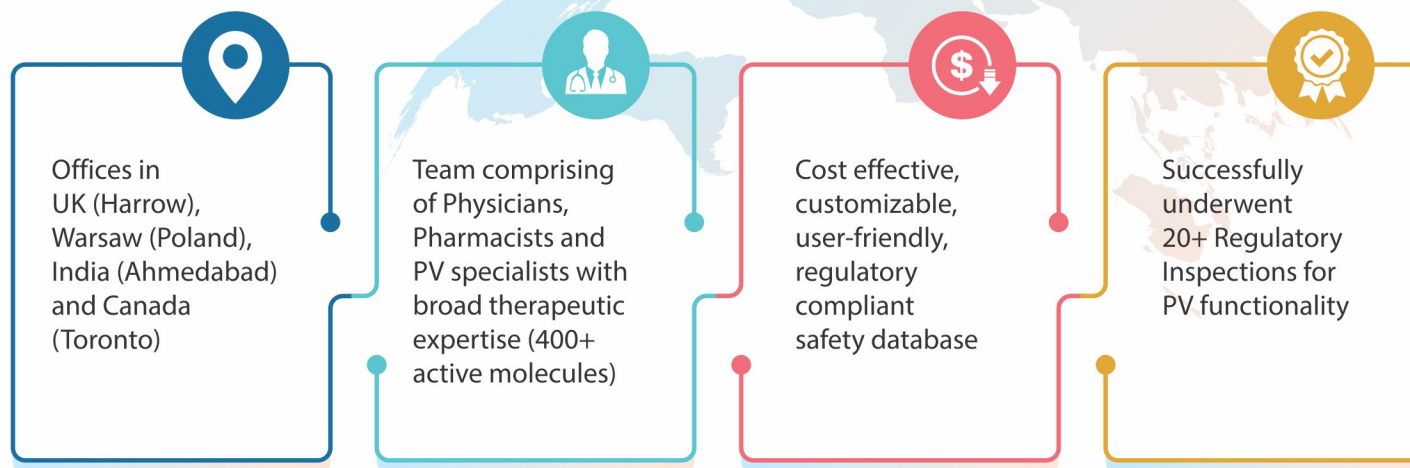
# BIOSTATISTICS & MEDICAL WRITING SERVICES



Teams with experience of handling global regulatory requirements

Expertise in eCTD submissions package for USFDA, EMA, DCGI, TGA, ANVISA, HC etc.

## PHARMACOVIGILANCE OVERVIEW



 **U.S. FOOD & DRUG  
ADMINISTRATION**

 **AIFA**  
AGENZIA ITALIANA DEL FARMACO

 **MHRA**  
Regulating Medicines and Medical Devices

 **Health  
Canada**

 **Ministerstwo Zdrowia**

## PHARMACOVIGILANCE SERVICES





## CENTRAL LAB 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



## MEDICAL IMAGING OVERVIEW



Panel of Board-certified  
Radiologists



Expertise in Oncology  
& Ophthalmic Studies



21 CFR Part 11 compliant  
digital solutions



Centralised Reading  
and Reporting



Automated, Paperless  
Processes



# BIOANALYTICAL OVERVIEW



## TEAM AND INFRASTRUCTURE

**GLP CERTIFIED**  
Bioanalytical lab

**150+**  
Qualified Scientists

**1400+**  
Validated Bioanalytical  
Assays

Capacity to Analyse  
**1,10,000+** samples  
per month

**8-10 NEW METHOD**  
developments per month

**EXPERTISE** in  
MD/MV of Complex  
Molecules and NCEs

**AUTOMATED** Sample  
Inventory Management Systems  
and Liquid Handling Systems

## 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

COUNTRY	LC-MS/MS	FTIR	LHS	ICP-MS
<b>INDIA</b>	<b>42</b>	<b>03</b>	<b>03</b>	<b>01</b>
<b>CANADA</b>	<b>14</b>	-	<b>1</b>	-





# BIOSIMILAR AND LARGE MOLECULES OVERVIEW



## 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



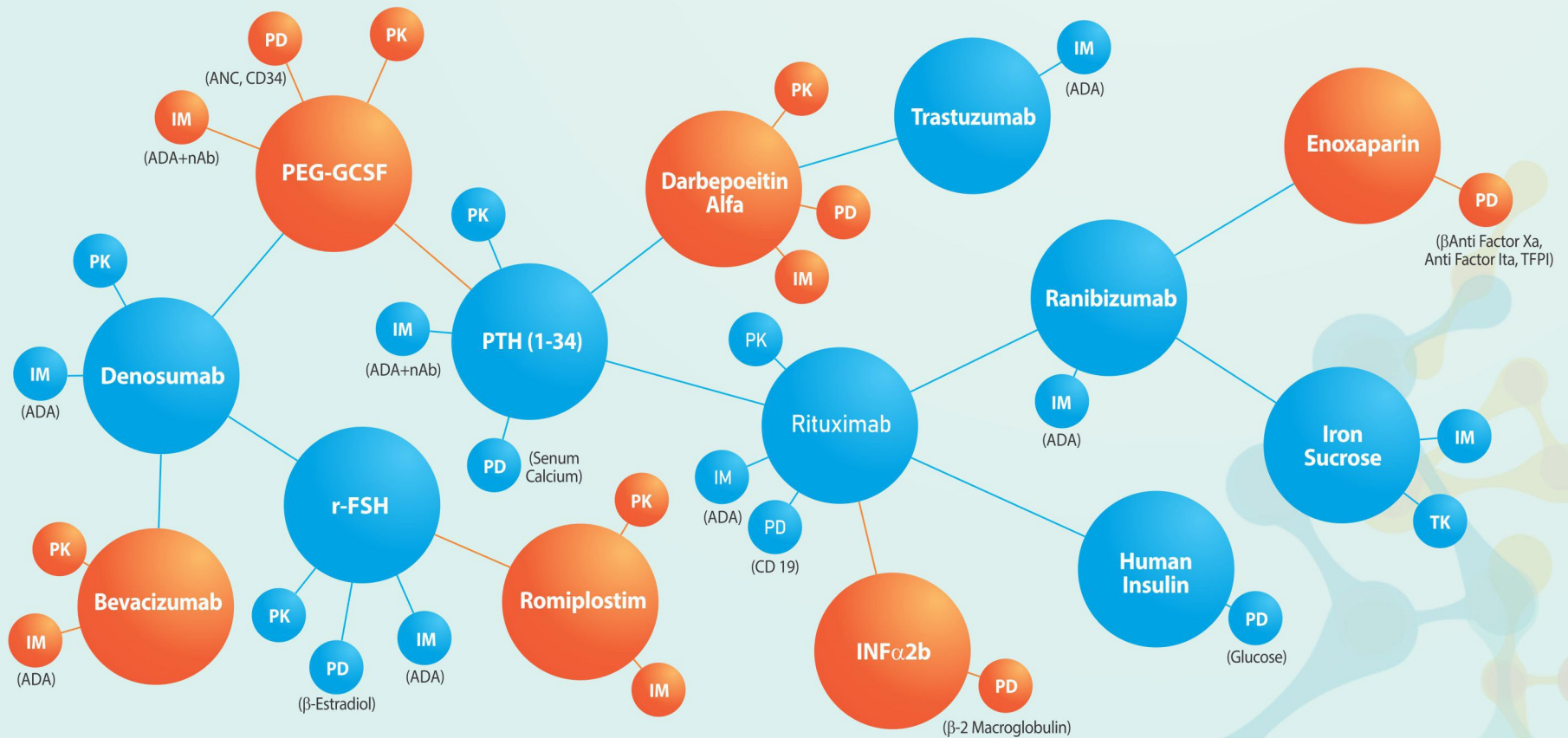
and



inspections for Biosimilar studies



# BIOSIMILAR AND LARGE MOLECULES EXPERIENCE





## GET THE LAMBDA / NOVUM EDGE



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



- 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%

## LET'S CONNECT

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For business queries, reach out to us at  
**[BD@lambda-cro.com](mailto:BD@lambda-cro.com)**



Follow us on:     | [www.lambda-cro.com](http://www.lambda-cro.com) | [www.novumprs.com](http://www.novumprs.com)