LAMBDA Research Accelerated | Novum PHARMACEUTICAL RESEARCH SERVICES

Global Full-service CRO

End-to-End Clinical Research and Biologics Development Solutions

- PK/PD Studies
- Phase I-IV Clinical Trials
- Labs – Bioanalytical Biosimilars, Clinical Lab
- Medical Imaging Analysis
- Biostatistics and Data Management
- Clinical Safety & Pharmacovigilance
- Regulatory Affairs & Medical Writing
- CDMO - Biologics Development

8,000+	290+	1,600+	1,200+
PK/PD Studies	Late Phase Trials	Validated Assays	Professionals

Extensive Expertise in:

NCEs & NDDS | **Biosimilars & Large Molecules** | **Oncology**

India | USA | Canada | UK | Spain | Poland

LAMBDA
Research Accelerated

Novum
PHARMACEUTICAL RESEARCH SERVICES

Global Presence

Toronto
- Bioanalyical Lab
- PV-MI

London
PV: UK QPPV & MI

Warsaw
PV: EU QPPV, LRP & MI

Las Vegas
Clinic (176 Beds +
15 Phase-1 Beds)

Barcelona
Novum-
Representative
Office

Mehsana
Clinic (170 beds)

Ahmedabad
- Clinic (360 beds + 16 Phase-1 Beds)
- Bioanalytical, Biosimilar & Clinical Lab
- Clinical Trials Operations
- PV Delivery & MI Services
- Medical Imaging Analysis
- CDMO
- Biostatistics and Data Management
- Medical Writing

PV – Pharmacovigilance
MI – Medical Information
LRP – Local Responsible Person
QPPV – Qualified Person for Pharmacovigilance

Ahmedabad

Las Vegas

Mehsana

Toronto

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Proven Regulatory Success

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

Novum

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8000+ BA/BE Studies

- End-to-end execution: **Feasibility to Reporting**
- Extensive Experience in Nasal/Inhalation with **Negative Pressure Dosing Chamber**
- Expertise in **Complex Generics & Biosimilars**
- 130+ **Nutraceuticals & Consumer Products** Studies
- Extensive Experience with **Proteins & Peptides**
- 200+ **Transdermal Patch** Studies
- Inspected by **USFDA, EMA, WHO, MHRA, ANVISA, AGES, NPRA, GCC & others**

CPUs in India & USA

750+ Beds

40+ Phase-1 Studies

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

Bioanalytical – Small Molecules

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.
- TAT < 10 days for 8000+ samples in support of 505(b)(2)/F2F studies dossier filings.
- 12 highly sensitive LC-MS/MS instruments, such as Sciex 6500, 6500+, Thermo Altis, Shmiadzu 8060 and Waters Xevo

	LC-MS/MS	FTIR	LHS	ICP-MS
Lambda	41	3	4	2
Novum	6	-	1	-

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

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BA/BE Studies for Inhalation Products

- **End-to-end study capabilities**
- Infrastructure designed for **controlled inhalation dosing and exposure assessment**
- **Trained clinical staff** with focused experience in inhalation technique supervision
- Capabilities across **metered dose inhalers, dry powder inhalers, and nebulized products**
- Processes aligned to support regulatory submissions for **generics and 505(b)(2) programs**
- Inhalation technique training during screening with enrollment limited to participants meeting predefined device handling criteria

Nasal / Inhalation Experience : 40+ Clinical Studies Conducted

Bronchodilators

- Albuterol
- Salbutamol
- Formoterol
- Ipratropium
- Tiotropium
- Glycopyrronium

Inhaled Corticosteroids

- Budesonide
- Fluticasone
- Mometasone
- Ciclesonide
- Triamcinolone

Nasal & Other Therapies

- Azelastine
- Azelastine/Fluticasone
- Sumatriptan
- Zolmitriptan
- Cyanocobalamin

Combination Products

- Albuterol/Ipratropium
- Budesonide/Formoterol
- Fluticasone/Salmeterol
- Formoterol/Mometasone

Negative air inhalation chambers
at Las Vegas & Ahmedabad clinics

Specifically designed to prevent small airborne drug particle cross-contamination.

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Insulin Studies Capabilities

- Hands-on experience in metabolic research and complex clamp study execution
- Stable, high throughput clamp operations
- Dedicated Phase I units with standardized infusion and sampling procedures, real time glucose monitoring, and controlled inpatient settings
- Validated insulin and glucose assays with high frequency sample handling and integrated PK PD data evaluation

Extensive Capabilities support complex metabolic studies.

Euglycemic hyperinsulinemic clamp studies

Comparative clamp studies for biosimilar insulin development

PD focused clamp studies for glucose lowering agents

Hyperglycemic clamp studies

Advanced Biochemistry Analyzer

to support accurate glucose assessments

Supports accurate glucose assessments with high throughput, consistent calibration, & stable clamp operations.

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Transdermal & Topical delivery system

Early Phase BA/BE Studies

Experience of Over 200 Transdermal Patch Studies

PK, Adhesion, Skin Irritation, and Sensitization Study Expertise

Comprehensive Study Execution provide end-to-end study services from protocol design to report submission ensuring consistent methodology.

Pharmacokinetic (PK) Evaluations	Skin irritation and sensitization assessments	Adhesion performance assessments
Dermal safety evaluations and scoring	Accurate dosing, weighing, and application site control	Standardized patch application and removal procedures

Proven Clinical Study Expertise

- Buprenorphine
- Clonidine
- Dapsone
- Diazepam
- Diclofenac
- Doxepin
- Estradiol
- Ethinyl Estradiol
- Fentanyl
- Granisetron
- Ketoprofen
- Lidocaine
- Methylphenidate
- Nicotine
- Norelgestromin
- Oxybutynin
- Progesterone
- Rivastigmine
- Rotigotine
- Scopolamine
- Selegiline
- Testosterone

Injectable Study Experience

Integrated clinical study support for complex injectable drug products including suspensions, emulsions, depot formulations and liposomal products

Experience of 100+ injectable studies

- PK, PD and immunogenicity assessments for biologics, peptides and complex injectables
- Clinical studies in healthy volunteers and patient populations
- Experience with prefilled syringes, autoinjectors and pen devices
- Study conduct aligned with USFDA, EMA and global regulatory expectations
- Integrated clinical, bioanalytical, biostatistics and medical writing support

Long Acting Injectables (LAI)	• Octreotide acetate • Cabotegravir extended release • Naltrexone extended release • Medroxyprogesterone acetate
Liposomal & Specialty Injectables	• Liposomal Amphotericin B • Iron sucrose • Enoxaparin sodium • Phytonadione
Complex Injectable Suspensions	• Triamcinolone acetonide • Methylprednisolone acetate • Penicillin G benzathine (prefilled syringe)
Peptides, Hormones & Biologic Injectables	• Semaglutide (prefilled pen and multidose pen) • Teriparatide • r hFSH • Cetrorelix acetate • Progesterone • Trastuzumab (subcutaneous) • Ustekinumab (autoinjector and prefilled syringe) • Filgrastim (subcutaneous)

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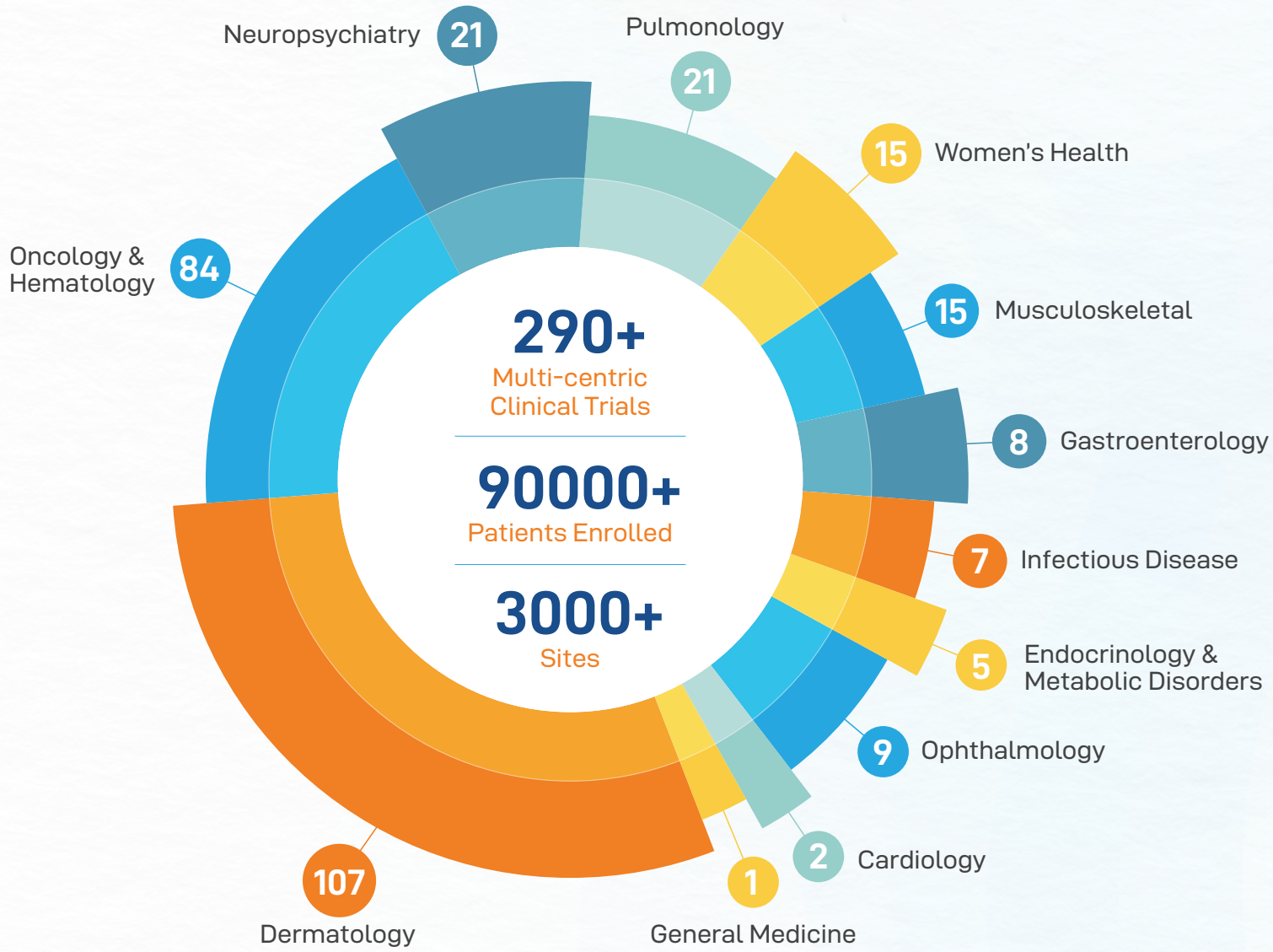
Late Phase Clinical Development

Vast Therapeutic Expertise, Global Reach, and Seamless Execution

- End-to-End Trial Execution
- Site & Patient Strategy
- Clinical Monitoring & Medical Affairs
- Data Management

Global regulatory submission experience across major health authorities

- Biostatistics & Medical Writing
- Medical Imaging Analysis
- Safety & Pharmacovigilance
- Central Laboratory Services



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Medical Imaging Analysis for Clinical Trials

Centralized imaging review for consistent and reliable endpoints

- Panel of leading qualified radiologists
- Centralized reading and reporting through 21 CFR Part 11 compliant digital solutions.
- Specializes in a wide range of imaging modalities: OCT, FA, CFP, DXA, CT, PET scan, MRI

Wide Experience in End-to-End Imaging Support

Oncology	Ophthalmology	Musculoskeletal
17 Multi-centric Trials	**4** Global Multi-centric Trials	**2** Global Multi-centric Trials
1480 Patients Enrolled	**546** Patients Enrolled	**750** Patients Enrolled
250 Sites	**72** Sites	**65** Sites
Experience	**Experience**	**Experience**
Breast cancer, Lung cancer, Prostate cancer, Lymphoma	Diabetic retinopathy, Wet/dry AMD, Retinal vein occlusion, & Ocular safety in systemic therapies	Osteoporosis & Bone safety assessments

10000+ images reviewed | 2500+ Patients

Inspected by **DCGI, USFDA, EMA**

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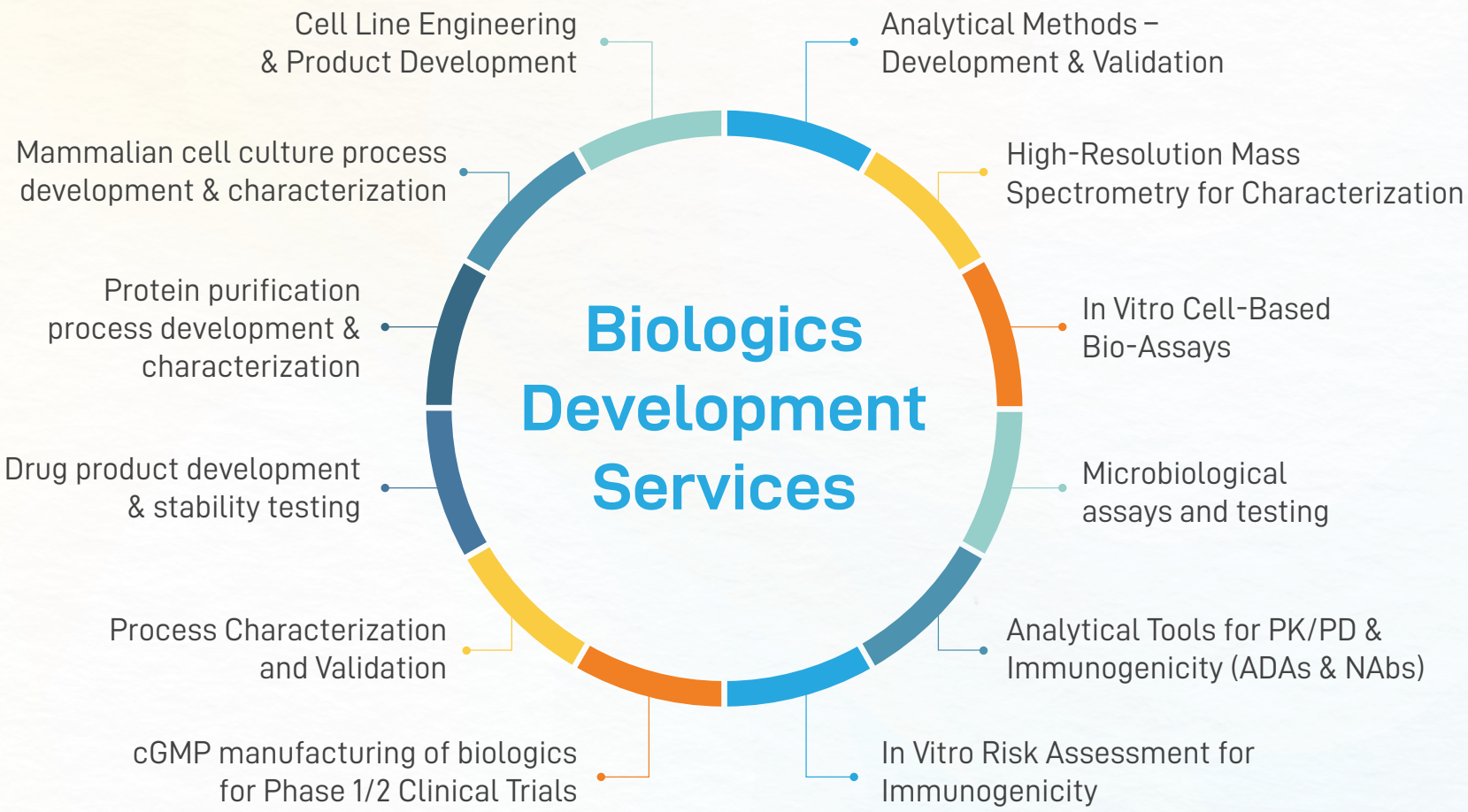
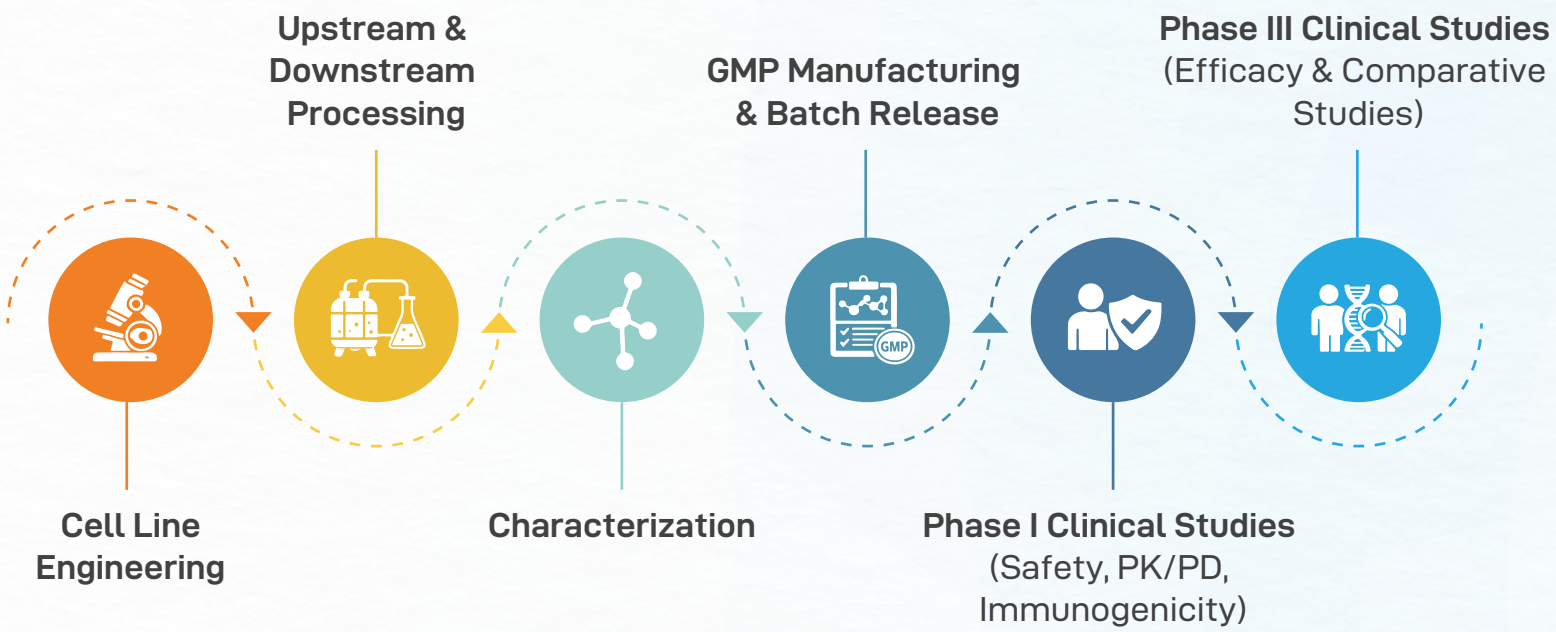
Biologics Development
CDMO and GxP-compliant Solutions





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Extensive Experience in Biosimilar Studies

Healthy Volunteer Studies

15+ Studies

2300+ Participants

- Bevacizumab
- Pegfilgrastim
- Denosumab
- Pertuzumab
- Ustekinumab
- Trastuzumab
- rFSH
- Vedolizumab

In Patients

25+ Studies

4000+ Patients Enrolled

500+ Sites

Oncology

- Rituximab
- Bevacizumab
- Trastuzumab
- Pertuzumab
- Trastuzumab Emtansine
- Serplulimab
- Daratumumab
- Pembrolizumab
- Nivolumab
- Pertuzumab + Trastuzumab

Ophthalmology

- Bevacizumab
- Ranibizumab
- Aflibercept

Immunology & Bone Health

- Denosumab
- Teriparatide
- Golimumab

Gastroenterology

- Vedolizumab

Inspections successfully cleared for Biosimilar Studies

Bioanalytical Package	Regulatory Authorization Received
• **PEG-GCSF** (PK, PD, ADA, nAb)	• **US FDA** and **DCGI**
• **rh-PTH** (PK, PD, ADA, nAb)	• **MHRA, EMA** and **ANVISA**
• **rh-Romiplostim** (PK, ADA)	• **DCGI** (Romy®, World's 1st Romiplostim Biosimilar)
• **Enoxaparin** (PK, ADA)	• **ANVISA**
• **Denosumab** (PK, PD, ADA, nAb)	• **EMA** and **US FDA**

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Biotherapeutics & Large Molecule Bioanalytical Services

End-to-end bioanalytical support for Complex large molecules

FULL SPECTRUM OFFERINGS

- **PD/Biomarker** Evaluation
- **Immunogenicity** Assessment
- Method **Development**
- Method **Validation**
- **Toxicokinetic** Measurement
- **Pharmacokinetic** Assessment

ANALYTICAL PLATFORMS

- **Enzyme-Linked Immunosorbent Assays** (ELISA)
- **Electro-Chemi-luminescent Assays** (ECLIA,MSD)
- **Cell-based Assays** (for Neutralizing antibodies [Nab])
- **LC/MS-MS** (For Peptide & mAbs)
- **Enzymatic Assay** (blood factors)
- **In-vitro diagnostics Assay** (for Biomarkers)

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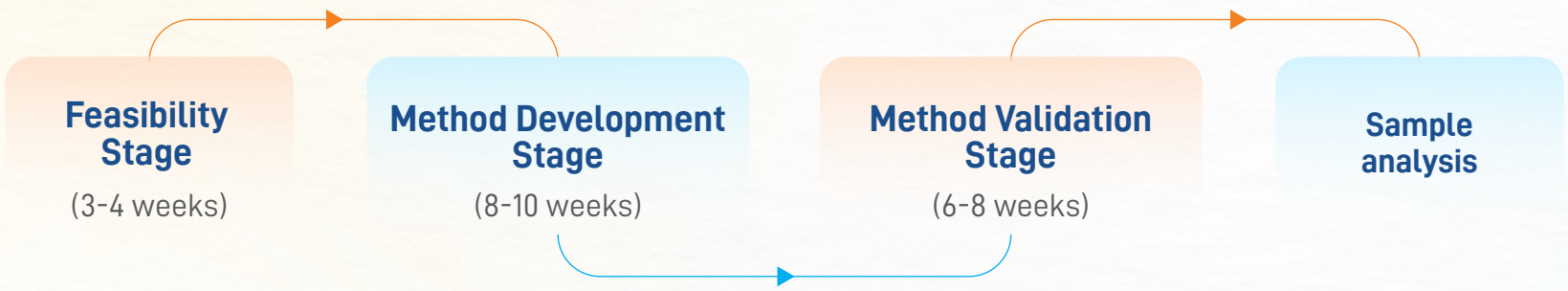
Biotherapeutics & Large Molecule Bioanalytical Services

Normal Bioanalytical Workflow for Method Readiness (~6 Months Before Sample Analysis)



Expedited Bioanalytical Workflow with Developed Methods (~2.5 Months Before Sample Analysis)

Biosimilar	Pharmacokinetic Assays	Immunogenicity Assay		Pharmacodynamic Assays
		Anti-drug Antibody	Neutralizing Antibody	
Bevacizumab	✓	✓	✓	-
Denosumab	✓	✓	✓	✓(P1NP, CTx)
Adalimumab	✓	✓	✓	-
Ranibizumab	✓	✓	✓	-
Trastuzumab (SC)	✓	✓	✓	-
Pertuzumab	✓	✓	✓	-
Rituximab	✓	✓	-	✓
Romiplostim	✓	✓	-	-
Teriparatide	✓	✓	✓	✓
FSH	✓	✓	✓	✓(β – Estradiol)
Filgrastim	✓	✓	✓	✓(CD34+)
Pegfilgrastim	✓	✓	✓	✓(ANC)
Vedolizumab	✓	✓	-	-
Aflibercept	-	✓	✓	-
Hyaluronidase	-	✓	✓	-
Semaglutide	✓	✓	-	-
Trastuzumab - DM1	✓	✓	✓	-
Tras Pertu Hyaluronidase FDC	✓	✓	✓	-
AAV Seroprevalence study in Hemophilia patients	-	✓	✓	-

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Accelerating your path from Molecule to Market

with Integrated CRO & Biologics CDMO Services

Advance your clinical programs with expert support

BD@lambda-cro.com

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