



Global Full-service CRO and Biologics CDMO

End-to-End Clinical Research and Biologics Development Solutions



Extensive Expertise in:

**NCEs &
NDDS**

**Biosimilars &
Large Molecules**

Oncology

India | USA | Canada | UK | Spain | Poland

Global Presence



Ahmedabad



Las Vegas



Mehsana



Toronto



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



8500+ 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 High-Sensitivity LC-MS/MS Platforms: **SCIEX 7500+, 6500+, 6500, ThermoAltis, Shimadzu LCMS-8060, and Waters Xevo**



	LC-MS/MS	FTIR	LHS	ICP-MS
India	41	3	4	2
Canada	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

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
- Fluticasone/Salmeterol
- Budesonide/Formoterol
- Formoterol/Mometasone

**Negative air
inhalation chambers**
at Las Vegas & Ahmedabad clinics

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



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.



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)

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

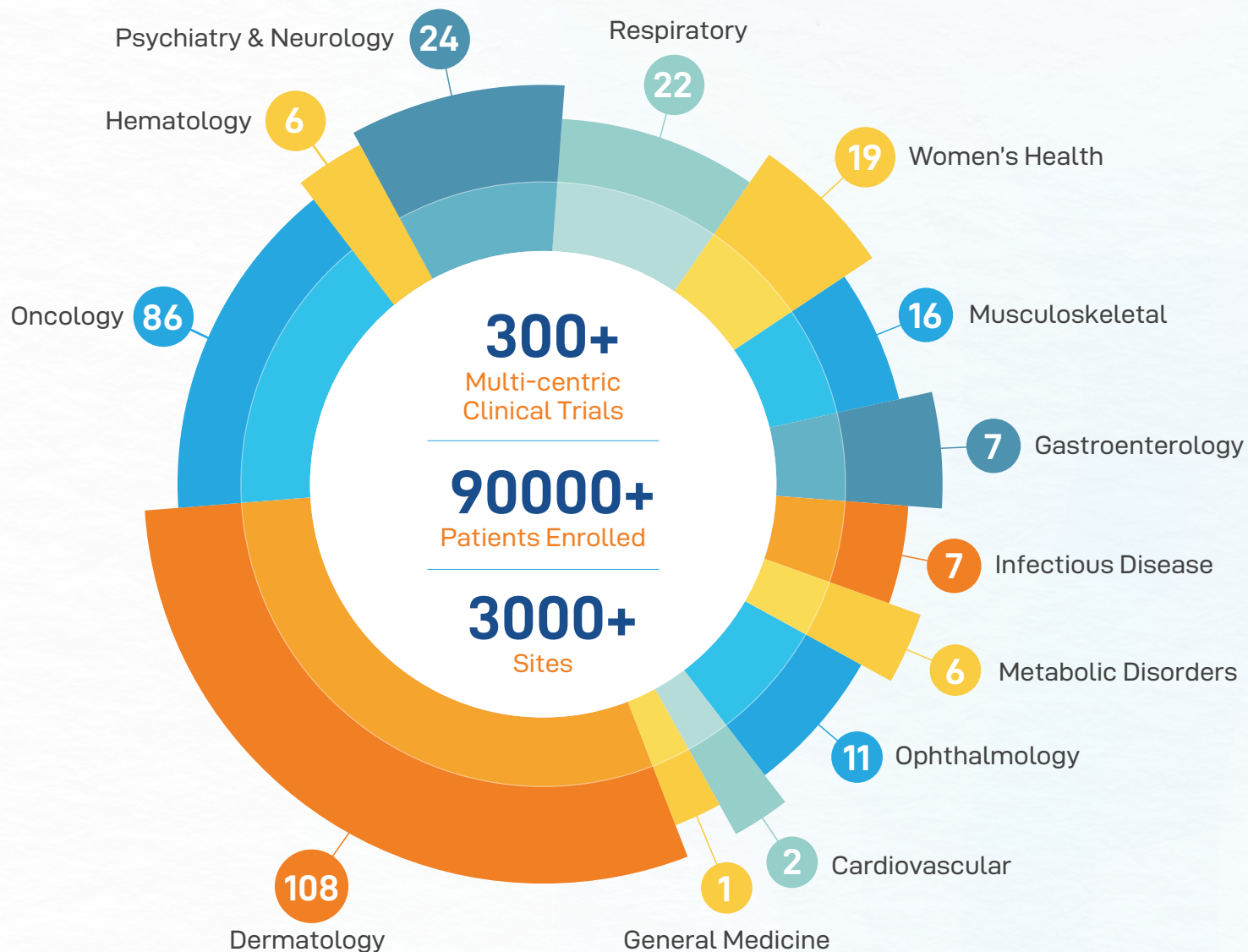
Global regulatory submission experience across major health authorities

Biostatistics &
Medical Writing

Medical Imaging
Analysis

Safety &
Pharmacovigilance

Central Laboratory
Services

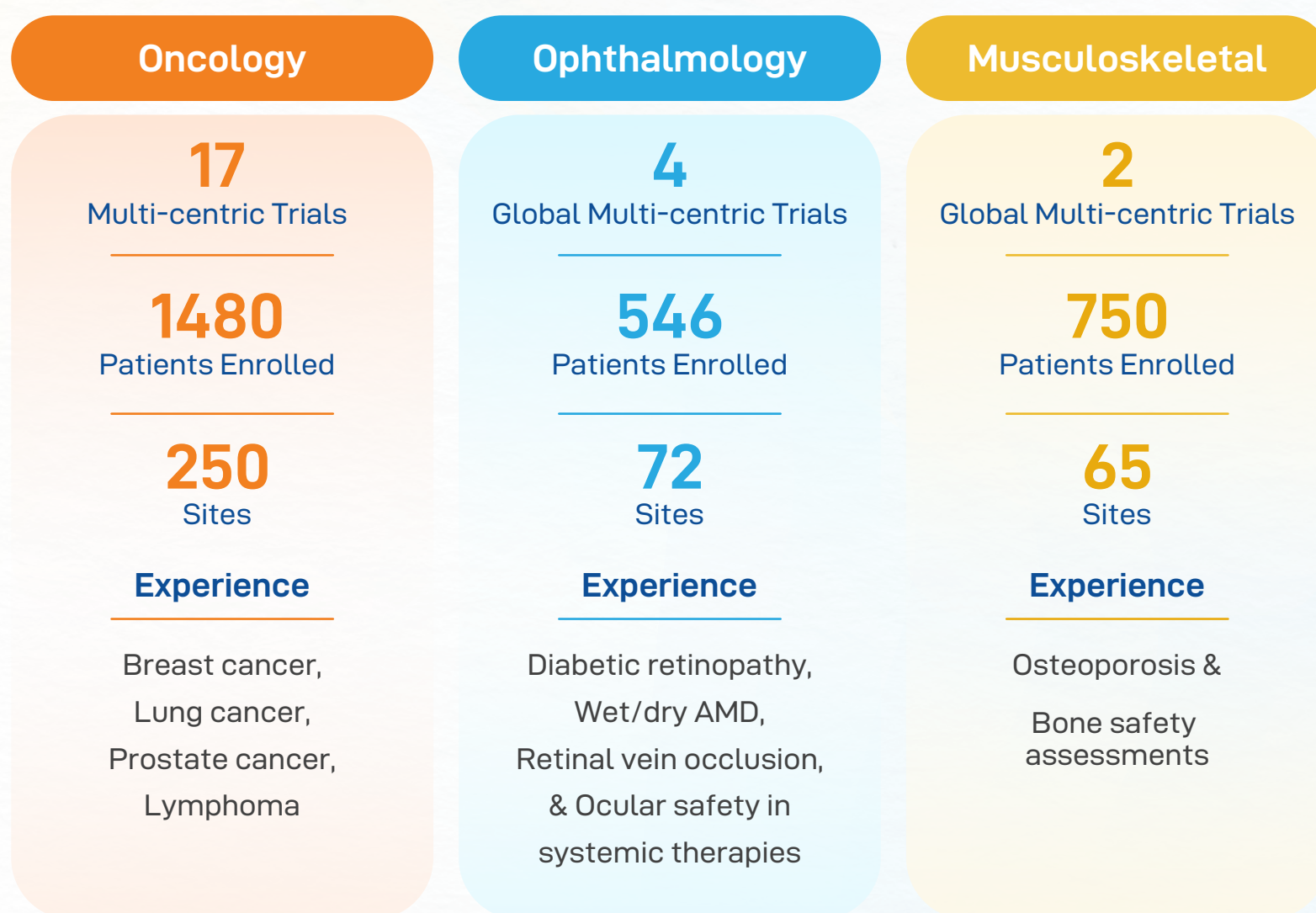


Medical Imaging Analysis for Clinical Trials

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

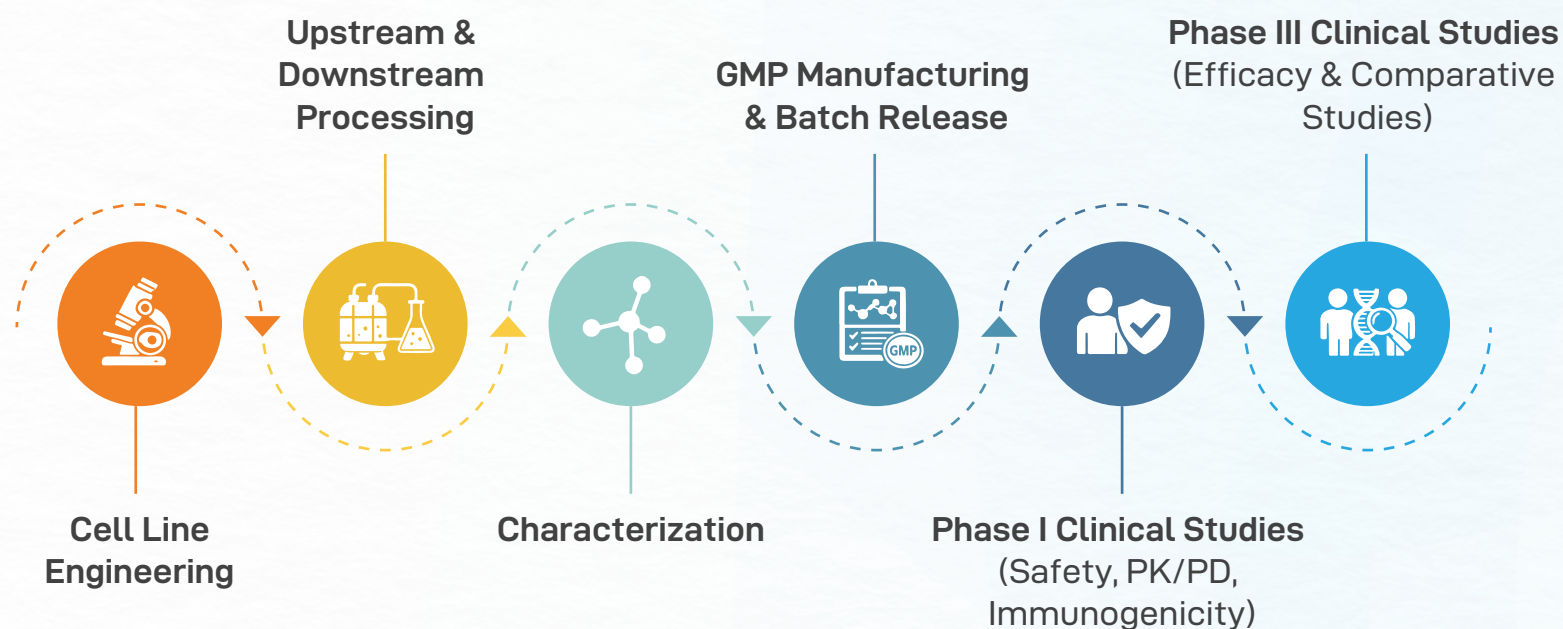
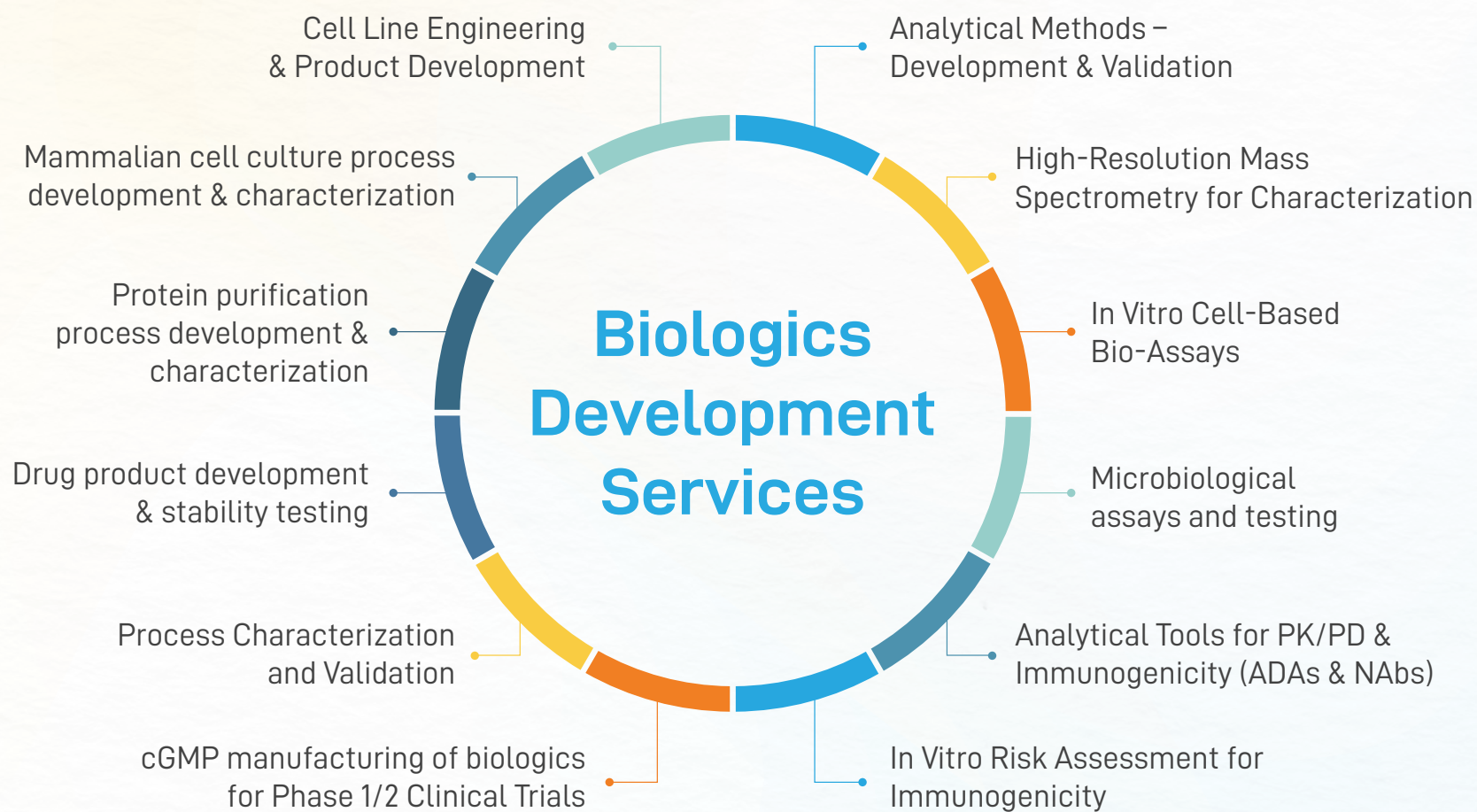
Wide Experience in End-to-End Imaging Support



10000+ images reviewed | **2500+** Patients

Inspected by **DCGI, USFDA, EMA**

Biologics Development CDMO and GxP-compliant Solutions



Extensive Experience in Biosimilar Studies

Healthy Volunteer Studies

15+

Studies

2300+

Participants

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

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

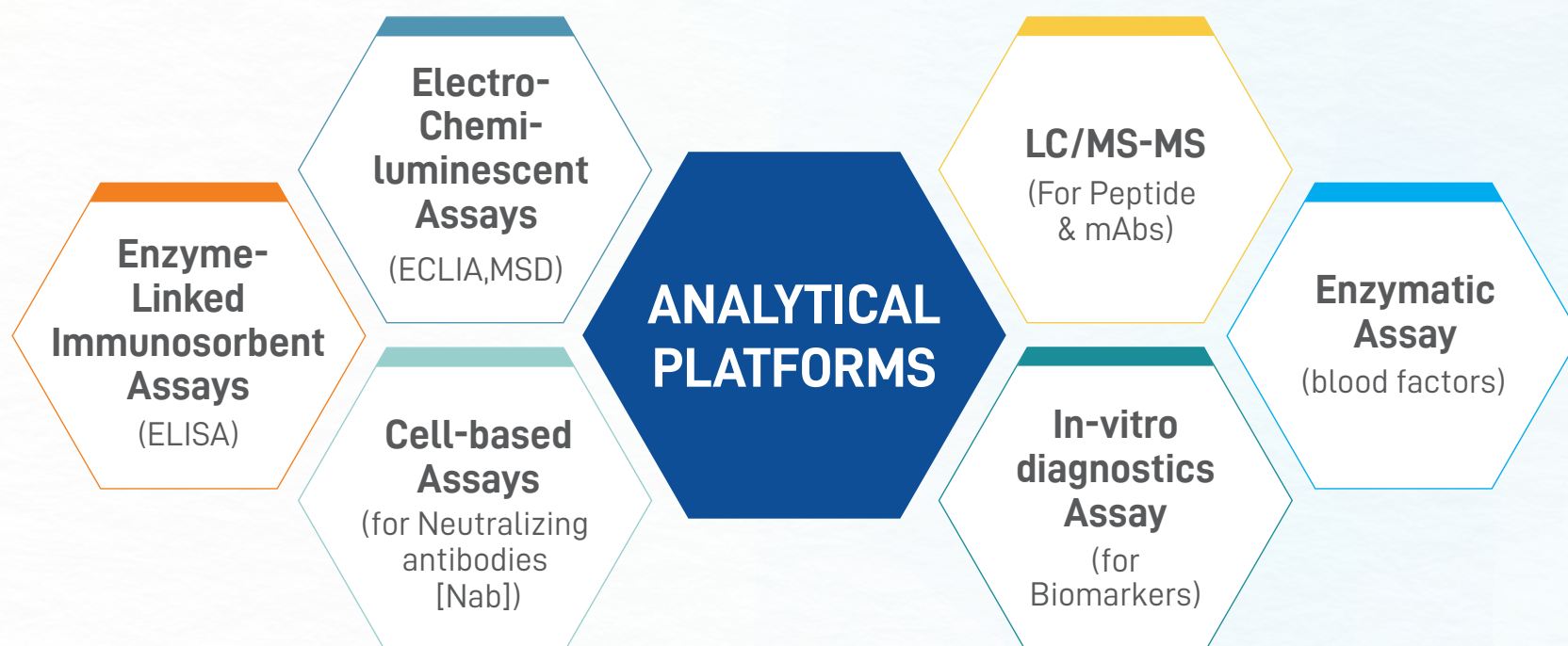
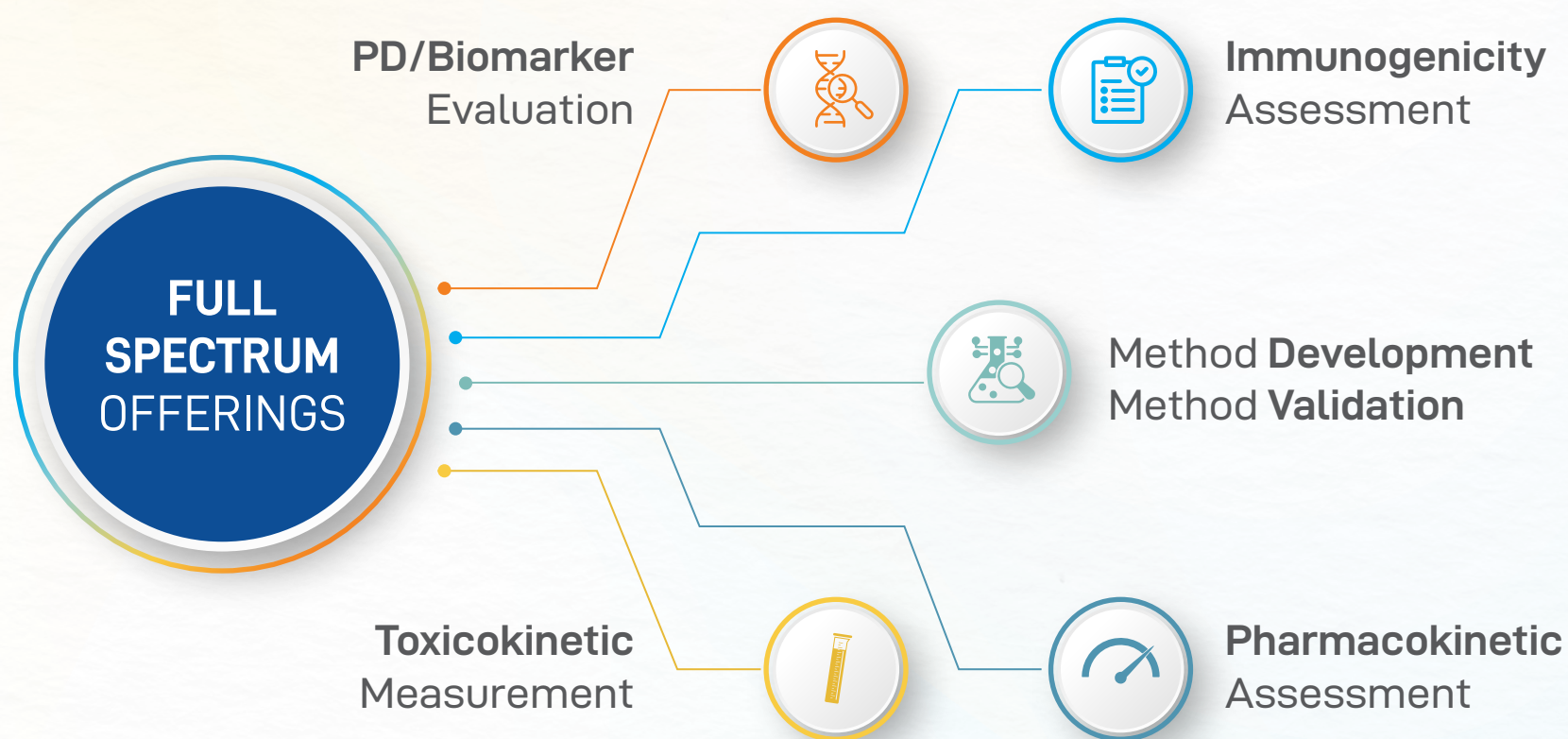
- Vedolizumab

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 1 st Romiplostim Biosimilar)
• Enoxaparin (PK, ADA)	• ANVISA
• Denosumab (PK, PD, ADA, nAb)	• EMA and US FDA
• Ranibizumab (PK, ADA, nAb)	• EMA

Biotherapeutics & Large Molecule Bioanalytical Services

End-to-end bioanalytical support for Complex large molecules



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	-	✓	✓	-

**Accelerating
your path from
Molecule to Market**

with Integrated CRO
& Biologics CDMO
Services

Advance your clinical programs with expert support



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