

MISSING BIOSIMILARS PORTFOLIO IN YOUR PIPELINE?

Bridge the Gap with Lambda's End-to-End
Biosimilar Development & Clinical Trials Expertise

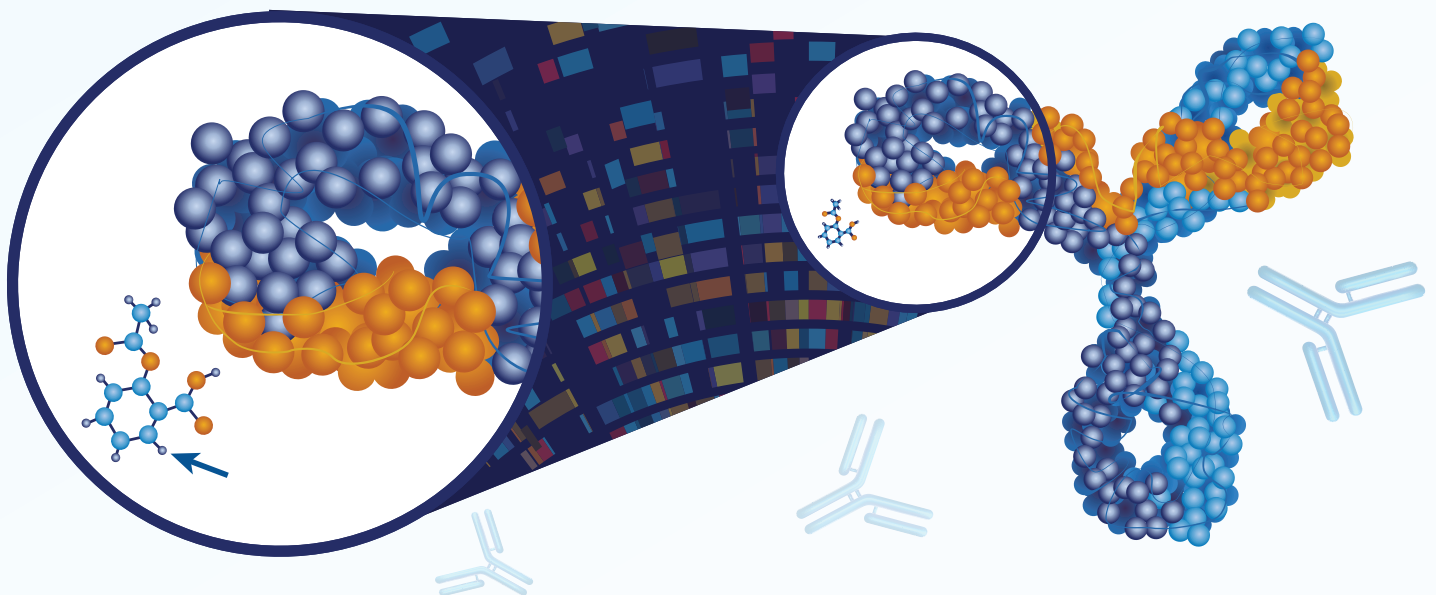
- | Cell Line Development
- | Upstream & Downstream Bioprocessing
- | Characterization
- | GMP Manufacturing & Batch Release

Phase I Clinical Studies

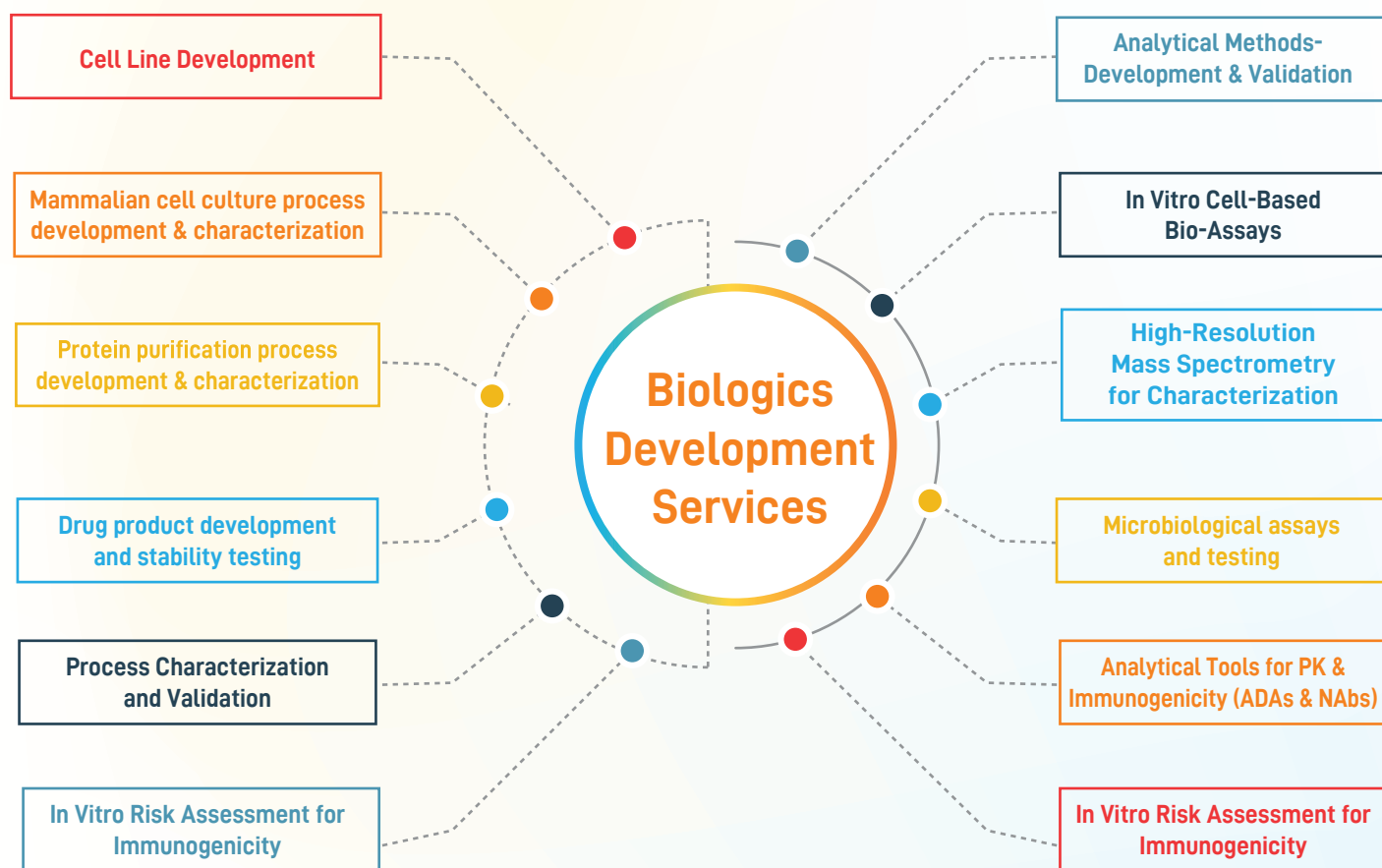
(Safety, PK/PD, Immunogenicity)

Phase III Clinical Studies

(Efficacy & Comparative Studies)



END-TO-END SERVICES FOR MABS, ADCS AND BI-SPECIFICS: FROM CELL LINE TO CHARACTERIZATION



INTEGRATED CLINICAL TRIAL SOLUTIONS ACROSS ALL PHASES

- Phase I-Safety Studies (PK/PD)
- Immunogenicity Studies
- Phase III - Efficacy Studies in Patients
- Comparative PK/PD Studies in healthy volunteers and target populations
- Full Regulatory Affairs support across all phases

HEALTHY VOLUNTEER STUDIES FOR BIOSIMILARS

15+ Studies

2,300+ Subjects

Submission: US FDA | EMA | DCGI

Bevacizumab

Pegfilgrastim

Trastuzumab

Daratumumab

Pertuzumab

Ustekinumab

Denosumab

rFSH

Vedolizumab

THERAPEUTIC EXPERIENCE FOR LATE PHASE CLINICAL TRIALS

20+

Biosimilar Clinical Trials

3,500+

Patients Enrolled

400+

Sites

Oncology

Bevacizumab

Denosumab

Pertuzumab

Rituximab

Daratumumab

Trastuzumab & Trastuzumab Emtansine

Gastroenterology

Vedolizumab

Ophthalmology

Bevacizumab

Ranibizumab

Afilibercept

Orthopedics

Denosumab

Teriparatide

END-TO-END LABORATORY CAPABILITIES FOR BIOSIMILARS & LARGE MOLECULES

Biosimilar	Pharmacokinetics Assay	Immunogenicity Assay		Pharmacodynamics Assay
		Anti-drug antibody	Neutralizing antibody	
Bevacizumab	✓	✓	✓	—
Denosumab	✓	✓	✓	✓ (P1NP, CTx, NTx)
Adalimumab	✓	✓	✓	—
Ranibizumab	✓	✓	✓	—
Trastuzumab (SC)	✓	✓	✓	—
Pertuzumab	✓	✓	✓	—
Rituximab	✓	✓	—	✓ (CD19)
Romiplostim	✓	✓	—	—
Teriparatide	✓	✓	✓	✓ (Serum Calcium)
FSH	✓	✓	—	✓ (β-Estradiol)
Filgrastim	✓	✓	✓	✓ (CD34+)
Pegfilgrastim	✓	✓	—	✓ (ANC)
Vedolizumab	—	✓	—	—



Excellence Validated

Successfully cleared **EMA, MHRA & FDA** Inspections for **Biosimilar Studies**.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



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ADMINISTRATION



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INTEGRATED SERVICES

- Study Design, Protocol & Reports
- Regulatory affairs
- Clinical development
- Central Laboratory services
- Clinical supplies management
- Clinical safety and pharmacovigilance
- Bioanalytical services - PK/PD, Immunogenicity
- Biostatistics



Connect with us to explore how we can accelerate your clinical trials.

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