

Leaders in Biosimilars

Biosimilars Overview

Celerion has extensive experience and expertise in supporting biologics and biosimilar development programs.

- Over 30 years of experience in developing robust assays for measuring concentration of the biologic activity and antibodies including neutralizing antibodies and immunogenicity assessments in plasma/serum and other biological matrices.
- Celerion’s large phase I clinics provide an excellent environment to conduct PK/PD comparisons of biosimilar versus innovator in a highly controlled study facility using large cohorts to keep study variability to a minimum.
- Strong track record of market approved biological and biosimilar products.
- Celerion’s experience in managing clinical studies of biologics in patients provides an excellent basis to support clinical studies supporting similarity in oncology, respiratory disease, autoimmune and ophthalmic diseases.
- Pharmacokineticists, statisticians, physician investigators, medical writers and regulatory professionals knowledgeable in optimized study sizing and design to evaluate similarity that meet regulatory requirements.

	Bioanalytical Experie	Clinical Studies
Monoclonal Antibodies		
Adalimumab (Humira)	PK, ADA	✓
Bevacizumab (Avastin)	PK, ADA	✓
Cetuximab (Erbix)	PK, ADA	
Denosumab (Prolia)	PK, ADA	✓
Omalizumab (Xolair)	PK, ADA	✓
Palivizumab		✓
Panitumumab		✓
Ranibizumab	PK	
Rituximab (Rituxan)	PK, ADA	
Secukinumab		✓
Trastuzumab (Herceptin)	PK, ADA	✓
Ustekinumab (Stelara)	PK, ADA, CB	✓
Vedolizumab		✓
Fusion Proteins		
Abatacept		✓
Aflibercept	PK, ADA	✓
Etanercept (Enbrel)	PK, ADA	✓
Cytokines		
Filgrastim (Neupogen)	PK, ADA	✓
Interferon-alpha-2a	PK, ADA	
Interferon-beta-1a		✓
Interferon-beta-1b	PK	
Peg-Interferon-alpha-2a	PK, ADA	✓
Peg-Interferon-alpha-2b	PK, ADA	✓
Romiplostim (Nplate)	ADA, CB	
Hormones		
Darbepoetin	PK	
Erythropoetin (EPO)	PK, ADA	✓
Follitropin-alpha (FSH) (GonalF)	PK, ADA	✓
Glucagon (drug, biomarker)	PK	✓
Insulin	PK, ADA	✓
Insulin analogues glargine, aspart, detemir, lispro	PK, ADA	✓
Parathyroid Hormone (1-34), (Teriparatide)	PK, ADA	✓
Somatotropin (hGH)	ADA	
Other		
Hyaluronidase		✓
Low Molecular Wt Heparins	PK	✓
Octreotide	PK	✓

PK = drug assay; ADA = anti-drug antibody assay; CB = cell-based assay