

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 Assays	Clinical Studies
Monoclonal Antibodies		
Adalimumab	PK, ADA	✓
Bevacizumab	PK, ADA	✓
Cetuximab	PK, ADA	
Denosumab	PK, ADA, CB	✓
Natalizumab	PK, ADA	✓
Omalizumab	PK, ADA	✓
Palivizumab		✓
Panitumumab		✓
Ranibizumab	PK, ADA	
Rituximab	PK, ADA	
Secukinumab		✓
Trastuzumab	PK, ADA	✓
Ustekinumab	PK, ADA, CB	✓
Vedolizumab		✓
Fusion Proteins		
Abatacept		✓
Aflibercept	PK, ADA	✓
Etanercept	PK, ADA	✓
Cytokines		
Filgrastim	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	ADA, CB	
Hormones		
Darbepoetin	PK	
Erythropoetin (EPO)	PK, ADA	✓
Follitropin-alpha (FSH)	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