celerion
Translating Science to Medicine

Leaders in Biosimilars

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

– Over 25 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.

– 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 efficient study sizing and design to evaluate similarity that meet regulatory requirements.

	Bioanalytical Assays	Clinical Studies
Monoclonal Antibodies		
Adalimumab	PK, ADA	✓
Cetuximab	PK, ADA	
Bevacrizumab	PK, ADA	✓
Ranibizumab	PK, ADA	
Trastuzumab	PK, ADA	✓
Natalizumab	PK, ADA	
Omalizumab	PK, ADA	✓
Rituximab	PK, ADA	
Secukinumab		✓
Ustekinumab	PK, ADA, CB	✓
Fusion Proteins		
Etanercept	PK, ADA	✓
Cytokines		
Filgrastim	PK, ADA	✓
Peg-filgrastim	PK, ADA, CB	✓
Interferon-alpha-2a	PK, ADA	
Peg-Interferon-alpha-2a	PK, ADA	
Peg-Interferon-alpha-2b	PK, ADA	
Interferon-beta-1a		✓
Interferon-beta-1b	PK	
Hormones		
Insulin	PK, ADA	✓
Insulin analogues glargine, aspart, determir, lispro	PK, ADA	✓
Somatotropin (hGH)	ADA	
Erythropoetin (EPO)	PK, ADA	✓
Darbepoetin	PK	
Glucagon (drug, biomarker)	PK	✓
Parathyroid Hormone (1-34)	PK, ADA	
Follitropin-alpha (FSH)	PK, ADA	✓
Other		
Hyaluronidase		✓
Low Molecular Wt Heparins	PK	
Octreotide	PK	✓

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