

Our mission is to deliver bioanalytical excellence

BIOSIMILARS

REGULATED BIOANALYSIS CAPABILITY



Why Agilex Biolabs?



Unparalleled Experience

>150 years of combined experience in early phase research.



Data Integrity and Quality Assurance

Our FDA-inspected facilities have OECD GLP recognition and ISO 17025 Accreditation with NATA. Highest quality data acceptable to all regulatory agencies.



Timeliness and Speed

Fast turnaround for Single Ascending Dose (SAD) and Multiple Ascending Dose (MAD) studies.



43.5% R&D Tax Incentive

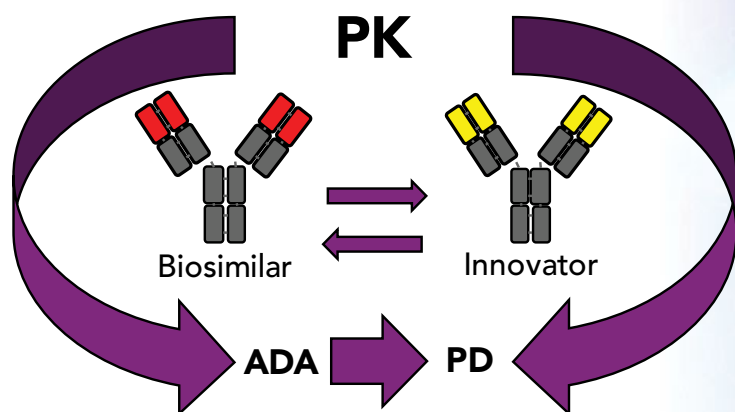
Eligible biotechs can receive a 43.5% cash refund of Australian R&D expenses.

Biosimilar capability

For Biosimilar approval by regulatory authorities, comparison testing against the reference innovator product is required for safety, purity, potency, stability and immunogenicity.

The bioanalytical assays required to support a clinical trial for biosimilars include:

- PK
- Immunogenicity:
 - Antidrug antibody (ADA)
 - Neutralising antibody detection (Nab)
- Pharmacodynamic biomarkers



Biosimilars validated assay list

Agilex Biolabs has developed PK and immunogenicity assays for a wide range of biosimilars. These have been tested in clinical studies against US and EU innovator compounds.

- Allows for time and cost effective setup of the required assays for your trial.
- Strong biosimilar experience across different compounds and assays reduces risk.
- High scientific expertise utilised for every project ensuring the best outcome.

Originator	Biosimilar	Target	PK Assay	ADA Assay	PD Assay
Lucentis®	Ranibizumab	VEGF-A	X	X	VEGF
Forsteo®	Teriparatide	PTH1 receptor	X	X	
Avastin®	Bevacizumab	VEGF-A	X	X	VEGF
Actemra®	Tocilizumab	IL-6 receptor	X	X	
Xolair®	Omalizumab	IgE Fc	X	X	IgE
Herceptin®	Trastuzumab	HER2/neu	X	X	
Soliris®	Eculizumab	C5	X	X	X
Stelara®	Ustekinumab	IL12/IL23	X	X	

Immunoassay formats and instrumentation

Agilex Biolabs operate the largest bioanalytical lab in Australia. Our highly skilled expert scientists utilize a broad range of assay formats and access high-end instrumentation to deliver robust compliant assays enabling clinical trials for regulatory submission.

- ELISA
- Meso Scale Discovery MSD – immunogenicity platform
- Gyrolab xPlore – automated nanoliter-scale immunoassays
- LC-MS/MS – alternative allowing for lowest risk assay
- Watson LIMS – laboratory information management system

Bioanalytical expertise for biosimilar development

PK assays

Assay development de novo or by method transfer. Utilization of multiple instrument platforms. Range of molecules and assay types. Measuring either free or total drug in serum or plasma.

Immunogenicity assays (ADA)

Single ADA assay (screening, confirmatory and titer assay) to demonstrate anti-drug antibody binding using techniques such as acid dissociation, affinity capture elution (ACE), precipitation and acid dissociation (PandA) or solid phase extraction with acid dissociation (SPEAD) to optimise assays to mitigate interferences and meet sensitivity and drug-tolerance. ADA statistical analysis is applied for cutpoint assessment using the latest industry-accepted guidelines.

Neutralising antibody assays (NAb)

To demonstrate neutralising effects of ADA's supporting immunogenicity risk assessment. Either by competitive ligand binding assay approach or cell-based assay solution.

Pharmacodynamic biomarker assays (PD)

Agilex can develop and validate a variety of ligand binding biomarker assays to confirm mode of action of the drug in serum or plasma.

Get in touch with our expert scientists to learn more about how we can help you deliver your next project.