

World Leaders in Biomarker & Bioanalysis Research Services

Synexa is an industry leader in contract bioanalytics and biomarker research services specializing in biopharmaceuticals.

For nearly 20 years we have supported our Biopharma partners across the globe to achieve their clinical milestones. As a deeply scientifically-driven CRO we deliver bespoke bioanalytical solutions to meet our client's specific challenges.

Our global purpose-built laboratories have been designed and fitted to meet the fast-changing and ever-evolving complexity of drug development pipelines.

Guided by a combined scientific experience of over 800 years, our team of world-class scientists pride themselves on going the extra mile to deliver high levels of customer service and quality science that meets your expectations.



Clinical Research Services

Synexa specializes in providing bespoke end-to-end biomarker and bioanalytical solutions, developed and validated to meet your specific challenges.

- Large and novel molecule bioanalysis
- Biomarker analysis
- Immunogenicity & Pharmacokinetics
- Cell-based assays
- Pharmacogenetics
- ProtoTrials®
- Regulatory approval
- *De novo* method development and validation



Technology Platforms

Our bespoke bioassay solutions are paired with proven advanced technology platforms, capable of assessing biomarkers across the biological spectrum.

DNA

- TargetedPGx
- Microarray
- Electrophoresis

Protein

- ELISA
- MSD-ECL
- ELISpot
- Protein arrays
- Nephelometry

RNA

- NanoString®
- RT-qPCR
- PCR expression array

Cell

- Flow Cytometry
- Cell culture assays

Tissue

- NanoString®
- Organotypic culture

Committed to Driving the Successful Development of your Therapeutic

Our approach is simple - to work as a fully integrated partner providing consultative and collaborative support every step of the way.

Your Global Partner in Biosimilar Research Science

Synexa integrates a world-class scientific foundation with professional service delivery. We specialize in the development and validation of assays according to a sponsor's priorities and requirements on any Biosimilar, BioBetter or NBE molecule.

Examples of our experience in providing pharmacokinetic and immunogenicity solutions for biosimilars include:

SPONSOR-DERIVED BIOSIMILAR | HUMIRA®

Adalimumab

Insights: High levels of ADA's detected for Adalimumab. Additional immunogenicity assays should be accounted for.

SPONSOR-DERIVED BIOSIMILAR | NEULASTA®

Pegfilgrastim

Insights: No clinically relevant levels of immunogenicity for Pegfilgrastim

EPOGEN® | EPREX® | BINOCRIT®

Erythropoietin

Insights: Variations in WHO standard for Erythropoietin may require additional validation using alternative standards.

SPONSOR-DERIVED BIOSIMILAR | STELARA®

Ustekinumab

Insights: Assay builds will require consideration of basal interference by IL-12 and IL-23 in study samples.

RECOMBINANT ASPARAGINASE

Asparaginase

Insights: High levels of hypersensitivity in patients including high levels of nAb development.

LEUKINE®

GM-CSF

Method under development.

ECULIZUMAB BIOSIMILAR | SOLIRIS®

Eculizumab

Method under development.

PROLIA® BIOSIMILAR | PROLIA®

Denosumab

Method under development.



Quality Expertise

We adhere to the strictest of quality standards, guided by the relevant regulatory bodies, ensuring that the science we provide is sound, reliable and valuable in every study.

- All activities conducted according to **GCP/GCLP** guidelines and in compliance with **ISO/IEC15189:2012**.
- All methods are **validated** according to **FDA/EMA guidelines**.
- **Global footprint** with 3 specialised laboratories.
- **70+** Masters and PhD-level scientists.
- **10 000** bioanalytical samples processed annually.
- **30 client-tailored bioanalytical methods** validated annually.

Quality Science
Delivered On Time
and within Budget

Contact our specialist team to discuss how we can support you to achieve your clinical milestones.



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Get in Touch

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