Biosimilars development

Accelerating Biosimilar Development

The PPD™ clinical research business of Thermo Fisher Scientific is at the forefront of biosimilar development with extensive experience that spans a broad spectrum of therapeutic areas and services. We have the expertise, commitment and dedicated team of global biosimilars professionals to support any size organization.

Unparalleled biosimilar expertise

Our goal is to help overcome challenges and expedite full development to bring your biosimilar to market faster. Some of our achievements include:

- Supported the development of all top 10 selling biologic products
- Successfully delivered the first monoclonal antibody biosimilar to the EU market
- PPD™ Laboratory services Bioanalytical lab has developed assays and tested more than 300,000 samples
- Proven track record of accelerating enrollment in biosimilar studies

We offer a full range of biosimilar drug development services, from cell line development and characterization to clinical development and market approval.

Successfully delivered first monoclonal antibody biosimilar to EU market

Biosimilars intelligence group

An extension of your team, our biosimilars intelligence group provides expert insights on every element of your program, from regulatory strategy and protocol design, through execution and validation to approval. You'll engage directly with physicians, scientists, regulatory professionals, project managers and business development strategists throughout your trial.

Biosimilar product development services

- Preclinical development
- Start-up
- Global Clinical Supplies
- Biosimilar Investigator Network
- Clinical Development
- Regulatory affairs
- PK/PD
- CMC support
- Biostatistics

Our cross-functional and cross-therapeutic area experts work as an extension of your team to optimize your development plan and protocol, operationalizing best-practice approaches to shorten timelines while ensuring validation and delivery of the safety and efficacy data required to gain regulatory approval and speed entry of your biosimilar asset to market.

We have conducted:

65 biosimilar studies

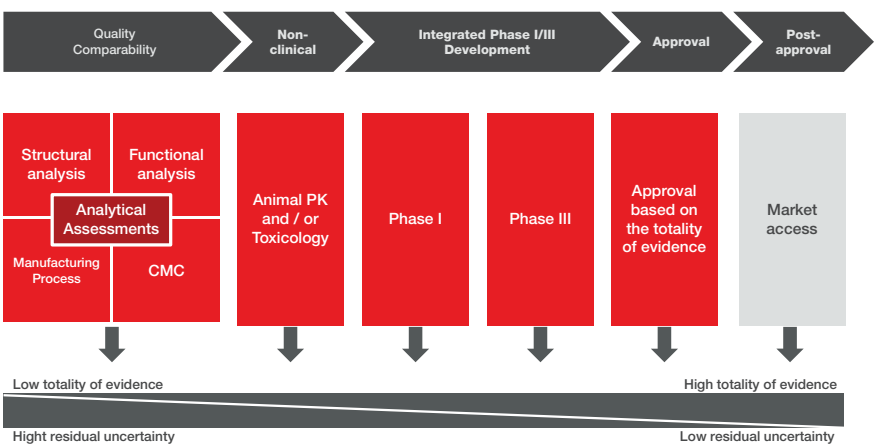
Across **3,700 sites** around the world

Involving **17,000 patients**

A seamless approach keeps your biosimilar on track

Your program is fully integrated and streamlined in a way that results in maximum efficiencies and effectiveness. This approach integrates structural and functional comparability assessments with the clinical program and regulatory submission strategy in a stepwise fashion to reduce residual uncertainty.

Seamless development



- Immunology / Dermatology
- Hematology / Oncology
- Ophthalmology
- Metabolic / Women's Health

Strategic guidance

- Our experienced team can provide strategic guidance in all operational activities:
- Global footprint with access to our network of top performer countries/sites for biosimilar studies based on experience, regulatory landscape and site relationships
- Activated and contracted with more than 2,200 sites across all 4 regions, from Phase I to Phase IV biosimilar studies
- Our site startup team has a track record of delivering site activations for faster biosimilar studies
- Innovative technology empowers you with analytics-driven insights, efficacy and safety data required to gain regulatory approval

Using data-driven feasibility and in-depth regulatory intelligence, we'll identify the best country and site mix for your program.

Spanning the entire continuum of biosimilar development

Regardless of where you are in the biosimilar development process, we have the robust capabilities and clinical support required to support a designation of interchangeability.

Learn more at **thermofisher.com/ppd**