Biosimilar

Accelerate your clinical trial with our expertise in biosimilar development

ppd

Biosimilars: Unlock the future of medicine

In the rapidly evolving world of health care, biosimilars represent a breakthrough in providing high-quality, cost-effective therapeutic options. At the PPD™ clinical research business of Thermo Fisher Scientific, we are at the forefront of biosimilar development, harnessing cutting-edge technology and unparalleled expertise to bring innovative solutions to market. We have supported the **development of all top 10 selling** biologics and successfully **delivered the first monoclonal antibody biosimilar** to the European Union market.

Our commitment to excellence

We are dedicated to advancing biosimilar development through:

- **Biosimilar intelligence group:** An extension of your team, our biosimilar intelligence group provide expert insight on every element of your program development
- **Regulatory expertise:** Navigating the complex regulatory landscape is our strength. We ensure biosimilars strategy submission plans meet all regulatory requirements, providing confidence on timelines and rapid approval
- **Strategic partnerships:** We collaborate with leading health care organizations, research institutions, and industry partners to accelerate the development and commercialization of biosimilars.

Shape the future

Embrace the potential of biosimilars and transform health care with the PPD clinical research business as your Contract Research Organization (CRO) partner. Together, we can make high-quality, affordable biologic treatments accessible to all, improving lives and advancing medical science.

Integrated biosimilars services - expert advice and support at every stage of the process

We provide clients with a fully integrated approach to the development of biosimilar medicines.

Our experience encompasses strategic consultancy from pre-clinical, analytical, regulatory, and clinical development to MAA/NDA/BLA submission for international sponsors, as well as execution of various phases of clinical trials with biosimilar compounds.

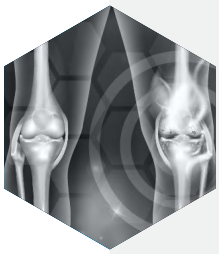
We have conducted:

67 biosimilar studies

Across **3,900** **sites** around the world

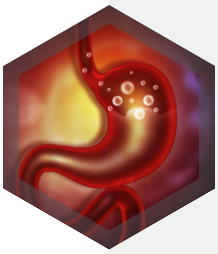
Involving **20,000** **patients**

Benefit from our more than 10 years of biosimilar experience, spanning all clinical trial phases and a broad spectrum of therapeutic areas including: immunology, dermatology, hematology, oncology, ophthalmology, metabolic and women's health for organizations of all sizes.



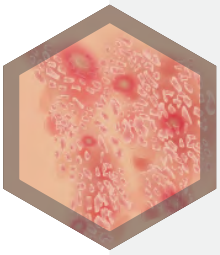
Rheumatology

- Rheumatoid arthritis
- Osteoarthritis
- Ankylosing spondylitis
- Psoriatic arthritis
- Myositis
- Gout



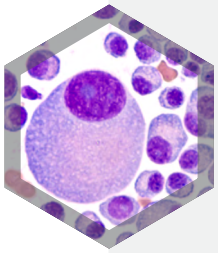
Gastroenterology

- Celiac disease
- Gastroparesis
- GERD
- Irritable bowel syndrome
- Ulcerative colitis



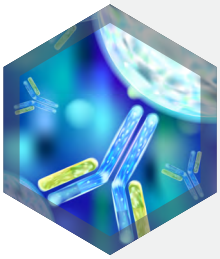
Dermatology

- Atopic dermatitis
- Psoriasis
- Prurigo nodalaris
- Skin infections & open wounds
- Uremic Pruritus
- Glabellar lines



Hematology/oncology

- Leukemia
- Anemia
- Lymphoma
- Hemophilia
- Myeloma
- Breast cancer
- Melanoma
- Prostate cancer
- Ovarian/uterine cancer
- Colorectal cancer
- Lung cancer



Immunology

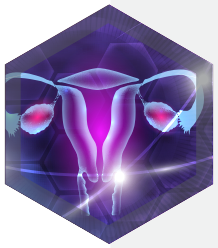
- Hereditary angioedema
- Lupus
- Sjogren's syndrome
- Vasculidites

Respiratory

- Asthma
- Allergic rhinitis
- COPD
- Respiratory infections
- Idiopathic pulmonary fibrosis
- Cystic fibrosis

Ophthalmology

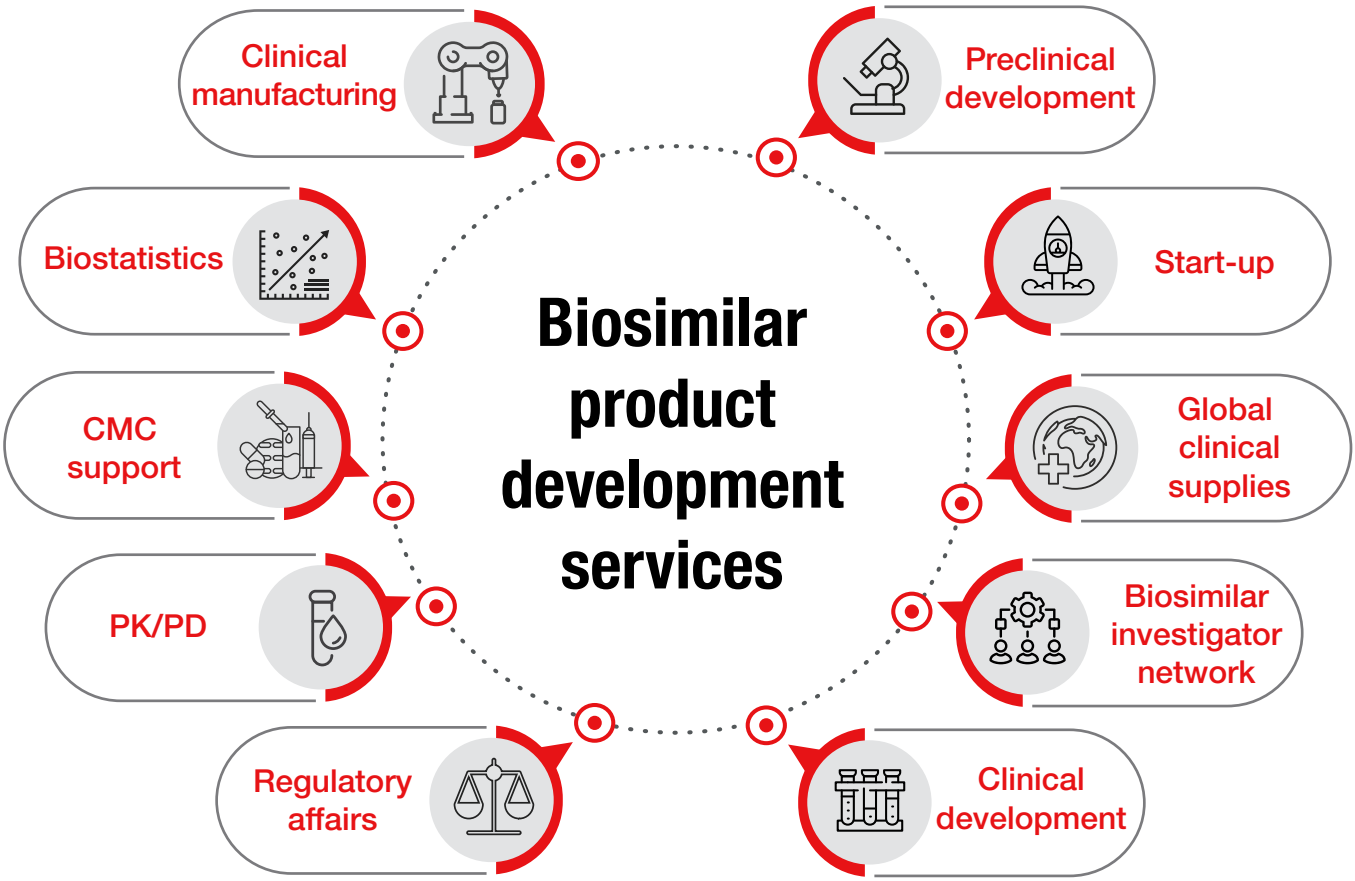
- Acute optic neuritis
- Age-related macular degeneration
- Conjunctivitis
- Corneal wound healing
- Diabetic macular edema/diabetic retinopathy
- Dry eye
- Geographic atrophy
- Glaucoma/ocular hypertension



Metabolic and women's health

- Endometriosis
- Uterine fibroids
- Cervical Intraepithelial neoplasia (CIN)
- Women's infertility
- Menopausal disorders
- Pregnancy complications
- Preeclampsia
- Premature ovarian failure

Biosimilar product development services



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.

A seamless approach keeps your biosimilar on track

Your program will benefit from an integrated approach where your Phase I – Phase III trials will be delivered with smooth interaction and fast delivery. This approach integrates structural and functional comparability assessments with the clinical program and regulatory submission strategy in a stepwise fashion to reduce residual uncertainty.

Our global footprint provides access to our network of top performer countries/sites for biosimilar studies based on experience, regulatory landscape and site relationships.

We have an intensive investigator database of **more than 2,200 sites** across over **51 countries**.

Our site start-up team has a track record of delivering site activations for faster biosimilar studies.

We have implemented strategies involving countries that had not previously accepted biosimilar application and where established guidelines were not available.

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

Early development stage

Developing a biosimilar requires demonstrating its close resemblance to the original biologic while proving equivalent therapeutic and clinical effects. By combining our early phase, biosimilar development expertise, targeted dermatology and psoriasis experience, and network of top-performing sites, we will deliver a customized operational plan. We work seamlessly to meet your study objectives, including achieving your final clinical study report (CSR) goal earlier than your anticipated timeline and delivering the high-quality data you require to continue development.

With early phase development, an experienced biosimilars partner is needed in order to guide development. Through the knowledge and guidance of our early phase and biosimilar subject matter experts (SMEs), and our biosimilars intelligence group (BIG), we will apply best practices to optimize your study design.

With an accelerated operational strategy based in careful country planning to engage the ideal sites, we can support planning for your study. We have the ability to develop Global scenarios to meet your study needs. Each scenario offers the experience and capabilities needed to conduct your study, and enrollment to meet your required timelines.

We have sites in North America and network partner sites in Poland, Australia, New Zealand and South Africa. We can provide the right scenario that offers the experience and capabilities needed to conduct your study, and enrolment.

Targeted early phase experience in the last eight years

- **800+** phase I studies involving more than **10,000** NHVs and patients, including:
- **205+** PK studies
- **20+** biosimilar studies
- **32+** studies of monoclonal antibody (mAb) assets

Accelerator™ Drug Development 360° CDMO and CRO Solutions

The manufacturing process in biosimilar drug development is fundamental to the success of the product. It ensures the final product meets the necessary regulatory standards and provides the necessary evidence that the biosimilar is comparable to the reference biologic in terms of quality, safety, and efficacy. The key areas in the biosimilar manufacturing process include the following:

- Consistency and quality
- Comparability to the reference product
- Regulatory Approval
- Scalability and reproducibility

Gain an advantage by partnering with a CRO that also has CDMO expertise with the biosimilars manufacturing process.

Thermo Fisher Scientific is a leading global provider of a full suite of innovative CDMO (contract development manufacturing organization) and CRO services as core offerings. Partner with Thermo Fisher Scientific at any point in your unique drug development journey to accelerate your goal of getting treatments to patients faster, and benefit from our biosimilar expertise in both CRO and CDMO solutions.

We deliver:

Speed – Working with one partner, instead of multiple vendors, eliminating timeline gaps, regulatory challenges, and proactively mitigating risks.

Operational flexibility – Meet your unique biosimilar development and research requirements, both locally and globally, with our innovative solutions and scaleable manufacturing and clinical research solutions.

Collaborative partnership – Get the integrated expertise you need across all phases of your drug development journey.

More than 120 biotech and biopharma companies are currently accelerating their time to market by partnering with Thermo Fisher Scientific across our CDMO and CRO services on more than 350 protocols.

Accelerator™ Drug Development

Partner with us starting at **any point**, in **any phase**

Preclinical, IND, Phase I

Benefits:

- De-risk early-phase development
- Gain speed to IND and Phase I trials
- Scientific and regulatory expertise

Phase II-III, NDA

Benefits:

- Speed to market
- Cost efficiency
- Streamlined supply chain and labs
- Patient recruitment and retention
- Global reach and expertise

Commercialization and post-approval studies

Benefits:

- Maximize an asset's market potential
- Manufacturing capacity
- Post-approval studies
- Real-world data (RWD) and real-world evidence (RWE)

Accelerating your unique **drug development journey** with **innovative 360° CDMO and CRO solutions**, supporting your aspiration to get treatments to patients faster.

Every drug development journey is unique. That is why you can partner with Thermo Fisher Scientific at any point, in any phase of your drug development and gain benefits by using combinations of our global expert CDMO, CRO, clinical supplies, labs, regulatory and consulting services.

If you are in pre-clinical development, we can provide you speed to IND by partnering with us to manufacture your investigational medical product, use our GMP labs for testing, and use our expert CMC and regulatory consulting services for your IND application and Phase I trial planning.

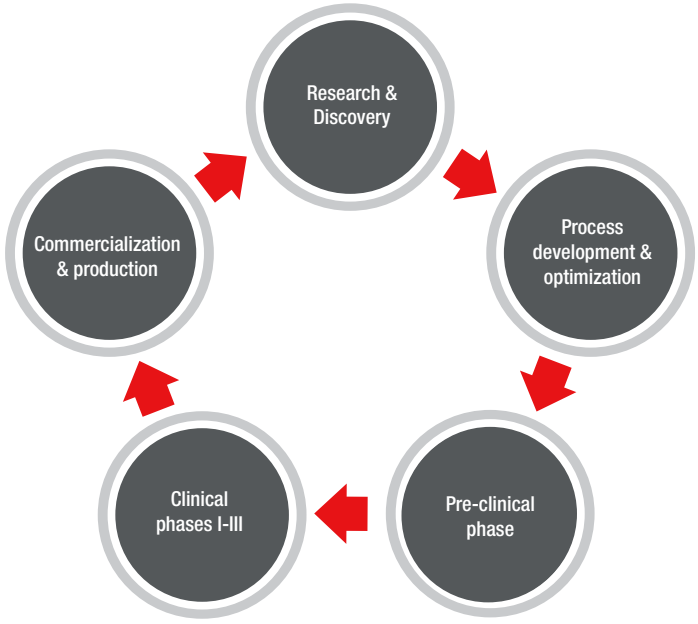
We can provide benefits for Phase II and III trials if you partner with us for your clinical research, clinical trial supplies, and central lab services by using our integrated trial supply and demand forecasting systems.

Your greatest time savings and your highest return on investment can be achieved by starting your drug development journey with us. We understand that every customer has different immediate needs and business objectives. We have a comprehensive array of services that can meet your needs including, utilizing the combination of our drug substance and drug product services, our clinical research services, and our GMP and central lab services.

Regardless of where you are in your journey – we can enable you to achieve the ultimate goal of getting your treatments to patients faster.

Get your biosimilar approved

Our full suite of services enable you to advance your biosimilars development program. We have the experience to support your drug development at every critical stage of the process with proven expertise and operational efficiency. Together, we operationalize 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.**



Biosimilar regulatory expertise

The PPD™ clinical research business of Thermo Fisher Scientific, in partnership with Thermo Fisher, is the only CRO able to provide a fully integrated solution to biosimilars developers.

Our regulatory affairs team is clear that developing biosimilars is one way patients gain access to more care options. Our mindset enables us to accelerate biosimilars development through effective regulatory and clinical design strategies.

We have an experienced regulatory team with real practical knowledge of the global framework of biosimilars and a clear understanding of the anticipated evolution of requirements over time.

Regulations

We have a continuous landscape scanning approach allowing us to identify new trends in regulatory guidance (FDA/EMA/APAC/LA) and how these apply to the competitive environment for product developers. Having a proactive approach facilitates quick interpretation of requirements to keep our regulatory and cross functional teams aware of any changes.

We ensure the following regulatory strategy input:

- **Determining most appropriate regulatory strategies related to:**
  - Integrated phase I/III study design
  - Phase III study with no Phase I data available
  - Active involvement in determining successful country mix depending on data availability to support the applications and clinical design
- **Guidance in defining important considerations:**
  - Justification/rationales for Phase I data and/or integrated study design
  - Data/information required in Protocol, IB and IMPD (CMC modules)
  - Choice of reference product and procurement decisions
  - Regulatory agency advice meetings to validate expected data requirements for marketing applications
- Interchangeability/switching
- Defining sample size criteria for biosimilar assets of target
- Reimbursement information

Our experience has enabled us to build databases

- Regulatory requirements for Phase I data and integrated Phase I/II study design
- Lessons learned from Proposals
- EU-Clinical Trial Regulation (EU CTR) lessons learned
- Requests for information (RFIs) and responses to RFIs across the regions

Trainings/instructions

- Biosimilar Subject Matter Experts (SMEs) are providing strategic input and biosimilar guidance to Regulatory Leads in support of customer discussions
- Maintaining intelligence in our proprietary regulatory intelligence database that all employees can access for up-to-date information on biosimilar regulatory requirements

Our regulatory experience

- Extensive experience developing strategy to support Clinical Trial Application (CTA) development for biosimilars
- More than 14 years of experience in biosimilars for top global regulatory high reference agencies including EMA, MHRA and FDA
- Interchangeability and extrapolation expertise in multiple countries and regional frameworks
- Evaluating and creating successful analytical similarity exercises
- We have worked in more than 30 Biosimilars programs in more than 25 markets globally

Your benefit

- One single provider for your full strategy
- Deep understanding of the global challenges and experience in biosimilars
- Centralized development approach considering the actual and evolving requirements for biosimilars
- Clinical and Manufacturing expertise integrated with multi-expertise; inclusive MAA submission planning, dossier authoring, compilation and response to questions leading to successful authorization through to established product life cycle maintenance

Biosimilar development: Bioanalytical Laboratory services

The PPD Laboratory services Bioanalytical Lab has supported more than 20 biosimilar programs in support of U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) submissions. We also have experience working with nine of the top 10 biosimilar lunched in the market.

The development of biosimilar drugs requires a bioanalytical lab with extensive experience, broad technical capabilities and a deep understanding of the regulatory pathway. We understand that the development needs for biosimilar are unique relative to other biopharmaceutical compounds:

- They must demonstrate comparable results (safety, purity, potency, stability and immunogenicity) to the innovator product and across product lots
- Assays developed for the innovator product may require adjustments and/or redevelopment and validation due to the physicochemical attributes and functional activity of the biosimilar
- Biologics by nature are more variable than small molecules, making the analytical methods subject to variation across instruments, critical reagents, operators and even day-to-day and lab-to-lab differences
- Biosimilar development is complex and each project has specific needs

In addition to bioequivalence (BE) studies, anti-drug antibody (ADA) safety and efficacy testing are critical to the development of biosimilar to explain and justify changes from the innovator drug. Disease states can also affect pharmacokinetic (PK) and ADA assessments (even in Phase I studies). Manufacturing changes introduced between studies for scale-up or patent reasons can also have an effect on those assessments.

We have an excellent FDA audit record, including more than 70 inspections. In addition, we are one of only a very few labs that has been audited for its work in support of biosimilar submissions.

Competition in the biosimilar arena breeds extremely tight timelines, so we work closely with clients to meet these needs.

Learn more at **ppd.com**