Why Choose Syneos Health™ for Your Biosimilar Clinical Trials?

The biosimilar market is evolving rapidly, with an ever-changing regulatory landscape and new market entrants in both emerging and developed markets. Since the first biosimilar regulatory framework was introduced by EMA in 2003 (followed by U.S. in 2009, WHO in 2010 and India in 2016) the industry has matured.

The regulatory process today allows for more rapid and streamlined development of these much-needed biosimilar drugs. EMA and FDA biosimilar guidelines have come closer in terms of sensitive patient population, selection of endpoints and extrapolation of indications.

Moreover, the willingness of one legislative region to recognize comparative biosimilar data generated against the originator product in another region has eliminated doubling of efforts and costs. However, there are still significant differences that have to be considered when designing a global development program to obtain biosimilar approval.

> **“At Syneos Health, we have a dedicated Biosimilar Consortium that specializes in the development and delivery of integrated biosimilar development programs, maximizing the opportunity to achieve expected ROI.”**

Syneos™ Health

What Are the Critical Success Factors for Your Biosimilar Programs?

Lean Protocol Design

Drives cost efficiency and accelerated patient enrollment

Minimizes clinical and comparator expenses

Time to Market

Careful selection of indication and endpoints for time efficiency

Patient/Physician Access

May require nontraditional site selection

Biosimilar Data Acceptability

Regulatory bodies, physicians and payers/ insurance companies

How Is Syneos Health Uniquely Placed to Ensure the Success of Your Biosimilar Clinical Trials?

An Established and Dedicated Biosimilar Consortium

In order to better serve our customers in their drive to develop high-quality biosimilars, Syneos Health established the Biosimilar Consortium in 2011.

Consisting of experts from the various functional areas of expertise involved in the development of biosimilars, including experts and leaders in regulatory science, therapeutic area, clinical operations, market access and pricing, pharmacokinetics and biostatistics, our dedicated team brings together the expertise of Syneos Health in the biosimilar arena, providing a holistic, end-to-end view of biosimilar development.

The Biosimilar Consortium leverages our experience and insights from executing multiple biosimilar studies conducted since 2006 in oncology, immunology, inflammation, neurology and endocrinology. Starting with the first generation protein biosimilars, Syneos Health has been involved in more than 25 programs including peptides, proteins and several monoclonal antibodies.

Key members of the Biosimilar Consortium work with the customers of Syneos Health in strategic partnerships throughout the entire biosimilar clinical development program, while the expanded group can be available to provide valuable input into the design and execution of your program. The expanded resources for biosimilar studies contain Chemistry, Manufacturing and Controls (CMC) experts (including ex-FDA officers who assessed innovator biologics), several toxicologists and nonclinical experts, therapeutic specialists from ophthalmology, oncology, immunology, hematology, infectious disease, and endocrinology, regulatory consultants, and commercial consultants.

Each biosimilar development program is unique and has its own challenges. While we build on the experience from previous trials, we always look for time efficient and cost effective alternatives that satisfy the latest regulatory guidance.

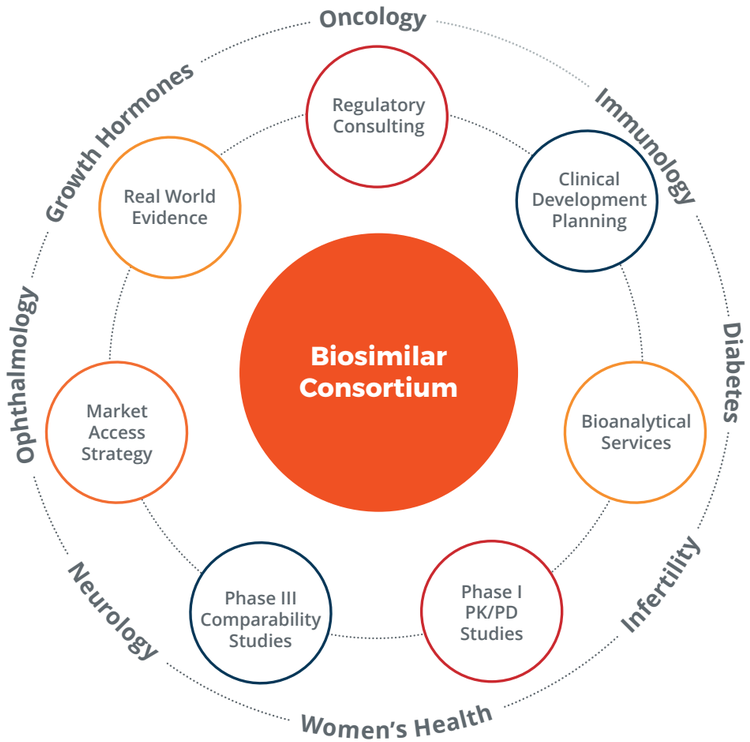
We also help navigate the commercial complexity that follows after regulatory approval by mapping out the routes to market, understanding the healthcare/payer mechanisms that influence access, the ability and discretion of stakeholder groups to influence adoption and, ultimately, how originators and competitors can compete to attain market share.

We provide end-to-end development services, starting with the generation of full clinical development plans, through the conduct of post-marketing studies and activities, we also offer individual services such as Regulatory Consulting to provide support at meetings with regulatory authorities such as FDA, EMA, PMDA and others; Clinical Development support for the conduct of Phase I pharmacokinetic/pharmacodynamic (PK/PD) studies as well as clinical comparability Phase III studies; and Commercial Consulting to assist with market access and pricing strategies.

Real World Evidence

Current metrics show that only one third of drug product launches meet expectations, despite the view from most manufacturers involved that they felt ready for launch. Therefore, capturing the full potential means anticipating possible obstacles at the earliest opportunity and generating the appropriate evidence to mitigate these. To achieve this, it is important that, at the Phase III planning stage, there is an Integrated Medical Plan in place that has clearly identified the evidence gaps for not only the Regulator but also Payers, Patients and Physicians, to ensure that at product launch there are no impediments to reimbursement and return on investment (ROI) can therefore be maximized.

At Syneos Health, we have a dedicated Global Consulting, Real World and Late Phase Unit that specializes in the development and delivery of Integrated Medical Plans to maximize the opportunity to achieve expected ROI. This unit partners with sponsors to answer the questions; why, what, when, and importantly how, to achieve the data generation and advocacy required to ensure that all evidence gaps are addressed.



Regulatory Consulting

- Experience with FDA, EMA, PMDA and others
- Scientific advice meetings
- Biosimilar product development (BPD) Type 2 meetings

Clinical Development Planning

- Selection of indication
- Selection of most sensitive patient population
- Selection of endpoints

Bioanalytical Services

- PK assessment
- Immunogenicity (ADA and NAB)

Phase I PK/PD Studies

- Healthy volunteers and patients
- Cross-over and parallel designs
- Capacity for large studies with more than 200 volunteers

Phase III Comparability Studies

- Global capabilities
- Therapeutic understanding
- Selecting the right countries and sites

Market Access and Pricing

- Differentiating on value
- Driving adoption
- Increasing access

For More Information

The Biosimilar Consortium at Syneos Health is ideally placed to partner with you in your biosimilar product development, please contact us at one of the telephone numbers listed below:

Corporate Headquarters
3201 Beechleaf Court
Suite 600
Raleigh, NC 27604-1547

Phone: +1 919 876 9300
Fax: +1 919 876 9360
Toll-Free: +1 866 462 7373

syneoshealth.com

About Syneos Health

Syneos Health™ (Nasdaq:SYNH) is the only fully integrated biopharmaceutical solutions organization. Our company, including a Contract Research Organization (CRO) and Contract Commercial Organization (CCO), is purpose-built to accelerate customer performance to address modern market realities. Created through the merger of two industry leading companies – INC Research and inVentiv Health – we bring together more than 21,000 clinical and commercial minds with the ability to support customers in more than 110 countries. Together we share insights, use the latest technologies and apply advanced business practices to speed our customers' delivery of important therapies to patients. To learn more about how we are shortening the distance from lab to life™ visit SyneosHealth.com.

Syneos™ Health