



an inVentiv health company

Biosimilars

Full-spectrum capabilities from a trusted partner

i3 draws on its vast therapeutic, scientific, and regulatory expertise to provide sponsors with insight and full-service tools to develop and market biosimilars. Because your ultimate goal is to develop a product that is safe, effective, and gainful of market share for a significant return on investment, we start with these ends in mind. Then, working closely with you, we leverage the core competencies of teams throughout i3 to deliver the best possible outcome.

Therapeutic and scientific expertise

To guide sponsors in clinical planning, our medical and scientific experts draw on a deep understanding of the product's basic underlying science gained by:

- Applying expertise in specific therapeutic areas (e.g., oncology, vaccines)
- Understanding unmet needs from a therapeutic perspective and thinking opportunistically to understand the medical applicability to a different indication
- Effectively managing patients
- Understanding disease states and the mechanisms of action of therapies to provide guidance on biosimilars development across multiple therapeutic areas

Health policy, legislative, and regulatory guidance

i3 carefully considers all the nuances of conducting a trial of a biosimilar compound. Our regulatory team knows the global regulatory landscape for biosimilars and uses this expertise to develop solid regulatory strategies.

We take a global regulatory approach that features centralized oversight, but we execute on a regional basis, due to the different regulatory requirements each country and each region has for bringing a biosimilar to market.

Because regulatory approval for biosimilars is a linear but integrated process, i3 offers tailored services from its specialized areas of expertise throughout the development lifecycle.

i3: Your bridge from development to commercialization

i3's proven multi-disciplinary expertise and full complement of services bridge the gap between the development of biosimilars and their successful long-term commercialization.

We team with you to identify your compound's full potential, and anticipate and address challenges along the way, to help you deliver a safe, effective, and economically rewarding product that can improve, or even save, patients' lives.

Look to i3 for:

- A collaborative partnership attuned to your goals
- Customized solutions based on your unique needs
- Proven processes and insight-rich resources
- Guidance through critical decision points
- An integrated, strategic, end-to-end approach

Clinical expertise

The i3 approach to patient recruitment for biosimilar trials employs a combination of planning strategies, contingencies, and tools to meet or exceed patient enrollment objectives. Because we know the potential patient recruitment challenges sponsors can face with a biosimilar study, we work with you to identify these challenges and develop solutions tailored to your needs.

We will also carefully coordinate with you our planning and preparation of proven study awareness initiatives, patient educational materials, and site recruitment tools. These tools include two powerful solutions proprietary to i3: our extensive global investigator database, and, to provide additional help in recruiting for US studies, clinical informatics that target patient populations based on de-identified claims data.



Portfolio analysis

To help a sponsor better understand how its portfolio can be expanded to accommodate a biosimilar, i3 offers comprehensive analysis services that model biosimilars after branded generics. Taking this approach, our analysts can:

- Help you prioritize therapeutic areas within your portfolio
- Provide custom analysis and consulting for reimbursement planning
- Help you assess the clinical viability of certain products

Find out how i3's specialized approach, proven expertise, and vast resources can help your team successfully develop safe, effective, and productive biosimilars.

Contact us

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About i3

i3's full-spectrum functional and therapeutic expertise helps pharmaceutical, biotechnology, and medical device companies gain sharper insights that lead to better patient care. Faster and more efficiently. With less risk and expense. For solutions that combine consulting-firm flexibility with the scientific depth of an integrated research organization, look to the specialists of i3.

Clinical Research

Strategic Regulatory Services

Data Services

Drug Safety

Strategic Partnerships

Staffing

Cardiology

Central Nervous System

Oncology

Respiratory & Infectious Disease

Endocrinology & Metabolic Disease