PRA Health Sciences

FACT SHEET

Biosimilars

Biosimilar drug development is unique and complex. At PRA, our cross-functional team of experts guide you through the many nuances of the biosimilar landscape and empower you with effective and efficient strategies to bring biosimilars to market. We built a global ecosystem of capabilities and relationships to successfully navigate this landscape. This includes understanding of the quality, analytical, nonclinical and clinical requirements of biosimilars while balancing the need to execute against competitive timelines.

Executive Summary

The goal of biosimilar development is to demonstrate the candidate drug is highly similar to the originator reference product with no clinically meaningful differences in safety and effectiveness. PRA has extensive experience supporting biosimilar development and clinical trials. Our team of subject matter experts has a deep understanding of the quality, analytic, regulatory, clinical pharmacology, statistical, clinical and drug supply requirements and unique challenges of biosimilar development. Our experts help guide creation of the quality target product profile (QTPP), support scientific advice meetings with regulatory agencies, design and execute the integrated development strategy and ultimately achieve marketing approval, covering multiple indications when possible, and beyond.

We have extensive experience in executing the required pivotal studies, including the larger and more complex Phase I studies and, as needed, Phase III efficacy and safety comparability studies as well as pharmacovigilance activities (e.g. RMPs, PASS). We understand there is no room for error in data management, data quality or safety, and we are cognizant that it is essential to gain first to market advantage post patent expiration of the originator product. Our mission is to deliver successful biosimilars on time, using a thoughtful, customized approach to building a full development program informed by our knowledge and best practices gathered from other successful trials.

Commitment to Patients

At PRA, patients are the center of all we do. We design our trials to be as patient-friendly as possible for successful recruitment. Biosimilars present a unique challenge, as patients often do not understand what a biosimilar is and may be hesitant to enter a trial. We provide both patient and site education so that our patients understand the risk and benefit of participating and our investigators can transfer their knowledge of the biosimilar trial process to their teams and patients. It is critical that patients understand the potential value of biosimilars, including evidence that biosimilars can provide affordable alternatives to more costly, branded therapies.

"Biosimilars serve a critical market demand to provide more affordable treatments to patient populations in need. We are committed to developing creative solutions to solve the unique challenges posed by biosimilar development."

MARK LANE
Executive Director, Center of Global Drug Development, PhD, MS

Expertise & Experience

We have participated in the conduct of pivotal or supportive trials and/or key Biological License Application (BLA) support services that led to US Food and Drug Administration (FDA) and/or international regulatory approval for numerous products across therapeutic areas including support for some of the initial biosimilars to be approved globally. In addition, we have provided non-clinical services for many biosimilars projects.

Selected operations roles with biosimilar trial delivery experience:

- Over 20 Project Directors
- More than 60 Project Managers
- Over 150 Clinical Team Managers
- More than 350 Clinical Research Associates

Our cross-functional team of experts assists biosimilar clients in:

- Creation and execution of biosimilar development programs (including interchangeability studies)
- Supplementing or synergizing with client resources as a joint development team to execute and oversee programs
- Collaborate closely or oversee directly internal PRA study teams to ensure on time and high-quality outcomes
- Regulatory strategy and meetings and submissions of all types

From knowledge of local regulatory requirements, to ensuring the right clinical pharmacokinetics, pharmacodynamics data, comparative analytical and sensitive clinical endpoints are captured, we excel in designing and executing efficient development programs to get biosimilar candidates to market rapidly.

Next Steps

For expert guidance in your biosimilar clinical program, contact us at PRGDDteam@prahs.com.

Key Features

PRA has a notable record of managing clinical trials involving biological drugs (e.g., biologics, monoclonal antibodies,) including biosimilars and biobetters from early phase development through successful regulatory submission and post-marketing pharmacovigilance activities. Our team offers:

- Experience: Our senior biosimilars experts in drug development, regulatory, therapeutic expertise (clinical), pharmacology/ pharmacokinetics, biostatistics, chemical, manufacturing and controls (CMC), operations and patient safety work directly with our study teams and your development team.
- Scientific knowledge: We fully understand the therapeutic area in which the compound competes. Our team of board-certified Therapeutic Experts assists with selection of the most sensitive and appropriate study populations, pharmacokinetic/pharmacodynamic, efficacy and safety endpoints and reference product.
- Strategic analytical studies: Our CMC experts provide guidance and feedback to ensure the adequacy of analytical comparability work (e.g., structural and functional data) to support evidence of equivalence/similarity.
- Custom solutions: We create custom solutions that leverage efficiencies to reduce both time and cost.