Altasciences
CLINICAL RESEARCH

Biosimilars

Patents for several innovator biologics blockbusters, primarily monoclonal antibodies, will expire in the next few years. Driven by biopharmaceutical companies' needs to diversify their product portfolio as well as create new revenue streams, the development of biosimilars is expected to grow substantially over the coming years. It has been reported that the average estimated cost for developing a biosimilar could range between $75 and $250 million USD.

The FDA issued a Draft Guidance in May 2014 entitled Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product. In the guidance, they define the term biosimilarity in section 351(i) of the Public Health Service Act to mean that the biological product is "highly similar to the reference product notwithstanding minor differences in clinically inactive components" and that there are "no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product."

The guidance stipulates that clinical pharmacology studies provide the data that describes the degree of similarity in drug exposure between the proposed biosimilar and the reference product.

Altasciences Clinical Research has been providing clinical research services to the global biopharmaceutical industry for 25 years. We offer clinical pharmacology expertise to support biosimilar development plans, especially when entering into Phase I clinical trials.

Clinical trials for biological products require experience and specialty knowledge. Immunogenicity, rare adverse events, and efficacy are all factors to take into consideration when developing a biosimilar.

To overcome the knowledge hurdle, companies that are developing biosimilars are collaborating with Altasciences because of our experience and speed with conducting biosimilar clinical trials.

As a leading full-service clinical pharmacology research CRO, we have extensive expertise in the execution of a wide range of early phase studies. Our conduct of complex clinical pharmacology trials in healthy normal volunteers and patient populations with biologics and biosimilars is diverse.

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Approach to Biosimilar Trials

Biosimilar trials require a customized approach based on the therapeutic indication and study specific goals. Altasciences works with sponsors to develop an effective plan and execution strategy for these study types.

Distinctive Recruitment Strategies

Success in the development of biosimilars relies on the ability to clearly demonstrate PK similarity in a single dose clinical trial. Enrolling healthy volunteers can be the most sensitive approach in order to detect PK differences between the test product and the innovator.

Understanding Regulatory Complexities

We are flexible in adapting to the continuously evolving international guidelines: an example being our in-depth understanding of the immunogencity requirements for Phase I biosimilar studies.

Dedicated Research Physicians

Our Principal Investigators are intricately involved in all aspects of clinical trials, ensuring that proper medical and technical procedures are completed to the highest degree of quality. This is especially important when conducting clinical trials involving monoclonal antibodies.

Specialized Pharmacy

Our facilities are ideally designed to support biosimilar studies as we are equipped with an ISO 8 rated ante room attached to an ISO 7 clean room containing a Class II Biological Safety Cabinet. This is used for sterile compounding and is designed to support the evolving needs in the development of large molecule pharmaceutical products.

Bioanalytical Support

When performing an evaluation of clinical pharmacology similarity, it is critical to use the appropriate bioanalytical methods to evaluate the PK and PD properties of a proposed biosimilar product and its reference product. In addition to our available Ligand Binding Assay platforms, LC-MS and more recently LC-HRMS have been gaining momentum as robust alternatives for the bioanalysis of antibodies in biological matrices. The TripleTOFTM 5600 when specifically used for targeted quantification (MRMHR) can be a powerful tool in the bioanalysis of large molecules including biosimilars. We are happy to discuss what approach would best suit your development program.

Tailored Integrated Services

Altasciences includes Algorithme Pharma, Vince & Associates Clinical Research and Algorithme Pharma USA. We provide comprehensive early stage clinical drug development services in Phase I, including the necessary support services in this critical stage of drug development.

- Recruitment
- Clinical Conduct
- Pharmacy
- QA/QC
- Protocol Development
- Data Management
- Biostatistics
- Medical Writing
- PK and PD Analysis
- Quantitative Bioanalysis
- Method Development and Validation
- Project Management

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