Case study

Biosimilar development

Our integrated strategies provide accelerated delivery of a second-generation biosimilar

Background

Biosimilar development is characterized by significant time-to-market pressure. Return on investment (ROI) depends on the number of biosimilar versions for the same originator product in the market.* The PPD™ clinical research business of Thermo Fisher Scientific has the experience to successfully manage competition for accelerated delivery strategies.

Challenges

To achieve higher ROI, biosimilar developers must ensure they are among the first on the market. There are several unique challenges associated with this:

- Finding an appropriate partner to support the full development of a biosimilar
- Complex development of biosimilars
- Time-to-market pressure
- Multiple studies running simultaneously
- Patient and site competition

Solution

We have proven, integrated submission strategies to support the full development of a biosimilar and overcome the competition:

- **Beat time-to-market pressure** — Ad hoc submission strategies accelerate biosimilar trial's approval and execution
- **Smoothly execute simultaneous studies** — Our biosimilars development team has a proven track record of regulatory intelligence to reduce the time interval between Phase I and Phase III development
- **Overcome patient and site competition** — We have refined the biosimilar footprint by developing a list of high-performing investigational sites worldwide. Specifically for Eastern Europe, internal reviews found some of these countries have a patient-to-site ratio four times higher, that of Western Europe or the U.S.

Results

Our team managed the execution of five studies of the same second-generation biosimilar asset — successfully owning 50% of the anticipated clinical development market. By leveraging our operational and regulatory experience, all studies were delivered on time or earlier. Compared to the original assumptions and timelines, enrollment timelines were reduced by 25%, with a 20% to 30% reduction in the number of investigational sites.

Our team cut timeline projections by 25% to get biosimilars to market faster

Deployment of diversified strategies to transform experience into acceleration

*Biosimilar Development (online version), The Second Wave Of Biosimilars: New Scenarios,+New Rules Guest Column | December 15, 2020, Jose Ignacio Diaz.

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