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Practical considerations in clinical strategy to support the development of biologics device combination products

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Over the past thirty years, biotechnology products have grown enormously, becoming the main stream of targeted therapeutic agents and promising to bolster the future treatment options for challenging and rare diseases. This increasing trend of developing biologics has boosted intensive efforts in developing various types of biologics-device combination (BDC) products, in which the primary mode of action (PMOA) is from the biological agent. The development of a BDC product is an intricate and evolving process from the drug substance to the final delivery system and can take multiple iterations at any of the steps. These iterations could involve changes in cell line, manufacturing site, formulation, primary container or safety features. Moreover, because of the complexity of the work involved and the high investment required, the commercial target dosage forms may not be available by the time the pivotal trials commence. These changes, occurring at different stages of a BDC product development, can present substantial challenges and often require a scientifically sound and robust clinical bridging strategy before they can be introduced into the clinic safely and efficiently.

The development of BDC products is now a strategic imperative across the pharmaceutical industry. A successful clinical strategy to address changes in manufacturing processes for drug substance as well as for BDC presentations needs to be risk-based and scientifically sound. An analysis of common issues, as well as review of current regulatory requirements and industry trend have shown that the rigor of a bridging package depends on the risk associated with the changes and clinical studies are required when important changes that could consequently affect PK and/or PD, efficacy and safety profiles in a clinically relevant manner and occur at a relative late stage of clinical development.

Biography

Zhaoyang Li is the Director of Translational Medicine and Clinical Pharmacology at Sanofi. She has received her BS in Chemistry from Peking University, China and PhD in Pharmaceutics from the Ohio State University, USA and has over 17 years of industry experiences in clinical pharmacology and drug development of both small molecules, RNA based therapies and monoclonal antibodies. She is also a Clinical Study Director for Phase-I clinical pharmacology studies, responsible for design, execution and reporting of the trials. Her research interest includes traditional clinical pharmacology topics (e.g., PK/PD, metabolism, drug-drug interactions and special populations), patient focused medicines development and biosimilar. She also serves as a Member on a variety of working groups and councils in Sanofi, including Immunogenicity Council, PK Working Group, Patient-Centered Integrated System Design Working Group and Patient Engagement Task Force.

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