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Clinical development of biosimilars for Western markets: Planning for success

Clinical development of biosimilars is an expensive and time consuming undertaking. The biosimilars space continues to evolve rapidly and presents a number of unique challenges and fierce competition. There are as many as 20 biosimilars in development for some of the top-selling biologicals creating an intense race for the sponsors, especially those wishing to enter the Western markets. To avoid any delays, biotech companies need solid clinical development plans built on the latest regulatory guidance with intimate knowledge of the clinical trial landscape. This presentation will discuss how companies could design their clinical development plans to meet the Western regulators expectations. It will share insights on determining the extent of clinical data requirements, design of clinical studies, considerations on the study population/indication, endpoints, evaluation of risk of immunogenicity and designing global development programs. Further, the presentation will share insights on efficient operational delivery of the safety and efficacy studies and outline best practices for accessing and retaining patients in biosimilars clinical studies.

Biography

Charu Manaktala is an MD in Pediatric Medicine, the Senior Director, Strategic Drug Development (Asia) and Head of Asia Pacific Biosimilars Centre of Excellence at QuintilesIMS, Canada. She has over 20 years of work experience in the healthcare and pharmaceutical industry and has worked in all stages of clinical drug development from Phase-I through commercialization. Her experience spans a variety of disciplines including drug development, medical writing and pharmacovigilance. She has comprehensive experience in clinical development of pharmaceutical/biopharmaceutical products and advises biotechnology companies on region specific and/or global clinical strategies for the development of biopharmaceutical products with a special focus on biosimilars.

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