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Clinical development of biosimilars: Overcoming challenges

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Over the last 2-3 decades biologics have changed the way many of the chronic and life threatening diseases are treated. With the expiry of patents for many of these block buster medicines comes an opportunity for development of biosimilars. Given the large and complex structure of biologic medicines, development, evaluation and approval of biosimilar versions of these medicines is a complex process. The regulatory pathways for biosimilars are in place in most major markets and many emerging countries around the globe. EU has already approved many biosimilar products starting in 2005. Understanding the characteristics of the target biologic product as well as the regulatory expectations are the cornerstones in designing a successful clinical development program for a biosimilar. This session proposes to examine the key challenges involved in clinical development of biosimilars and the possible ways to overcoming these challenges. Session will cover aspects such as determining the extent of clinical data requirements, choice of reference product, designing a global development program, evaluating the risk of immunogenicity, the choice of indication/study population, study design, end-points, extrapolation of clinical data across different approved indications and accessing patients for clinical trials.

Biography

Charu Manaktala has comprehensive experience in clinical development of healthcare products, and demonstrates expertise spanning complete clinical product development and post authorization lifecycle management. She worked in all stages of clinical drug development from Phase 1 through to commercialization. Her experience spans a variety of disciplines including medical writing and pharmacovigilance. She has 18+ years experience in healthcare industry including 12 years in the pharmaceutical industry. Before joining Quintiles, she held various positions of increasing responsibility at Ranbaxy Laboratories Limited in India. She did her Medical graduation (MBBS) and post graduation (MD) in Pediatrics from University of Delhi, India with research thesis on the effect of maternal iron status on the fetal iron status and outcomes. Prior to joining Pharma industry, she has had 6 years of experience in clinical medicine spanning community medicine, blood banking, general medicine and pediatric medicine, including 2 years at a high end pediatric cardiac intensive care unit.

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