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Clinical trials of biosimilars in developing nations: Obstacles and opportunities

N Srinivas

Malla Reddy Institute of Pharmaceutical Sciences, India

Biopharmaceuticals are a cornerstone of therapy for a wide spectrum of disorders, from cancer to autoimmune diseases. Currently, the patents for several well-established biopharmaceuticals have expired or are approaching expiration. The development of biosimilars creates several opportunities and challenges. The cost advantage of biosimilars is incontrovertible albeit lack of physician or public acceptance could delay, if not derail, their use. The clinical trials concern is a thorn that will have to be dealt with somehow. Patients may be very reluctant to participate in a clinical trial of biosimilars for various reasons. Clinical trials will need to be indication-specific to establish interchangeability must be proven in all indications to satisfy the 'any given patient' standard. The obstacles include reduced speed of clinical trial completion owing to time for regulatory approval and recruitment of clinical trial patients. The site cost per patient will increase, as the investigator has to devote more time and effort per recruited patient for ensuring data quality & regulatory compliance. Increase in the number and duration of EC meetings, and additional work for the EC members and support staff. This could result in increase in EC fees. The cost of medical management, compensation for clinical trial related SAE, and exhaustive monitoring and audit will have a big impact on the trial budget. The challenge of meeting regulatory expectations of compliance and ensuring quality would require a change in mindset of all the stakeholders. This would require harmonization between research and practice and make documentation into effective vital practice for clinical trial conduct. The focus should lie on making biosimilars with interchangeability, accessible to a broader number of patients in less privileged areas of our planet.

Biography

N Srinivas has completed his PhD from JNT University Hyderabad in the area of bioanalysis & clinical pharmacokinetics. He is the Professor and Principal of Malla Reddy Institute of Pharmaceutical Sciences, Secunderabad and has a blend of 18 years teaching and 4 years industrial experience. His prior experience includes training of clinical research to life science students and industry professionals. He has 10 papers in reputed journals and has guided 20 post graduate projects. He is serving as Member in institutional ethics committees (IEC) of couple of reputed hospitals.

nsap9042@gmail.com