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Biosimilar globalization-A silver lining in untested waters

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Twenty-four countries have already approved biosimilars. Some of them, like China and Russia, are not WHO compliant or have developed a biosimilar specific development pathway. Biosimilar authorisation poses a number of substantial scientific and regulatory challenges for local regulatory authorities. Overall, the WHO perspective drives the similar biotherapeutic products globally. The WHO promotes a stepwise comparability exercise indicating that more work is done in pre-clinical comparability, less work is needed in clinical studies. The clinical requirements vary accordingly to existing knowledge of the reference product and the claimed therapeutic indication(s). This presentation focuses on two challenges that, in our opinion, are common across the globe. Clinical studies are necessary to demonstrate comparative efficacy. Special attention should be devoted to immunogenicity which must be always investigated for all products with due consideration to risks in different indications. Clinical Safety is to be monitored closely via risk specification and pharmacovigilance plan (PV). From a regulatory perspective, a risk management plan (RMP) or PV plan requirements do not differ in biosimilars from other biologic therapeutics. Extrapolation of safety and efficacy data is justified from one indication to another with a comprehensive comparability program with the innovator and when the target receptor and the mechanism of action are identical. We reckon it critical to discuss extrapolation of data in the context of major changes in the manufacturing process of the originator biologicals. In such situations, the clinical data and the overall information of the exercise from one indication could be allowed to other indication extrapolation.

Biography

Candida Fratazzi devised the concept of SCIO, cost-effective trial design, and streamlining solutions. She has been involved in the development of several biosimilars. As President of BBCR, she acts as a consultant to biotech, pharmaceutical, medical device companies and investors. She is a renowned Immunologist and has over 15 years of experience in Orphan Drug development. She is the recipient of 2013, 2014 and 2015 Best Pharmaceutical Consultant, Cambridge Award and 2014 top ranked US Executives. She helps international companies to enter the US and EU markets. She has had her training at the Johns Hopkins University, Harvard University and at Imperial College in London, UK.

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