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The End of Phase 3 Clinical Trials in Biosimilars Development?

Abstract

Most patients still have limited or no access to life-changing therapeutic proteins in the treatment of their cancer or autoimmune disorders. The current clinical development model of biosimilars is expensive, and in most cases, large, phase 3 trials do not provide meaningful information on the clinical equivalence of biosimilars and reference compounds. At the same time, the development of state-of-the-art orthogonal analytical methods has enabled a better understanding of the structure and structure-function relationship of biotherapeutics. Hence, we suggest here that a solid chemistry, manufacturing, and controls (CMC) package and meaningful phase 1 studies will leave limited uncertainty on biosimilarity, which can be addressed-if needed-by post-approval, long-term follow-up studies (post-approval studies, pharmacovigilance, real world evidence data and registries, and possibly new post-approval models to be developed). We believe that this new approach may be more appropriate than 600- to 1000-patient, phase 3 trials in assessing biosimilarity and therapeutic equivalence, under the condition that the administered biosimilar given to individual patients can be clearly identified. The situation is evolving in this direction with many key-regulators having recently accepted this new approach for compounds such as peg-filgrastim. Obviously, there will probably never be a "one size fits all" development model, and an individualized, risk-based approach to biosimilar development will always have to be considered and discussed early with regulators.

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Biography

FX Frapaise is a US/French MD with 40 years of international (USA, EU) pharmaceutical industry experience including senior/ C-level Positions (CEO, VP Medical Affairs and R&D, Clinical Operations, CSO, and CMO) in Drug Development, Pharmacovigilance, Medical Affairs and Strategic Marketing/Strategic Planning. He has extensive experience of Biosimilars development at Pfenex, Boehringer, Merck, Prestige Bio, MundiPharma. He has given multiple presentations during international biosimilar congresses and has published in 2018 an article challenging the current biosimilar development paradigm.

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