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What is the real value of phase three trials in biosimilars assessment?

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Whether phase three clinical trials are necessary in biosimilar assessment is a complex issue with ongoing debate and evolving regulatory landscapes.

Even if current regulatory requirements still mandate require phase three clinical trials for most biosimilars, typically comparing the biosimilar to the reference product in terms of efficacy, safety, and immunogenicity. However, Regulatory agencies are actively exploring ways to streamline biosimilar development while maintaining patient safety exceptions are emerging; indeed, under specific conditions, regulatory agencies may waive or modify phase three requirements. This often depends on the complexity of the molecule, the availability of robust analytical data.

Many patients' organizations and prescribers still express concerns on the true similarity of biosimilars with reference compounds. This is mainly because they ignore that the so-called "reference compounds" also change overtime.

Many arguments exist against running phase three trials: these include the High cost and time burden (Large-scale phase three trials can be expensive and time-consuming, potentially hindering access to affordable biosimilars); and for well-characterized biosimilars with high analytical similarity, extensive clinical data may not provide significant additional value. Ethical concerns have also been voiced as Exposing patients to additional clinical trials when adequate evidence already exists might be considered unethical.

Conclusion: We believe that the day will come sooner than later when virtually all biosimilars will be approved without phase three trials.

Biography

Francois Xavier Frapaise, MD, has over 40 years of international drug development, strategic planning and marketing experience at major pharmaceutical companies, including: Sanofi, Bayer and Abbott, and has held multiple C-level positions (CSO, CMO, CEO) in different Pharmacos in the US and Europe. He is currently heading a Clinical/Regulatory Consulting Company. Xavier has extensive experience in biosimilars development (Merck KGaA, Boehringer-Ingelheim, Pfenex) and more recently at Bio-Sourcing (Liege, Belgium). He held an academic position at the Thrombosis Research Center at the Loyola Medical Center in Maywood (IL). He holds an MD degree from Faculté de Médecine René Descartes, Paris France, and is an INSEAD alumni.

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