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The end of phase 3 systematic confirmatory clinical trials in biosimilars development, are all stakeholders aligned?

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Background: Many 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 many cases, large phase 3 trials do not provide meaningful information on the clinical equivalence (efficacy/safety/immunogenicity) between 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.

Observations: In the recent years many agencies such as EMA and the FDA accept applications for compounds such as peg-filgrastim based on a state-of-the-art Chemistry, Manufacturing and Controls (CMC) package and phase 1 study. At the same time, some other regulators, hospitals drug committees, clinicians continue to request evidence of efficacy/safety in patients before approving/prescribing biosimilars. From a clinicians' perspective, this is understandable, however considering the objectives of biosimilarity assessment, namely finding a suitable, sensitive model to assess differences if they exist, this approach of testing equivalence in patients is more difficult to justify. Indeed, in some indications, validated surrogate markers of efficacy are available (neutrophils count for peg-filgrastim); furthermore, safety is virtually impossible to compare in a population that has spontaneously around 90% Adverse Events, such as cancer patients; immunogenicity is also difficult to compare in subject who are immuno compromised and/or receive immunosuppressant therapy. Running patient's trials that are not likely to provide the expected evidence also raised ethical concerns.

Conclusion: We believe that increased regulatory harmonization, better understanding of biosimilar development objectives and methods, education of all stakeholders on biosimilars would help ensuring patients have early access to life-saving compounds many of them currently cannot afford.

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, has hold multiple C-level positions (CSO, CMO, CEO) in different Pharmacos in the US and Europe. He is currently heading a clinical/Regulatory Consulting Company; he has extensive experience of biosimilars development (Merck KGaA, Boehringer-Ingelheim, Pfenex). 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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