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The end of phase 3 clinical trials in biosimilars development

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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 these biotherapeutics. Hence, we suggest here that a solid chemistry, manufacturing, and controls (CMC) package and meaningful phase 1 studies will leave limited uncertainty on bio similarity, 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. 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.