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Evaluating immunogenicity in biosimilars

Adoption of biosimilars is increasingly attractive to payers around the globe due to the mounting financial pressure from high expenditures on medical treatments. Clinical evaluation of comparative immunogenicity constitutes an important component of the regulatory review for biosimilar candidates. The anti-drug antibody formations are interpreted, during the review process, in relation to pharmacokinetics, pharmacodynamics, efficacy, and safety parameters. Evaluation of the immunogenicity associated with the biosimilar includes its negative impact on clinical relevant outcomes compared with the innovator product. Unwanted immunogenicity may lead to clinical consequences such as reduced or loss of efficacy, altered pharmacokinetics (PK), general immune and hypersensitivity reactions, and neutralisation of the natural counterpart (e.g. the physiological hormone). Relevant areas of discussion are: Testing strategies for immunogenicity assessment; and scientific progress on the product-related factors that may contribute to the development of immunogenicity, in particular that are related to protein aggregation and post-translational modifications. For chronic administration products, immunogenicity monitoring is required for a 12-month period of continuous treatment. Furthermore, the anti-drug antibody titers (i.e., erythropoietin, growth hormone, follitropin-alfa) interpretation is influenced by product quality differences and supported by a single-dose comparative pharmacokinetic study in healthy volunteers. The acceptance margins of detected ADA incidence for the biosimilar candidate versus the innovator product have not yet been defined by EU regulators. Indeed, until now, there is no standard bioanalytical assay sensitivity adopted nor any generalization has been made on the negative influence of clinical evidence on ADA incidence. In conclusion, immunogenicity and ADA evaluation are both complex processes that start during pre-clinical comparability and continue throughout pre approval and post-approval monitoring.

Biography

Candida Fratazzi devised the concept of SCIO, cost-effective trial design, and streamlining solutions. She has been involved in the development of several bosimilars. 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 award, Cambridge Award and ranked among the 2014 top ranked US Executives. She helps international companies to enter the US and EU markets. She has been trained at the Johns Hopkins University, Harvard University and at Imperial College in London, UK.

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