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Challenges in demonstrating biosimilarity and interchangeability of biosimilar products

Rodeina Challand
PRA Health Sciences, UK

The market of biologics is growing at nearly twice the rate of pharma as a whole. The expiration of patents and other intellectual property rights for originator biologicals over the next decade opens up opportunities for biosimilars to enter the market and increase industry competition. In order to be cost effective a biosimilar product needs access to global markets based on a single development programme that meets the requirement of regulators internationally. Despite increasing alignment in the regulatory requirements for biosimilars between EMA, FDA, WHO and other jurisdiction, there are still many scientific and practical challenges for demonstrating biosimilarity and interchangeability including scientific factors, drug interchangeability and statistical considerations.

Key messages:

- Scientific factors
- How similar is similar?
- Study design and choice of endpoints
- Interchangeability designs
- Safety assessment
- Statistical considerations
- Criteria for biosimilarity
- Biosimilarity versus non-inferiority Current status with substitution and interchangeability

Biography

Rodeina Challand has 25 years of experience in healthcare, cancer research, and the pharmaceutical industry across a wide range of roles including clinical development strategies for biosimilars and serving as head of clinical operations globally. For over 10 years, she directed the conduct of Phase I-IV clinical trials, including large pivotal biosimilar multi-national, multi-center trials and several post-authorization safety studies for biosimilars. Experienced in all aspects of biosimilar development including global strategies, study design and regulatory agency discussions (Europe, US, Japan, Australia, Singapore, and South Korea) and has worked on 10 biosimilar molecules across a range of products and indications, including ESAs, Filgrastims, Heparins, Insulins and monoclonal antibodies. While in the Pharmaceutical industry she was the company's representative in several EMA consultations with regard to the development of the EMA Biosimilar Guidelines and was a member of the European Biopharmaceutical Group, which is a sector of the European Generic Association.

ChallandRodeina@prahs.com