SESSION I
GETTING SERIOUS ABOUT BIOSIMILARS

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Biosimilars are being developed across the globe as the patent lives of biologics come to an end to reduce the high cost of (chronic) biologic therapy and to allow access to greater numbers of patients. In contrast to generic drugs that are chemical copies of the originator, biosimilars are produced in living cells that attempt to replicate the tertiary and quaternary structures of proteins and their surrounding carbohydrate moieties of the originator protein. Due to the numerous factors related to post-translational carboxylation, exact duplication is not possible, as even originator products have some degree of internal variation within and between each batch.

Therefore, regulatory authorities have developed pathways that prioritize structural analytics and functional characteristics including immunogenicity over (costly) clinical trials for each indication and allow extrapolation across all approved indications based on clinical data from "representative" disease populations.

To this point, biosimilar development has focused on primarily rheumatologic and/or dermatologic indications for tumour necrosis factor-α biologics to compare biosimilars with infliximab, adalimumab, and etanercept, with limited prospective data in IBD populations. Both head-to-head comparisons and single- or multiple-switch studies have formed the basis of regulatory approvals for infliximab and adalimumab in rheumatoid arthritis, ankylosing spondylitis, and psoriasis that have been extrapolated to IBD indications.[1-7] Several small trials will be reviewed as well as recent abstracts from the United European Gastroenterology Week.[8-11]

References

1. Zineh I, Christl LA. The biosimilarity concept: toward an integrated framework for evidence assessment. *Ann Intern Med*. 2016;165(8):595–96.
2. Gecse KB, Lakatos PL. Biosimilar monoclonal antibodies for inflammatory bowel disease: current comfort and future prospects. *Drugs*. 2016;76(15):1413–20.
3. Fiorino G, Fazio M, Danese S. Biosimilar therapies in inflammatory bowel disease: should we care about patient profile? *Expert Rev Clin Immunol*. 2016;12(4):361–3.
4. Chingcuanco F, Segal JB, Kim SC, et al. Bioequivalence of biosimilar tumor necrosis factor-alpha inhibitors compared with their reference biologics: a systematic review. *Ann Intern Med*. 2016;165(8):565–74.
5. Ben-Horin S, Vande Casteele N, Schreiber S, et al. Biosimilars in inflammatory bowel disease: facts and fears of extrapolation. *Clin Gastroenterol Hepatol*. 2016 May 21. [Epub ahead of print]