BIOSIMILARS
— A Podcast Series —

The New Era of Management in Gastroenterology and Rheumatology

The Regulatory Pathway to Biosimilar Approval

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Learning Objective	Podcast Discussion Summary
Summarize Analytical Testing for Comparative Structural & Functional Characterization	These studies involve a comprehensive comparison of the physicochemical and structural properties of the biosimilar and the reference product. The goal is to demonstrate that the biosimilar has the same molecular structure, amino acid sequence, and critical quality attributes as the reference biologic.
Summarize Non-clinical Testing to Evaluate Safety	Non-clinical tests, also known as preclinical studies, are conducted to assess the pharmacokinetics, pharmacodynamics, toxicity, and immunogenicity of biosimilars. These studies are typically conducted in vitro or in the laboratory, and in animal models prior to human trials. Non-clinical studies are an important part of the totality of evidence for biosimilars, providing valuable information on their safety and biological activity.
Summarize Comparative PK/PD Studies & Immunogenicity Assessment	These studies use human subjects to evaluate various outcomes. In this portion of the totality of evidence, pharmacokinetic and pharmacodynamic studies are conducted to assess the biosimilar's absorption, distribution, metabolism, and elimination in the human body (pharmacokinetics) and its effects on the target or relevant biomarkers (pharmacodynamics). These are typically the initial evaluation of the biosimilar in a small group of healthy volunteers. Immunogenicity assessment involves monitoring the development of anti-drug antibodies in patients. Immunogenicity studies help determine if there are any differences in the immunogenic potential between the biosimilar and the reference biologic. They provide important information on the risk of immune reactions and potential impact on the biosimilar's safety and efficacy.
Summarize Comparative Clinical Studies	In certain cases, additional comparative clinical studies may be warranted to help ensure that there are no clinically meaningful differences between the products. This is typically done when there's some incongruent comparative data between the biosimilar and reference product raising the question that there may be a clinically meaningful difference in terms of safety or efficacy. These additional clinical studies are the way to answer that question.

Supported by educational grants from Amgen and Pfizer, Inc.