BIOSIMILARS
— A Podcast Series —

The New Era of Management in Gastroenterology and Rheumatology

Biosimilar Extrapolation

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Learning Objective	Podcast Discussion Summary
Define Extrapolation	Extrapolation is a concept used in the development and regulatory assessment of biosimilars. It refers to the extension of data and evidence from one indication or patient population to another, based on scientific justification and a thorough understanding of the underlying biological and clinical factors.
Understand Why Extrapolation is Important	Extrapolation improves the efficiency of the biosimilar development and regulatory approval process. Conducting separate clinical trials for each potential indication would be time consuming, costly, and duplicative. Extrapolation allows for a more efficient development process by leveraging existing scientific knowledge and data from the reference biologic to support the approval of a biosimilar for multiple indications.
Understand the Key Aspects That May Be Considered for Scientific Justification of Extrapolation	A comprehensive comparative analytical assessment is crucial to establish similarity. This assessment involves characterizing the structural, physicochemical, and biological properties of both products to demonstrate that they are highly similar. Understanding the mechanism of action of the reference product and its relationship to the targeted disease is essential. The biosimilar should demonstrate that it shares the same MoA as the reference product, as well as the same receptor or target engagement, signaling pathways, and functional activities relevant to the therapeutic effect. Pharmacokinetics and pharmacodynamics studies are conducted to evaluate the similarities between the biosimilar and the reference product in terms of their ADME (PK), as well as their therapeutic response or effect (PD). Immunogenicity refers to the potential of a biological product to elicit an immune response. The biosimilar should demonstrate comparable immunogenicity to the reference product. After all of those non-clinical factors, clinical studies are conducted to establish the similarity of the biosimilar to the reference product in terms of safety, efficacy, and immunogenicity. While extrapolation allows for the use of data from one indication to support approval in other indications, additional clinical data may be required to address any uncertainties or differences that could arise in the extrapolated populations or disease settings.

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