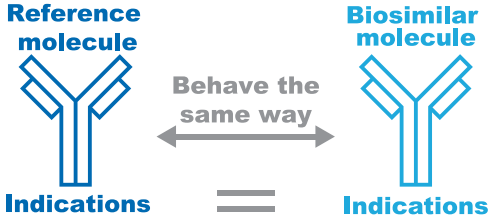
Extrapolation

Extrapolation is the scientific and regulatory process of granting a clinical indication to a medicine without conducting a separate clinical efficacy and safety study.[1,2]

The safety and efficacy of a reference medicine is assessed, during the development program, in every indication for which it is approved.[1]

The biosimilar molecule matches the reference molecule. This is demonstrated through all the information generated in the biosimilar development program i.e. the totality of evidence.[1,2]

Therefore, the biosimilar molecule can be expected to behave the same way as the reference molecule in all indications and patient populations.[1]



Sandoz, a Novartis division, supports extrapolation based on the totality of evidence generated during the development process.

1. European Commission. What you need to know about biosimilar medicinal products. 2013. Available from: http://www.ec.europa.eu/DocsRoom/documents/8242 [Accessed:June 2019]
2. European Medicines Agency and the European Commission. Biosimilars in the EU: Information guide for healthcare professionals. April 2017. Available from: http://ec.europa.eu/DocsRoom/documents/22924 [Accessed: June 2019]

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Regulators such as the FDA and the EMA make decisions on extrapolation