

The role of scientific justification in the nascent US biosimilars approval pathway

Ben Kaspar

MMS Holdings Inc. USA

The term “scientific justification” is used 15 times in the FDA Guidance for Industry entitled “Scientific Considerations in Demonstrating Biosimilarity to a Reference Product.” Approaches to biosimilar development requiring justification include minor protein alterations, duration of immunogenicity studies, and the types of clinical trials to be conducted based on available sponsor and innovator data. Frequent mention of scientific justification suggests that, in the absence of mechanisms to establish the identical character of a biosimilar and innovator, the quality of existing data will impact clinical trial requirements. Openness to scientific discussion creates an opportunity to review the specific evidentiary needs of each biosimilar with the Agency and to tailor development programs accordingly. It also creates an implicit partnership between sponsors and the FDA in developing scientifically sound approaches to biosimilar approval. Meeting this partnership challenge requires effective scientific dialog with the FDA.

Herein we review the specific instances where scientific justification is mentioned in the recent FDA Guidance with an emphasis on obtaining maximum leverage from available data to focus and drive clinical development. We compare and contrast the proposed biosimilars pathway with international guidelines and the 505(b)2 pathway, a regulatory mechanism established for comparison of variant small molecule drugs with innovators. In addition, we illustrate a number of development scenarios including how data from previous approval of a biosimilar in Europe may affect the direction of additional clinical trials. We conclude that sponsors must prepare for and lead scientific discussion to successfully navigate the nascent US biosimilars pathway.

Biography

Ben Kaspar obtained his Master's degree in Biochemistry from Case Western Reserve University in 2008. He is a regulatory strategist and writer at MMS Holdings Inc., Canton, MI. Ben has worked on multiple regulatory scenarios involving biosimilars and co-authored a recent manuscript on the future of biosimilars regulation in the United States that was published in the Journal Clinical Therapeutics.

bkaspar@mmsholdings.com