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VALUE & OUTCOMES SPOTLIGHT
PUBLISHING, SUBSCRIPTION, AND ADVERTISING OFFICE:
Value & Outcomes Spotlight
Print: ISSN 2375-866X
Online: ISSN 2375-8678
USPS: 019121

Published bi-monthly by:
ISPOR
505 Lawrence Square Blvd. South
Lawrenceville, NJ 08648 USA
Tel: 609-586-4981; Toll Free: 1-800-992-0643
Fax: 609-586-4982; website: www.ispor.org

Periodicals Postage paid at
Annapolis, MD 21401
and at additional mailing offices.

POSTMASTER: Send address changes to:
Value & Outcomes Spotlight
505 Lawrence Square Blvd., South
Lawrenceville, NJ 08648 USA

FROM THE EDITOR

Our theme for this issue of *Value & Outcomes Spotlight* is biosimilars. Global authorities (FDA, EMA, WHO) have aligned around a common definition of a biosimilar as a type of biologic developed specifically to have no clinically meaningful differences in terms of safety, efficacy, purity and biological activity in comparison with another biologic, commonly referred to as the "reference" or "originator" biologic.

It is tempting to think of biosimilars by way of analogy to generic drugs. One could imagine a tricky fill-in-the-blank question on a college entrance exam, "Generics are to branded drugs as _____ are to biologics." Perhaps a few high achievers would choose "biosimilars," but the correct answer would really be "none of the above," as biosimilars differ from biologics in so many ways, from development through regulatory approval to production and ultimately to marketplace entry. In all these respects a biosimilar's journey bears little resemblance to that of a small-molecule generic drug. Indeed, about the only thing biosimilars have in common with generics is a relatively lower price.

Biosimilars present a variety of challenges and opportunities for those of us in the ISPOR community. For instance, while originator biologics must follow the standard regulatory path towards gaining approval in various indications, painstakingly conducting trials in each, a key short-cut in the regulatory approval process for biosimilars is known as "extrapolation," which enables the developer of a biosimilar to gain approval conducting clinical research in just one indication but then having the product label include all of the indications of the originator biologic. The resulting data gaps present a challenge to economic modelers (no data to estimate model parameters) and an opportunity to practitioners of real-world research (need to conduct studies to fill these gaps).

Our feature article presents the current state of affairs on biosimilars and seeks to identify reasons why extrapolation and other issues are impeding market uptake. It appears that physicians, payers and patients alike are not so eager to climb on board the biosimilars bandwagon. Understanding the reasons why is key to unlocking the cost-saving potential of biosimilars. The good news is that HEOR and RWE can play a role in that, as elaborated upon in a second article on the topic and illustrated by means of a hospital case study in a third.

In addition to the biosimilars themed content, we include a variety of material of relevance to our Society. Our ISPOR Central section features the incoming presidential address from Federico Augustovski, who deserves heartfelt *felicidades* for being ISPOR's first president from the Latin American region. Upcoming conferences are highlighted as well, including the ISPOR Asia Pacific 2018 Conference in Tokyo. For those of you thinking of traveling to Japan for the meeting, we include an article summarizing the current state of that country's health technology assessment pilot program.

See you in Tokyo!

David Thompson, PhD
Editor-in-Chief,
Value & Outcomes Spotlight