

# NACCME

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CME SURVEY **BIOSIMILARS**

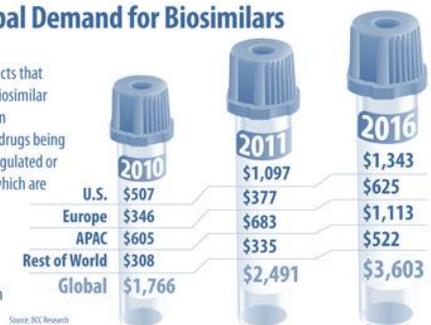
## Background

Discovery of recombinant DNA technologies in the 1970s and 1980s has allowed for production of pharmaceutical molecules of vastly expanded structural complexity in quantities sufficient for purification, leading to the introduction of biological products (biologics) to the treatment armamentarium. These innovative biologics (reference biologics) have helped countless patients across numerous therapeutic areas, however, at a high a financial cost. It is estimated that \$167 billion will be spent on biologics worldwide in 2015. Despite the clinical benefit for patients with cancers, rheumatoid arthritis, and multiple sclerosis among others, and coverage by insurance carriers, efforts are underway to help control these rising costs.

In an attempt to lower costs, the Affordable Health Care Act included the Biologics Price Competition and Innovation Act with a pathway for abbreviated regulatory procedure to license “biosimilar” drugs. An agent is considered biosimilar and is subject for approval if data show the product is highly similar to the reference biologic and there are no clinically significant differences between the biosimilar and the reference product in terms of safety, purity, and potency.

### Valuation of Global Demand for Biosimilars (U.S. millions)

These figures include only products that meet the regulatory criteria of biosimilar established by the EMA. The term “biosimilar” now often includes drugs being developed and tested in semi-regulated or unregulated markets, many of which are being targeted to regulated markets. Biosimilar versions of monoclonal antibodies, patent expiry, and evolving market acceptance portend even faster growth beyond 2016.



Although the introduction of biosimilars will impact all practitioners along the healthcare continuum, there is widespread confusion on the differences between biosimilars and generics (copies of small molecule medications) and potential disparities between biosimilars and reference biologics. To understand these knowledge gaps, their impact on practices, and resultant continuing educational needs, NACCME fielded a study across various disciplines, including oncologists, rheumatologists, managed care decision makers, pharmacists, and primary care practitioners, within its opt-in learner community database.

## Survey Design and Implementation

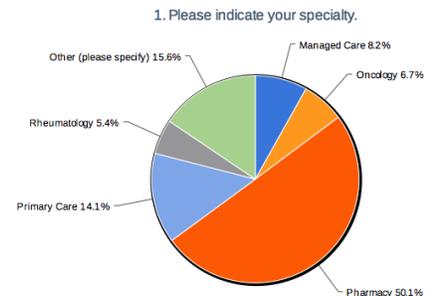
NACCME is an accredited continuing education company with several “educational communities of practice.” These are comprised of, among others, oncology, rheumatology, managed care, pharmacy, and primary care learners. NACCME distributed a brief, 5-part survey comprised of Likert scale-based and multiple-choice questions. The instruments were limited to collection of self-reported data.

From the NACCME communities - ConsultantCME (primary care), Coalition of Rheumatology Educators (rheumatology, gastroenterology and dermatology), Managed Care Learning Network (medical and pharmacy directors), Oncology Learning Network, and Pharmacy Learning Network - 405 learners responded to the survey as of the publication date of this report.

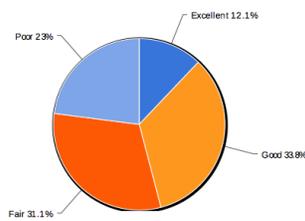


## Study Findings

Of the respondents, approximately half were pharmacists, about 14% were primary care, 8.2% indicated managed care as their focus, 5.4% identified as rheumatologists, and 6.7% said they were oncologists. These rates aligned closely with the databases sizes of NACCME and so do not necessarily indicate a proportional interest level.

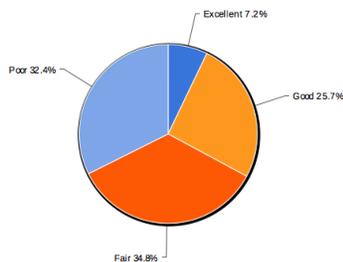


2. How do you rate your understanding of the differences between biosimilars and generics?



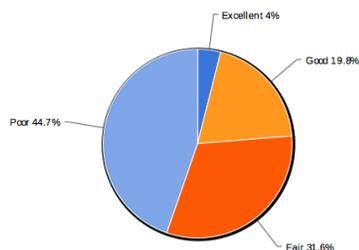
Learners indicated a low level of understanding the **differences between biosimilars and generics**. More than half of respondents (N = 405) rated their understanding of the differences between biosimilars and generics as only fair or poor.

3. How do you rate your understanding of the potential differences between biosimilars and reference biologics?



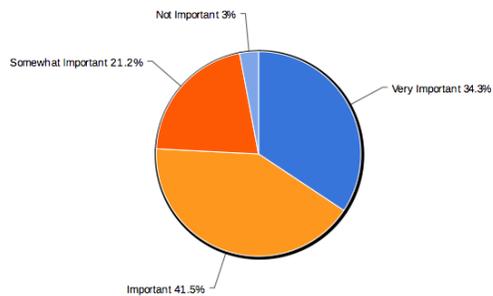
Learners indicated a low level of understanding the **differences between biosimilars and reference biologics**. Respondents had even less comprehension of the potential difference between biosimilars and reference biologics, with two-thirds rating their understanding fair or poor.

4. How do you rate your understanding of the regulatory approval pathway for biosimilars?



Learners indicated a low level of understanding the **regulatory approval pathway for biosimilars**. Additionally, 77% of survey respondents rated their understanding of the regulatory approval pathway for biosimilars as fair or poor.

5. How important do you feel continuing education on biosimilars will be for your practice?



Learners indicated a high level of need for **continuing education on biosimilars**. 97% of survey respondents felt that continuing education on biosimilars was at least somewhat important and three-quarters indicated it was important or very important to their practice.

## Discussion

Biosimilars are uncharted territory in the United States and the entire healthcare team will be responsible for ensuring their safe and effective utilization. Comprehensive education is needed on this emerging topic. An in-depth discussion of biosimilar versus generic is needed, as many if not most of the surveyed healthcare practitioners do not understand the distinction that drives both process and regulatory issues. European regulatory and clinical experiences are valuable lessons learned. The biggest challenges encountered in Europe with biosimilars so far have been differences in immunogenicity and dose equivalence. As biosimilars enter the US treatment armamentarium, these drugs will need to be viewed as new agents in order to avoid issues related to immunogenicity and potency; therefore, education on the safety and efficacy data related to biosimilars will be needed.