TARGET AUDIENCE
This educational activity has been designed to meet the educational needs of medical oncologists, hematologists, hematology-oncology fellows and other allied cancer professionals.

OVERVIEW OF ACTIVITY
The rising cost of healthcare in general and cancer care in particular has prompted growing concern in recent years about the long-term viability of the status quo. One noteworthy advance with the potential to drive down the cost of oncologic care without compromising patient outcomes is the development of biosimilar agents, and it has been projected that the introduction of “biosimilars” will reduce healthcare expenditures by up to $250 billion by 2024.

Importantly, while the market for biosimilars may be in its infancy now, widespread utilization is likely just around the corner, and oncologists must be prepared for this seemingly inevitable paradigm shift. One meaningful way clinicians can move toward this goal is through improved understanding and early adoption of biosimilar products. To facilitate and expedite such understanding and in turn facilitate the provision of high-quality, cost-effective cancer care, this educational activity focuses on the development and regulation of recently approved and investigational biosimilar agents and on available clinical research data.

LEARNING OBJECTIVES
• Evaluate the financial implications for the US healthcare system of the broad adoption of biosimilar agents in the management of various solid and hematologic cancers and related illnesses.
• Compare and contrast the discovery, development and reproduction of generic small-molecule drugs, biosimilars and their respective biologic reference agents, and use this information to counsel patients regarding the safety and efficacy of these therapies.
• Review the regulatory pathways created by the US Food and Drug Administration (FDA) to evaluate and approve biosimilars and reference biologics in order to increase confidence among cancer care professionals regarding the safety and efficacy of these agents.
• Recall available and emerging clinical research data evaluating the relative safety and efficacy of oncology biosimilars, and use this information to support the integration of these agents into the current and future care of patients with cancer.
• Summarize the “interchangeable product” designation assigned by the FDA for specific biosimilars, and explain the expected impact, or lack thereof, of product substitution on patient safety and outcomes.

ACCREDITATION STATEMENT
Research To Practice is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

CREDIT DESIGNATION STATEMENT
Research To Practice designates this enduring material for a maximum of 2 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

AMERICAN BOARD OF INTERNAL MEDICINE (ABIM) — MAINTENANCE OF CERTIFICATION (MOC)
Successful completion of this CME activity, which includes participation in the evaluation component, enables the participant to earn up to 2 Medical Knowledge MOC points in the American Board of Internal Medicine’s (ABIM) Maintenance of Certification (MOC) program. Participants will earn MOC points equivalent to the amount of CME credits claimed for the activity. It is the CME activity provider’s responsibility to submit participant completion information to ACCME for the purpose of granting ABIM MOC credit.

Please note, this program has been specifically designed for the following ABIM specialty: medical oncology.

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HOW TO USE THIS CME ACTIVITY
This CME activity consists of an audio component. To receive credit, the participant should review the CME information, listen to the MP3s, complete the Post-test with a score of 80% or better and fill out the Educational Assessment and
CONTENT VALIDATION AND DISCLOSURES

Research To Practice (RTP) is committed to providing its participants with high-quality, unbiased and state-of-the-art education. We assess conflicts of interest with faculty, planners and managers of CME activities. Conflicts of interest are identified and resolved through a conflict of interest resolution process. In addition, all activity content is reviewed by both a member of the RTP scientific staff and an external, independent physician reviewer for fair balance, scientific objectivity of studies referenced and patient care recommendations.

FACULTY — The following faculty (and their spouses/partners) reported relevant conflicts of interest, which have been resolved through a conflict of interest resolution process:

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Hardware/Software Requirements:
A high-speed Internet connection
A monitor set to 1280 x 1024 pixels or more
Adobe Flash Player 27 plug-in or later
Adobe Acrobat Reader
(Optional) Sound card and speakers for audio

Last review date: February 2019
Expiration date: February 2020
Select Publications


Harbeck N et al. Comparison of efficacy and safety of biosimilar filgrastim in a RCT (PIONEER) and real-world practice (MONITOR-GCSF). Proc ASCO 2018;Abstract 111.


Romera A et al. Bevacizumab biosimilar BEVZ92 versus reference bevacizumab in combination with FOLFOX or FOLFIRI as first-line treatment for metastatic colorectal cancer: A multicentre, open-label, randomised controlled trial. Lancet Gastroenterol Hepatol 2018;[Epub ahead of print].

