The Science of Clinical Outcome Assessment (COA) in Medical Product Development – An Intensive Online Educational Series

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CE Credits: 6.0 Contact Hours; 6.0 AMA PRA Category 1 Credits™

UAN: 0025-0000-18-105-H04-P

Fee:

Gov., Academia & Non-Profit	$279
Business & Industry	$399
FDA (No CE Credit)*	$159

* Requires use of FDA email at time of registration

Target Audience: Physicians, Pharmacists, & Researchers
Launch Date: September 30, 2018
Expiration Date: September 30, 2021

Clinical outcome assessments (COAs) are the tools used to assess clinical outcomes (i.e., how a patient feels, functions in day-to-day life, or survives) and are fundamental in establishing evidence of clinical benefit in medical-product development. Training in the science of clinical outcome assessments has been largely limited to academic degree programs hosted by universities.

The objective of this online COA continuing education (CE) series is to introduce COA fundamentals to working professionals in the area of medical-product development. The accessible format supports those seeking greater knowledge and skills in the emerging science of COA. Learners will include staff from government agencies (e.g., FDA and CMS), the biopharmaceutical industry, consulting companies, (e.g., clinical research organizations), and academia (faculty and graduate students).

Professionals can earn CEUs or take as a non-credit course.

Learning Objectives

At the end of this application-based activity, the learner should be able to:

1. Recognize and define terms used in Clinical Outcome Assessment (COA) in medical product development, including measurement types and instrument properties;
2. Apply the principles of the FDA Roadmap to Patient-Focused Outcome Measurement and COA Framework in the assessment of one or more COA measurement strategies in medical product development; and
3. Differentiate from among clinician-reported outcomes, observer-reported outcomes, performance outcomes, and patient-reported outcomes and the appropriate uses for each.

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For more information or to enroll: https://ce.pharmacy.umaryland.edu

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Technology Requirements: The following are required to access online courses: A computer or mobile device with a stable internet connection; a current internet browser, such as Google Chrome, Microsoft Internet Explorer, Mozilla® Firefox, or Apple® Safari that supports the Adobe® Flash® Player; a PDF Viewer; and the ability to view and update Microsoft Word® and PowerPoint® files.

Privacy and Confidentiality: The University of Maryland School of Pharmacy is committed to protecting the privacy of our learners. All enrollees are protected under The Family Educational Rights and Privacy Act (20 U.S.C. § 1232g; 34 CFR Part 99) (FERPA). The UMB Policy on Confidentiality and Disclosure of Student Records can be found at: https://www.umaryland.edu/policies-and-procedures/library/academic-affairs/policies/iii-630a.php.
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Successful Completion (for CE Credits): The participant must complete all activity components including the audiovisual presentations, tests, and an activity evaluation. Participants must receive a score of at least 70% on each of the tests in order to receive CE credit. The tests may be taken up to three (3) times each. A link to the activity evaluation will be available once a learner has successfully completed all other course segments. Learners must complete the activity evaluation in order to receive CE credit. Learners have 90 days to complete the online series. Statements of CE Credit will be available electronically via CPE Monitor within sixty (60) days of completion of the activity.

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- Dr. Benjamin is employed by AbbVie Pharmaceuticals
- Ms. Burke has nothing to disclose
- Dr. Oehrlein has received research funding from Pfizer, Inc.
- Dr. Papadopoulos has nothing to disclose
- Dr. Powers is a consultant for Corbus, Gilead, Janssen, and Romark
- Dr. Slagle is a consultant for Abacus DRG, Abbvie, Adelphi Values, Allergan, Andrews Performance Corporation, Bayer AG, Boehringer Ingelheim, Eisai, In, Genentech, Greenleaf Health, ICON, Janssen Global Services, Myovant Sciences, New England Research Institutes, Novartis, Phillip Morris, IQVIA (formerly Quintiles), Takeda, UCB, Ultragenyx, and VPG

Disclosures of the faculty and planning committee members are noted for all learners in the designated section of each educational module. No product-specific discussions are contained in these modules.

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