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

https://ce.pharmacy.umaryland.edu

UNIVERSITY of MARYLAND
SCHOOL OF PHARMACY

Instructors

Katy Benjamin, MSW, SM, PhD
Director, Clinical Outcomes Assessment, AbbVie

Laurie Burke, MPH
Affiliate Faculty of Pharmaceutical Health Services Research, University of Maryland School of Pharmacy; Founder/Principal, LORA Group

Elisabeth Oehrlein, BA, MS, PhD
Assistant Vice President, Research & Programs, National Health Council

Elektra Papadopoulos, MD, MPH
Acting Deputy Director of the Division of Clinical Outcome Assessment, Office of New Drugs, Center for Drug Evaluation and Research, US Food and Drug Administration

John H. Powers, III, MD, FACP, FIDSA
Professor of Clinical Medicine, George Washington University School of Medicine

Ashley Slagle, MS, PhD
Principal
Aspen Consulting

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

UAN: 0025-0000-21-122-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, 2021
Expiration Date: September 30, 2024

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.
3. Differentiate from among clinician-reported outcomes, observer-reported outcomes, performance outcomes, and patient-reported outcomes and the appropriate uses for each.

The University of Maryland School of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Contributors/Advisors

- Wen-Hung Chen, PhD, GlaxoSmithKline
- Selena Daniels, PharmD, PhD, US Food and Drug Administration
- Kathleen Dury, University of Maryland School of Pharmacy
- Rosie Love, MPH, University of Maryland School of Pharmacy
- Elektra Papadopoulos, MD, MPH, US Food and Drug Administration
- Eleanor Perfetto, BS, PhD, MS, University of Maryland School of Pharmacy
- Ester Villalonga Olives, PhD, MsC, University of Maryland School of Pharmacy
- Roxanne Zaghab, BA, MSW, DM, Principal and Senior e-Learning Advisor, Manage4Knowledge LLC

Contact Us

Office of Continuing Education at the University of Maryland School of Pharmacy
410.706.3381
CEHelp@rx.umaryland.edu

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.

Disclosure: The instructors and contributors/advisors for this activity report no relevant financial relationships.
It is the policy of the University of Maryland School of Pharmacy Office of Continuing Pharmacy Education to ensure balance, independence, objectivity, and scientific rigor in all its educational activities. In accordance with this policy, all persons in a position to control activity content of continuing pharmacy education activities must disclose their financial relationships with ineligible organization relevant to the content of the CPE activity. Any conflicts of interest identified are mitigated prior to presentation of the educational activity. Any off-label use of drugs or devices are disclosed during the activity.

Disclosure and Transparency in CME/CPD: It is MedChi's policy to ensure the independence, transparency, balance, objectivity, scientific rigor and integrity, as well as validation of content for all CME/CPD activities we accredit. To that end, faculty must disclose to the participants any relationships with companies identified as meeting the ACCME definition of a commercial interest. In the process of the disclosure process, all faculty and planners have disclosed the presences or absence of such relationships to MedChi. MedChi has identified, evaluated and where appropriate, attempted to resolve any potential conflicts of interest. This is done using content validation, the use of evidence-based data, and multi-disciplinary peer review. The information provided as disclosure to the learner, is to inform the learner and aide in judgment, not to imply that disclosed relationships will have a negative effect on a presentation.

Accreditation and Designation Statements: This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of MedChi, The Maryland State Medical Society and the University of Maryland School of Pharmacy. MedChi is accredited by the ACCME to provide continuing medical education for physicians.

MedChi designates this online educational activity for a maximum of 6 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Technology Requirements:

Supported Internet Browsers	Windows - Internet Explorer version 11 and above - Chrome 43 and above - FireFox 4.0 (or later) MacOS - Safari 13 and above - Chrome 43 and above
Minimum Memory	8 GB (or more)
Minimum Storage	6 GB (or more)
Minimum Processor	PC: 2 GHz or faster Intel processor MacOS: Multi-core Intel processor
Minimum Internet Speeds	High speed internet connection
Other	Participants must be able to play audio (either through speakers or headphones) as well as ability to open PDF files and view and edit Word, and PPT documents.

Refund Policy:
- A refund, less a $75 administration fee, will be made if cancellations are requested within 15 days of purchase. Other restrictions may apply. Refund requests must be submitted in writing to CEHelp@rx.umaryland.edu.
- Refunds are not available in the following circumstances: A learner has logged into a course or series; Has launched course materials; Course materials have been shipped; or Request is made after 15 days of the ordering date.
- Course registrations are non-transferrable.

MedChi
The Maryland State Medical Society