ARVO EDUCATION COURSE

Saturday, May 4, 2024
1-5pm
Seattle Convention Center
Seattle, WA

The ABCs of randomized controlled trials

Course organizers

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Course description

While researchers and clinicians attain expertise in their respective specialties, they usually do not acquire proficiency in clinical trial techniques as part of their PhD, postdoctoral, residency, or fellowship training. Yet, they often have research questions that would best be answered with a clinical trial, such as efficacy and safety of a new treatment. Grant reviewers may also need to understand and even judge clinical trial applications, as part of not-for-profit grant funding and /or pharmaceutical industry activities. This course provides an overview of the basics of clinical research, primarily randomized controlled trials (RCT), and the key steps to develop a good trial and /or to review grant applications that contain clinical trial activities.

Learning objectives

Attendees will leave this session with the ability to:

- Identify the different types of clinical trials.
- Describe the pyramid of evidence and the role of RCT.
- List methods to minimize bias in design and conduct of clinical trials.
- Explain role of the manual of procedures and its key elements.
- Name resources needed for RCT (clinical sites, coordinating center, reading centers etc.).
- Develop an effective clinical trial ensuring quality evidence and reproducibility.

Physician accreditation statement

The Association for Research in Vision and Ophthalmology (ARVO) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

Physician credit designation

ARVO designates this live activity for a maximum of 3.75 *AMA PRA Category 1 Credits™.* Physicians should claim only the credit commensurate with the extent of their participation in the activity.

International Attendees: The American Medical Association (AMA) has determined that physicians not licensed in the U.S. who participate in CME activities are eligible for *AMA PRA Category 1 Credits™.*

Statement of Need

Researchers and clinicians become experts in their needed skills, but typically do not learn clinical trial techniques during PhD, post doc training and/or residency or fellowship training. Grant reviewers may also need to understand and even judge clinical trial applications, as part of not for profit grant funding and /or pharmaceutical industry activities Once they launch their careers, they often have questions that would best be answered with a clinical trial, such as efficacy and safety of a new treatment, but have little experience or knowledge of how to develop or judge a robust clinical trial and determine if quality evidence will be produced.

Target Audience

The target audience includes researchers, clinicians, not for profit grant reviewers and industry personnel that work on clinical trials.

European Union of Medical Specialists (UEMS) CME/CPD requirements

European physicians can convert CME credit from the course to meet European Union of Medical Specialists (UEMS) CME/CPD requirements.

The American Medical Association has an agreement of mutual recognition of CME credits with the UEMS, the accreditation body for European countries. Physicians interested in converting *AMA PRA Category 1 Credit™* to UEMS-European Accreditation Council for Continuing Medical Education CME credits (ECMECs) should contact the UEMS at mutualrecognition@uems.eu.

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Learners interested in claiming *AMA PRA Category 1 Credits™* or obtaining a certificate of participation for participating in this course must pay the CME credits and Certificates fee as part of their Annual Meeting Registration. Payment is collected during the Annual Meeting registration process by adding "CME credits and Certificates" as a session. Learners who do not register for CME before the conclusion of the meeting will not be able to claim and request credit. Learners registered as guests are not eligible to receive CME credit.

Credits and certificates are awarded within our ARVOLearn platform. CME registrants will receive an email with instructions prior to the start of the course or within two business days of payment of the CME credits and certificates fee (whichever is later). All requests for credit must be submitted no later than 11:59pm U.S. Eastern Time on Friday, Aug. 30, 2024.

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Certificate of attendance

Certificates of attendance are available free to all attendees. These certificates state that one has attended the course but does not offer credit tracking. These certificates are available for self-service download from the Annual Meeting website.

Contact Us

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The following activity managers reported no relevant financial relationships.

> Tianjing Li, MD, MHS, PhD, (Course organizer), Cathy Conley (Activity Manager), Melissa Marick, MA (Activity Manager)

The following clinical content reviewers reported no relevant financial relationships.

Kimberly Zanon, BSN, RN *The following course organizers, activity planners and managers reported relevant financial relationships.*

Full name	**Role**	**Disclosure**
Penny Asbell, MD, FACS, MBA, FARVO,	Course organizer	Senju (C), Iolyx (C); Trefoil (C); Horizon (C); Azura (C); Hindawi (C); Regeneron (C); Glia (C); Vindico Eyenovia (C); Centricity (C); Visus (C); B & L (C); Regeneron (F), Mitotech (F)

Priya Chaudhary, PhD	PDEC	Alcon Research Institute (F)
Azza El-Remessy, PhD, PharmD, BC-ADM	PDEC	Nour Therapeutics, LLC (O)
Edmund Tsui, MD	PDEC	Kowa Company Ltd (C, F); Cylite Pty Ltd (F); EyePoint Pharmaceuticals (C)
Thomas Ach, MD, FEBO	CME	Apellis Pharmaceutical (R); Roche (R); Novartis (R, F); Bayer (R); Johnson & Johnson (R); Macregen (I) (ended Feb. 2022)
Ron Adelman, MD, MPH, MBA	CME	Identifeye (C); Johnson & Johnson/Jenssen (C)
Parisa Emami, MD, MPH	CME	Eyepoint Pharmaceuticals (C); Bausch and Lomb (C)
Sally Ong, MD	CME	Eyepoint Pharmaceuticals (C); Patent Cooperation Treaty (PCT) Application No. PCT/US2023/024209 - P
Laura Lanford	Activity manager	Johnson and Johnson (I); Pfizer (I)

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