Accredited Continuing Education Program Information

## The ABCs of randomized controlled trials

## Course Organizers

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## Course Description

Randomized control trials (RCTs) are a key tool in the evaluation of new strategies for the prevention and treatment of eye diseases and conditions since they provide the most evidence on efficacy and safety for making informed decisions on patient care.

This course introduces eye and vision researchers to the fundamentals of RCTs and engages them in a discussion regarding key considerations for designing and conducting RCTs. After taking this course participants will gain an understanding of the necessity of RCTs, and insights into how they are designed, initiated, organized, coordinated, monitored, and documented.

## 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 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

Like many employment sectors, the RCT workforce has been substantially affected in recent years. As a result, some RCTs conducted in eye and vision are of limited value in informing practice due to its poor design, conduct, and reporting. RCTs in eye diseases also present unique challenges. RCTs are a key tool in the evaluation of new strategies for prevention and treatment of eye diseases and conditions. RCTs provide the highest level of evidence on efficacy and safety for informed decisions on patient care. Although many ARVO participants are well trained in vision science, they may have limited experience and exposure to the methodology and implementation of RCTs.

## Target Audience

The course is intended for those seeking an introduction to fundamentals of randomized controlled trials (RCTs), and those who are likely to be involved in the design, conduct, management, analysis, reporting, and review of RCTs, including early-stage investigators, ophthalmologists, optometrists, translational scientists, biostatisticians, regulators, nurses, pharmacists, study coordinators, study managers, residents, post docs, and students.

## Educational Objectives

* After participating in this CME activity, participants should be able to:
* Describe RCT design: when and why RCTs are necessary
* Understand methods to minimize bias in the design and conduct of RCTs
* Recognize RCT conduct (protocol and data integrity)

## 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.

## CME Credits and Certificates Fee

Learners who register for “CME Credits and Certificates” as part of their Annual Meeting registration are eligible to claim *AMA PRA Category 1 Credit™* for participating in this course. This fee is paid once and covers credit claiming for an Education Course and the Annual Meeting.

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| **CME credits and certificate fee** | **By March 15** | **After March 15** |
| ARVO MIT/Nonmember-in-Training | $ 79 | $ 79 |
| ARVO Member/Exhibitor (paid full-meeting access badge)  | $ 99 | $ 119 |
| Nonmember/Exhibitor (complimentary full meeting access badge only) | $ 99 | $ 119 |

## Instructions to receive credit and/or certificates

Learners interested in claiming *AMA PRA Category 1 Credits™* or obtain a Certificate of Participation for participating in the 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. Attendees 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 your purchase (whichever is later). All requests for credit must be submitted no later than 11:59pm U.S. Eastern Time on Friday, Aug. 30, 2023.

## Certificate of Participation

ARVO is accredited to offer *AMA PRA Category 1 Credits™* to physicians. All other participants in the course may receive a Certificate of Participation that documents the number of CME hours attended\* by following the same instructions listed above and paying the CME credits and certificates fee.

\*Some accrediting agencies may award equivalent Continuing Education (CE) credit when presented with a Certificate of Participation from an activity that offered *AMA PRA Category 1 Credit™.* Check with your accrediting agency for information.

## 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. They will be available for pick-up onsite at the meeting registration desk and ARVO Central in the exhibit hall.

## Contact Us

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## Disclaimer

Education Courses provide a forum for the open exchange and discussion of research results and scientific advancements in the field of ophthalmology; however, ARVO makes no representation or warranty as to the truth, originality, or accuracy of the information presented at courses or in materials distributed in connection with them. Nor are the views expressed by the individual speakers necessarily the views of ARVO. ARVO supports the ACCME’s policy on evidence-based content and encourages faculty to adhere to these standards when planning a presentation.

Participants have an implied responsibility to use the newly acquired information to enhance patient outcomes and their own professional development. The information presented in this course is not meant to serve as a guideline for patient management. Any procedures, medications, or other courses of diagnosis or treatment discussed in this activity should not be used by clinicians without evaluation of patient conditions and possible contraindications on dangers in use, review of any applicable manufacturer’s product information, and comparison with recommendations of other authorities.

## Disclaimer off-label use

Education Courses may contain discussion of published and/or investigational uses of agents that are not indicated by the FDA. ARVO does not recommend the use of any agent outside of the labeled indications.

The opinions expressed in the educational activity are those of the faculty and do not necessarily represent the views of any organization associated with this activity. Please refer to the official prescribing information for each product for discussion of approved indications, contraindications and warnings.

## Disclosure of Relevant Financial Relationships

ARVO requires instructors, planners, managers and other individuals who are in a position to control the content of this activity to disclose all financial relationships with any ineligible company within the last 24 months. All identified relevant financial relationships are thoroughly vetted by ARVO for fair balance, scientific objectivity of studies mentioned in the materials or used as the basis for content, and appropriateness of patient care recommendations. All relevant financial relationships have been mitigated by ARVO.

ARVO considers presenting authors, not co-authors, to be in control of the educational content. It is ARVO’s policy and traditional scientific publishing practice to acknowledge all people contributing to the research, regardless of CME control of the live presentation of that content. ARVO may collect and publish disclosures from co-authors although they do not have control of the CME content.

**Disclosures for all individuals involved in planning and managing this accredited CE activity are listed here with their relevant disclosure information. Disclosure information for presenters and course moderators will be provided within a disclosure slide(s), prior to the start of the course and their respective presentations.**

*The following individuals on the Professional Development and Education Committee (PDEC) reported no relevant financial relationships.*Alison Abraham, PhD; Maria Fernanda Abalem, MD, MSc; Radwan Ajlan, MBBCh, FRCSC; Lin Cheng, MD, PhD; Ngozi Chidi-Egboka, OD, MPH, FNCO, FAAO; Helene Filipe, MD; Renu Kowluru, PhD, FARVO; Emily Patterson, PhD; Daisy Shu, PhD; Menglu Yang, MD, PhD

*The following individuals on the Continuing Medical Education Committee (CME) reported no relevant financial relationships.*Parisa Emami, MD, MPH; Shilpa Kodati, MBBS; Wendy Liu, MD, PhD; Yannis Paulus, MD; Sangly Srinivas, PhD; Mary Whitman, MD, PhD

*The following course organizers and activity managers reported no relevant financial relationships.*Tianjing Li, MD, MHS, PhD (course organizer), Cathy Conley (activity manager)

*The following clinical content reviewers reported no relevant financial relationships.*Lindsay Scott, PT, DPT, ATC

*The following activity planners and managers reported relevant financial relationships.*

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| **Full name** | **Role** | **Disclosure**  |
| Penny Asbell, MD, FACS, MBA, FARVO | Course organizer | Horizon: (C); Hawkeye: (C); Glia: (C); Senju: (C); Blephex: (C); B&L: (C); Blephex: (C); Regeneron: (C, F); Mitotech: (F); Sylentis: (F); Tear Science: (F); Allakos: (F) |
| Priya Chaudhary, PhD | PDEC | Alcon Research Institute: (F) |
| Azza El-Remessy, PhD, PharmD, BC-ADM | PDEC | Nour Therapeutics, LLC: (O) |
| William Foster, MD, PhD, FRCSC | PDEC | Altasciences (C); Lynthera (C); US Patent 9,050,171-Small diameter fragmatome for minimally traumatic retained lens fragments removal (P) |
| 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); Heidelberg Engineering: (R); MacRegen Inc.: (I) |
| Ron Adelman, MD, MPH, MBA | CME | Tesseract: (C); Johnson & Johnson/Jenssen: (C) |
| Natasha Kolomeyer, MD | CME | AbbVie/Allergan: (F, C); Guardion Health Services Inc.: (F); Equinox: (F); Nicox: (F); Olleyes: (F); Santen: (F); Glaukos: (F); Diopsys: (F); Aerie: (F); |
| Louis Pasquale, MD | CME | Eyenovia: (C); Twenty Twenty: (C); Skye Biosciences: (C) |
| Laura Lanford | Staff | Johnson and Johnson: (I); Pfizer: (I) |

*Financial relationship disclosure code definitions*

**C (Consultant/Contractor)** Indicates you are a consultant or independent contractor (including contracted research) for an ACCME-defined ineligible company.

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**I (Personal Financial Interest)** Indicates you are an investor in a company or competing company, including an ACCME-defined ineligible company, other than through a mutual or retirement fund.

**N (No Financial Relationship)** Indicates there is no financial relationship to disclose.

**O (Owner/Co-Owner/Founder/Co-Founder)** Indicates you are an owner, co-owner, founder and/or co-founder of an ACCME-defined ineligible company.

**P (Patent)** Indicates you are an inventor/developer designated on a patent, patent application, copyright, or trade secret, whether the patent, copyright, etc. is presently licensed or otherwise commercialized, or could be in competition with the technology described.

**R (Recipient)** Indicates you have received gifts, honoraria, travel reimbursement, patent royalties, or any other financial compensation in any amount from an ACCME-defined ineligible company.

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