EAC™

Endpoint Adjudication Committee (EAC) Services

Secure Independent Evaluation and Adjudication of Complex Clinical Trial Endpoints

Determinations of whether a participant met an endpoint or adverse event (AE) criteria are critically important in evaluating safety and efficacy in drug and device trials. When medical judgment is required, rely on Advarra's worldwide network of medical experts to provide an independent evaluation of events.

Independence | Experience | Performance

- Improve trust with independent adjudication of events requiring medical judgment
- Conform with U.S. Food and Drug Administration (FDA) and EU European Medicines Agency (EMA) guidelines for EACs
- Leverage a global network of 1,500+ statisticians, medical, and other research professionals
- Rely on 20+ years' proven experience in independent endpoint evaluation and adjudication
- Experience truly collaborative adjudication plan development and member selection
- Avoid delays in treatment, dose escalation, and other trial events with rapid delivery of adjudication results

Solutions for all Therapeutic Areas and Trial Designs

No matter the trial complexity, we design your EAC to provide the appropriate independent evaluation of events to support participant safety and statistical endpoint evaluations. We can support studies involving:

- Complex endpoints
- Lengthy duration
- Precision medicine
- Central nervous system
- Gene therapy
- Virtual trial modalities
- Decentralized trial modalities
- Worldwide sites
- Medical devices
- Oncology
- All therapeutic areas

Adjudication Plan Development

A robust plan helps ensure successful, reliable evaluation and adjudication throughout the trial. Our medical experts and EAC administrators work collaboratively with the sponsor's or contract research organization's (CRO's) clinical and medical teams to establish an appropriate adjudication plan. We take time to gather your input and confirm the committee's work supports the overall data safety monitoring plan in conformance with U.S. FDA and EU EMA guidelines.

Independent Committee: Truly Integrated Service

While the EAC review of participant events is independent from Advarra's other oversight and review services, the overall process is overseen by an experienced, integrated services team. EAC reviews and outcomes are coordinated with the DMC as appropriate to avoid delays during study conduct. All Advarra reviews are coordinated in collaboration with the clinical trial team. Your dedicated client success partner gets to know your study team and program to provide an unmatched level of knowledgeable, responsive support.

Enhanced Security

Your critical trial and participant data are protected at every step by our state-of-the-art data protection technologies. Advarra's EAC administration systems are compliant with all applicable international privacy regulations, including:

- Health Insurance Portability and Accountability Act of 1996 (HIPAA)
- General Data Protection Regulation (GDPR)
- Personal Information Protection and Electronic Documents Act (PIPEDA)
- FDA 21 CFR Part 11

Expert Consulting

Want help developing your statistical plans, endpoints, or the overall trial? Our experienced network of industry professionals can assist.

SOAR™ for EAC

Advarra's secure, compliant, flexible, and audit-ready platform is specifically configured for your project.

- Compatible with any electronic data capture (EDC) or similar clinical records system
- Configurable to handle sophisticated adjudication determinations with parallel, sequential, and other complex determination workflow types
- Integrates with your preferred DICOM tool/database
- Conforms to all major international privacy and compliance regulations
- One easy-to-navigate platform for:
  - Dynamic exchange of medical information and records including images
  - Re-time redaction of personal information
  - Dynamic translation of materials through Advarra's integrated translation vendor
  - Assembly and submission of complex dossiers
  - Management of queries
  - Review of data packages
  - Management of open and closed session non-conformance meetings
  - Return of adjudication assessments
  - Complete audit trail and secure audit ready document repository
  - And more