ADVARRA

EAC

EACs for even the most complex studies

Endpoint Adjudication Committees (EACs) are vital for studies where trial endpoints are complex, require medical judgment, or benefit from specialized therapeutic expertise beyond the scope of routine monitoring. With Advarra, you can find independent experts who can effectively assess whether patients have met a protocol-defined endpoint or whether an event is related to the disease or the study treatment.

Advarra has a network of experts that covers every therapeutic area and can assess complex endpoints or subjective clinical events. With over two decades of experience in comprehensive EAC management, Advarra can build and manage a qualified, independent committee to ensure consistency of assessments and security of your data.

Experts for Niche Therapeutic Areas

No matter how specialized your study is, Advarra's 1500+ member network of experts has clinicians and key opinion leaders who can evaluate even the most challenging endpoints across all specialties, including those with various comorbidities or confonding variables.

Fast Committee Formation and Adjudication Outcomes

Existing network relationships allow committees to be formed in ~5 weeks. Once the charter and adjudication forms are finalized and validated, assessments are delivered quickly and within the agreed timelines.

Client-Focused Collaboration

Advarra reduces trial team burden by managing all aspects of EAC oversight, enabling project teams to focus on the research, ensuring the security of your trial data, and the consistency of outcomes for key study endpoints.

Advarra's SOAR™ Platform Maximizes Data Integrity

The Safety Oversight Administration and Reporting (SOAR™) Platform from Advarra is a secure technology environment that supports active collaboration between the sponsor, EAC members, research sites, and Advarra during the study. SOAR stores study data, provides role-based access to adjudication data for review by committee members, and helps ensure inspection readiness for all EAC data, operations, and outcomes.

Workstream Efficiency

- Launch the platform quickly by using pre-configured workflows, or
- Create custom workflows to reflect specialized protocol requirements
- Perform initial dossier redaction with AI-enabled tools
- Automate query handling and outcome reporting with role-based access

Flexibility and Transparency

- Work easily with other study technologies, including Electronic Data Capture (EDC) systems, imaging, and other third-party vendors
- Support flexible adjudication workflows, such as parallel, sequential, and other custom workflow types
- Upload scans easily with an integrated DICOM image reader
- Enable transparent reporting of case outcomes to sponsors and other authorized parties while maintaining the confidentiality of individual adjudicator assessments

Compliance

- SOAR complies with all applicable international privacy regulations, including HIPAA, GDPR, PIPEDA, and FDA Part 11
- SOAR also provides a full audit trail of all data access by approved users and prevents unauthorized access to confidential information

EAC Management as Specialized as Your Trial

Member Identification & Charter Development

Advarra identifies potential members who have the required expertise for sponsor approval and manage qualification and contracts for the selected members.

Charter Development

Advarra collaborates with the clinical team to develop a charter that includes adjudication workflows, dossier components, assessment forms, event/endpoint definitions, potential actions, voting/non-consensus requirements, meeting plans, and other required elements.

Meeting Facilitation

The Advarra EAC project manager schedules and facilitates all committee meetings, including organizational kickoff, non-consensus, and ad hoc meetings where all EAC members collectively review cases and provide event determinations.

Comprehensive Event Management

Advarra manages each event through the adjudication process, responds to adjudicator queries, and provides outcome assessments while maintaining the confidentiality of event determination details.

Rapid Adjudication Turnaround

Adjudication assessments are documented within SOAR and then made available to the sponsor within the agreed turnaround times.

Streamlined Communications Across Review Committees

While the review committees are separate, the Advarra EAC project manager will align adjudication activities with the Data Monitoring Committee (DMC) activities to ensure recently adjudicated data are included in DMC data review snapshots, when appropriate.

Advarra's Clinical Trial Review Services

IRB

Institutional Review Board

Advarra is the #1 central IRB with experience in every trial phase and therapeutic area.

IBC

Institutional Biosafety Committee

Advarra IBC offers the fastest timelines and more registered sites than any other IBC to improve efficiency in genetic engineering research.

DMC

Data Monitoring Committee

Advarra has 20+ years of experience providing independent DMC oversight, supported by a 1500+ expert network.

EAC

Endpoint Adjudication Committee

Advarra provides end-to-end EAC management to ensure consistent outcomes for key trial endpoints.