ADVARRA

When Do I Need an EAC?

To better understand when you may need an endpoint adjudication committee (EAC), it's helpful to know the EAC's role in research.

- An EAC, also referred to as a clinical event committee (CEC), is an independent group of experts who conduct an evaluation of clinical trial participants' individual medical events.
- The primary purpose of an EAC is to determine if a medical event meets the protocol's pre-defined criteria, or if it was caused by underlying medical conditions, comorbidities, or other environmental factors.

When Would We Have an EAC?

- Clinical endpoint adjudication review and oversight is critical for **studies where trial endpoints are complex**, and some degree of medical judgment is necessary to determine if a participant has met a protocol-defined endpoint, or if the event was related to advancement of the disease state.
- Endpoint adjudication is also necessary **when specific therapeutic expertise is needed** beyond what a principal investigator or sponsor's medical monitor can provide.
- The number of participants meeting a defined endpoint is **essential to evaluating the safety and/or efficacy** of a new drug, biologic, or device.

Why are EACs Needed?

Independent EAC review and oversight is essential for **mitigating risks to study participants** and **ensuring appropriate medical judgment is employed** in evaluating individual medical events.

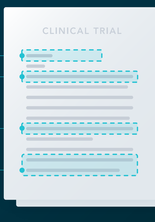
There are two guidelines strongly encouraging the use of an independent group of experts to conduct adjudication activities and reduce the perception of bias:

EU European Medicines Agency (EMA) "Guideline on Data Monitoring Committees"

U.S. Food and Drug Administration Guidance "Establishment and Operation of Clinical Trial Data Monitoring Committees"

U.S. FDA and EU EMA indicate an independent EAC can provide valuable insights, particularly for clinical trials where:

- Protocol-defined endpoints are subjective
- Protocol-defined endpoints require the application of a complex definition
- Substantial medical judgment is required to adjudicate whether an endpoint has been met
- The research intervention is not delivered in a blinded manner



If any of these attributes apply to your study, consider establishing an independent EAC or CEC. Your institutional review board (IRB), ethics committee (EC), or regulators may require it as well.

Additional reasons an EAC may be part of a study's design include:

- Eligibility and randomization
- Adverse event causality
- Safety and continuation

What Does an EAC Review?

Information regarding each presumptive endpoint may include:

Laboratory, pathology, and/or imaging data

Autopsy reports

Physical descriptions and medical records

The EAC is typically blinded to treatment assignment and masked to the assigned study arm when assessing events, regardless of whether the trial itself is blinded. This helps ensure the endpoints receive unbiased assessment.

Want to learn more about EACs? Watch our webinar:

Integrating Expert Opinions: Why Your Clinical Trial Needs an EAC