

eAdjudication ®

Flexible Endpoint Adjudication Software & Managed Services For Sponsors, CROs and AROs



by Ethical GmbH https://www.endpointadjudication.com

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Clinical endpoint adjudication meetings: Are you dealing with the process effectively?

Clinical endpoint adjudication is rapidly becoming standard procedure in many clinical settings. For clinical teams, this means planning, conducting and following-up on many additional meetings such as kick-off, experts training or consensus meetings. The proper management of these adjudication meetings can become an additional challenge. Solutions are therefore needed to prepare them quickly and efficiently, and keep all related documents in a safe and easily accessible repository.



Solution Description
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What began as an exceptional process reserved to special cases of complex clinical trials has gained widespread acceptance both from sponsors and regulators and is included as a standard feature in many clinical trials to guarantee unbiased review and experts' involvement. With widespread endpoint adjudication use, however, come **a host of requirements that put additional strain on clinical teams** but also on experts who are getting increasingly involved in the operational part of clinical trials. In this context, efficient organization and conduct of the adjudication meetings has become critical for the good execution and timely completion of the trials. Integrating meeting management tools directly in the endpoint adjudication platforms can alleviate part of the burden and help clinical teams manage the adjudication process more efficiently.

Endpoint adjudication has become a common activity in clinical trials.

Only a few years ago, clinical endpoint adjudication was still an exceptional and occasional procedure, applied only to very complex trials with difficult to determine outcomes. Today however, it has become a rather common, recurring activity that adds to the complexity of many clinical trials. Both sponsors and regulators feel more comfortable having experts review in a blinded way the clinical endpoints rather than rely on the opinion of the principal investigators who may be biased by their knowledge of the patients.

Experts are increasingly solicited to review and adjudicate clinical cases.

Being invited to contribute directly to a trial by reviewing clinical cases may seem appealing to a clinical expert: it is an intellectually attractive activity where one gets the chance to confront opinions with esteemed colleagues and contribute to the scientific foundation of new medicines for one's patients. But being involved in multiple concomitant trials means more work that comes on top of the day job: more protocols to read, more software to learn, more passwords to remember, and more adjudication meetings to attend **kick-off meetings, training meetings, monthly meetings, consensus meetings...** It is the role of the adjudication platform to facilitate the additional workload.

The management of adjudication meetings is time consuming for clinical teams.

Setting up the adjudication process for a clinical trial is no trivial task. One needs to define the adjudication points, prepare a charter, hire a software platform and, of course, gather a team of expert reviewers. Then comes the daily work of monitoring the adjudication activities part of which is setting up, conducting and reporting on various adjudication meetings. Time is always of essence. Deadlines must be met; quality and compliance are not negotiable, and you can't go over the budget. So, the clinical team must work in the most efficient way possible.

eAdjudication[®] software integrates meetings functions.

The clinical team's best option is a good adjudication platform like eAdjudication[®] allowing them to pilot as many aspects as possible from a single interface. Since adjudication meetings are an integral part of the adjudication process, why not integrate meetings management directly in the platform? eAdjudication[®] allows the clinical team to plan the adjudication meetings, **include agenda items and cases needing to be discussed** directly in the invitation, and track responses and changes. **In addition**, invitees are able to access all the necessary material directly from the invitation with links to the platform when needed.

About the eAdjudication® meeting functionality

A meeting functionality within eAdjudication® simplifies all adjudication meetings tasks, from scheduling the meeting to keeping track of documents versions and filing the recordings and transcripts.

By managing their meetings in eAdjudication®, clinical teams **keep a trace of all their meeting activity with minimum effort**, and all meeting outcomes, recordings, transcripts and attached documents are easily accessible in a single place:

- A pre-loaded template makes it easy to set up meetings, invite attendees, attach agenda...
- Agendas of consensus meetings are prepared in a few clicks.
- Meetings' documentation is kept in a single, easily accessible place.
- The history of each meeting is recorded in the audit trail.
- All the decisions related to the trial endpoint adjudication are documented.

The Clinical Endpoint Adjudication Handbook (36 pages)

The Manual / Reference Book with all the topics related to the Independent Endpoint Adjudication Committees Management.

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