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Kendle's Web-based endpoint adjudication system allows me to adjudicate events rapidly from my own office without being overwhelmed by binders full of the source documents. The system runs very smoothly ...this allows me to work much more efficiently.

*Professor of Cardiology, Aarhus University Hospital
Denmark (current adjudication committee member)*

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Benefits of integrated Web-based adjudication using Kendle's TrialEAS™ system

- Reduced or eliminated courier costs
- Easy translation to language of choice
- Allocation of events via several randomization protocols
- Adjudicator access to all documents, scans and images wherever and whenever needed
- Multiple specialist endpoint committees within a study
- Adjudication of events on an ongoing basis
- Shortened timeframe for endpoint assessment
- Transfer of adjudication to the clinical database on a regular basis, allowing ongoing medical review
- Reduced number of face-to-face committee meetings
- Over-recruitment risk minimized through more efficient endpoint adjudication

Overcoming geographical and language barriers in endpoint adjudication

The ever-growing need to demonstrate safety is placing increasing emphasis on simple and composite morbidity and mortality endpoints in clinical studies, to establish or reinforce each drug's safety profile.

Such endpoint studies tend to involve thousands of patients globally and require long-term treatment and follow-up. To ensure impartial confirmation that an event experienced by a patient is in fact an endpoint, an independent Adjudication Committee, consisting of clinical experts, is established.

Adjudication committee members are usually internationally based experts who face many demands on their time. This makes the logistics of holding frequent face-to-face adjudication meetings challenging.

A solution for international boundaries

Kendle is able to assist in setting up adjudication committees, suggesting possible candidates by drawing on the expertise of our Medical Affairs team, who work with many experts internationally. Experts can be recruited from any part of the world with access to the Internet. We have developed a training program for adjudicators and will travel to their location to train them on the system.

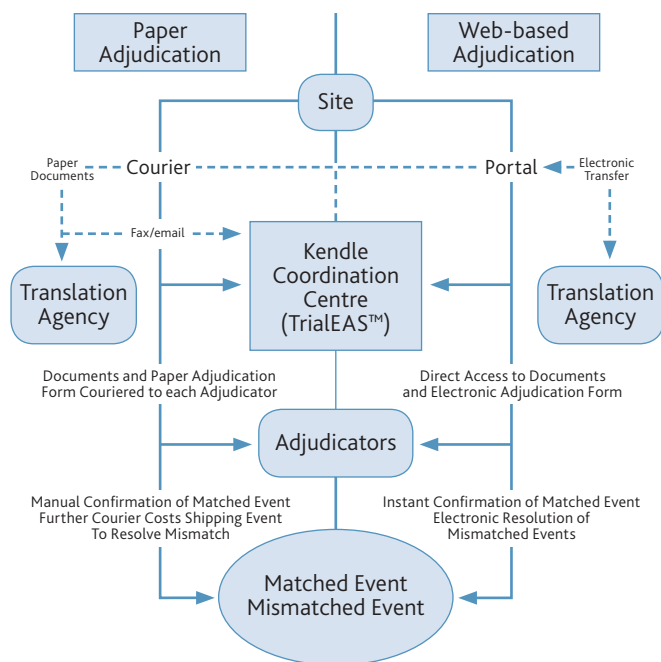
Endpoint adjudication with the TrialEAS™ system

The Kendle difference

At Kendle, we understand global endpoint studies pose unique challenges because of their size, duration and complexity of outcomes. To address this, we have developed TrialEAS™, an innovative, integrated and Web-based proprietary endpoint adjudication system. Geography is no longer a barrier, language is not an issue and face-to-face meetings are rarely needed to confirm that an event is an endpoint – increasing the speed and efficiency of endpoint adjudication.

In a paper-based adjudication system, an “event package” containing all of the paper information/images received for an event is shipped by courier to the expert committee. Next, the committee must meet to discuss the event and, finally, either confirms it satisfies the criteria of a study endpoint or “downgrades” the event. Under this system, the time taken to adjudicate an endpoint depends on the timing and frequency of the committee’s meetings.

By contrast, under Kendle’s TrialEAS™ Web-based system, the adjudicator can access an event package via the Internet from a secure Web site. All documents, including scans such as x-ray film, CT and MRI images, are available for review and the adjudication form (the cornerstone of the system) is completed online. The adjudicator remains blinded to the study treatment and unaware of any decisions reached by the other adjudicators.



Web-based adjudication using TrialEAS™

If the event package has been sent to two adjudicators and both agree in their endpoint assessment, the case is closed. If the experts disagree, a mismatch is recorded and either resolved at a specially convened expert committee meeting or allocated to a third adjudicator for a casting vote. Various randomization protocols can be incorporated into the system along with the allocation of events to separate adjudication committees. For example, one of our ongoing HIV studies involves panels of cardiologists, hepatologists, oncologists and HIV specialists, all of whom are sent event packages relevant to their specific discipline only.

Integration of our TrialEAS™ system with a study-specific portal enables documents or images from study sites to be uploaded and made available instantly to Kendle’s endpoint adjudication center. This reduces or eliminates costs associated with international couriers and minimizes the time between an event being reported at the site and its confirmation as an endpoint. Our approach also offers a solution to the language problem often affecting endpoint adjudication in global studies. By granting translation agencies access to a specific “translation room” within the study portal, the movement of foreign-language documents to and from translators becomes seamless.

The TrialEAS™ system is designed to be modular to allow easy configuration to protocol specific requirements. This includes the incorporation of customized electronic adjudication forms to capture the decision of the adjudicators.

For more information

about Kendle’s capabilities in endpoint adjudication, please contact us at info@kendle.com or at one of the telephone numbers listed below:

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