eAdjudication® Dossier

eAdjudication®

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

How do we help?

1 eAdjudication® Software

One powerful platform to connect the key adjudication actors and manage adjudication operations.

2 eAdjudication® Managed Services

Set up & manage clinical endpoint adjudication studies with the help of experts.

3 Two Provisioning Models

Meeting different customer needs.

From Ethical GmbH
Software Solutions for Clinical Research

300+
international clinical trials

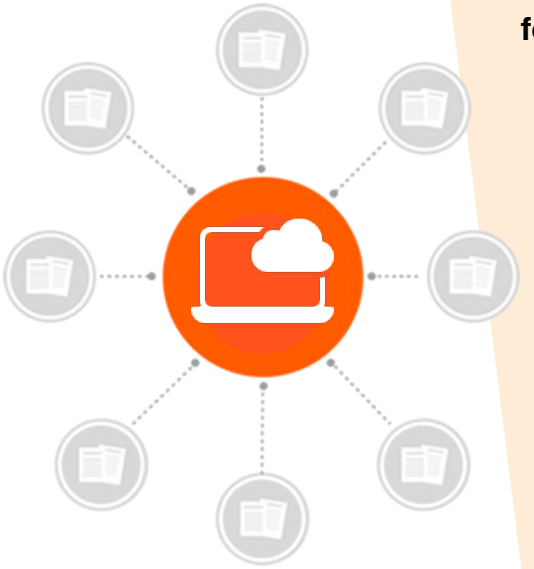
10,000+
investigator sites

100,000+
patients involved

14+ years
in endpoint adjudication

1 eAdjudication® Software

One powerful platform to connect the key adjudication actors and manage adjudication operations.



eAdjudication® is a powerful and user-friendly **cloud-based platform** supporting **fast, easy and compliant** endpoint adjudication.

Through **one central digital hub**, the Endpoint Office, Investigational Sites and Endpoint Adjudication Committee (EAC) members exchange medical records, redact personal information, assemble and submit dossiers, manage queries, review data packages and perform assessments.

All users interact effectively **online and in real time**, enjoying a user-friendly design and easy remote access.

eAdjudication® can be **configured to match any adjudication charter requirements.** Workflows are set according to the charter and all operations are recorded in a **GxP compliant audit trail.**

Software Main Features

- **Import Events** from EDC Systems (e.g. Rave) or CSV Files
- Collect from Sites & Redact Events' Medical Records
- **Track Data Changes** & Manage Sites' Queries
- Manage **Reviewers' Assessments and Disagreements**
- Monitor Process **Timelines & KPIs in Real-Time**
- Report & Export Adjudication Data & Audit Trail

Achieved Results

- **Save Staff Time** with a **Seamless Streamlined Processing**
- **Detect** Early **Inefficiencies** and Process Outliers & **Remediate Promptly**
- **Ensure GxP Compliance**, Audit Trail & Data Quality
- Support Committee Members with a Simple Ad-Hoc Solution
- Obtain a **Submission Package** as Required by FDA's Guidelines

What makes eAdjudication® powerful, robust and cost-effective?

eAdjudication® is highly flexible

- Integrates easily with any EDC system, DMS, safety database, DICOM/PACS systems and more
- Configurable to match any charter requirements: data collection, assessment forms, adjudication workflow
- Multiple DICOM viewer/PACS solutions depending on image quantity and size
- Standard and custom data exports (PDF, XML, SAS)

eAdjudication® is GxP compliant, secure and validated

- US 21-CFR Part 11; EU GMP Vol.4 Annex 11
- EU GDPR - General Data Protection Regulation
- ISO/IEC27001 hosting, back-up and business continuity
- GAMP5 validation documentation and support
- Audit trail

eAdjudication® supports efficiency

- Customizable KPMs and dashboard for real-time monitoring and control
- Automatic real-time notifications of event status based on user role
- Integrated Quality Control with random resubmissions
- Smart redaction technology

eAdjudication® is a multi-study platform

Clients receives a company-dedicated platform scalable for multiple, separate studies and sponsors

2 eAdjudication® Managed Services

Set up & Manage Clinical Endpoint Adjudication Studies with the Help of Experts

Ethical's team and network of experienced clinical endpoint adjudication experts provide tailored services for **setting-up, managing** and **running** clinical endpoint adjudication studies easily and efficiently.

From help in developing the Adjudication Charter to TMF archiving through Project Management support, Endpoint Office coordination, or Medical Review, customers benefit from the support they need throughout the study, **avoiding common pitfalls and enjoying flawless execution.**

Endpoint adjudication managed services

- Adjudication charter development
- Project Management
- EAC member selection and management
- Medical review of safety reports and medical records
- Translation and anonymization of medical files
- Consensus meeting scheduling and reporting
- Endpoint Office
- TMF archiving

Achieved Results

- **Comprehensive services**
- **Flexible and tailored to each particular study and charter**
- **Speed up the adjudication process**

Want to know how it works for your study?

Get a Free Demo of eAdjudication®

CLICK HERE TO REQUEST

3 Two Provisioning Models

Serving different needs of Sponsors, CROs and AROs.

Customers need varying degrees of flexibility and independence depending to a large extent on their **studies' complexity and the nature of their organization**. The two eAdjudication® **provisioning models meet these distinct customer requirements.**

Supplier-managed model — for maximum flexibility and support

Ethical creates, configures, customizes and manages the platform for the customer **until archival.**

The platform exactly matches the charter specifications, EDC integration and data export requirements and is delivered ready to start the study operations.

This model is suitable for any adjudication charter specifications and operational environment, and for any data and trial management architecture with **the maximum of flexibility.**

Customer-managed model — for independence and economies of scale

eAdjudication® Study Designer, a template and configurations editor, allows **trained customers to independently:**

- create studies on their company-dedicated platform,
- clone existing studies available as templates,
- create libraries of studies and forms.

This model is suitable for **organizations seeking independence** when configuring new studies and that have recurring or simple charters formats. Customers must have previously gained experience with eAdjudication® and the internal IT skills to manage the platform.

Who and how does eAdjudication® help?

eAdjudication® helps **Clinical Teams** and **Endpoint Adjudication Committees** work easier, faster and more accurately.

STAKEHOLDERS	HOW DOES eADJUDICATION® HELP
Clinical Trial Leaders	• Tailored Managed Services • Flexible configuration & strict charter compliance • Real-time oversight of all adjudication operations
Endpoint Adjudication Commitee Members	• Organized and easy to navigate events' packages • Easy submission of assessments • Package update notifications
Trial Coordinators Investigator Sites	• Fast upload of medical records • Smart redaction technology • Real-time query alerts
Quality Assurance Managers	• Validation package documentation • GxP compliance • Clone system for UAT and reviewers' qualification
Data Managers	• Flexible integration with any EDC • Real-time download of structured data and metadata • Integrated quality control

What do customers say about eAdjudication®?

"With eAdjudication®, the endpoint adjudication process, documentation and information is managed 100% by the web-based system *without any paperwork.*

The CEC members can log in to eAdjudication® *at any time and at any place.* This is very efficient and we have a great overview of the event status, submission and adjudication."

Pernilla Holmgren
Team Leader CEC Department
Uppsala Clinical Research Center

"Using an online eAdjudication® portal for our SERAPHIN study endpoints assessment *improved the efficiency of the data collection* and the *quality of our processes*, allowing a timely completion of the study.

On-line management of Adjudication allowed *rapid assessments of the study endpoints* and greatly facilitated the work of the *external clinical experts.*

The tool provided them an integrated *quality controlled environment* and all the information and forms required to assess the submitted endpoints."

Loïc Perchenet, PhD Director
Director, Global Post-Approval Studies
Actelion

ETHICAL
eADJUDICATION

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

Interested to know more?

Get a FREE DEMO of the eAdjudication® Software Solution

No commitment required!

Still in the planning phase?

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The Endpoint Adjudication
Handbook

Get a Free Copy of
The Event Adjudication
Charter Guide