



eAdjudication®

Improve Endpoint Adjudication Efficiency and Data Quality with Ethical's eAdjudication® Technology Platform & GxP Managed Services

For Endpoint Adjudication choose an All-inclusive Enterprise Software Service and relieve your Clinical Team from all the burdens associated with the software & data management of your Endpoint Adjudication Studies.

Ethical's eAdjudication as Cloud Software provides you

- Unlimited Role-Based Users;
- Events' Dossier Collection from Sites, Redaction and Assembling before submission environment;
- Adjudication Committee Members Management;
- Adjudication Forms with Edit Checks, Workflows and Major / Minor Disagreement Management;
- Query to Site and Re-Submission Management;
- Operations real-time Tracking & Audit Trail;
- Integration API & Forms for Medical Records and Events from Sites and trial databases (Medidata Rave / InForm / DICOM imaging / Medical Box);
- Standard / Custom Export of data/metadata (PDF, XML, SAS).

Ethical's eAdjudication as Service includes full support for

- ISO 27001 Cloud System Hosting & Management (backup/monitoring/security/business continuity);
- Software Validation packages, Stage Environment for Test and Training;
- Adjudication Charter based Software Configuration (forms, edit checks, workflows, data exports);
- Technical Support through integrate Help Desk

Adjudication Software Adoption Made Easy

Ethical is not just a technology company; we hold the experience and expertise in clinical trials GxP data management to make a difference in your costs and timelines. Our approach is simple, rapid and effective: **Charter Evaluation** we get your Charter and develop a software plan / URS for your study. **Software Configuration** we implement your approved Study Charter in the validation clone environment.

UAT and Acceptance you make tests and validation of the software checking all features against the Charter URS.

Production Release & Ongoing Support we release & keep working the eAdjudication and support you throughout the study, so you can focus on your goals.

"Using an online eAdjudication portal for our study endpoints assessment improved the efficiency of the data collection and quality of our processes, allowing a timely completion of the study. Online 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, Global Post-Approval Studies, Actelion





Benefits for Every Function

Ethical's Enterprise eAdjudication® platform makes adjudication easy and seamless by enhancing eAdjudication workflows for every stakeholder in the adjudication process.

Study Leaders and Staff benefit from lower total cost of ownership, strict charter compliance, and complete adjudication management oversight.

Committee Members experience limited training, user friendly interactions, easy access and assessment submissions, reminders and package update notifications.

Quality Assurance Managers can access fast validation with validation package, audit trail and SOPs, and a clone system for UAT and reviewer qualification.

Data Managers can easily download structured data and metadata, access SAS/XML configurable export and Integratability, and APIs and integration WebServices interfaces.

"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 of the CEC department at Uppsala Clinical Research Center

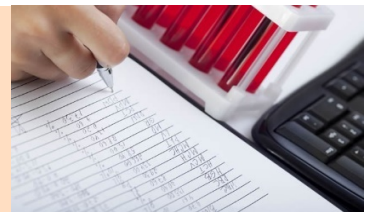
A Central Hub for Medical Records and Adjudication Packages Management

Ethical's Enterprise Endpoint eAdjudication® platform pulls data by integrating into numerous clinical platforms including EDC, Safety Databases, Data Management Systems, DICOM/PACS Systems and more. Ethical's integrated systems approach promotes eAdjudication efficiency through:

- Interactive key data submission
- Interactive/ batch document upload
- Integration API / web services
- Data / document versioning
- Data resubmission management

GxP Compliance

- GAMP 5 Documentation
- 21-CFR Part 11 Compliant
- EU GMP Vol.4 Annex 11
- ISO 27001 Certified



A Modern User Friendly design: also in mobility !

The screenshot shows the Ethical eADJUDICATION web interface. At the top, there is a navigation bar with 'Home / Adjudication 1', 'Helpdesk', 'My Profile', and 'Logout'. Below this is a search and filter area with buttons for '+ Add New Case', 'Pending Summary', 'Export CSV', and 'Export PDF'. A table displays adjudication cases with columns for Event, Patient, Case Status, Decision Status, and Last Submit Date.

Event	Patient	Case Status	Decision Status	Last Submit Date
TestEdit	TestEdit	Re-submitted due to data changes	Pending	04/02/2014 12:48:00
February 2014	381734			
March 2014	789382			
April 2014	554126	Submitted	Pending	04/02/2014 15:08:30

