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

Study Designer For Independence & Economies of Scale

We developed study designer specifically for organizations having recurring and simple charter specifications, and IT skills to administer the platform by themselves. The Study Designer tool allows trained staff to create, configure and manage studies without external help.

Study designer functionalities:

• Create a new study from the beginning
• Clone an existing study or part(s) of a study using templates
• Create libraries of studies and forms
• Edit templates and configurations
• Manage users profiles

Study designer comes with its own pricing model and deployment process. We will check with you if your organization profile could benefit from this tool.

“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.

“A 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, 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!