# eAdjudication<sup>®</sup> Dossier





# eAdjudication®

Simple and effective software for pain-free clinical adjudication

# Why use a software to manage clinical adjudication committees?

#### Do you find that:

- Managing large volumes of clinical data is risky?
- Ensuring data quality and GCP compliance is demanding?
- Coordinating adjudication activities is quite complex?
- Adhering to deadlines and governance is often a challenge?

### → eAdjudication<sup>®</sup> is the solution!

- Seamless integration with EDC systems, safety databases, DICOM/PACS clinical imaging
- Robust quality control process for adjudication consistency
- Flexible system configurations for forms, workflows, data exports, and integrations
- Real-time monitoring of process timelines and key performance indicators (KPIs)

## eAdjudication<sup>®</sup> Software Features

eAdjudication® is a comprehensive software solution supporting the full management of all types of clinical adjudication committees, incorporating process best practices, quality control, and the flexibility to adapt to any scenario.





### / Data Manageability

- Streamlined case preparation and processing
- Online editors for WORD, EXCEL, PDF and DICOM files
- Al-powered redaction tool for PDFs and DICOM images

#### Workflow & Communication

- Flexible system configurations for forms, workflows, data exports, and integrations
- Configurable adjudication workflow to adjust to sponsor, CRO, or ARO needs

### Security and Confidentiality

- Quality control metrics & process
- Inter/Intra-variability control
- Dedicated role-based views and • data segregation
- Adjudication forms with edit check

# **Process Governance**

- Real-time monitoring of process timelines and KPIs
- Self-service data export with real-time access
- GCP-compliant audit trail for transparency and compliance

#### eAdjudication® is GCP compliant, secure and validated



- ISO 27001 hosting, backup and business continuity. •
- GAMP5 validation documentation and support.
- Secure 21 CFR Part 11-compliant audit trail.
- EU GMP Vol. 4 Annex 11, EU GDPR.



### Who and how does eAdjudication<sup>®</sup> help?

 $eAdjudication^{\ensuremath{\mathbb{R}}}$  helps  $\ensuremath{\text{Clinical Teams}}$  and  $\ensuremath{\text{Endpoint Adjudication Committees}}$ 

work easier, faster and more accurately.

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

# What do customers say about eAdjudication<sup>®</sup>?

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This current system is undoubtedly worlds easier than a manual review. Reduces scan, signature, and upload times and ensures that everything is in order.

#### - Adjudication Committee Member

Using the eAdjudication® solution drastically simplifies the whole adjudication process. It can manage the entire process: training, event management, submission, and queries I love working with Ethical. They are always very flexible with the various formats and types of exports. It is also possible to schedule or obtain them in real-time from the platform.

#### - Data Manager

I find Ethical GmbH very innovative and flexible. They find solutions to all our requests and they constantly adapt to different volumes of events even with short notice.

- Sponsor's Study Leader



Clinical and Endpoint adjudication (CEA), Protocol Deviations (PD), Data and Safety Monitoring Boards (DSMB), and Data Monitoring Committees (DMC) management on cost-effective, compliant software solutions for over 16 years.



Are you interested to know more?

# Get a FREE DEMO of the eAdjudication<sup>®</sup> Software Solution

#### No commitment required!

Are you still in the planning phase?

Get a Free Copy of The Endpoint Adjudication Handbook Get a Free Copy of The Event Adjudication Charter Guide

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