



ETHICAL

CASE STUDY

Ethical GmbH Improves Its eClinical Software with PrizmDoc Viewer Redaction & Annotation APIs

Ethical GmbH's story started in 1997, when a group of software developers came together to create a web application for the healthcare industry. Their mission was to create an application that collects information about side effects or adverse events. This application would be the start of a variety of software that went on to set standards for safety and quality assurance in clinical trials.

From applications focused on study tracking and data collection to those specializing in query management, adjudication, data review, and more, Ethical's software developers travelled around the world to train investigators and support clinical studies' data management. In 2004, Ethical delivered its first eAdjudication software in the Cloud. The solution simplifies work for Endpoint Adjudication Committees and assures their data is managed in a compliant way.



Overview:

In the process of building eAdjudication, Ethical recognized a need for a document viewer that specializes in secure redaction technology. In fact, the Endpoint Adjudication process requires that a panel of experts examine the data and documents related to a specific clinical event and express a judgement on it. The experts must assess the data in a blind and independent way, without any bias on the trial context or patient background.



When we first started looking for a redaction tool, we researched several different companies. We compared Accusoft to a company in Europe, and concluded that Accusoft is the most experienced and advanced solution for APIs.



Mimmo Garibbo
Director and Founder, Ethical GmbH

Challenges:

In clinical trials, data about specific events must be collected and objectively evaluated. In some cases, when the interpretation is difficult or subjective, a panel of clinical experts is involved in a process called Endpoint Adjudication. In this process, the event information that is passed to these experts must be redacted in a way that ensures compliance with common healthcare regulations.

eAdjudication users originally used Adobe Acrobat to redact information. However, using an external tool was not very efficient and made it impossible for the eAdjudication software to track all document changes as required by healthcare regulations. The challenges included:

- **A need for keeping all versions of each redacted document.**
- **A need to record who made changes, when, and what exactly was changed.**
- **A need to add value to the current eAdjudication software with a document viewer that incorporates tracked annotation in a secure way.**

After speaking with Accusoft's technical customer support team, Ethical decided to integrate PrizmDoc's redaction and annotation APIs into its eClinical software.

Results:

Since integrating PrizmDoc Viewer APIs into eAdjudication, Ethical has started to test the functionality in their demo with current customers and prospects. Given the strong regulations for healthcare software, the new addition will need to go through a variety of reviews to get final approval for use in the industry.

"There is a process called computer system validation. We have to perform a lot of tests and prepare a lot of documentation for review, but we are confident that this new feature will provide a streamlined way to collaborate on case trials, while simultaneously providing secure redaction of participant information," reports Garibbo.

Learn how PrizmDoc APIs can help your business solve document challenges.

Schedule a Demo Today
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About Ethical GmbH

Beginning as eClinical developers, our staff gained experience spanning the range of the eClinical world: eClinical technology, clinical systems, and data management in global trials, clinical trial quality and data compliance, and of course, endpoint adjudication (EA). We gained the experience in successful engagements with academic research organizations (AROs), biopharmaceutical or medical device enterprises, clinical research organizations (CROs), and independent review committees. We have become expert in the creation, performance, and management of the EA process workflows and forms validation, private health information management and compliance, clinical trial and GxP compliance, clinical systems design, integration and management, as well as web and mobile interface design.

About Accusoft

Accusoft is a software development company specializing in content processing, conversion and automation solutions. From out-of-the-box and configurable applications to APIs built for developers, we help organizations solve their most complex content workflow challenges. Our patented solutions enable users to gain insight from content in any format, on any device with greater efficiency, flexibility, and security.

