



Ethical eAdjudication® Integrates With Guardtime KSI-Blockchain®

Blockchain Technology Improves Quality and Data Integrity of Ethical's eAdjudication® Software for Clinical Endpoint Adjudication

BASEL, Switzerland, May 1, 2018 (Newswire.com) - Ethical GmbH, the Swiss company providing eClinical Software Services with a special focus on Clinical Endpoint Adjudication, integrates with KSI-Blockchain® to provide a new strong proof-of-evidence for data integrity and time of Audit Trail Records.

The Challenge

Since the implementation of GxP standards the ALCOA and more recently the ALCOAC ALCOA – C: Attributable – Legible – Contemporaneous – Original – Authentic – Complete principles have been a basic requirement of quality and compliance when interacting with regulatory authorities in the field of medicinal and device products.

For any regulator such as EMA, FDA, JPMA or any Notified Body one basic requirement of any electronic system used in managing data related to a pharmaceutical or device product is the ability to produce an indelible Audit Trail. In this context the term indelible is key. Indeed, regulators must rule out with 100 percent certainty that audit trail data – i.e., the evidence about who recorded any data for the first time and when, who modified it and when, and finally who released it as genuine data – that such Audit Trail data has been tampered with – i.e., modified without leaving any trace of the change – after the original recording of the data in the system's user database.

In the "old days" carbon copies – or with a bit more modern technology so-called NCR paper – was used to provide the generator of the data – e.g., a trial investigator – with his personal contemporaneous copy. In case of suspicion of any wrongdoing by the sponsor of a trial – e.g., the sponsor tampering with the audit trail by accessing this data through an "administrator's back-door" – the contemporaneous copy left with the investigator would have allowed a regulatory inspector to detect such fraud.

With the move to fully electronic data capture systems the contemporaneous copy became, in fact, a copy on what got stored on the electronic system that is typically under the direct or indirect (when hosted by a CRO/vendor) control of the sponsor – aka the potential suspect. Not surprisingly this makes inspectors and Health Authorities uncomfortable as they can no longer produce bulletproof evidence that audit trail data is genuine and hence trial data is genuine.

Recent repeated cases where CMOs tampered with batch records to make out of specifications batches "acceptable", have spurn regulators concerns. Solutions presented to rebuild trust in audit trail data are typically paper-based "solutions": print the records and have them signed and dated by the investigator or another accountable person. A bit more elegant but still saddled with practical issues: generate a contemporaneous PDF copy on the local computer of the data generator (besides the fact that this generates a plethora of files that need to be managed for future retrieval many organizations do not allow importation of alien files for obvious cybersecurity reasons).

Ethical eAdjudication® Solution using Guardtime KSI-Blockchain

Every time an operation is performed in the eAdjudication System a new Audit Trail Record is generated in its database. For every record and for every audit trail information a unique KSI-Signature is created. The KSI-Signature serves as proof-of-evidence that data integrity, time and authorship have not tampered. The KSI-Signature is stored in the Adjudication ® System, and the evidence is registered in the Guardtime KSI-Blockchain.

At any time after, the Audit Trail Records present in the Adjudication ® System database can be matched with the corresponding KSI-Signature. In addition, the record and signature can be validated against the KSI-Blockchain to ensure that no data whatsoever has been altered or even deleted since the time of its first registration.

This is not a plan but has been implemented – at the moment in a successful proof of concept test – as a future standard feature of the eAdjudication platform offered to clients. This feature provides irrefutable evidence that any data point entered by an adjudicator or other contributor has never been modified without a GxP audit trail stating reasons, time and originator of the change.

Important Notes (Benefits)

Only the Hashvalues of the eAdjudication ® Audit Trail are sent to the KSI-Blockchain while the actual sensitive data generated by the system are only recorded in the original database and, therefore, ensuring compliance with all applicable data privacy and protection laws and regulations such as the GDPR and HIPAA.

The core software and processes of the eAdjudication ® System do not need to be heavily modified – and hence fully revalidated – but only the features to synchronize the Audit Trail recordings with the external Blockchain gets added to the system with a limited and well-defined impact on the validation status of the system.

Mimmo Garibbo (Ethical's Director): "Data integrity is a key requirement for clinical trials and all other tasks related to drug development and lifecycle management of a medicinal or device product. I'm convinced Blockchain technology offers an incredible opportunity for making compliance processes leaner and at the same time more reliable and more robust."

Beat Widler (Ethical's Head of QA): "Blockchain is an intriguing technology that our QA community

needs to fully understand. Even as a 'no techy' I can see how we can overcome old ways of thinking that are based on paper trails and multiple layers of QC checks, with smart reports providing seamless evidence of data integrity."

About Ethical

Founded in Basel in 2014 Ethical is operating in the eClinical Software and Clinical Data Management sector with a special focus on Endpoint Adjudication software services.

www.ethicalclinical.com

About Guardtime

Guardtime is a team of more than 150 cryptographers, developers, and security architects, with decades of experience, defending networks from nation-state attack(s). Over the last decade, we have built a technology platform called KSI that allows us to tackle challenging problems in security, supply chain, compliance, and networking.

www.guardtime.com

Clinical Endpoint Adjudication

Is crucial for reducing patients' risks and study bias when assessing and comparing an endpoint at baseline vs. study end in a multi-center clinical trial when subjective – such as image-based endpoints represent a pivotal efficacy and/or safety parameter.

In fact, where endpoint assessment is complex, includes reader's driven components – aka subjective assessments – and/or cannot be blinded, a central assessment of efficacy or safety events, made by a panel of independent experts following a blinded standardized procedure increases accuracy, transparency, and homogeneity of judgments.

About Ethical eAdjudication®

A Cloud Software Service supporting Endpoint Adjudication Committees' operations and data management in a quality controlled environment.

Media Contact:

Mimmo Garibbo

email: mimmo.garibbo@ethical.ch

Source: Ethical GmbH