eAdjudication®

Flexible Endpoint Adjudication Software & Managed Services For Sponsors, CROs and AROs

FOR SUBJECT MATTER EXPERTS

The 6 Steps of The Clinical Endpoint Adjudication Process with eAdjudication®

v.1.0

1. Event Import in Database

2. Event Information Collection

3. Event Information Processing

4. Event Package Submission To Committee Members for Adjudication

5. Disagreement Resolution

6. eAdjudication® Process Output

From Ethical GmbH
Software Solutions for Clinical Research

300+
international clinical trials

10,000+
investigator sites

100,000+
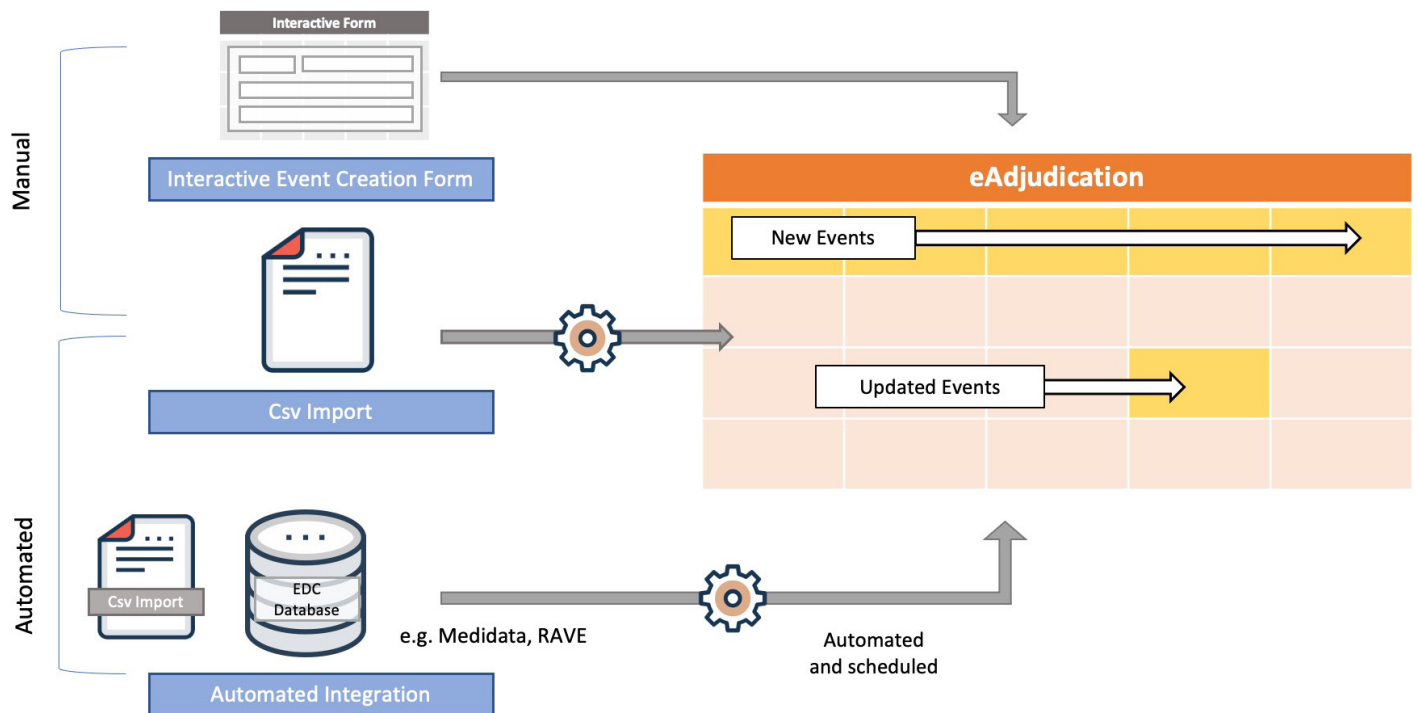patients involved

14+ years
in endpoint adjudication

1. Event Import in Database

In the first step of the adjudication process, the events data must be imported into the database.

Using eAdjudication®, there are **three main methods** of import.

As you can see, there are two **manual import solutions** and the **automated method.**

The first manual method uses an **interactive event creation form** to manually enter each event information into the system.

However, this solution can be quite time-consuming. F**or the import of more than 10 events we recommend using a csv import.**

For a manual CSV import, one first prepares a csv document using a predefined format and subsequently uploads it to the platform.

eAdjudication will take care of creating new events or updating existing events in the database.

If you are dealing **with a large amount of events, and the process of import needs automation**, we have the option of **automated csv import or integrating existing EDC Database** such as Medidata, RAVE, etc. into eAdjudication using a custom API. This automation must be set at the configuration stage, at the time of study implementation.

2. Event Information Collection
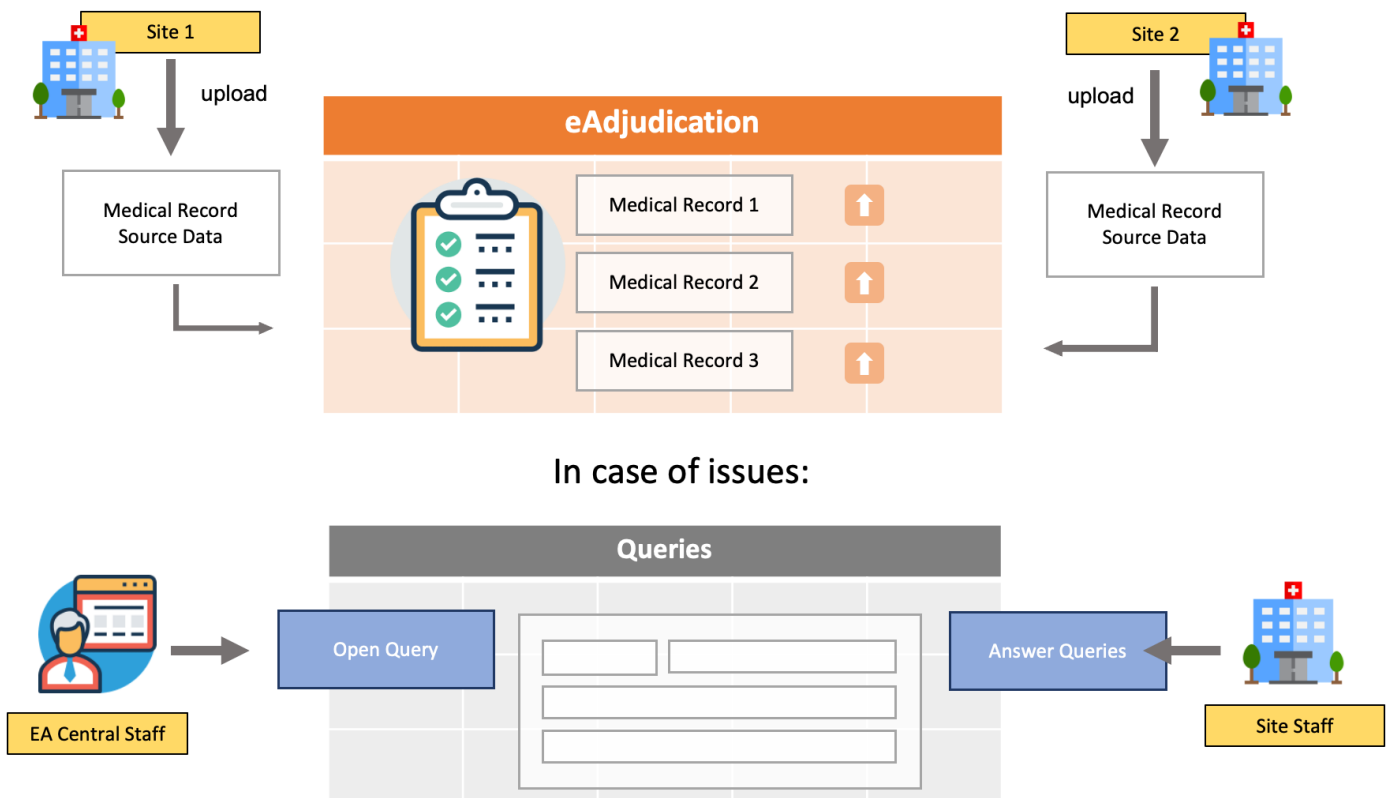
The second step is the event information collection.

In this step, site staff members are required to upload the events medical records into eAdjudication®.
Remember that e**Adjudication® is cloud-based and serves as one central repository** for all the study adjudication data packages.

The records required from the sites are displayed in eAdjudication® **as a checklist** so it is easy for both site staff and central staff (sometimes also called endpoint office) to monitor the level of completion.

On the interface of the central staff, the documents are reviewed carefully for quality, completeness, anonymization, etc.

In case of issues, **central staff can open queries** asking the sites for new documents.

The query is closed when the site has uploaded a new correct version.

3. Event Information Processing
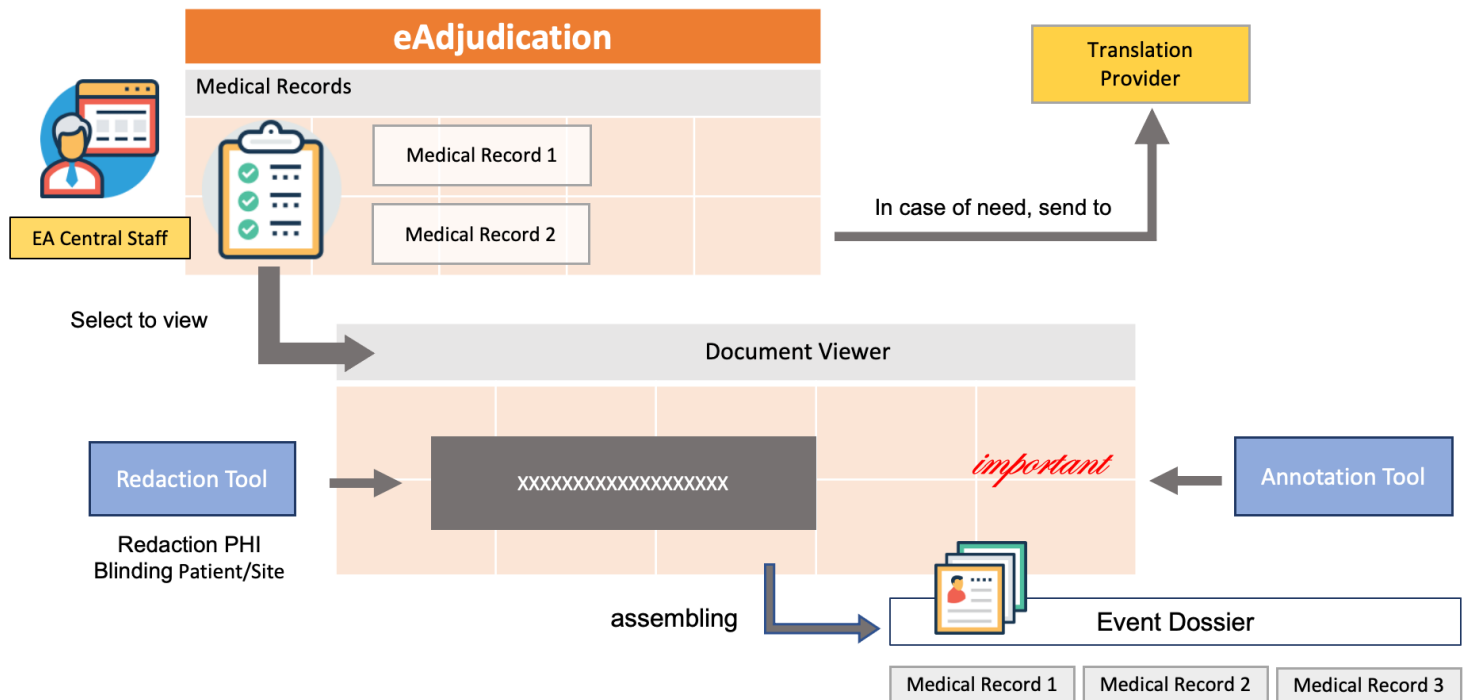
Let's take a look now at the 3rd step of the endpoint adjudication process: the "Event Information Processing".

At that point, the events information is further processed by the EA Central Staff.

Here the eAdjudication® platform provides the **Central Staff tools for document redaction and annotation.**
If the document needs translation, Central Staff can also share it with an external translation provider **through the platform.**

Once all the documents are processed, the EA central staff **assemble them into the Event Dossier** in different formats (PDF, excel, etc.) **using the built-in tool.**

4. Event Package Submission To Committee Members for Adjudication
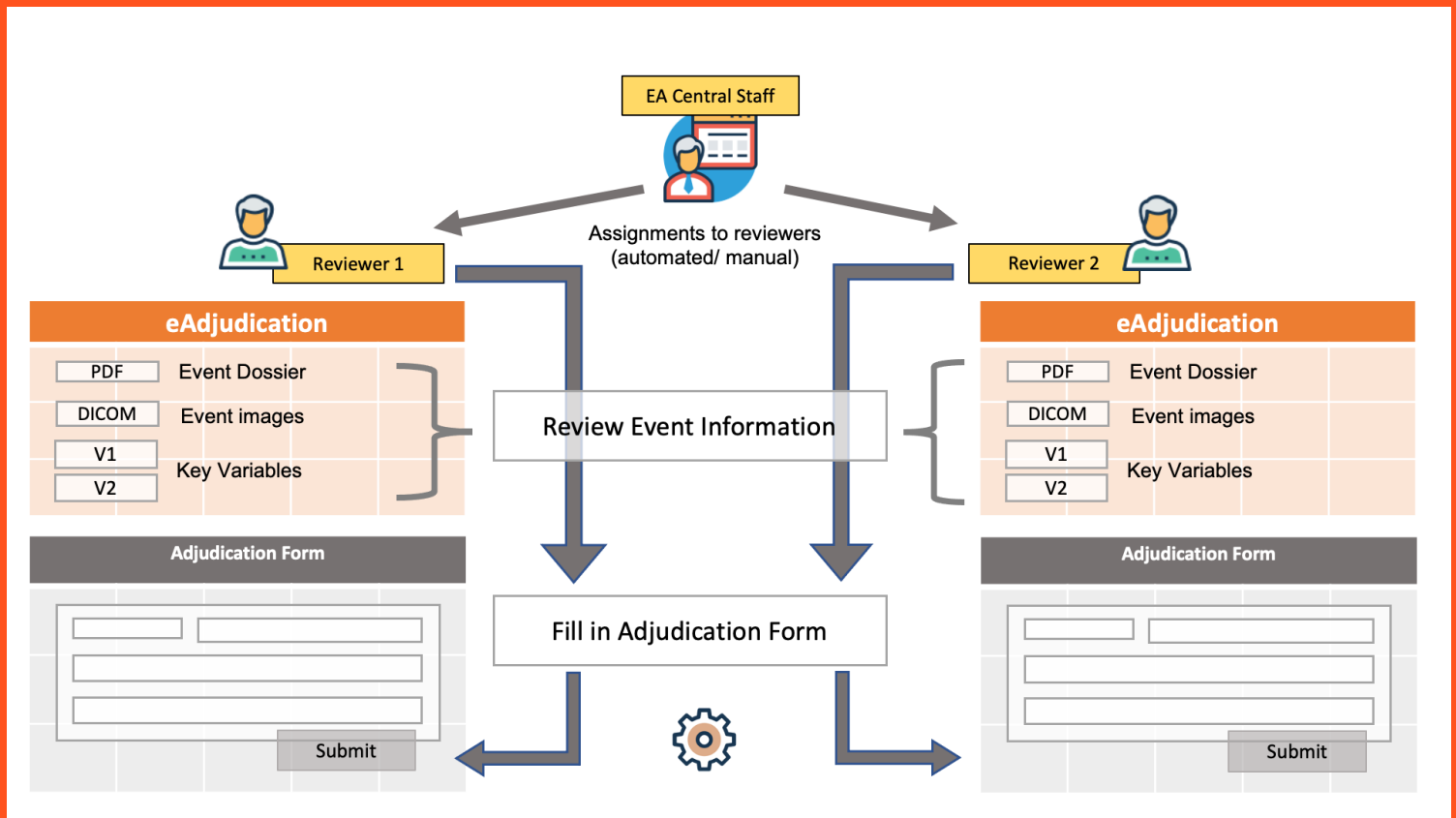
Now comes the fourth step: the event package submission to the Endpoint Adjudication Committee (EAC) members for adjudication.

After the event medical records have been compiled into Dossiers, the **EA Central staff assign these Dossiers to the reviewers** for adjudication.
This task again is **performed through the eAdjudication® platform.**
The assignments can be made automated or manual.

The reviewers then carefully review the event information, in an independent and blinded way, and provide their assessments using the **interactive Adjudication forms inside eAdjudication®.**

You can now clearly see the benefits of using a cloud-based platform with **independent interfaces for different roles** (central staff, sites, EAC) as it allows a seamless endpoint adjudication process from beginning to end.

5. Disagreement Resolution
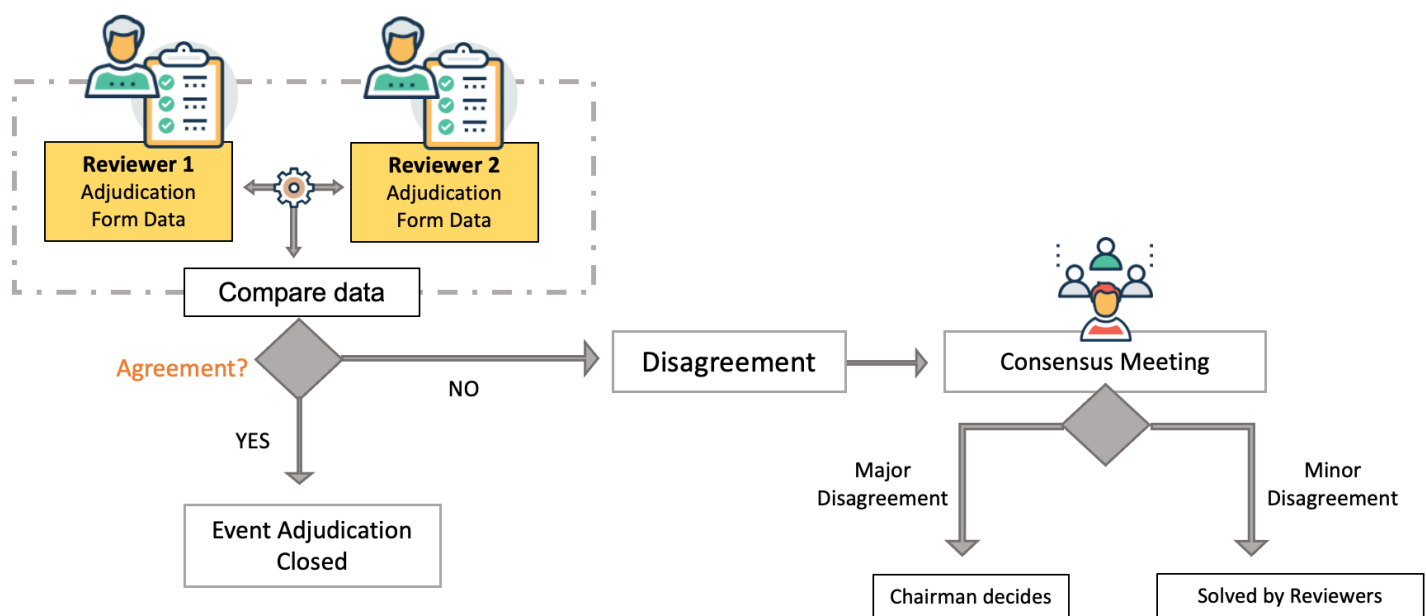
And finally, let's look at what happens once the reviewers have entered their assessment in the platform through the adjudication form.
As you can see, we have called this step: Disagreement resolution.

The system compares the reviewers' adjudication forms.

At this step, **there are 3 possibilities.**
- **If the forms match**, this means that the reviewers are in agreement, the adjudication for that event is marked closed and no further discussion is required.
- **If the forms don't match**, the event is considered in "disagreement", eAdjudication® supports the **setting up of a consensus meeting for resolution** of the conflicting assessment(s).
- *If the disagreement is minor*, the consensus meeting can be between reviewers only and the disagreement solved by the reviewers themselves
- *If the disagreement is major,* the consensus meeting will usually call the Chairman who will make the final decision.

The application also offers the possibility to move the event to the Chairman, whose assessment will be considered as final (superseding the others').

The disagreement resolution process can vary according to the studies and this will be specified in the Charter. **We thoroughly review the charter for all the configurations of the platform.**

6. eAdjudication® Process Output
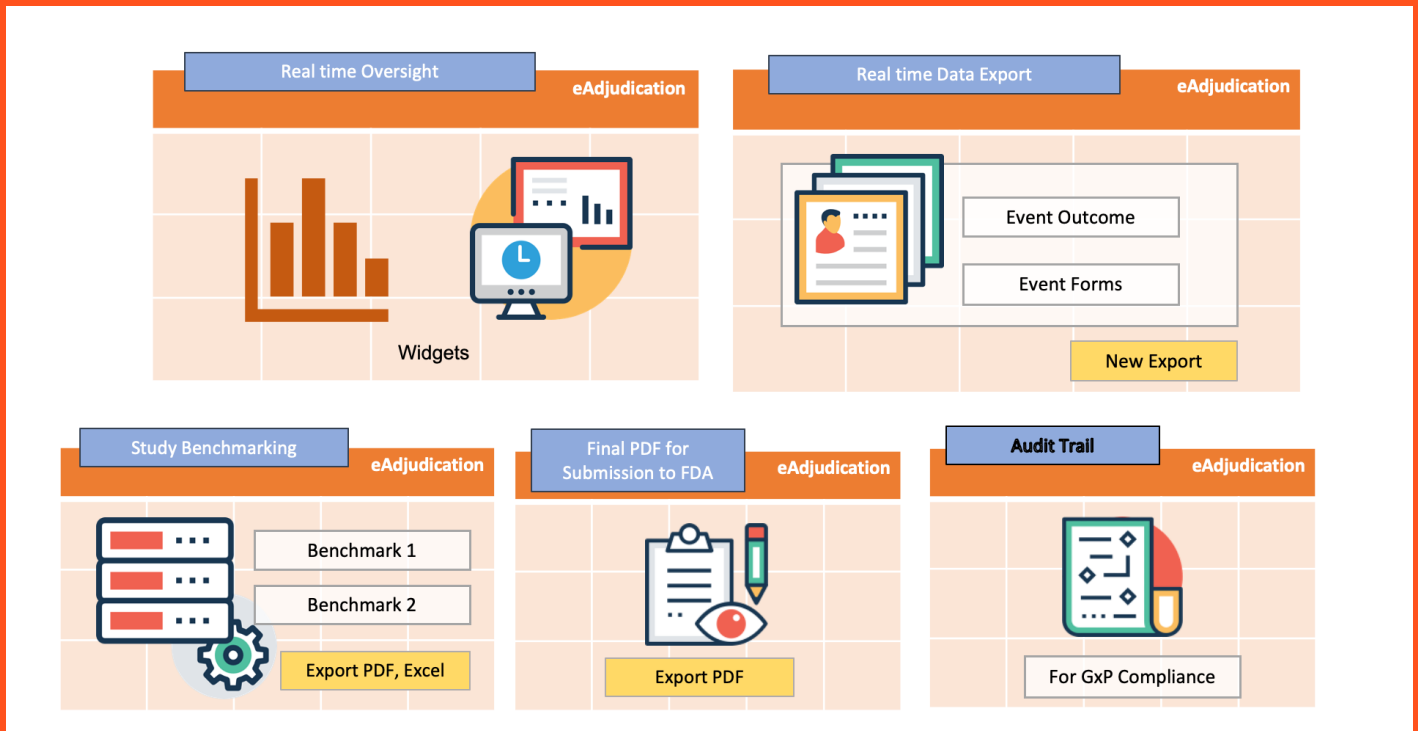
At the end, all operations and data involved in the clinical event adjudication process are stored and tracked in the eAdjudication® platform.

So, **within the platform**, there is a great deal of information that are useful (1) for the study conduct and (2) that will be needed at the end of the study for the submission to health authorities:

- The platform dashboard provides **real-time oversight** of events status and sites/reviewers/central staff operations status in easy-to-understand charts and widgets;
- The **Study benchmarking** provides statistics such as time to event submission, time to adjudication, days to query reply, etc. that are exportable in Excel or PDF;
- Users can **export real time data and Audit Trail** to coordinate with regulatory meetings or site visits;
- Finally, eAdjudication® provides the tool to **export the final pdf to health authorities in a compliant format.**

ETHICAL
eADJUDICATION

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Managed Services
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No commitment required!