ETHICAL

eReconciliation®

Flexible SaaS solution for high-volume SAE data reconciliation

Find out in this leaflet how eReconciliation® helps to:

- Automate the reconciliation process of SAE records with minimal human input.

- Automate change-tracking in source data throughout the study.

- Keep oversight of the entire data reconciliation process with minimum burden.

- Secure peace of mind with workflow features and full audit trail.

From Ethical GmbH
Software Solutions for Clinical Research

300+
international clinical trials

10,000+
investigator sites

100,000+
patients involved

24+ years
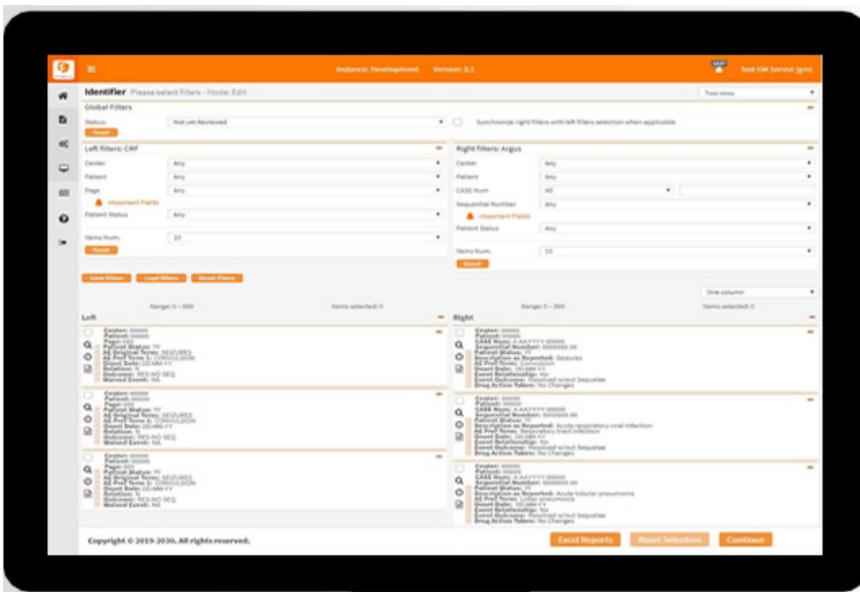in Data Management

1 About eReconciliation®

Is it challenging to keep up with the number of incoming SAE records to reconcile?

Do you waste precious time keeping track of the changes in source data throughout the study?

Is it difficult to look for discrepancies when data is coded in various ways?

Do you find it challenging to track and document all your reconciliation operations for GxP compliance?

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eReconciliation® was designed for you!

eReconciliation® is a **highly automatable** software solution for SAE Reconciliation, that helps you **save tremendous time**, **minimize errors** and **prevent major compliance breaches.**

SAE data reconciliation is not just about automating the process of data comparison at the end of the study. It's about doing it *early and regularly*, **with minimal human input**, to save precious time at clinical database closure.

Equipped with *automation features, smart tools, hands-on task management features and a secured audit trail*, eReconciliation® allows data management, clinical and safety teams to perform SAE data reconciliation **all along the study with minimum burden**, simplifying operations management, supporting data quality and guaranteeing GxP compliance.

With eReconcilation®, data can be imported automatically from designated databases. The reconciliation can then be performed automatically following pre-defined rules but also manually if preferred in some specific instances.

Once the datasets are imported in the system, records are displayed in a side-by side view of **the clinical and safety datasets.**

The system can automatically create groups of reconciled records based on level of relevance.

Groups that did not totally satisfy the rules can be reviewed by a team member who will check what needs to be fixed. Unmatched records are sorted and displayed conveniently for follow-up.

In a single, user-friendly interface, users perform and track all their reconciliation operations.

eReconciliation® is a highly configurable Software as a Service (SaaS) platform scalable for multiple studies.

How eReconciliation® works	How eReconciliation® helps
Reconciliation Smart Matching Tool	• Shows the clinical and safety records side by side. • Based on the "matching score", records are grouped and the relevant follow-up action automatically assigned. • Sorts and displays unmatched records for follow-up.
Automated Data Update Flagging Tool	• Automatically flags the record when the system detects a change in source data. • Only displays the latest data so users can skip all interim changes.
All-in-one operation management tools	• Allows managers to follow all tasks at any stage (labelling, flagging, commenting, assigning actions). • Provides full data exporting, reporting and audit trail. • All involved functions benefit: Quality Assurance, Data Managers, Regulatory Affairs…

eReconciliation® offers a **full range of tools and functionalities** designed to save time and simplify reconciliation operations management.

Users do report that eReconciliation® truly **makes their lives easier.**

Here's a selection of some of the **most appreciated tools** and happy **users' feedback.**

eReconciliation® top-ranked tools	What do users say about these tools?
The "Automated Grouping" tool can automatically approve the grouping suggestion when a matching level is obtained or lists the matches by relevance (for the user to perform manual grouping)	*"eReconciliation® is able to match the corresponding records from the clinical and safety datasets. We save a lot of time by not having to search and match ourselves the newly matching records after each import."* - Data Manager
The "Action" menu and "Comment" field allow users to assign actions to functions (e.g.: Data Manager, Global Data Safety, Monitor…) or set the group as "Reconciled", and to document the agreed follow-ups	*"eReconciliation® facilitates cross-functional collaboration with Data Management, allowing us to jointly review the discrepancies and decide on the appropriate action."* - Medical Safety Officer.
The **"Changed After Review" filter** allows to flag data fields that were updated in a previously reconciled group after a new import. If the fields are still matching, a new version of the group with the corresponding "Action" are automatically created.	*"Once a discrepancy is resolved and either the safety or the clinical database is updated, the system detects this change automatically and brings it to Data Management attention. The risk of missing a change in source data is considerably reduced."* - Medical Safety Officer.
The "Export" function allows to export in Excel files all actions performed in the system, such as commented and accepted discrepancies or sites-specific SAE reconciliation queries.	*"eReconciliation® allows to export a list of all the pending queries for a specific site that can be easily shared with the CRA for verification at a subsequent monitoring visit".* - Clinical Trial Leader.
The Audit Trail function ensures a secure, computer generated, time-stamped electronic record that allows reconstruction of the course of events relating to the creation, modification, and deletion of an electronic record.	*"eReconciliation® supports any regulatory inspection with its ability to proof the full tracking history of operations to the auditor. Furthermore, in case of staff turnover, a new team member easily steps in from being able to quickly understand the status of operations."* - Quality Assurance Manager

4 Why should you choose eReconciliation®?

As seen previously, eReconciliation® supports data reconciliation efficiency. Furthermore, it has the flexibility to be customized for any study and is GxP compliant, secure and validated.

eReconciliation® is therefore the must-have software securing **peace of mind** to any organization performing SAE data reconciliation.

eReconciliation® supports efficiency

- Filters, automated grouping tool, control panel and task management features are designed to save users' time and facilitate cross-functional collaboration.
- In case of staff turnover, the reconciliation continues smoothly as all operations are recorded.
- The SAE reconciliation is performed during the study; DB lock is not delayed by the final SAE data reconciliation.
- eReconciliation® is delivered as a ready-to-use SaaS platform scalable for multiple studies.

eReconciliation® is customizable for any study

- eReconciliation® accepts any source system (RAVE, EDC, ARGUS, ARISg…) and as many as needed.
- eReconciliation® accepts as many data points as necessary (Center, Patient, AE Term, AE Onset date, AE number…).
- The data fields that make up a record and those that must be identical in the right and left datasets to create a group are set at configuration.
- The left and right datasets filters as well as the global filters are configurable.

eReconciliation® is GxP compliant, secure and validated

- Complete Audit Trail for real-time export during regulatory inspections.
- ISO 27001 hosting, backup and business continuity (Customers may choose to install eReconciliation® web application on their own data center)
- GAMP5 validation documentation and support.
- Secure 21 CFR Part 11-compliant records management.
- EU GMP Vol. 4 Annex 11, EU GDPR.

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eRECONCILIATION

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Interested to know more?

Get a FREE DEMO of the eReconciliation® Software Solution

No commitment required!

Still in the planning phase?

| Get a Free Copy of The SAE Reconciliation Handbook | Get a Free Copy of The SAE Reconciliation Process Checklist |