

AMEDON SAE Database

REPORTING WITH FULL COMPLIANCE REGARDING ICH GUIDELINE E2B (R3)

Our SAE database framework comprises all options for the documentation and reporting of Serious Adverse Events from clinical trials and in market surveillance to EudraVigilance according to the current ICH Directive E2B (R3) and the EU Business Rules.

RECORDING AND MANAGING SAE MESSAGES

In the database, SAE messages are documented in a user-friendly case input mask.

The input mask contains all necessary and optional input fields that are described in the most up-to-date version of the ICH guideline E2B Revision 3 and the subsequent EU Business Rules.

Your documented cases are listed on overview pages which can be filtered and sorted with the most important parameters. Additionally, filtered overviews can be downloaded in xlsx tables.

You are always supported in the documentation by tool tips and by direct feedback upon violation of documentation rules in order to document compliant to ICH guidelines.

SUPPORTING YOUR PROCESSES

Individual Case Safety Report

- § Official format for EudraVigilance reporting
- § PDF: EudraVigilance standard layout
- § XML: Up-to-date ICH scheme, automatically validated

➔ Report by click: Direct transfer to EudraVigilance via Gateway



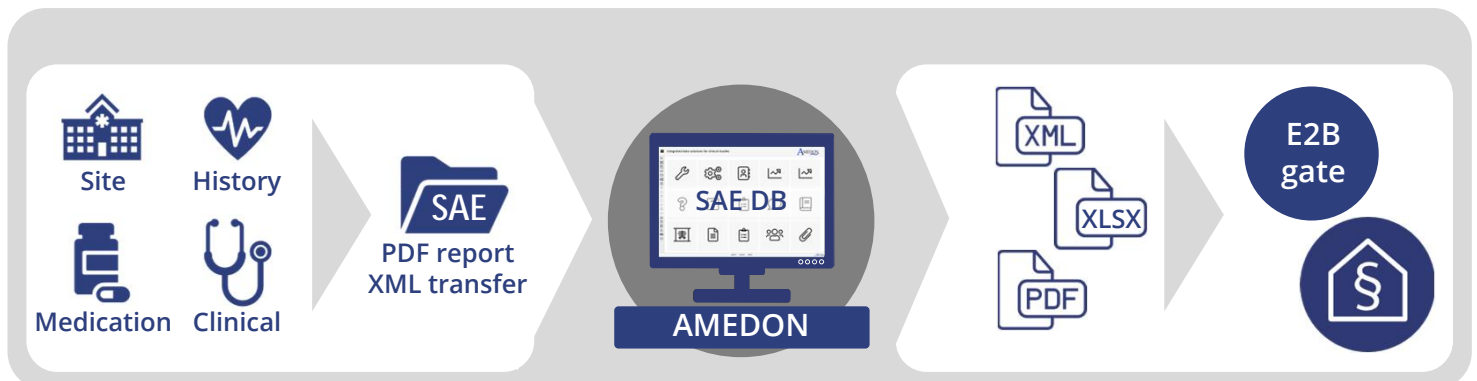
CIOMS report:

- § Common standard for individual reporting to ethic committees
- § Completed reports directly out of the application

Reconciliation listing and Line listing:

- § Overview with multiple case information for reconciliation within clinical studies and regular reporting to authorities

CENTRAL DOCUMENTATION AND REPORT CREATION / TRANSFER



COMPLIANT SAFETY CASE DOCUMENTATION AND REPORTING

REPORT IDENTIFICATION

Each case is documented and reported via a calculated or pre-documented Worldwide Unique Case Identification Number and additional identifiers as required.

LITERATURE AND DOCUMENTS

Unlimited uploads with additional description of literature references and other documents within a case.

TESTS AND PROCEDURES

Test results can be documented easily and repeatably with normal values and standardized units.

PATIENT CHARACTERISTICS

Demographics, medical history, past drug history, age, and death information of the patient as well as crucial information of a parent - if required - can be documented.

EVENTS / REACTIONS

Documentation of (multiple) reactions or events with terms, MedDRA codes, seriousness classification, date, duration, and linking to drugs/devices within a single case.

DRUG AND MEDICAL DEVICE

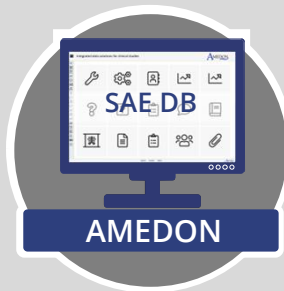
Identification of study, concomitant and other drugs and devices, indication, and usages can be documented with multiple relatedness assessment results.

SOURCE AND SENDER

Qualification and contact information about the reporter(s) and sender(s) of a case are centrally entered and stored and can be reused within a project to facilitate workflows and data consistency.

STUDY IDENTIFICATION

If a case is reported within a study, additional information can be documented. Details of Study, Sponsor and Site can be reused via single click if already documented before.



AMEDON



E2B ICSR



1-click transfer



ICSR REP



CIOMS



CIOMS blind



line listing



reconciliation

SECURITY AND STANDARDS

- Data stored in Germany – German Data Protection standards
- Data security: Data center ISO/IEC 27001 certified
- Total Quality Management system

- Validation processes based on GAMP guideline
- Applications prepared to be compliant to FDA 21 CFR part 11



M.A.R.C.O.

Institute for Clinical Research and Statistics
Business Unit AMEDON eSolutions

■ M.A.R.C.O. GmbH & Co. KG
Business Unit AMEDON eSolutions
Willy-Brandt-Allee 31c
23554 Luebeck – Germany

■ Tel.: + 49 (0) 451 38 45 0 0
Fax: + 49 (0) 451 38 45 0 11

■ info@amedon.de
www.amedon.de

INTEGRATED DATA SOLUTIONS FOR CLINICAL STUDIES
Comfortable – Capture – Compliant

