PRODUCT INFORMATION

SafetyEasy™

The most cost-effective drug safety database software for effortless E2B(R3) pharmacovigilance compliance, medical device vigilance, cosmetovigilance and nutrivigilance.

SafetyEasy™ is designed to streamline your pharmacovigilance, medical device vigilance, cosmetovigilance, and nutrivigilance processes quickly and effectively. Maintaining safety data is a mandatory regulatory requirement. Yet despite the undoubted benefits it brings, it can be a time-intensive and costly process that ultimately contributes little to bottom-line revenue.

SafetyEasy™ enables you to minimize costs and deliver best-practice monitoring and reporting workflows crucial to your business success.

Create, review, submit and maintain all safety data and event reports within a single, easy-to-use multivigilance application.

Ensuring compliance with E2B(R3) and HL7 eMDR safety regulations

Built specifically to support the E2B(R3) EudraVigilance system and MedDRA coding standards, SafetyEasy™ handles the reporting and management of all serious and non-serious adverse events. Its future-proof approach can generate PSUR, PBRER, and DSUR documentation and is ready for forth-coming standards such as IDMP. It also supports eMDR XML file creation. In addition, through an EMA-certified gateway, SafetyEasy™ provides you with a direct link to the regulatory authorities, eliminating the need for manual submission.

Streamline workflows, optimize your productivity

SafetyEasy™ also enables you to readily track and monitor the status of workflows with every project in your organization. Through email notifications and online dashboards, SafetyEasy™ provides users with reminders about imminent activities they need to perform. Now, you can ensure that your team members stay productive and in the know. This guarantees submission deadlines are met, and other legal obligations are never overlooked again.

Benefits

Ensure compliance

- Readily monitor safety activities and track submission deadlines
- Compliant with latest E2B(R3) and future drug safety regulations

Reduce costs

- Single database for safety data
- Cloud-based platform with no need for customization
- Easy-to-use with minimal training effort

Increase efficiency

- E2B gateway solution
- Bi-directional data exchange
- API connection for data or functionality exchange

AI-driven Case Creation

- Automatically convert unstructured case information e.g. from emails, into structured ICSR format, reducing manual intake by up to 70%.

Business Intelligence for Compliance & Analysis

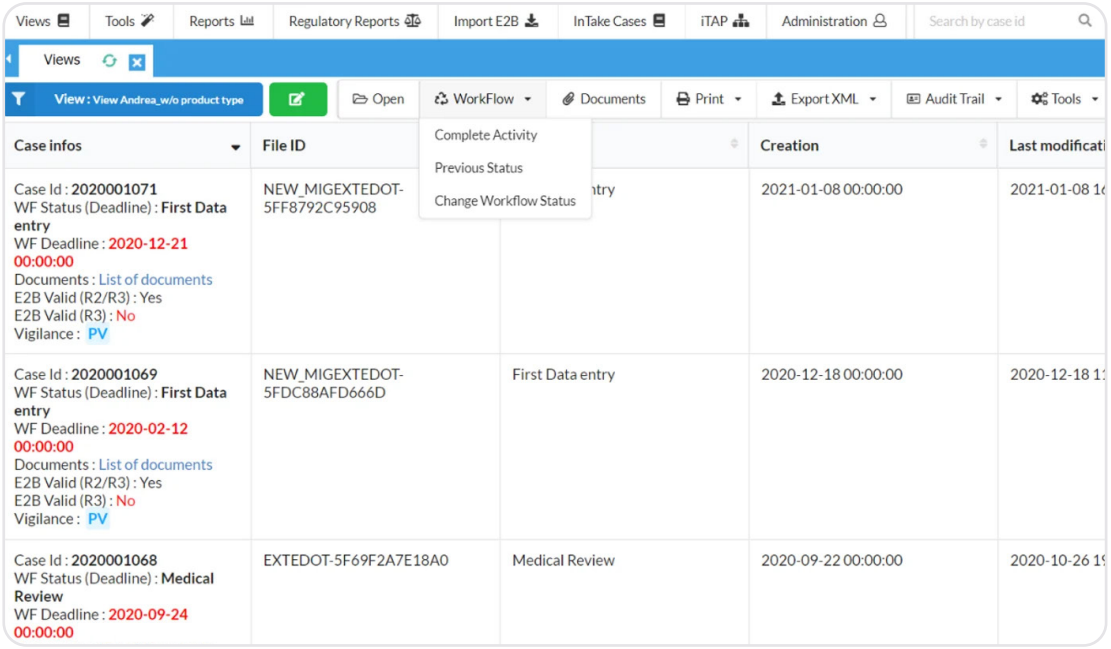
- Gain a 360° view of data for enhanced analysis and compliance with AI-powered Business Intelligence.

Efficient Case Conversion with Converter Module

- Automate data extraction from forms, reducing case intake time by up to 70%.

Comprehensive Surveillance with Literature Manager

- Efficiently triage literature with AI, reducing screening volumes and automating case creation.



Configurable case overview

Enhanced Pharmacovigilance with Artificial Intelligence (AI)

The CasEasy AI module leverages advanced Natural Language Processing (NLP) to streamline case creation. With CasEasy AI, imported or added ICSR verbatim text can automatically be converted into a case in SafetyEasy™, significantly reducing manual case creation times. It supports importing files in PDF, JPEG, and PNG formats, even handwritten documents if needed.

This module also uses AI to suggest Adverse Events (MedDRA-coded) and flag potential serious cases.

Streamline Your Workflow with the SafetyEasy™ Converter

The SafetyEasy™ Converter module is designed to save your team valuable time when entering cases into the system. By incorporating Optical Character Recognition (OCR), this AI-powered module automatically extracts and processes case information from uploaded forms, such as CIOMS, Medwatch, or SAE. The Converter not only reduces case intake time by up to 70% but also ensures that all required data is accurately captured and entered directly into SafetyEasy™.

Enhanced Compliance and Analysis with the BI Module

Furthermore, the Business Intelligence module provides a 360° dynamic view of your scientific data, which enhances case analysis and improves the detection of safety signals. This powerful BI module is powered by Qlik Sense technology, which is also used by the US FDA and helps to boost your company's efficiency and compliance. Compliance levels increase and reporting and KPI follow-up speed up.

Optimized Surveillance with the SafetyEasy™ Literature Manager

The Literature Manager module optimizes surveillance by saving your team time on article screening. This comprehensive solution automatically connects to PubMed, helping you find, analyze, review, and create potential cases. The Literature Manager supports an unlimited number of products and uses advanced Artificial Intelligence to triage and sort only potential pharmacovigilance cases, significantly reducing screening volumes. Abstracts are processed through CasEasy AI, seamlessly creating cases in SafetyEasy™.

Cloud-based pharmacovigilance, medical device vigilance, cosmetovigilance and nutri-vigilance software-as-a-service

As a secure, cloud-based service, SafetyEasy™ is lightning quick to implement and requires no customization. In many instances, SafetyEasy™ can be configured and validated within two weeks. Its simple, intuitive, and user-friendly interface speeds user adoption and eliminates

the need for extensive training. It is a complete, out-of-the-box solution for health science organizations of any size, location, and specialty.

Used worldwide for guaranteed compliance

Used by more than 300 organizations across 90 countries, SafetyEasy™ is the simplest and most cost-effective way to ensure effortless compliance with current and future drug safety regulations. With ICH, EMA, FDA, EU GMP Annex 11, US FDA 21 CFR part 11, and EMA's Good Pharmacovigilance Practice (GVP) guidelines, SafetyEasy™ is compliant with many regulations and directives from around the world.

Triage and assessment of ICSRs in E2B(R3) with iTAP

iTAP is a fast, efficient solution created to help you triage and assess your ICSRs in the E2B(R3) format with customizable filters.

L2A and/or MLM cases are retrieved from the Eudravigilance database and evaluated, enabling you to select relevant cases for your product portfolio. Every decision for each ICSR you make is tracked by iTAP so you can upload suitable E2B XML files with SafetyEasy™ directly to your database quickly and easily.

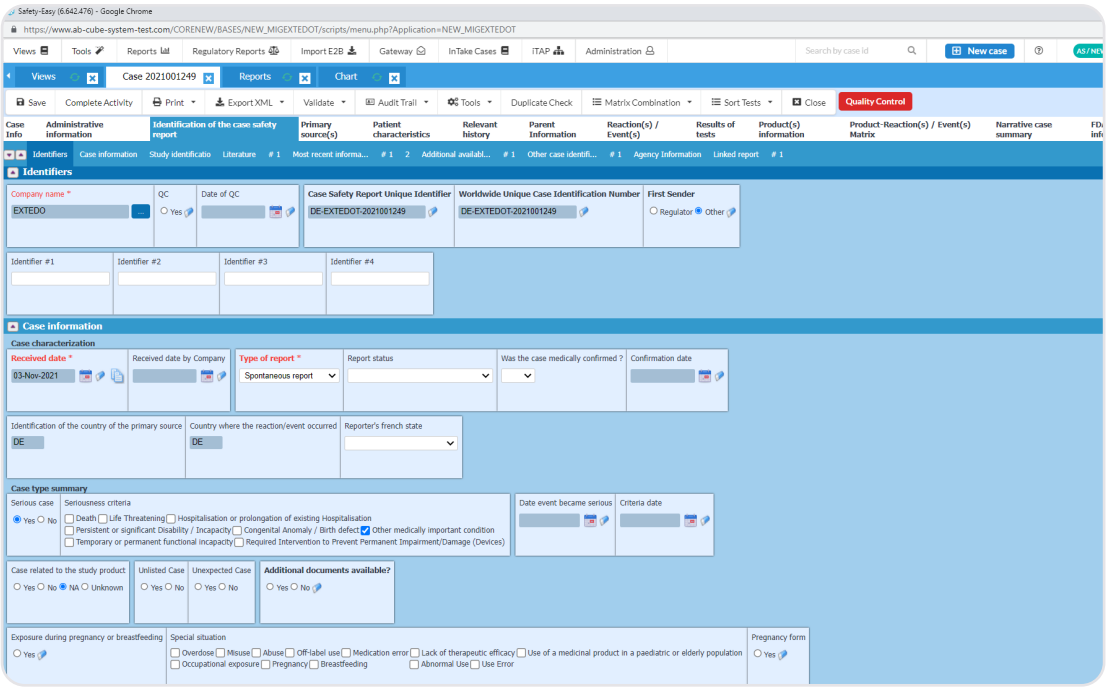
Additional available modules

Gateway

Automatic transmission and reception of E2B compliant XML-files to and from FDA, EMA and NCAs

iTap

Enables you to select customized criteria for selection and import of ICSRs, product per product.



User-Friendly Data Entry Mask

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