SafetyEasy

EXTEDO
eRegulatory Affairs

Product Information

SafetyEasy™

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

Benefits

Ensure compliance

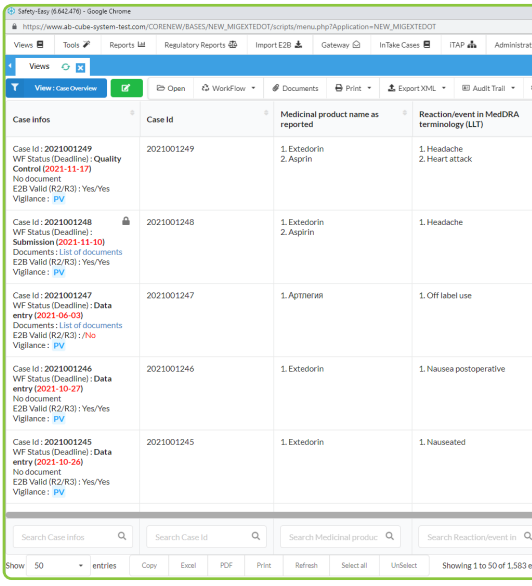
- Readily monitor safety activities and track submission deadlines
- Compliant with latest E2B(R3) and future drug safety regulations

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



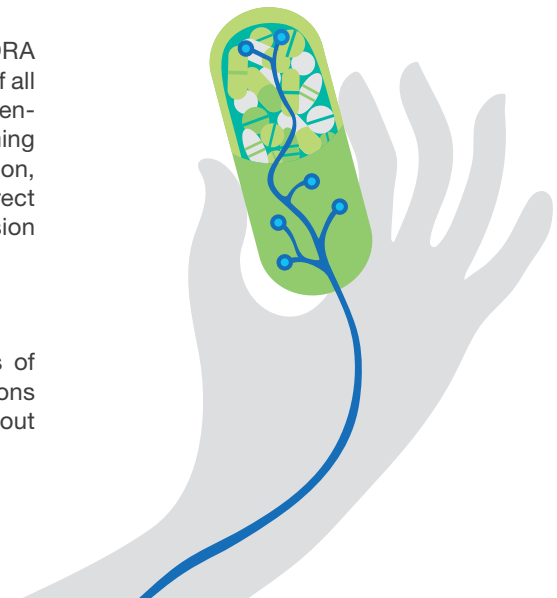
Configurable case overview

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 of reports.



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.

Cloud-based pharmacovigilance, medical device vigilance, cosmetovigilance and nutrivigilance 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.

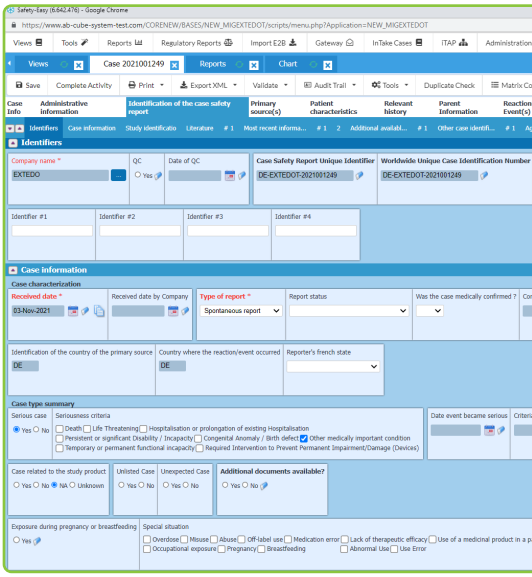
Available Modules

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.



Data entry mask

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About us

EXTEDO is a leading solutions and services provider in the field of Regulatory Information Management (RIM). We focus on optimizing our clients' eRegulatory business processes and are the only vendor that provides solutions covering the entire regulatory landscape. Today, EXTEDO enables more than 35 regulatory authorities and over 1000 maintained customers across 65 countries to deliver Effortless Compliance™.

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