

CASE STUDY

PSI CRO Counts on SafetyEasy® to Drive Pharmacovigilance Services for Sponsors

OUR CUSTOMER

PSI is a leading full-service global Contract Research Organization (CRO) with a key strength in predictable patient enrollment across multiple therapeutic areas. Headquartered in Switzerland, the company provides clinical trial sponsors working across oncology, hematology, IBD, infectious diseases, multiple sclerosis and many rare diseases - with specialist guidance and experience gained from delivering some of the most complex clinical projects in the industry.

Since 2007, PSI has offered full pharmacovigilance (PV) services for clinical trial sponsors, initially leveraging onpremises safety software. In June 2021, the business began its initial journey with AB Cube, moving to SafetyEasy® Suite's compliant, cloud-based solution in 2022 when E2B(R3) format became mandatory for ICSR submissions in the EU.

THE SOLUTION

With SafetyEasy® now in standard use, PSI's PV team has benefited from its clear interface and easy-to-navigate hierarchy, which makes it easy for PV staff to learn how the system works 'on the job'. As a pre-validated, audit-ready and fully documented solution, SafetyEasy® Suite also successfully passed many audits, where its high standard of quality and complete sets of documentation were noted.

THE BENEFITS

SafetyEasy® empowers PSI to provide best-in-class PV services to its sponsors without the technical limitations of traditional on-premises safety database software. End users report that list preparation is much easier now - multi-case lists can be adjusted according to need and Excel spreadsheets produced instantly on-demand.

Reliable, easy to use system

For PSI's clients, SafetyEasy® Suite delivers a reliable and easy to use safety solution, backed by strong support from AB Cube's experts providing fast, efficient and co-operative issue resolution via the Freshdesk facility.

Adapts to reality of CRO business

PSI really values the flexibility SafetyEasy® offers in terms of starting new projects and setting up new databases, given the reality of the CRO business model which means that some projects may be short duration engagements.

AT A GLANCE

SafetyEasy® solution

- Pre-validated & compliant
- Automated workflow
- Scalable 0 to 1M cases
- Seamless SaaS upgrades
- Fast & efficient support
- Business Intelligence

SafetyEasy[®] benefits

- Adaptable & simple to use
- Intuitive for non-IT staff
- Ease of list prep & creation
- Streamlines operations
- Reduces effort & resources
- Supports all development
 phases & clinical trial types

Ţ

"SafetyEasy® has become an essential tool, enabling us to efficiently deliver PV services to our clients.

As a CRO we are taking advantage of SafetyEasy®'s onboarding flexibility, seamless upgrades and effective AB Cube support."

Jiri Sikac Associate Director, PV Technology

