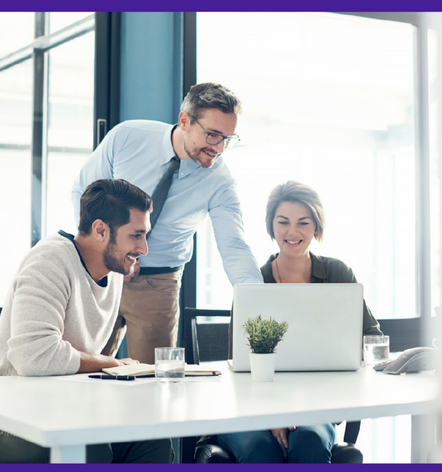
cencora
PharmaLex



psiXchange

Intelligent, automated clinical trial safety reporting software

Automates distribution, tracking, and acknowledgement for business-critical clinical trial safety documents to Sites, Ethics Committees, Competent Authorities, Notified Bodies, and Institutional Review Boards for any defined country.

Embeds continuously updated regulatory intelligence, transforming safety reporting efficiency and accuracy for global drug manufacturers and CROs.

Offers coverage in 55 countries representing the majority of industry-sponsored clinical trials, with more countries added regularly.

Intelligent safety reporting

Automatically distributes the right safety document to the right recipients in the right format at the right time. Easily connects to your data sources, including all leading safety databases and Clinical Trial Management Systems (CTMS).

Fully automated distribution

Incorporates the latest global and local safety reporting requirements and organizational information – freeing your safety team from the manual burden of managing high volumes of complex, multi-recipient distributions.

Centralized command center

Helps reduce the time, effort, and compliance risk involved in third-party submissions by automatically preparing everything required for the submission package. Includes a library of Investigator Brochures and relevant safety information for the trials being conducted.

What does psiXchange deliver?

up to 90%
reduction in time per submission*

up to 80%
reduction in operational costs*

up to 95%
site responsiveness rates§

up to 90%
reduction in resourced demand*

Supported by a global team of pharmacovigilance professionals with strong regional expertise

site responsiveness rates§

*customer-reported outcomes; actual results may vary

§system data for multinational biopharmaceutical company – site responsiveness improved from 41.2% to 75.2% within 12 months and to 95.2% within 24 months

psiXchange provides:

psiQ intelligence

The embedded regulatory intelligence "brain", psiQ provides up-to-date clinical trial safety reporting expertise at your fingertips. Maintained by our global PV experts and configurable with your own regulatory intelligence in psiXchange.

End-to-end automation

Embedded distribution rules encompass complex reporting requirements and variables including recipient information, specific formats required for each delivery instance, delivery according to recipient preferences, and multilingual support.

psiCentral smart portal

View, download and acknowledge safety reports, enabling an at-a-glance overview per study and site – in real-time. Proactively manage all aspects of distribution from a central master source.

Flexible Delivery & Pricing

psiXchange software license only

Includes startup package & version upgrades

Enterprise software license

Unlimited studies & sites at a fixed cost

Site-based software license

Predictable costs based on number of studies & sites

Safety Reporting as-a-Service

Our safety experts manage everything for you for a fixed cost based on number of studies & sites

Plus professional services from our global PV team including application configuration according to your business processes, support for 3rd party submissions (courier services, web portal), and more

Book a psiXchange demo for your safety team today and discover intelligent distribution

www.pharmalex.com/psixchange