cencora
PharmaLex

psiXchange

intelligent, automated safety document distribution software

Boost Speed & Accuracy

psiXchange automatically distributes the right safety document to the right recipients in the right format at the right time.

Dramatically boost your clinical trial safety reporting speed and accuracy, while reducing effort and compliance risk for your organization.

Transform your clinical trial safety reporting

psiXchange entirely automates distribution, tracking, and acknowledgement for business-critical clinical trial safety documents. Offering intelligent process automation combined with continuously updated regulatory intelligence, psiXchange transforms safety reporting efficiency – helping to reduce the cost, effort and resources required for global drug manufacturers and contract research organizations.

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

What's more, psiXchange easily connects to your data sources, including leading safety databases and Clinical Trial Management Systems (CTMS).

Improve reporting accuracy and consistency

Reduce time, manual effort and cost

Enhance oversight and regulatory compliance

Comprehensive clinical trial safety reporting

psiQ - embedded PV regulatory intelligence

psiQ is an embedded regulatory intelligence "brain", making up-to-date clinical trial safety reporting expertise available at your team's fingertips. Actively updated by our global team of experienced PV experts and easily configurable with your own regulatory intelligence in psiXchange.

Fully automated distribution

End-to-end automation of the complex distribution, tracking, and acknowledgement receipt process for business-critical clinical trial safety documents to Sites, Ethics Committees, Competent Authorities, Notified Bodies, and Institutional Review Boards for any defined country.

psiCentral smart portal

psiCentral provides a user-friendly smart portal for all recipients - supporting day-to-day business for recipients and helping to ensure that everyone involved in the process is working from the same information at all times.

psiXchange gains

Built by experienced industry professionals for use by safety and clinical teams, psiXchange delivers a measurable impact on reporting efficiency.

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 resource demand*

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

psiQ - embedded regulatory intelligence

Harness clear and actionable intelligence, continuously updated by our global PV experts. With automated checks and immediate notification of changed regulations, your team always has access to current rules - with no need to interpret.

55 countries Americas, Europe, Middle East, Africa & Asia-Pacific - comprehenisve coverage of international clinical trials.

Your clinical trial safety reporting compliance solution

psiXchange helps reduces the time, effort, and compliance risk involved in safety document distribution by automatically preparing everything required for the submission package. Spanning up-to-the-minute intelligence around reporting instructions with the ability to track submissions and acknowledgements against timelines and priorities, our intuitive psiXchange system is designed by safety and clinical experts for use by busy PV, clinical and site teams - with no intensive set-up or programming required.

Intelligent Safety Reporting

Embedded distribution rules encompassing reporting requirements	●
Specific content formats needed per delivery, e.g. blinded/unblinded	●
Compliance with EU and international regulations	●
Multiple points of QC across configuration & country data for user	●
Automatically scheduled reviews for optimal regulatory accuracy	●
Workflows built around industry-standard regulatory processes	●
Activities captured in comprehensive audit trial	●

Fully Automated Distribution

Automatically generates cover letters; collects and tracks acknowledgements	●
Local form templates to speed reporting process	●
Safety reports automatically sent to sites/ECs with full tracking & audit trail	●
Multiple elements combined for efficient single distribution	●
Cross-validation of data acquired from different systems pre-use	●
Flexibility & scalability in number of parameters (data relations) utilized	●

Centralized Command Center

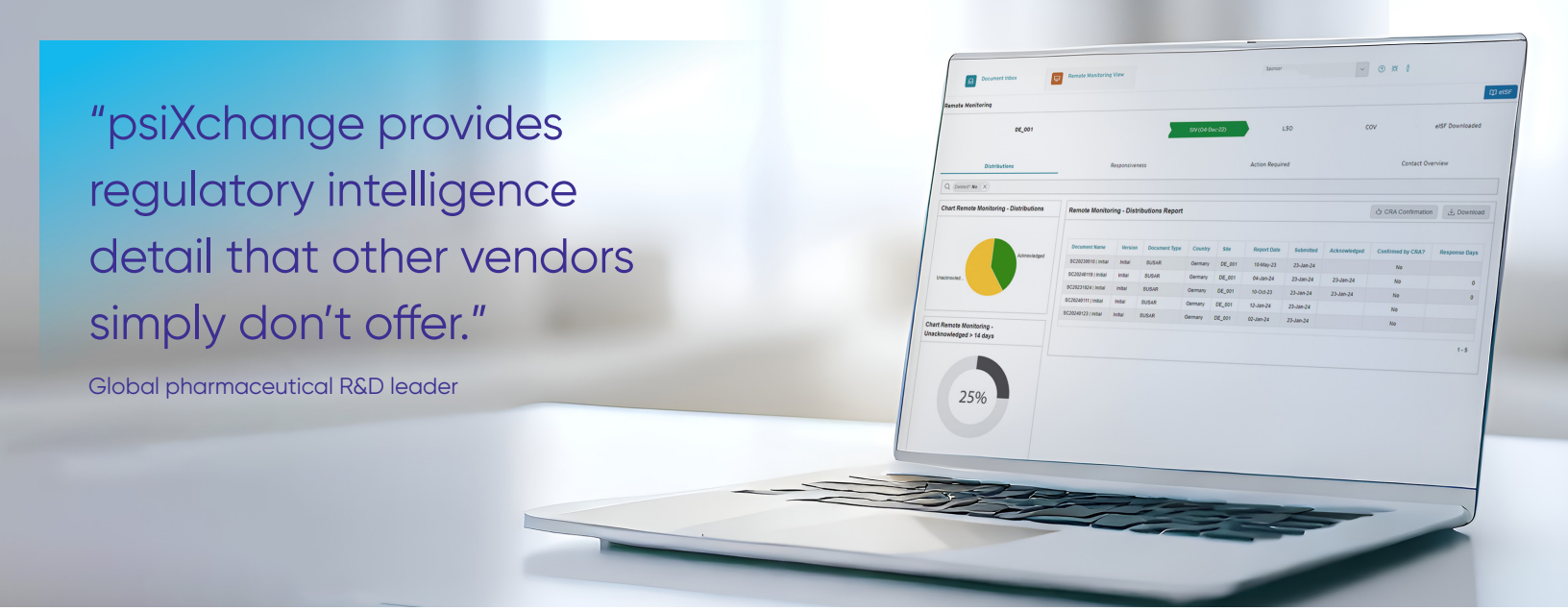
Preconfigured industry-standard reports for key metrics	●
Configurable alerts & summary reminders focus attention & reduce alert fatigue	●
Comprehensive remote monitoring capabilities to improve efficiency	●
Investigator Brochure (IB) library & safety info, replacing GAP packs	●
Designed for CRA use to reduce burden on clinical teams	●
Complete electronic audit trail to improve inspection-readiness	●
Supports third-party submissions, reducing effort and risk	●
Cross-reporting, retrospective reporting and compliance reports	●

psiCentral - smart portal for complete oversight

psiCentral allows you to view, download and acknowledge safety reports, providing an at-a-glance overview of all relevant information per study and site in real-time. Proactively manage all aspects of distribution from a centralized master source.

Real-time status insights

Track compliance status, site responsiveness & key metrics with pre-configured.



"psiXchange provides regulatory intelligence detail that other vendors simply don't offer."

Global pharmaceutical R&D leader

Customer success story

Global pharma R&D leader boosts safety reporting output with psiXchange

Customer challenge

The Safety Alert Reporting team at a leading global research and development pharmaceutical company is enjoying measurable benefits from using psiXchange. Previously using a home-grown database to serve its regulatory intelligence needs, evolving this had proved cumbersome for the team – requiring a high degree of manual effort. The team needed a solution that could automate and efficiently manage distributions.

psiXchange solution

The psiXchange system provided a level of regulatory intelligence detail that other vendors simply don't offer. Manual effort has been significantly reduced - with full confidence that the system is pulling in the right recipients every time.

Platform for growth

Today, psiXchange is delivering a proven benefit in the team's ability to issue a high volume of reports. Feedback from end-users and stakeholders has been excellent. In an evolving industry with changing regulations, maintaining compliance while ensuring that end-users are happy is an ongoing challenge – one that psiXchange is helping our customer to achieve.

Solution highlights

- Sends any critical safety document to any recipient
- Easily connects to existing data sources, including leading databases & CTMS
- Smart contact management - CTMS or in-platform
- Delivery to exact recipient preference (email, download link, courier, smart portal)
- Multi-lingual support and global delivery based on local laws and regulations
- Accepts any document format (XML/PDF/XLS), reducing data entry & errors
- Easily configurable for alignment with existing business processes

Intelligent distribution: controlled, consistent, compliant

Engage your way - flexible delivery & tiers

Our flexible delivery and pricing options meet the needs of every business - from the smallest organizations to global biopharmaceutical companies and CRO

psiXchange is your proven business solution for clinical trial safety compliance. The software is supported by Cencora PharmaLex's global team of PV experts experienced in all aspects of drug safety regulations and best practices at a regional and local level – so you have a knowledgeable partner on hand to support your compliance journey. Transform your safety efficiency with industry software built specifically for global and local safety reporting. Book a demo for your safety team today

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