

psiXchange is a highly adaptable and forward thinking system that provides the foundation for facilitating, managing and supporting the automatic receiving, processing and distribution of electronic files in a secure and controlled manner.

psiXchange can be configured to automatically receive source files or documents for further mass distribution. These incoming files can arrive through different user-definable source channels, including email or FTP. Intended distribution recipient information (such as email addresses, fax numbers and other key recipient identification data) is also received into psiXchange via similar input channels. Upon receipt into psiXchange, optional and customized pre-processing such as the extraction of key metadata from the incoming files and/or distribution recipient data can occur.

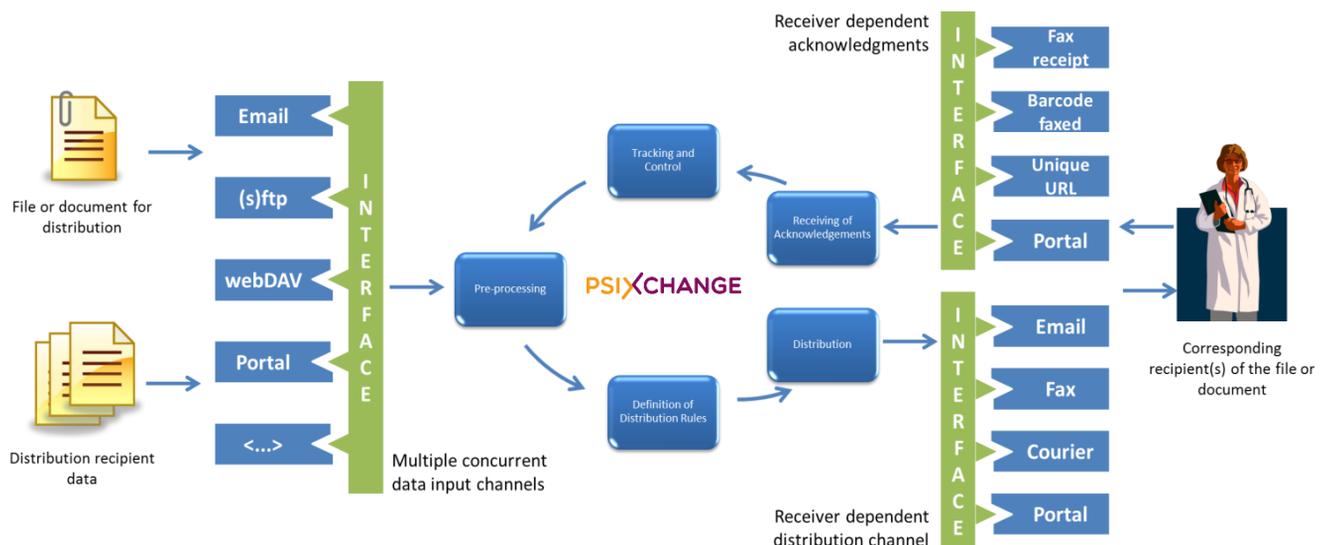
The distribution of the files and documents is controlled by defining rules within the powerful and flexible Distribution Rules subsystem. Behind-the-scenes analysis of these rules then combines a file or document with its intended set of distribution recipients. Further optional and customized post-processing, such as the creation of corresponding cover letters, can then also occur prior to distribution.

psiXchange facilitates the actual distribution of the files and documents through various user-definable output channel types – even for the same source file. More importantly, the system then tracks and manages receipt acknowledgments such as those from email or fax responses, or from recipient-specific barcoded documents – all of which can be managed and viewed from a user-friendly and meaningful activities dashboard.

Since psiXchange allows for the definition and customization of both source and output channels (adapters), allows for highly flexible distribution rules and workflow subsystems, and also permits the definition of custom pre-processing and post-processing steps, the potential of the psiXchange system and its industry-independent capabilities are virtually limitless!

Key Features

- Define adapters to handle all forms of incoming source and outgoing distribution channels, as well as document types
- Distribute using a powerful and flexible Distribution Rules subsystem
- Deliver the same file to different receivers using different output channel types
- Track and manage distribution receipt acknowledgments
- Oversee distribution via a user-friendly and meaningful activities dashboard
- Integrate seamlessly with existing processes
- Full audit trail of entire distribution process flow
- Lightweight technology footprint



Powerful Distribution Rules Subsystem

At the heart of psiXchange is its flexible, yet extremely powerful, Distribution Rules subsystem. Clients can input a set of distribution rules against which psiXchange will analyze and process both the file or document, and the corresponding distribution recipient information, to determine the proper set of intended recipients. With the understanding that the complexity of rules may differ for different document types, the Distribution Rules subsystem is flexible enough to handle simple distribution needs through to those which require in-depth assessment and comparison of numerous file/document and recipient parameters.

Flexible Incoming Source and Outgoing Distribution Methods

psiXchange can receive files and documents via a flexible and user defined interface with any number of source systems and links them with recipient information (also from any source system). Through processing of the defined distribution rules, the system can then automatically determine the appropriate recipient(s) and distribute the file via the available user-defined distribution methods. Each file or document can be sent to different intended recipients via different output channel methods. So for example, if Recipient A prefers email notification and Recipient B prefers fax notification, the system can accommodate that without requiring the file to be submitted multiple times.

Although the extent of outgoing source distribution methods is flexible and endless, examples of possible distribution methods include:

- Fax: Documents can be faxed to one or multiple recipients via a fax server;
- Email: Files can be attached to emails with an accompanying cover email;
- Download URL: Files can be downloaded via a secure URL. The specific URL can be configured to work only once or multiple times, or for only a certain duration, in order to provide recipients permanent or temporary access to the files;
- Via a Browsing Interface: With a username and password, recipients can connect to a browsing system in which they can access all files assigned to them for the timespan allowed for each individual file.

Critical Distribution Tracking

A key feature of the system is its ability to track and audit trail the entire distribution process, from initial source file/document receipt through to outgoing distribution, and also any corresponding receipt acknowledgments. Optional manual actions are also tracked. For instance, re-distribution may sometimes be required, perhaps due to an incorrect initial fax number. In such cases, the re-distribution and any subsequent acknowledgments are also tracked. Recipient acknowledgment "strength" can be configured to meet client needs:

Disabled: No acknowledgement is required nor collected;

Enabled, such as:

For Fax machines, the fax electronic receipt protocol is collected;

For Email, possibly either an email delivery/read receipt, or via the access of a specific URL link included within the email;

Strong: Recipients must send back (possibly by fax or email) a formal acknowledgment, possibly including a provided barcode which is uniquely and automatically identified by the system.

“Based on our current pipeline with low risk products and mainly outsourced studies, this application may save Grünenthal between €200.000 and €500.000 in a phase 3 study.”

Karin van Dort Boomsma

Information Manager / Manager Safety Reporting in Global Operations Support

The Business Challenge – ‘EU Directive on Safety Reporting’

The distribution of safety information to investigators, Ethics Committees/IRBs, and study team members is both a logistical and a compliance challenge. Timely reporting and collection of acknowledgements in accordance to the “EU Directive on Safety Reporting” and the “ICH Topic E 6 (R1) Guideline for Good Clinical Practice” requires strict control of the delivery process from the printing to the delivery of a safety report. Multiple delivery channels like fax, email or courier; along with the communication with dedicated country contacts; and the versatile reporting rules to local, regional and central Ethics Committees are difficult to manage manually.

Business Requirements

- Autonomous distribution of safety documents (e.g., SUSAR, DSUR, Line listing) to EC/IRB and investigators;
- Collect and track acknowledgments of distributed documents;
- Implementation and enforcement of local/regional/central EC/IRB reporting rules;
- Control access to unblinded information;
- Alert/escalation management of delivery failures and acknowledgment delays;
- Retrieve contact details from CTMS;
- Repository of distributed documents including meta- and tracking data;
- Manual resend of information;
- Extensive reporting functionalities;
- Automatic generation of cover letters.

Technical Requirements

- Seamless, lightweight interface with ANY safety system (via email, SFTP or WebDAV);
- Seamless, lightweight interface with ANY CTMS system (via email, SFTP or WebDAV);
- Manage user access privileges and minimize user maintenance activities (no user management for recipients);
- Automatic derivation of safety reports metadata like blinded/unblinded, reporting timelines, etc.;
- Distribution of documents via fax, email or download link;
- Support of courier distribution and acknowledgement via barcoded faxback page.

pharmasol implemented a Safety Reporting distribution system for a major pharmaceutical company using psiXchange. The system was designed to receive various safety reports, including some from their corporate safety reporting system, and process against potential recipient information received from their home-grown clinical trial management system (CTMS). Leveraging psiXchange’s powerful Distribution Rules subsystem, tediously complex distribution rules derived from multiple regulatory-based and internal guidelines are efficiently captured in the system. The ability to distribute via fax, email and courier options have been implemented, along with critical acknowledgment tracking, and the ability to initiate further manual (and optional) notification and/or distribution actions as required.

This company now manages their safety reporting distribution needs from a single system and ensures proper compliance to critical reporting guidelines. Furthermore, this system allows the company to realize cost savings since manual oversight has been significantly reduced and processes are greatly streamlined and improved. The flexibility of the system also lends itself to adapting to the company’s changing technology needs in the future allowing psiXchange to truly be a long-term solution!

A pharmasol Applications overview

psiXchange

psiXchange is a revolutionary solution designed to automate the distribution and tracking of files and documents in a highly secure and controlled manner. Built to be highly flexible, yet also powerful and user-friendly, the system can be seamlessly integrated into existing processes with minimal adoption overhead and minimal end-user impact. Furthermore, psiXchange can be used to meet all your company's file distribution needs, allowing you to ensure:

- **Real-time delivery of confidential and critical information;**
- **Realization of significant cost savings (personnel, manual couriers, etc.);**
- **Reduction of risks; and**
- **Overall process improvements.**

For More Information

To learn more about pharmasol services or software solutions, please contact info@pharmasol.de or visit www.pharmasol.de

Watch an introductory video here.
<https://vimeo.com/105905293>

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