

FREQUENTLY ASKED QUESTIONS

THIS DOCUMENT HAS BEEN DEVELOPED TO PROVIDE CLEAR RESPONSES TO THE QUESTIONS THAT ARE MOST OFTEN ASKED WHEN DISCUSSING PSIXCHANGE.

TECHNICAL

How do recipients connect to the system?

Recipients continue to collect messages via existing methods — email, fax, courier etc. — and therefore never need to connect to psiXchange directly.

Does psiXchange support Wide Area Networks?

Yes. We have a connection approach that runs across the internet. So, you can run psiXchange in our secure hosting environment, whilst maintaining your systems under your own control.

How are documents distributed by emails protected?

psiXchange uses unique, SSL-encrypted links as a secure alternative to email attachments. "Message managers" inside your organization control how many downloads are allowed for each file, how long a link is valid for and for how long any access is valid following the first download.

How does this security model compare to password-protected files?

The psiXchange model is more secure. Passwords are typically sent via email. As such, if the email account is compromised, so are all the files.

What hardware needs do I have for this application? How does it scale?

psiXchange relies on proven and highly-scalable database technology. However, if you use our hosted infrastructure you don't require any hardware or have any IT overheads.

Is the system available both on premise and hosted in a regulated datacentre?

Yes.

Can psiXchange integrate with data from different sources?

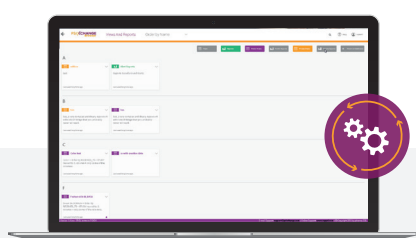
Yes. psiXchange can work with data from any existing source in any format. However, we don't need to integrate at a system level. Instead we take the definition of your data in the source systems and identify and establish the relations between them. This means that psiXchange dynamically adapts to any changes in these data to allow for seamless automation.

Which delivery methods does psiXchange support?

Any. psiXchange's open programming interface allows for OUT-adapters that can trigger faxes, emails, uploads to existing document management systems (portals), interfacing with courier APIs, etc.

Which external systems can be integrated?

Any. psiXchange's open programming interface-based IN-adapters enable integration with any third-party system e.g. portals, financial systems, Etmf, etc.



UNLEASH THE POWER OF YOUR DATA THROUGH BUSINESS AUTOMATION WITH PSIXCHANGE.

TECHNICAL

Which data formats does psiXchange support?

Any. psiXchange's open programming interface-based EXTRACTION-adapters allow for the extraction of metadata from incoming files of any format.

What is a Dynamic Data Hub?

psiXchange is really a new category of software. It allows you to exploit relations in data from multiple sources and thus make the data actionable. psiXchange introduces dynamicity into your data. As it can be the "man in the middle" for many data sources it definitely has a hub function. Based on these qualities we have categorized psiXchange as a dynamic data hub.

Why are data relations stable?

Data relations are at the core of establishing data integrity. Unlike rules in a rule-based system where new rules are almost constantly modified, e.g. when a country is added, the data relations are qualities of the data structure and do normally not change once they have been established. That is why we talk about stable data relations.

Why does psiXchange not need hundreds or thousands of rules?

Unlike rule-based systems, psiXchange does not rely on hard-coded rules, but uses relations between data sets defined through the data itself. Because these relations are stable, exploiting them allows reuse which dramatically reduces the number of "rules" needed.

Does psiXchange have an audit trail?

Yes. psiXchange can audit trail any activity performed. This information can then be used for monitoring purposes in the dashboard.

Can psiXchange send alerts and push notifications?

Yes. In the definition of the business process, escalations can be defined. One option for such an escalation is to send an alert as an email or present it on the management dashboard.

Can I validate my incoming data?

Yes. psiXchange can perform cross-validation of data from the sources it works with. In effect, this is one of the key elements to higher data quality in your business processes.

BUSINESS

Is psiXchange accepted by all recipients, like ECs?

Yes. psiXchange's use of existing communication channels renders traditional barriers to acceptance, such as training and user account management irrelevant.

Does psiXchange require training for the recipients?

No. The use of existing communication channels means no training is required for recipients.

Is psiXchange exclusively for the pharmaceutical industry?

No, psiXchange can be used within any industry. As we are used to working in highly regulated environments we understand about stringent demands of change control and audit trails. However, these are at the core of how psiXchange does what it does and the flexible data model can model any process in any industry.

If being used for document distribution, does psiXchange only allow for the sending of safety documents?

No, psiXchange allows for the automated distribution of any document type, so this could include insurance claim forms, CVs, job applications.

What are the required business process updates?

One of the key advantages of psiXchange is the minimal footprint on existing business processes. psiXchange can be configured to adapt to your business process and data rather than the other way around!

How long does it take on average to implement psiXchange into a company?

The technical simplicity of integrating psiXchange means implementation time depends on the identification and documentation of business processes. The configuration and automation in psiXchange itself is a comparably quick and low effort activity.

BUSINESS

Does pharماسol offer support for the implementation of psiXchange?

Yes. We offer technical, business process, validation, project management and pharmacovigilance consulting to support any aspects of your implementation.

How much effort is needed to maintain the business logic?

None. psiXchange adapts according to the defined relationships between your data. So, the initial set-up doesn't require any ongoing maintenance.

Can psiXchange really model any desired process?

Yes. psiXchange has a flexible data model that adapts to your existing data. It allows for the definition and automation of your business process consisting of as many or few sub-processes as needed.

How do stable data relations make my data actionable?

Once established, the data relations between the multiple data sources which psiXchange works with remain stable. This allows psiXchange to trigger actions based on the data and these relations. The data becomes actionable.

What is psiXchange?

We categorize psiXchange as a dynamic data hub. It works with multiple data sources, and based on relations in the data from these sources can execute any set of actions. All such actions are audit trailed.

Can you give examples of actions which can be triggered based on my data?

Actually, the actions rely on relations between the data sources. One task could be the cross-validation of data from multiple sources and the generation of a quality report. The most common application is to qualify documents and recipients and ensure correct delivery of the appropriate document versions to the right recipients. Typically, a confirmation of receipt is also collected.

PRODUCT

Can psiXchange be used as central document repository allowing users to browse, index, and protect all documents?

Yes. psiXchange is not a true "Document Management System" but it does retain all the source documents that have ever been sent in and allows for sophisticated searching and filtering. Access is controlled at various levels, for example by study, document type and confidentiality (blinded/ unblinded).

Does psiXchange require regular admin tasks?

No. psiXchange utilizes the power of stable data relations. Therefore, little maintenance is required. psiXchange also comes with an intuitive dashboard to monitor ongoing activities. Additionally, users can schedule reports to be sent to them by email. Finally, psiXchange can be configured to alert the appropriate people for the rare circumstances when manual intervention is required.

PRICING

What is your pricing model?

psiXchange is delivered as a pay per use application. Depending on your business case the price is adapted to fit your needs. For example if using psiXchange for document distribution the price is based around the number of distributions.

DISTRIBUTION

Is psiXchange designed to work exclusively with safety documents?

No. psiXchange can be used for any business case with a defined workflow. For example study start-up (investigator brochures, contracts), protocol amendments etc.

Does psiXchange support generation of multi-lingual email and cover letters?

Yes. Any number of emails and cover letters in any language can be defined, stored in psiXchange and automatically sent out according to your process.

DISTRIBUTION

Does psiXchange allow users to define workflows requiring manual intervention?

Yes. Some customers use this, for example, to translate safety letters by local contacts prior to distribution.

What's the average effort in FTEs to maintain the automated business process?

Minimal. Manual input is only needed when automated processing fails, for example when recipient information is missing or incorrect. Our customers have seen an 80% reduction in internal resource requirements for this process.

Does psiXchange handle incorrect recipient contact information?

Yes. Users can create recipient-specific configurations based on your business process that means that psiXchange automatically tries alternative distribution methods if the primary form of communication fails.

Does psiXchange handle duplication of recipient data?

Yes. psiXchange determines whether a recipient is unique based on your defined criteria to ensure they only receive each message once.

Does psiXchange support grouping of outgoing messages?

Yes. Documents that apply to multiple trials are sent only once to each user. A cover letter lists the trials related to the document.

Who maintains the country specific reporting requirements in psiXchange?

You can use your internal staff, pharmaSol or in fact any third party to maintain the reporting requirements. These can be maintained in any third-party applications, but also directly inside psiXchange if desired, with full audit trail.

How do I get an overview of my compliance for a specific document or recipient?

psiXchange allows the definition of compliance criteria and custom filtered reports which can be extracted to PDF, HTML, and Excel.

DRUG SAFETY

Does psiXchange handle reporting to those joining an on-going trial?

Yes. The system supports "retrospective" reporting. Documents remain in the distribution process for a predefined duration that you control. Any new contacts added during this time will receive the document.

Is there any configuration needed on a per study basis?

No, psiXchange does not require study by study set-up. However, if you need specific business logic, which is study related, then the initial configuration allows for this to be handled.

Can psiXchange automatically send documents to my eTMF or a portal?

Yes. The open adapter architecture is used to link with any 3rd party application. Then, any business process, together with the required business rules, can then be defined in psiXchange to allow for uploading to other applications.

Does psiXchange link with safety systems?

Yes. psiXchange interfaces with any safety system (ArisG, AERS, Argus etc.) and any CTMS system.

FIND OUT MORE

If you are interested in further information or would like to arrange a demo, please contact:

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Or visit our website where you can find further information about the product:

www.psixchange.com



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