PSIXCHANGE
MAKE YOUR DATA WORK

WHITE PAPER

COMPLETE CONFIDENCE IN FULFILLING YOUR REPORTING OBLIGATIONS

A controlled document distribution process, in which getting the right information to the intended recipients within a desired, or required, timeframe and being able to track delivery status and confirm receipt, is a challenge for regulated industries.

Companies in the Life Sciences domain, regardless of whether they do business on a global or regional scale, continuously face many reporting obligations, a very prominent example being reporting on adverse drug reactions or adverse events. Whether the data originates from marketed drugs or from clinical studies, a process needs to be executed that delivers the documents to a variety of recipients within a predefined timeframe, using predefined methods of delivery and required formats. All this must take into account the relevant global, regional or local regulations as well as internal business requirements relevant for each recipient.

A reliable, fully automated, system allowing for efficient management of reporting obligations, that is not only accepted by all recipients, but also compliant with all applicable regulations, is the preferred way of supporting such a process.

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

A BUSINESS SCENARIO

A PHARMACEUTICAL COMPANY ENGAGED AS A SPONSOR IN CLINICAL STUDIES HAS SEVERAL RESPONSIBILITIES WITH RESPECT TO, FOR EXAMPLE, SAFETY REPORTING. LAWMAKERS AROUND THE GLOBE HAVE ESTABLISHED REGULATIONS WHICH ARE SUBSEQUENTLY ENFORCED BY COMPETENT AUTHORITIES. THESE REGULATIONS ARE OFTEN THEN COMPLIMENTED BY ADDITIONAL INTERNAL BUSINESS CONSTRAINTS.

Regulatory Requirements

The list below gives an overview of the complexity of regulatory requirements with regards to safety reporting from clinical studies:

- **Adverse events must be recorded**
- **Suspected unexpected serious adverse reactions (SUSARs) must be reported to authorities and the Ethics Committee (EC) or Institutional Review Board (IRB) of the respective study (global and local)**
- **Participating investigators must be informed**
- **Annual safety reports need to be distributed to authorities and EC/IRB**

Using the example of a SUSAR, below are the considerations which need to be considered according to the EU regulations and guidance[1]. The US IND reporting also has very similar requirements as both are based on the ICH E2A:

If a SUSAR is fatal or life-threatening, the SUSAR must be reported within seven days and subsequent follow-up reports of the SUSAR, as well as non-fatal or life threatening SUSARs, must be reported in most countries within 15 days. For reporting to authorities, an electronic format is usually required, such as E2B(R2) or E2B(R3). As information must also be provided to all investigators, a concise and practical approach could be a line listing, accompanied by a concise summary of the evolving safety profile of the IMP.

Authorities and Ethics Committees expect to receive the unblinded reports, whereas investigators should only receive blinded information unless the unblinded version is judged necessary for safety reasons or the study is an open-label trial. Exceptions to this, for example different needs for local and central ECs, must also be handled.

Importantly, late joining sites should also retrospectively receive the reports that have not yet been included in the Investigator Brochure (IB) and that were reported before the site joined the study.

[1]Regulation (EU) No 536/2014: On clinical trials on medicinal products for human use repealing Directive 2001/20/EC – Annex III

If a SUSAR is fatal or life-threatening, the SUSAR must be reported within seven days and since as much time as possible should go into producing quality information, efficient delivery to hundreds of recipients following multiple different regulations must still be as quick and efficient as possible.

Business Needs

In addition to following the regulations, companies implement internal rules to achieve compliant and cost-effective processes. Examples would be:

- **With multiple different sources of information available, it should be possible to configure how, and which, information will be taken from each source**
- **The effort to perform and track a distribution shall be minimal as shall be the effort to maintain the system**
- **As activities are performed in a regulated environment, every activity performed on electronic data needs to be audit-trailed**
- **To keep the study intact, access to unblinded information will only be given on a need to know basis**
- **To create an efficient process, master data, such as recipient information, shall be provided from appropriate systems, such as a CTMS**
- **Personalized cover letters are required in multiple languages and should be generated automatically**
- **A possibility must exist to view or print reports, detailing:**
  - Who received information for a specific case (SUSAR)?
  - Who received which information for a specific study or a group of studies (program)?
  - Which information did a specific recipient or group of recipients receive for a specific study or program?
    - » When was the information distributed, received, and acknowledged?
    - » Was it part of retrospective reporting?
    - » By which means was the information delivered?

  This will, for example, help CRAs to do an effective job on their next visit to a center and may also feed into some risk-based monitoring algorithms.

The above list is by no means complete, but it hints at important qualities of an efficient, controlled distribution process. The critical elements are: compliance with regulations; minimized effort for execution and simple tracking of distributions; low maintenance effort; and quick and effective oversight.

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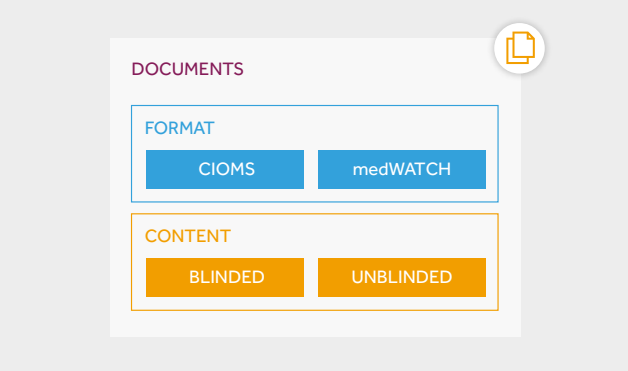
THE CORE OF A TECHNICAL SOLUTION

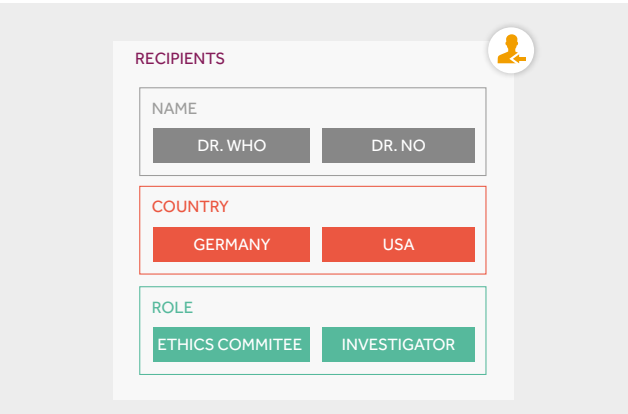
The key to making data actionable, and thus implementing the business needs, is to identify appropriate relations between your data sources. Look at the (simplified) example below, where we take a SUSAR as a specific document type:



A SUSAR can be distributed on paper in different formats, such as CIOMS or MedWatch. In addition, the content can be unblinded or blinded.

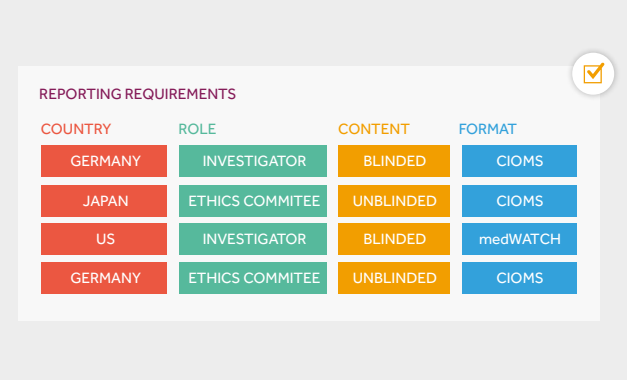
A member of an Ethics Committee will receive unblinded information whereas an investigator will usually receive blinded information.

Which of these roles is assigned to a recipient is defined in a different set of available data, perhaps within a CTMS.



The country of residence of a recipient links to the jurisdiction under which the SUSAR is distributed and is used to define the format in which the document should be distributed.

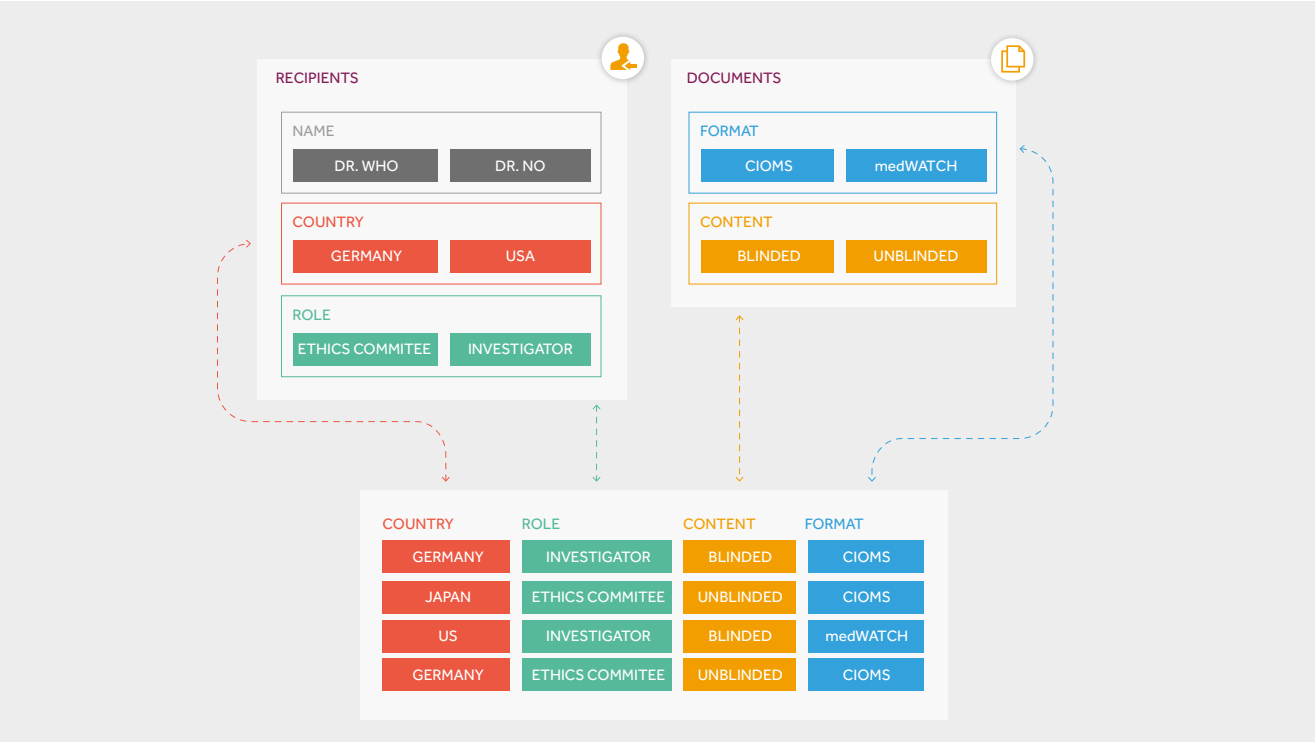
The reporting requirements, which are based on regulations, and which may additionally be complemented with internal conditions, can be maintained as a table which complete the link between the safety data and the recipients.



To manage the millions and millions of possible combinations between your data sources with a minimal effort, stable data relations must be established.

The technical system needs to either learn, or be taught, what the relations between the data are.

The data relations are typically stable and do not require regular updates. The key to a great system is the availability of the correct data and the quality of the relations.



FLEXIBILITY IN THE PROCESS

To get the most out of a distribution solution, flexibility needs to be built into the system in numerous ways:

- **To work with different source systems, the system must be able to receive data in different formats and through different routes.**
- **Distributions should be logged and process-steps be monitored and visualized.This is critical where regulations on electronic records, such as 21CFR Part 11 apply.**
- **To handle error conditions, it should be possible to define escalations, such as using alternative routes of distribution and producing related warnings.**
- **Flexible delivery methods must be available based on the needs and circumstances of the recipient (e.g. e-mail, FAX, courier).**
- **Successful delivery must be tracked with minimal effort.**
- **A dashboard which provides quick and relevant information on system, distribution, and acknowledgment status is very desirable.**
- **Implementation needs to be easy, ideally no training and maintenance will be necessary.**
- **The central process must be accepted by all recipients.**

A SOLUTION DELIVERED

WITH PSIXCHANGE, PHARMASOL HAS CREATED A TOOL WHICH ESTABLISHES THE RELATIONS BETWEEN DATA FROM MULTIPLE SOURCES, THUS MAKING YOUR DATA ACTIONABLE. THIS IS WHY WE CALL IT A DYNAMIC DATA HUB.

With its innovative approach, psiXchange overcomes flexibility challenges and limitations of traditional systems. Whilst it is a tool applicable for a variety of data management challenges across all disciplines, psiXchange is 100% fit for purpose to support the distribution of safety documents, which is what the application was originally built for.

The tool includes full audit-trails throughout, combined with monitoring and alert mechanisms to enable full compliance in regulated industries. By leveraging existing delivery methods, psiXchange can be seamlessly implemented without the need for recipient training and the system achieves high levels of user acceptance, increasing compliance and saving resources.

Customers have reported an 80% reduction in costs, 90% reduction in resource requirements and are experiencing compliance rates above 97%.

If you are interested in further information or would like to arrange a demo, please contact pharmasol at **info@pharmasol.de** or visit the website **www.psixchange.com**

DYNAMIC DATA HUB

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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ABOUT PHARMASOL

PHARMASOL IS A LEADING PROVIDER OF INNOVATIVE APPLICATIONS, GXP COMPLIANT HOSTING AND IMPLEMENTATION SERVICES TO THE LIFE SCIENCES INDUSTRY. WITH TOOLS TO AUTOMATE COMPLEX BUSINESS PROCESSES AND THE DEPLOYMENT OF APPLICATIONS IN A SECURE MANAGED DATA CENTRE, PHARMASOL IS TRUSTED BY LEADING PHARMACEUTICAL, MEDICAL DEVICE AND CONTRACT RESEARCH COMPANIES TO SUPPORT THEIR CORE BUSINESS PROCESSES AND ENSURE COMPLIANCE.

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