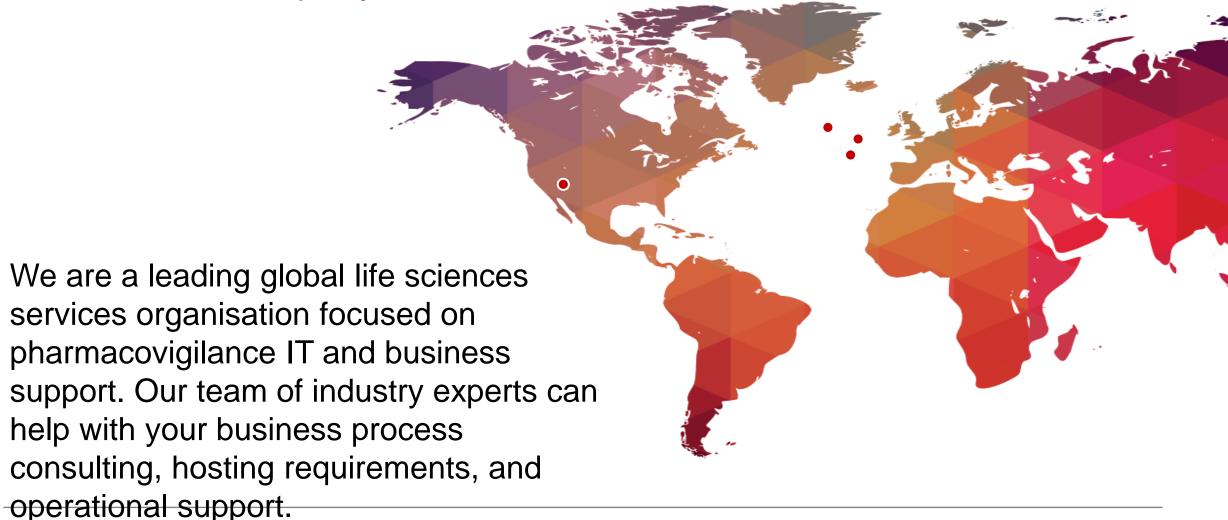




**Company Overview** 





### Quick facts

- Founded in 2001
- Staff in Germany, UK, Denmark, France and US
- 100% life sciences focused
- Oracle Gold Partner
- Oracle Argus Specialized
- ISO 9001 certified



Specialized Oracle Argus Standard Edition 7



## Consulting team with rich PV expertise

- Business process consulting
- Migration from legacy applications
- Upgrade projects
- Software implementation
- Validation services
- Safety Letter Distribution services
- Regulatory Intelligence Management



## Hosting overview

- Our state of the art data centres, located in Germany, are dedicated to hosting for GxP controlled companies requiring the highest levels of compliancy, privacy and reliability.
- Controlled according to our strict ISO compliant processes
- We provide managed hosting services to many of the top 10 global lifesciences companies, across EDC, Safety, and other third party applications, including our own.



## psiXchange – automating document distribution

- No manual intervention no impact on the recipient
- Delivering safety documents to 1000s of sites, ECs, authorities and others using end to end automation to ensure reduced overheads and increased compliance proving our industry expertise and innovative approach.





# Document distribution – for Safety Documents General challenges

- Huge and costly efforts
- Maintaining changing reporting requirements that vary from country to country
- Recipients may desire multiple distribution methods
- Recipients may include ECs, Sites, RAs and others
- Need to automatically remind, track, escalate
- Strict regulatory environment, time critical process
- Over reporting very common
- No overview of compliance
- Historically a manual task with a lack of control



### psiXchange -> Moving from Manual to Automated



#### **Information**

Use existing information from multiple sources



### Knowledge

Identify relations, cross-validate data and link it to an action



#### **Action**

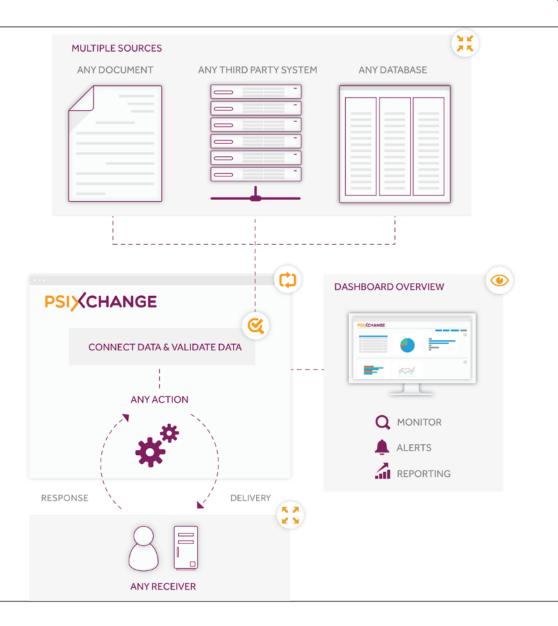
Utilize the knowledge and execute the action



#### **Control**

Monitor and review the automated executions – ensuring traceability and compliance







## Distribution focused on recipient's needs

- e-mail with secure link
- fax
- courier
- smart portal
- e-mail with attachment
- With automated reminders and escalations according to your preferred process



### Additional use cases

- Dear Healthcare professional letters
- Investigator brochures
- Study start-up

 In fact, any document that requires controlled distribution



### Find out more

psiXchange.com

white papers, case study, videos

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