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PSIXCHANGE

HELPING GRÜNENTHAL MAKE CERTAIN

The key insight: pharmasol has enabled Grünenthal – the international research-based pharmaceutical company – to distribute clinical trials information in a more efficient, cost-effective, and productive manner.

ADDRESSING AN INDUSTRY-WIDE CHALLENGE

Distributing safety reports is typically a headache for clinical trial sponsors:

- Reporting requirements vary from country to country, and committee to committee
- Requirements range from ad hoc case reports to line listings for set periods of time
- The complexity is magnified by the sharing of reports between different studies of the same therapy

In other words, a simple, one-size-fits-all approach is impossible.

> "psiXchange allows us to go from a fully manual process to an automated, standardised, and transparent way to distribute safety information."
>
> Karin van Dort Boomsma
>
> Information Manager / Manager Safety Reporting in Global Operations Support

It's a problem made worse when an adverse event occurs during a trial, which in turn requires all investigators or ethics committees involved with other studies of the drug to be informed – making coordination of reporting a major task.

A small mistake in this complex process can have big implications: ethics committee reports generally disclose whether a patient was taking the trial medication or the comparator, a placebo, or standard of care drug. So, if a sponsor employee involved in running the study sees the wrong version of the report, it can partly unblind the research.

That places the integrity of the whole trial in jeopardy.

Recognition of these problems prompted Grünenthal to ask a simple question – is there a better way?

PROJECT SNAPSHOT

The need:

To improve reliability and traceability, reduce manual efforts, and optimise the overall management of safety information distribution in clinical trials.

The solution:

psiXchange, a fully configurable document distribution solution that enabled Grünenthal to redesign its process and integrate existing safety and clinical trial management systems.

The benefit:

Grünenthal has reported a significant reduction in resource requirements, clinical trial costs, and the risk of human error in the safety information distribution process.

GRÜNENTHAL: THE SITUATION DAY 1

At Grünenthal, the distribution process was largely manual and time-consuming. It was also decentralised, which hampered the development of a robust central overview. Both blinded and unblinded reports were transmitted from the safety system to Microsoft Outlook distribution lists, which delivered the output to local distributors of the Grünenthal country organisations – or contract research organisations performing the clinical trial.

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During the course of a trial, the Clinical Research Associates (CRAs) had to verify whether all applicable reports were available during site visits. That meant collecting information on what was actually sent to the site, and confirming that this material was complete – which posed a recurring challenge. It was critical to reduce the impact on the existing processes and also the recipients.

> "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."
>
> Marc Riteco
>
> Senior Director, Global Operations Support

INTRODUCING CERTAINTY

The approach

After analysing existing software to manage adverse event reports, pharmasol worked with Grünenthal to build a new system from scratch. Using an iterative prototyping method in which new functionality was developed, released to business users, and refined based on their feedback, psiXchange was built as a fully configurable distribution solution.

The technology

psiXchange allows for centralised management of all aspects of report distribution by a few dedicated experts, which in turn relieves the global organisation of a logistical burden. In addition, the solution manages distribution rules for a specific country based on local law and regulations, rather than for each trial separately. Once set up, the country rules need only be updated if the regulatory requirements change.

The process

Reports are usually sent out via an e-mail containing a secure download link, automatically collecting acknowledgments of receipts, allowing each recipient to specify their preferred delivery method (fax, e-mail, courier). psiXchange is also able to manage manual distribution processes – for example, via courier. If a recipient doesn't acknowledge receipt of a report via their preferred method of communication, reminders can be sent out and it's then also possible to automatically retransmit the report via an alternative route.

If there's an error in the contact data, psiXchange can follow an automatic escalation path with alternative routes of transmittal.

The overview

A reporting interface enables Safety Reporting Managers and study team members to have an up-to-date overview of the distributed information sorted and filtered to any parameter – for example, per site.

The conclusion

The distribution of safety information in clinical trials is essential for a research-driven pharmaceutical company like Grünenthal. With the new psiXchange solution, the organisation aims to reduce the manual effort and the likelihood of human error, as well as improve the overall reliability and transparency of the process.

For more information

To find out more about psiXchange and other pharmasol services and software solutions, please contact: tim.billington@pharmasol.de or visit www.psixchange.com

Watch an introductory video here.

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