PHARMASOL
enabling excellence

CASE STUDY
Grünenthal

GRÜNENTHAL

How pharmasol worked with Grünenthal

How pharmasol worked with Grünenthal to increase productivity of safety Information distribution in clinical trials.

Distributing adverse event reports to investigators and ethics committees is a headache for clinical trial sponsors. Reporting requirements vary from country to country, and committee to committee. One might ask for ad-hoc single case reports, while others want line listings for set periods of time. A simple, one-size-fits all approach is impossible.

The logistical complexity is magnified by the need to share reports between different studies of the same therapy. If an adverse event happens in one trial, all investigators or ethics committees involved with other studies of the drug need to know. Coordination of reporting is a major task.

A small mistake in this complex reporting process has big implications for a trial. Ethics committee reports generally disclose whether a patient was taking the trial medication or the comparator, a placebo or standard of care drug. If the investigator or a sponsor employee involved with running the study see this report, it partly unbinds the research. The integrity of the whole trial is at stake.

Despite its importance, distribution of adverse event reports has traditionally relied on flawed processes. Fax, courier and emails based on distribution lists created by the study teams are typically used, but these make it difficult to collect acknowledgments of receipt from all parties in a uniform manner.

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

The Situation

At Grünenthal the distribution process was largely manual and distributed across the organization, which was time-consuming and hampered a robust central overview.

Both a blinded and an unblinded report were transmitted from the safety system to Microsoft Outlook distribution lists, which delivered the reports to local distributors of the Grünenthal country organizations or CROs where the clinical trial was performed. These lists were maintained by each study team separately. Each distributor was required to maintain lists of applicable recipients for the clinical trials.

During the course of a clinical trial, the Clinical Research Associates (CRAs) had to verify if all applicable reports were available during site visits. Collecting information on what was actually sent to the site and confirming that this material was complete posed a recurring challenge.

It was critical to reduce the impact on the existing processes and also the recipients. With Grünenthal already relying on Oracle Argus Safety for the case management it meant that the "out of the box" integration with psiXchange was perfect to remove any impact on the core safety processing work.

The Approach

After analysing existing software to manage adverse event reports, Grünenthal decided to develop a new system from scratch. Using an iterative prototyping approach in which new functionality was built up, released to business users, and then refined based on their feedback, pharmasol developed psiXchange as a fully configurable document distribution solution. The system allows for centralized management of all aspects of report distribution by very few dedicated experts, relieving the global organization of a logistical burden.

Standardization

psiXchange configures distribution rules for a specific country based on local law and regulations, rather than for each trial separately. Once setup, the country rules need only to be updated if the regulatory requirements change.

The need:
To further improve reliability and traceability, reduce the manual effort and optimize the overall management of safety information distribution in clinical trials.

The solution:
pharmasol collaborated with Grünenthal to redesign their process and integrate the existing safety and clinical trial management systems with psiXchange, a fully configurable document distribution solution.

The benefit:
psiXchange enables Grünenthal to significantly reduce their manual effort, clinical trial costs and risk of human error in the safety information distribution process. The solution also provides a central information portal to all parties involved in the process.

> "psiXchange allows us to go from a fully manual process to an automated, standardized and transparent way to distribute safety information."

Karin van Dort Boomsma
–
Information Manager / Manager Safety Reporting in Global Operations Support

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Tracking and Escalation

Reports are distributed via fax, email and a web portal, automatically collecting acknowledgments of receipts, allowing each recipient to specify his preferred route. psiXchange is also able to manage manual distribution processes, e.g. via courier. In case a recipient does not acknowledge receipt of a report via his preferred method of communication, reminders are sent out and it is then possible to transmit the report again via an alternative method. If an error is contained within the contact data, psiXchange is able to follow an automatic escalation path with alternative routes of transmittal.

Comprehensive 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, e.g. per site.

The Ongoing Benefits

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

By enabling CRAs to retrieve specific information on the reports received by that site, the new solution should help improve the overall transparency of the clinical trial.

> “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
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Information Manager / Manager Safety Reporting in Global Operations Support

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A pharmasol Applications case study **psiXchange**

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/82372814)

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