Case Study:

Modernized Pharmacovigilance Signal Management Solution Improves Process and Traceability

OVERVIEW:

Pharmaceutical and biotech companies need a solid signal management process. One retrospective analysis of the World Health Organizations (WHO) pharmacovigilance database substantiates this need.

An investigation of ADRs in the WHO database, VigiBase, reported by physicians between 1 January 2010 and 31 December 2019 (male and female patients aged ≥18 years), showed that among the millions of ADRs recorded there were 43,685 fatalities.

These Adverse Drug Reactions (ADR) related fatalities are the reason that a strong signal management system needs to be in place with the proper activities to determine whether there are new risks associated with an active substance or a medicinal product, or if known risks have changed. The processes put in place also need to provide related recommendations, decisions, communications, and tracking assistance in reducing these fatal outcomes.

In this case study we present how ResultWorks assisted a top 10 pharmaceutical company to develop a modern signal management environment for pre-marketed and marketed products.

BUSINESS CHALLENGE

This pharmaceutical company needed to improve the design of the workflows and data flows relative to their safety signal management environment for both their pre-marketed and marketed products. ResultWorks was brought in to define the requirements for their new signal management environment in preparation for commercial vendor solution evaluation and selection.

HOW RESULTWORKS ENABLED SUCCESS

ResultWorks engaged with company's safety team to design workflows, data flows, metadata, and systems for both marketed and pre-marketed products.

A business analysis was performed by ResultWorks which included:

- A background analysis and research relative to the existing signal management environment.
- Conducting stakeholder and subject-matter expert reviews to further understand and analyze signal management challenges and future needs.
- Developing views of the Current State and desired Future State and aligning the client team on the needs.

From the business analysis, a draft of user and system requirements to address the future state needs was developed that included:

- Detailed process steps, user stories, and user requirements related to the desired workflows and data flows.
- System requirements for non-workflow specific needs (e.g., Security/Permissions, Dashboards, Configurations, Metadata, Search/Reporting, etc.).

ResultWorks reviewed and refined Signal management user requirements with Client team to gain alignment and finalized and Delivered Signal Management User Requirements to support Client's vendor evaluation and selection process.

THE RESULTWORKS IMPACT - KEY BENEFITS

In collaboration with the client, ResultWorks:

- Specified the framework for a modern signal management environment for pre-marketed and marketed products that included details on the following key topics:
  - Collection and processing of signal data
  - Tracking and reporting for potential signals, signals, and risks
  - Document storage (e.g., surveillance plans, safety topic reports, literature, etc.)
  - Compliance
  - Security and permissions, including requirements to support restriction/access to blinded data
  - User experience, workflow orchestration, and operational metrics

- Defined the required integrations and data feeds from numerous sources
- Identified roles, responsibilities, and ownership across the signal management lifecycle
- Determined requirements for a new signal management environment that would
  - Enable visibility
  - Facilitate workflows
  - Increase process automation
  - Centralize signal information
  - Improve traceability

I was impressed with how quickly you were able to pick up on the processes and you guys took all of that and consolidated that very nicely. Speed and agility with that was wonderful
-Safety Signal Product Owner

It went very smoothly. We had an initial timeline, and everything was hit along the way. A lot of good engagement from our team and we have our quality product at the end.
-PV Technical Lead

For more information, visit our website (www.resultworksllc.com or www.astrixinc.com) or contact us at:

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