Case Study:

BioPharma Company Enhances Pharmacovigilance Systems and Critical Business Capabilities

OVERVIEW:

As we know, Pharmacovigilance (PV), or drug safety involves the research and practices connected to recognizing, measuring, understanding, and preventing adverse effects or other probable drug-related problems. Those in this area are tasked with the responsibility of the prompt collection, recording, and dissemination of safety data, as well as proper evaluations and accelerated and periodic reporting of this information.

The PV specific systems and connected technologies are required to gather data on Adverse Events (AEs), as well as other safety-related data such as off-label usage, pharmaceutical mistakes, overdose, counterfeit goods, etc. Therefore, robust PV systems are imperative for the evaluation of information related to causation, severity, and risk of observations. Capabilities for risk management, product safety profiles, and labeling are equally important as modifications may result from these evaluations.

Without the proper business and technology strategy in the PV area, an organization can find itself being reactive to issues it faces in the safety area versus proactive and strategic. In this case study we discuss how ResultWorks assisted a top 10 pharmaceutical company with a global footprint to:

- Achieve organizational alignment to a Safety technology strategy that enhanced critical safety business capabilities.

- Develop a future state strategy to address key technical capabilities needed including the transactional platform, data analytics, and intelligent automation.

- Develop an actionable 3-year roadmap that enabled the Safety teams to focus on the most complex cases, deploying automation to address simpler cases and alleviate the reporting burden to health authorities.

- Achieve optimized end-to-end case processing workflow.

BUSINESS CHALLENGE

This global pharmaceutical company understood that their safety business processes and the technologies that were supporting them had fallen behind and needed to be modernized. The technology was in a constant state of repair in order to keep systems and the safety operation functioning.

At the same time, other parts of the global development operation were undergoing massive change with commensurate investments in technology. In particular, solutions in the safety area needed to align with clinical development for a more seamless flow and handling of patient data.

Having already completed the clinical development technology strategy, ResultWorks was engaged to assist in the definition of the safety technology strategy.

HOW RESULTWORKS ENABLED SUCCESS

Current State Assessment
In order to set a baseline, ResultWorks conducted stakeholder interviews & working sessions with the organization's PV ant IT team to first understand and assess what was and wasn't working. The current workflows and dataflows, the technology environment, and specific issues, gaps and opportunities were identified by the PV team. Major processes included case intake, case processing, reporting, risk management, and signal management. Tools and technologies encompassed data intake, automated case processing, data storage, data analysis, and workload management.

Emerging Technology Trends
Relevant emerging technologies were explored for application in PV including natural language processing, blockchain, robotic process automation, advanced data analytics, interactive visualization, and others.

An assessment of the pharmacovigilance vendor landscape was also conducted touching over two dozen vendors. These vendors were evaluated for capabilities such as AI-enabled case intake, safety database integration, enhanced medical coding, and signal management. A subset of vendors was identified whose technologies would significantly advance the client safety operations.

Future State PV Technical Strategy & Architecture
The current state analysis and the emerging technology trends informed the future state Pharmacovigilance technology strategy and technical architecture. A PV business and technology framework was developed to structure the definition of business and technical capabilities needed by the PV organization.

PV Business and Technical Framework
Generalized Example
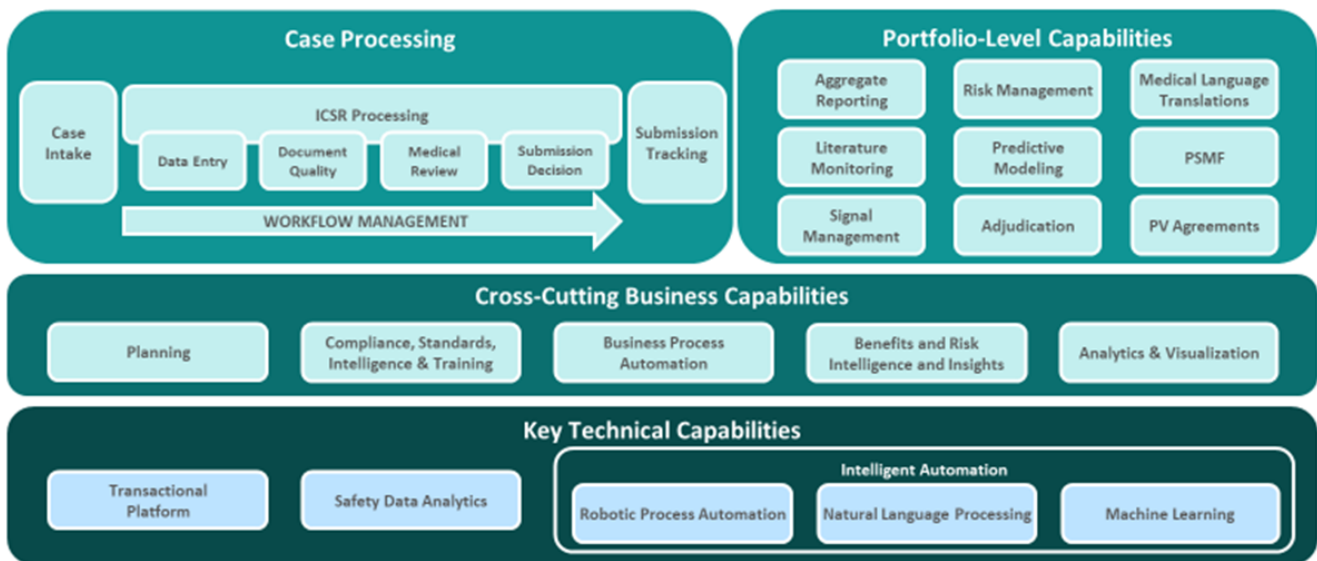
Each functional grouping (e.g., case processing) and capability (e.g., case intake) was broken out and described in terms of business impact and opportunity areas. The key technical capabilities including use of emerging technologies was further defined by identifying how they would enable needed business capabilities.

A conceptual technical architecture was defined that would support the desired business capabilities. The defined PV architecture was aligned with ongoing enterprise work to implement shared architecture and tools across the organization. Integral to this was a shared core data layer to manage metadata, data storage, and data access and security between safety and other related areas. Data flows were likewise developed depicting the potential flow of information across technology platforms.

Strategy Documentation and Roadmap
The prioritized projects to achieve the future state were defined and categorized into the following areas

- Core PV solution foundations
- Core PV solution implementation
- Cross-cutting PV solutions
- Operational governance
- Organizational change management

Projects were then organized into an actionable project roadmap including:

- A Roadmap Trajectory identifying the high-level objectives to be achieved in each planning and investment cycle.

- A Strategy Roadmap which defined the key business and technology projects and activities to be undertaken over a multi-year timeframe. The roadmap projects were further described in a one-page callout that defines the project, dependencies, business value, etc.
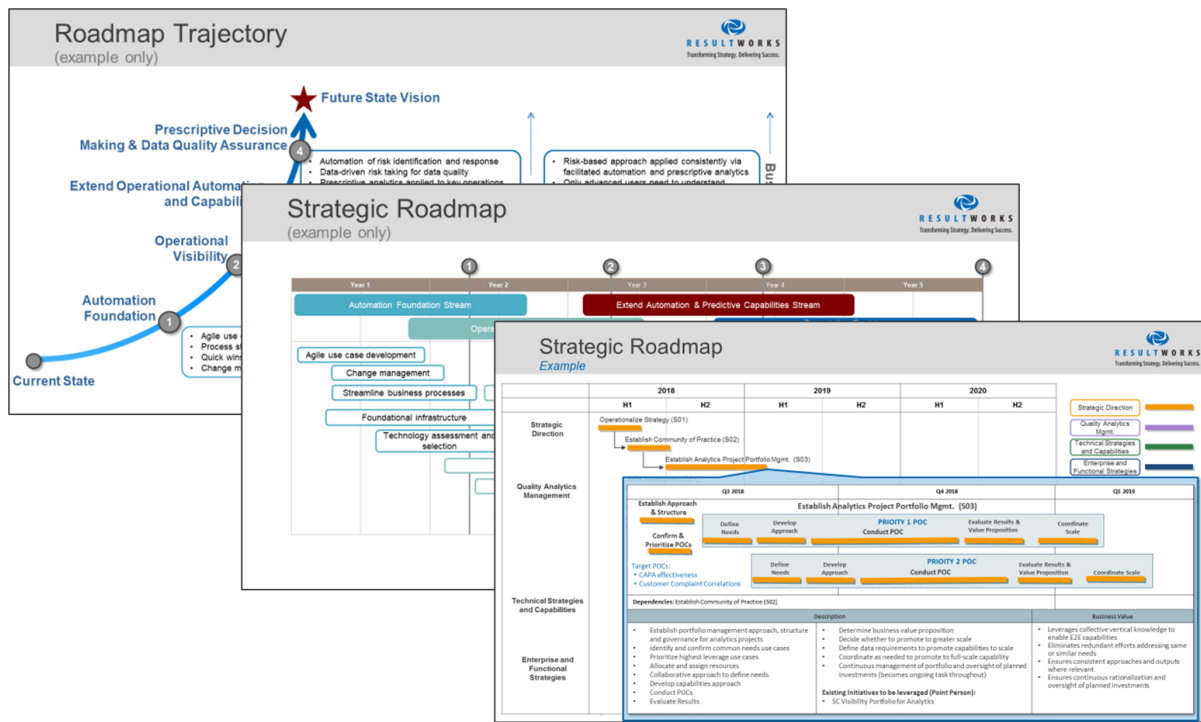
THE RESULTWORKS IMPACT - KEY BENEFITS

Through ResultWorks' efforts, this client organization:

- Achieved organizational alignment to a PV technology strategy that enhances critical safety business capabilities.

- The future state PV strategy addressed key technical capabilities needed including the transactional platforms, data analytics, and intelligent automation.

- The actionable 3-year roadmap enabled the safety teams to focus on the most complex cases, deploying automation to address simpler cases and alleviate the reporting burden to health authorities.

> *"The strategy roadmap will bring a lot of value for future planning and discussions. The concrete plan and having everything written down was very helpful for us and we could not have done it on our own."*
>
> Executive Director, Drug Safety

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

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