Case Study:

How a Global Pharmaceutical Company Digitally Transformed Clinical Development



OVERVIEW:

Clinical Development is continually challenged to optimize operations and to ensure efficiency, effectiveness, and compliance. However, given how complex the data and systems environments are today, it requires a thorough understanding of how the organization can leverage them to optimize their unique situation relative to people, processes, and technology.



Accomplishing this while at the same time continuing to produce results, is challenging. It may therefore require assistance from external experts who can bring their knowledge and expertise in to help the organization succeed in their efforts.

The following case study reveals how ResultWorks assisted a global pharmaceutical company by leveraging a proven approach, to define their required business and technical capabilities, design a logical technical architecture, conduct an assessment of commercial technologies, and assist in aligning their strategy and roadmap to achieve success.

BUSINESS CHALLENGE

This global pharmaceutical client was struggling with the need to evolve their technical capabilities across the Clinical Development organization.

Their existing technology infrastructure had the following challenges:

- It was insufficient to handle the current operations.
- The technologies were aging and siloed.
- Stakeholders couldn't easily access and leverage:
 - Available trial data
 - Real world data and other relevant information to inform the trial design and management.

The client organization business goals were:

- To enable innovative trial designs and strategies, patient, site, and user experiences.
- To enhance business and operational capabilities.
- To scale with increasing numbers and complexity of clinical trails

1

ResultWorks was engaged to work with the technology and business teams to develop a data and platform centric strategy. The organization needed a strategic approach to be based on new and emerging technologies that would empower clinical innovation, enable patient centricity, and enhance the client's ability to accelerate data driven decisions.

HOW RESULTWORKS ENABLED SUCCESS

ResultWorks began the process by working with the senior leadership teams across Clinical Operations, Clinical Data Management, Biostatistics, and several other related functions (e.g., Safety, QA/QC, Medical Affairs, and others) to align on the overarching business imperatives and priorities that needed to be addressed.

The stakeholders needed to align on a vision for the future and develop high level guiding principles for the strategy. These guiding principles were then used throughout the engagement to ensure that the strategy did not deviate from the desired objective for the initiative.

Once the guiding principles were agreed to, ResultWorks collaborated with the business and technology stakeholders to define the foundational and aspirational capabilities that the new Clinical Development technical ecosystem would need to support.

Together with the client, capabilities were grouped and organized into a framework to address the progression of clinical trials from planning, to



conduct, to analysis, to reporting. Both function specific and shared capabilities were identified and documented as were technical considerations, and current challenges and opportunities.

As part of the aspirational capability definition, ResultWorks provided an overview of emerging technologies to ensure the team was aware of technology trends that could be used to enhance the clinical development environment. Emerging technologies for digital patient engagement, novel therapeutics, enterprise data fabric, and others were identified.



After defining the capabilities, a smaller focused group of business and technology stakeholders participated in defining the prioritization and urgency of needed capabilities. This prioritization effort was later used to develop a strategic roadmap for implementation.

ResultWorks then developed a logical technical data and platform centric architecture. The architecture tied directly to the required business and cross cutting capabilities previously prioritized. Each platform was detailed and reviewed iteratively with the client team to build alignment on the strategy.

Based on the future state strategy, the client then asked ResultWorks to conduct a Request for Information (RFI) to help clarify the vendors that might be engaged to support their newly defined Clinical Data Platform (CDP) as well as other elements of the architecture. Recognizing that no single vendor can deliver all the required clinical platforms, vendors were assessed based on the strengths, and heat maps were developed to capture best fits across the range of capabilities.



The outcome of the logical technical architecture strategy definition and the RFI were then used to inform the development of a high level, actionable, 5-year strategy roadmap. In addition, detailed project plans were established with resourcing and a preliminary business case to secure funding for the overall program. In addition, the RFI work was used to shortlist to a select group of vendors for separate CDP and Strategic Platform Request for Proposal (RFP) efforts that were defined on the strategic roadmap. This initiated immediately following the strategy engagement.

THE RESULTWORKS IMPACT - KEY BENEFITS

Business & Technical Capabilities Definition:

Working with the business stakeholders, defined foundational and aspirational business and technical capabilities, and prioritized those capabilities for gated investment.

Logical Technical Architecture Design:

Designed a logical technical architecture, based on technical and business capabilities and which defined technical platforms to support the clinical trial process incorporating patient engagement, workflow and execution, data management, biostats, data science, and other agreed capabilities. I am really impressed with the quality of the work and the details regarding (capability) prioritization.

- Associate Vice President IT

Clinical Commercial Technology Assessment:

Conducted a technology assessment of leading commercial solution providers to understand their current and future product plans to support the defined platforms.

Aligned Strategy & Roadmap:

The client team aligned on the technology strategy and adopted a 5-year strategy roadmap for execution.

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

Astrix Technology, LLC, CORPORATE HEADQUARTERS, 125 Half Mile Rd, Suite 200, Red Bank, NJ 07701, 732-661-0400