

Defining a Clinical and R&D Data Strategy for a Gene Therapy Company

A global biotechnology company on a mission to engineer solutions for rare diseases was facing challenges across R&D with data orchestration to empower exploratory analysis and allow its scientists to more efficiently use clinical and non-clinical data. With a primary focus on research at the forefront of gene therapy, RNA-targeted exon skipping, and gene editing, the client had several commercial products in place as well as several late-phase clinical trials.

The company's R&D organization saw an opportunity to streamline its data for easier access and more flexible analyses. They had an aspiration to better leverage the company's array of R&D data, including preclinical experimental data, clinical data, and operational data to drive even more value for patients and the business.

The client engaged Clarkston's strategy, clinical, R&D, and data analytics experts to assess their current landscape and define how R&D data processes could be holistically managed and aggregated to facilitate effective and efficient ways to derive value from data across multiple functional areas and data sources.

Life Sciences Case Study

PROJECT OVERVIEW



INDUSTRY:



Life Sciences

PRODUCTS AND SERVICES :



Rare Diseases

PRIMARY OBJECTIVES:

- Define the scope of the problem and understand current business processes, data flows, and use cases around R&D data
- Identify critical challenges and corresponding strategies to solve for in preparation for the future build and rollout of data aggregated solutions
- Assist the company in setting and prioritizing a short-term and long-term transformation strategy, including identifying quick wins and impact drivers for each recommendation
- Develop a roadmap to outline the path to operationalize requirements and other strategic considerations, including people, process, and technology current and future needs

RESOLUTION:

- Conduct interviews and working sessions with 50+ cross-functional owners to understand processes and uses across different datasets, including clinical, operational, and pre-clinical groups
- Develop data flows to illustrate and better understand data inputs, outputs, uses, and key opportunities for data orchestration
- Pressure test understanding of in-progress initiatives owned by IT to determine to what extent their future work would alleviate current state business challenges
- Create high-level recommendations and strategic considerations for potential technology and business process solutions that would meet the company's needs
- Create a working prototype for what data pipeline aggregation and corresponding data visualization elements could look like to expedite exploratory analysis
- Support the alignment between R&D and IT teams to understand the necessary steps and data governance needs required to establish a Data Lake leveraging enterprise tools (e.g., *Snowflake, AWS, Alation, R-Shiny, among others*)

KEY BENEFITS:

- Leverage the value of clinical data with dynamic dashboards and visuals with the ability to view subsets of data at a patient level
- Enable exploratory analysis across studies – which was once difficult and time-consuming – by granting the company the ability to leverage existing data to drive better research
- Define the dynamics of a partnership between R&D and IT to jointly achieve future ambitions and interlock activities with enterprise and commercial needs
- Drive toward data excellence by building the foundation around systematic data ingestion and report development
- Gain internal alignment on the organizational design and resources needed to achieve the R&D data orchestration ambition

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