Life Sciences Case Study

PROJECT OVERVIEW

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Cell Therapy Data Management: Complex Challenges to Data Sharing Across Treatment Lifecycle

This client is a global pharmaceutical company that makes and sells a number of branded prescription drugs. The company also makes over-the-counter medications, such as cold remedies and vitamins.

As the organization was maturing its cell therapy business unit in early 2021, it strived to not only optimize its current performance, but also to make groundbreaking, life-saving discoveries. The business believed that the cure for major chronic disease is trapped in the data they already generate today.

The organization engaged Clarkston Consulting to help unleash the power and potential of this data. In this project, Clarkston compared the current state processes, identifying where data is generated and how it is stored, to an aspirational data management process. The team worked with every functional group within research, clinical operations, as well as clinical and commercial manufacturing, to recommend a corresponding roadmap to implement the change in data management processes.

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INDUSTRY:

Pharmaceuticals

PRODUCTS AND SERVICES :

Branded prescription drugs, over-the-counter medications, and innovative cell therapies

PRIMARY OBJECTIVES:

- Defining capabilities needed in the CTTE and how to leverage the groups outside of cell therapy within the company
- Creation of a strategy and corresponding processes to address data challenges, such as inconsistent data quality, data silos, data availability, and data management
- Creation of a roadmap and a plan to enable efficient and effective data curation, collection, behaviors and analysis leading to new discoveries

RESOLUTION:

- Defined the current data management process and roles, and identified and addressed gaps
- Defined capabilities needed in cell therapy and how to leverage groups outside of cell therapy
- Created a strategy and corresponding processes to address data challenges, such as inconsistent data quality, data silos, data availability, and data management
- Created a roadmap and a plan to enable efficient and effective data curation, collection, behaviors and analysis leading to new discoveries

KEY BENEFITS:

- Provided use cases for the importance and need of data availability:
  - Starting Material Selection
  - Raw Material Selection
  - GMP Readiness
  - BLA Filing
  - Manufacturing Process Improvement – Increasing Throughput, Reducing Cycle time
  - Selecting critical process parameters and measurement
  - Predicting patient outcomes
  - Evaluating process changes
  - Tech transfer to another site
- The data flow assessment uncovered 43 discrete findings of varying significance.
  - Findings were categorized into people, process and technology and further broken into logical groupings (e.g., ELN, Process Harmonization, Data Integrity, etc.)
- 35 mitigations of various effort levels were identified to address the findings.
  - The mitigations can address more than one finding and build upon one another.
  - The mitigations were organized into 3 programs: Digital Readiness, Digital Enablement, and Data Visualization

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Through the project, 3 key elements were identified as enablers of cell therapy data management:

1.

Structure and Stability are needed to create repeatable processes, data capture, and nomenclature for functional groups integrated across functions.

2.

Dedicated Organization Roles and Responsibilities to create ownership and accountability Cross-Functional

3.

Communication to break down silo's and enable collaboration and coordination

CONTACT US

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