Life Sciences Case Study

PROJECT OVERVIEW

Post-Merger Clinical Operations Support for an Oncology Division

The client specializes in the development and commercialization of orally administered oncology treatments for a range of cancers. It has a robust pipeline of small molecule clinical candidates targeting solid tumor and hematological malignancies, with additional candidates in pre-clinical development. The client recently acquired the clinical assets from another biotechnology company and was looking to fully integrate dozens of ongoing global clinical trials (across the US, EU, and several other global markets) within a ~six-month window.

Clarkston was engaged to support delineating all critical tasks required to successfully integrate the clinical assets during the desired timeframe. The Clarkston team brought a tailored post-merger integration plan to accelerate success, and a roadmap designed to meet clinical trial timelines, ensuring a positive outcome in planning, governance, and relevant submission updates throughout the world.

Clarkston's work provided subject matter expertise (SME) perspectives and managed activities across their Quality, Regulatory, Clinical Operations, and Supply Chain areas. The project defined what needs to change relative to the sponsor ownership change by identifying key tasks/activities across functional areas. A strategic and tactical roadmap and plan was developed, tracking critical interdependencies. Working with clinical study directors and clinical supply leaders, the team developed a comprehensive list for regulatory document changes, sponsor change label changes, and SOPs changes required to be submitted prior to December 2024.

Given Clarkston's deep expertise and proven track record in guiding similar organizations through complex clinical and commercial acquisitions and integrations, we successfully partnered with the client and acquired company to navigate the complexities of this integration, supporting a seamless transition of clinical assets and key activities. At the conclusion, Clarkston was able to lead collaboration across multiple functional groups and provide senior management with a detailed strategic and tactical plan to deliver the required changes for the integration of the clinical assets.

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PROJECT OVERVIEW

INDUSTRY:

Life Sciences

PRODUCTS AND SERVICES :

Development and commercialization of orally administered oncology therapies

PRIMARY OBJECTIVES:

- Conduct a thorough assessment to develop a strategic plan to ensure successful integration of all clinical assets
- Provide oversight to fully integrate the acquired clinical assets within a ~six-month window.
- Collaborate across the relevant functional areas to identity critical activities required for study sponsor updates
- Develop a post-merger integration plan to accelerate success and meet timelines
- Generate a tracker to monitor the tasks for the key activities, deliverables, and SOPs relevant to the sponsor change integration

RESOLUTION:

- Provided subject matter experts related to M&A and clinical operations integration to help identify any missing activities relative to the Sponsor change
- Defined what needs to change or stay the same to achieve the integration of the clinical assets, per regulatory requirements
- Worked with functional areas (Quality, Clinical Operations, Regulatory, and Supply Chain) to review and identify missing tasks/activities required
- Identified interdependencies and aligned on an action plan for execution
- Created a transition plan for all key activities and assigned owners and initiated a tracking progress
- Created master tracker to assist in the organization and execution of the project plan
- Evaluated all SOPs to assess potential compliance issues during the transition
- Tracked the updating and creation of new SOPs related to the sponsor's name integration

KEY BENEFITS:

- Key deliverables identified for the sponsor change and acquired clinical assets
- Critical regulatory and submission-related activities tracked to complete integration
- Integration successfully performed on time and without issues

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KPIs

- Identified an average of 30 activities related to the acquisition and sponsor name change per study, per regulatory requirements
- Identified 60+ SOPs to be decommissioned
- Tracked 20 new and revised SOPs to be updated related to the changes

CONTACT US

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