Life Sciences Case Study

PROJECT OVERVIEW

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Optimizing the Market Research Process in Biotech

The client is a well-recognized biopharmaceutical company specializing in developing therapeutics using RNA interference (RNAi). The company's primary emphasis lies in creating RNAi therapeutics that target diseases arising from the excessive production of particular proteins, often attributable to genetic mutations.

As the client expands into new markets including the EU, APAC, and Brazil, they recognized the need for a streamlined process for review and approval of market research projects. The client observed that their current review process was more cumbersome and risk-averse than what was required to be compliant with Market Research standards like EphMRA, which led to delays in project approvals for time-sensitive studies. Market research projects were funneled through the standard MLR process for materials review instead of a more tailored process for market research materials. The client sought out Clarkston's support to standardize a market research approval process with adherence to global standards to improve efficiency when completing MLR reviews.

Clarkston's process optimization experts were engaged to facilitate an assessment of current market research processes and build a global and risk-based approach for conducting market research in the future. As part of this process assessment, the Clarkston team incorporated market research industry best practices and standards from EphMRA and BHBIA and engaged ~20 stakeholders in workshops to define the future approach. As a result, the Clarkston team delivered a comprehensive global market research standard operating procedure and training checklist tool.

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INDUSTRY:

Life Sciences

PRODUCTS AND SERVICES :

Biotech,
RNAi Therapeutics

PRIMARY OBJECTIVES:

- Design and vet a risk-based market research approval approach that is aligned to industry standards
- Optimize the market research approval process based on the level of risk associated with different market research needs and required inputs across Medical, Legal, and Regulatory stakeholders, where applicable
- Standardize the global and local market research approval processes to encompass 100% of market research across the organization
- Develop a Standard Operating Procedure (SOP) to formally document the future state market research approval process

RESOLUTION:

- Facilitated a series of workshops to determine the objectives, associated metrics, and guiding principles to drive the process improvement effort
- Documented the current state market research approval process based on cross-functional inputs and identified gaps based on industry best practices
- Conducted review sessions with Legal, Medical, Regulatory, and Compliance stakeholders to document and confirm what a future-state global market research process should look like for the organization
- Developed a global SOP and supplemental training tool for adherence to organization's market research guidelines

KEY BENEFITS:

- Achieved cross-functional alignment amongst stakeholders for the strategic vision of the market research approval process
- Revised the global market research approval process flow, optimized for efficiency of review and compliance aligned to industry standards
- Established global market research approval SOP for all commercial teams to utilize
- Prepared the organization for future training content development through checklist tool creation
- Reduced time spent reviewing market research by revising required materials and steps in review

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KPIs

- Facilitated 3 cross-functional process design sessions to develop global Market Research SOP and accompanying training checklist tool
- Conducted 10+ working sessions to iterate upon global MR SOP and training checklist tool
- Anticipated a 20% reduction in time spent on review through fewer materials and steps to complete
- Expected an increase in the speed of getting studies to the field by 30%

CONTACT US

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