

## Medical Device Company

### *Improving clinical research effectiveness through better a process for assessing portfolio progress*

#### Challenge

A large clinical research group within a medical device company had little consistency in how they set and reported objectives for the 40+ studies within their portfolio. Managers were allowed to develop their own processes, which led to a situation where there was no set of standards for developing objectives. This lack of consistency meant that it was difficult to assess the progress of the projects and programs within the portfolio. Leadership, including the function's Vice President and the General Managers of the businesses, were hindered in their strategic decision-making abilities due to these inconsistencies.

**The purpose of this project was to develop a set of shared and standardized study objectives to improve study execution and communication about the health of the portfolio to leadership.**

#### Improvement Approach

##### *Data Analysis*

The first step in understanding the universe of possible objectives was to analyze past objectives. All objectives going back five years were collected, cleaned for duplicates, and standardized such that similar objectives were given consistent wording. Any objective appearing only once or twice was eliminated because of its uniqueness. This left about 80 objectives.

#### Case Study Synopsis

##### **Problem**

Lack of standardization in process for tracking and reporting clinical research study progress

##### **Methods**

Surveys  
Stakeholder interviews  
Expert working group  
Pilot testing

##### **Tools**

Qualtrics  
SharePoint  
Power BI

##### **Results**

A standardized and shared set of objectives across all businesses, with an online process for collecting and reporting objectives, allowing for improved strategic decision-making

## ***Stakeholder Engagement***

The next step was to pare down the 80 objectives to a more manageable list. This step involved two approaches: a survey of key stakeholders and an expert opinion working group. First, approximately 30 key stakeholder leaders were identified across functions. These stakeholders completed a survey to share their opinions about the most important objectives to study success. They were asked to select objectives across the study lifecycle and study health. The results of this survey were analyzed with the mostly highly-rated objectives, around 35, moving on to the next phase.

Second, an expert working group was assembled to discuss the remaining objectives and pare it down to a final list of around 15. The working group of 8 members met approximately five times and discussed and rated each objective based on four criteria, 1) generalizability, the objective needed to work for studies of different types and sizes, 2) measurability, the objective needed a clear way to be assessed, 3) singularity, the objective would not be assessing more than more aspect of study health, and 4) importance, the impact that the objective has in determining overall study success. Using these criteria, experts in the working group reduced the number of objectives to approximately 20.

## ***Pilot Testing***

The final step in the process was to pilot-test the objectives with project managers to gather feedback to make further refinements. These project managers were given the objectives and were asked to select the appropriate ones for their study. A form was used to collect their insights and feedback on areas of confusion. These data were then reviewed and the objectives were revised again. Primarily, this round of revisions was to the clarity and wording of the objectives, however, a couple of objectives were eliminated.

The final list of 17 objectives was presented to leadership for their approval with some minor changes made with their feedback.

## **Process Solution**

### ***Process***

A process for collecting objectives was created once the objectives were finalized. This process outlined how the objectives would be tracked (a SharePoint list), the frequency

of collection (quarterly), and a timeline for entry (last week of the quarter through the first week of the next quarter).

This process was outlined in a series of documents that described the objectives and the process for collection and reporting. Two training sessions were held for staff and a video of the process was created to assist with on-going training.

### ***Technology***

A SharePoint list housed on a departmental SharePoint site was utilized to collect and update objectives. The benefits of this system were its accessibility, ease of use, and compatibility with other reporting tools. The design of the system was completed by the project's manager.

### ***Reporting***

Power BI was utilized to create a dashboard to analyze the objectives and report results to leadership. This dashboard was the primary way that the portfolio of studies was determined by leadership to be on- or off-track. Managers used the dashboard to assess the health of the studies in their programs. Study managers used the dashboard to demonstrate the trajectory and health of their study to a variety of functions responsible for study execution.

### **Evaluation**

In the last quarter of the fiscal year, feedback was solicited from a variety of stakeholders to assess the suitability of the objectives and the process for collection. A survey was completed along with a set of interviews with key staff. Updates were made to the objectives and process based on this feedback. Additionally, enhancements to reporting and the dashboard were made to drive decision-making based on the data.