Study Build Managed Services

The Challenge

Founded in 2010, a leading biopharmaceutical company is a public biopharmaceutical company based in Waltham, Massachusetts. The company is devoted to developing transformative oncology therapies, which requires efficient execution of numerous, complex study protocols and designs. Given a leading biopharmaceutical company's rapid growth, the company was searching for a trusted partner that could provide innovative clinical trial solutions able to seamlessly scale alongside its evolving needs.

The Solution

A leading biopharmaceutical company decided to leverage Medidata's Study Build Managed Services, fully outsourcing its clinical trial programs to Medidata's unified platform. Both organizations jointly defined value driving metrics to track performance and clearly illustrate the value gained from the collaboration. Specifically, a leading biopharmaceutical company wanted to maximize value related to its study design, data cleaning, data quality, and site monitoring processes.

Business Impact

Since 2013, a leading biopharmaceutical company has run 20+ clinical trials on the Medidata platform, resulting in improved data quality and faster study design, patient data capture, and data cleaning cycle times. Further, leveraging Medidata's end-to-end platform has allowed a leading biopharmaceutical company to scale its operations smoothly alongside the company's natural growth.

Operational Improvements From Core Platform Usage

Study Design and Planning

28% ↑
Better than Industry Median eCRF Design Cycle Time (as of November 2017)

61% ↑
Increase in eCRF reuse (since 2014)

All business outcomes have been validated with the TESARO Data Management team

Data is current as of November 2017

Study Execution

26% ↑
Faster monitoring visit report approval cycle time (since 2016)

20% ↓
Reduction in SDV coverage (since 2014)

36% ↓
Lower query volume (since 2014)

75% ↓
Reduction in patient data capture cycle time (since 2014)

40% ↑
Faster subject visit to query close cycle time (since 2014)

34% ↓
Reduction in shipping costs from streamlining drug assignment

39% ↓
Reduction in package waste from improving drug utilization (since 2014)

1.1M ↓
Reduction in monitoring cost (for one study using TSDV – since 2014)

Summary of Value Attainment

Study Design and Feasibility

- **28%** Better than Industry Median eCRF Design Cycle Time
- **61%** Increase in eCRF Reuse

Value attainment comparison is for 2014 vs. 2016 scores.

Study Planning and Startup

- **40%** Faster Subject Visit to Query Close Cycle Time
- **36%** Lower Query Volume

Study Conduct

- **20%** Reduction in SDV Coverage
- **$1.07 MILLION** Reduction in Monitoring Travel Costs
- **26%** Faster Monitoring Visit Report Approval Cycle Time
- **60%** Faster than Industry Median Patient Data Capture Cycle Time

Study Closeout

- **34%** Reduction in Shipping Costs from Streamlining Drug Assignment
- **39%** Reduction in Package Waste from Improving Drug Utilization

A leading biopharmaceutical company KPI Analysis

eCRF Design Cycle Time Value Attainment

Directional Value Attainment Per Study Designed (Compared to industry median)		Notes
eCRF design period (in weeks) — Industry Median	14	From Medidata Insights
eCRF design period (in weeks) — A leading biopharmaceutical company	10	From Medidata Insights
A leading biopharmaceutical company's study design is faster than Industry Median by (in weeks)	4	Calculated (=14 weeks – 10 weeks)
Number of FTEs designing studies	2	Estimate validated by a leading biopharmaceutical company team
Number of hours saved (40 hours per work week)	320	Calculated (=4 weeks x 2 FTEs x 40 hours per week)
Data Manager cost per hour to design eCRF	135	Medidata PICAS benchmark
Total study design cost savings per study	**$43,200**	**Calculated ($135 per hour x 800 hours)**
Total study design cost savings across 13 studies	**$561,600**	**Calculated ($43,200 x 13 studies)**

Study Build Managed Service
Medidata can help establish KPIs for subsequent analyses that clearly illustrate the value of outsourcing your study build