Study Build Services

The Challenge

A leading biopharmaceutical company devoted to the development of providing transformational therapies to those facing cancer, was experiencing rapid growth and wanted to ensure their requirements of efficient execution of their numerous, complex study protocols and designs. The company was searching for a trusted partner that could provide innovative clinical trial solutions able to seamlessly scale alongside its evolving needs and provide the expertise needed to ensure their study builds were on time and on budget.

The Solution

The company decided to leverage Medidata's Study Build 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, the 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

46%↑
Better than Industry Median eCRF Design Cycle Time

61%↑
Increase in eCRF reuse

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

- **46%** 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

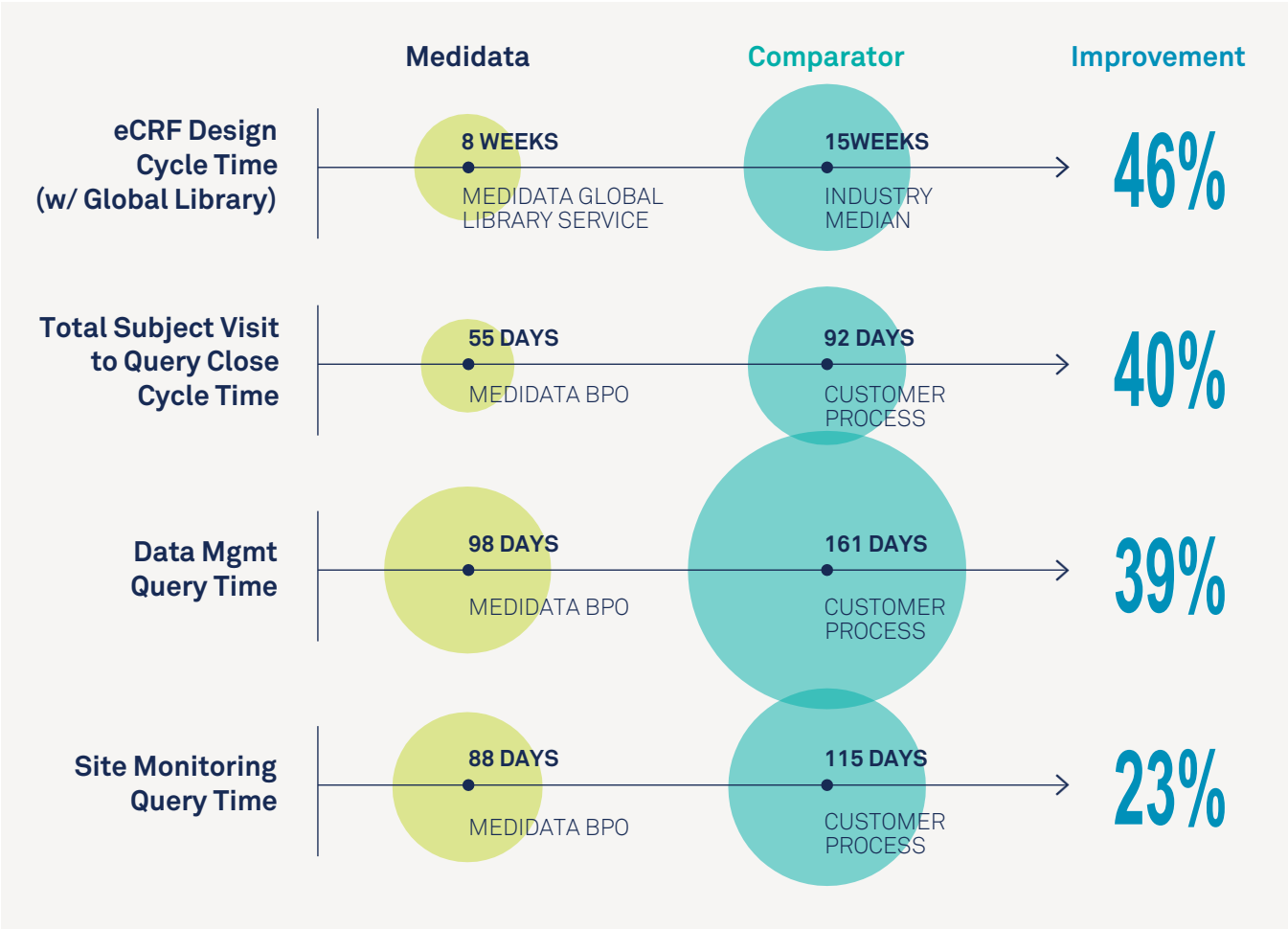
- **34%** Reduction in Shipping Costs from Streamlining Drug Assignment
- **39%** Reduction in Package Waste from Improving Drug Utilization

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	15	From Medidata Insights
eCRF design period (in weeks) — A leading biopharmaceutical company	8	From Medidata Insights
A leading biopharmaceutical company's study design is faster than Industry Median by (in weeks)	7	Calculated (=15 weeks – 8 weeks)
Number of FTEs designing studies	2	Estimate validated by a leading biopharmaceutical company team
Number of hours saved (40 hours per work week)	560	Calculated (=7 weeks x 2 FTEs x 40 hours per week)
Data Manager cost per hour to design eCRF	75	Medidata PICAS benchmark
Total study design cost savings per study	**$42,000**	**Calculated ($75 per hour x 80 hoursX7 weeks)**
Total study design cost savings across 13 studies	**$546,000**	**Calculated ($42,000 x 13 studies)**

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



About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,400 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data.

Medidata, a Dassault Systèmes company (Euronext Paris: #13065, DSY.PA), is headquartered in New York City and has offices around the world to meet the needs of its customers. Discover more at http://www.medidata.com and follow us @medidata, The Operating System for Life SciencesTM.

 info@medidata.com +1 866 515 6044

Reduced costs | Improved time to market | Faster decisions | Minimized risk