MEDIDATA DETECT

PROACTIVELY IMPROVE DATA QUALITY AND REDUCE TRIAL RISK

THE RISKS OF DATA QUALITY ISSUES

17%
trials are delayed by 3 months due to data quality issues

24%
applications that require one or more resubmissions before approval[1]

52%
resubmissions that had inconsistent study results[1]

435 days
median approval delay after a first unsuccessful submission[1]

THE IMMEDIATE IMPACT OF CSA AND MEDIDATA DETECT TECHNOLOGY

20%-40%
reduction in number of edit checks

83%
reduction in case review time by Medical Monitors

20-30
minutes vs. 2-3 hours review time per case

5 days
vs. ~4 weeks from LPLV to Database Lock for critical studies

TRANSFORM DATA MANAGEMENT TO REDUCE RISK, CYCLE TIME, AND COST

Identify studies with potential misconduct and drill down diagnostic findings from study to country to site to subject level.

Through statistical algorithms and tests, Medidata Detect uncovers data errors, trends, and anomalies and helps you **perform root-cause investigations and proactively take corrective actions.**

Reduce Edit Checks

20%-40% reduction in number of edit checks

Pattern recognition and outlier detection reduce pre-programmed edit checks

Reduce costs of requirements gathering, logic development, programming, validation, project management

Automate Data Review

50%-55% of data reviews automated by CSA

Flag data errors, trends, and anomalies

Compute KRIs for early indication of clinically significant trends

Reduce Custom Reports

Leverage pre-set data listings, summary tables, patient profiles, scatter plots, and box plots

One central system for multiple review outputs (PPs, outlier detection, listings, KRIs, etc.)

Shorten reviews, cycles and time by weeks

Faster Database Lock

30 days to 5 days database lock reduction in critical studies

Reduce LPLV to DBL cycle time resulting in earlier filing of NDA

Decrease number of database unlocks after initial database lock

Reduced Study Risk

80% of studies with site differences

Reduce risk of submission delay by submitting cleaner study

Limit risk of additional regulatory review

1. *Sacks LV, Shamsuddin HH, Yasinskaya YI, Bouri K, Lanthier ML, Sherman RE, "Scientific and Regulatory Reasons for Delay and Denial of FDA Approval of Initial Applications for New Drugs, 2000-2012." JAMA.2014;311(4):378–384. doi:10.1001/jama.2013.282542*

WHY MEDIDATA IN NUMBERS

6.5M Trial Subjects

780K+ Sites

14,000+ Total Complete Trials

70+ Study Therapeutic Areas

Visit medidata.com/en/products/detect/ to learn more.

medidata joins DASSAULT SYSTEMES