MEDIDATA DETECT

PROACTIVELY IMPROVE DATA QUALITY AND REDUCE TRIAL RISK

THE RISKS OF DATA QUALITY ISSUES

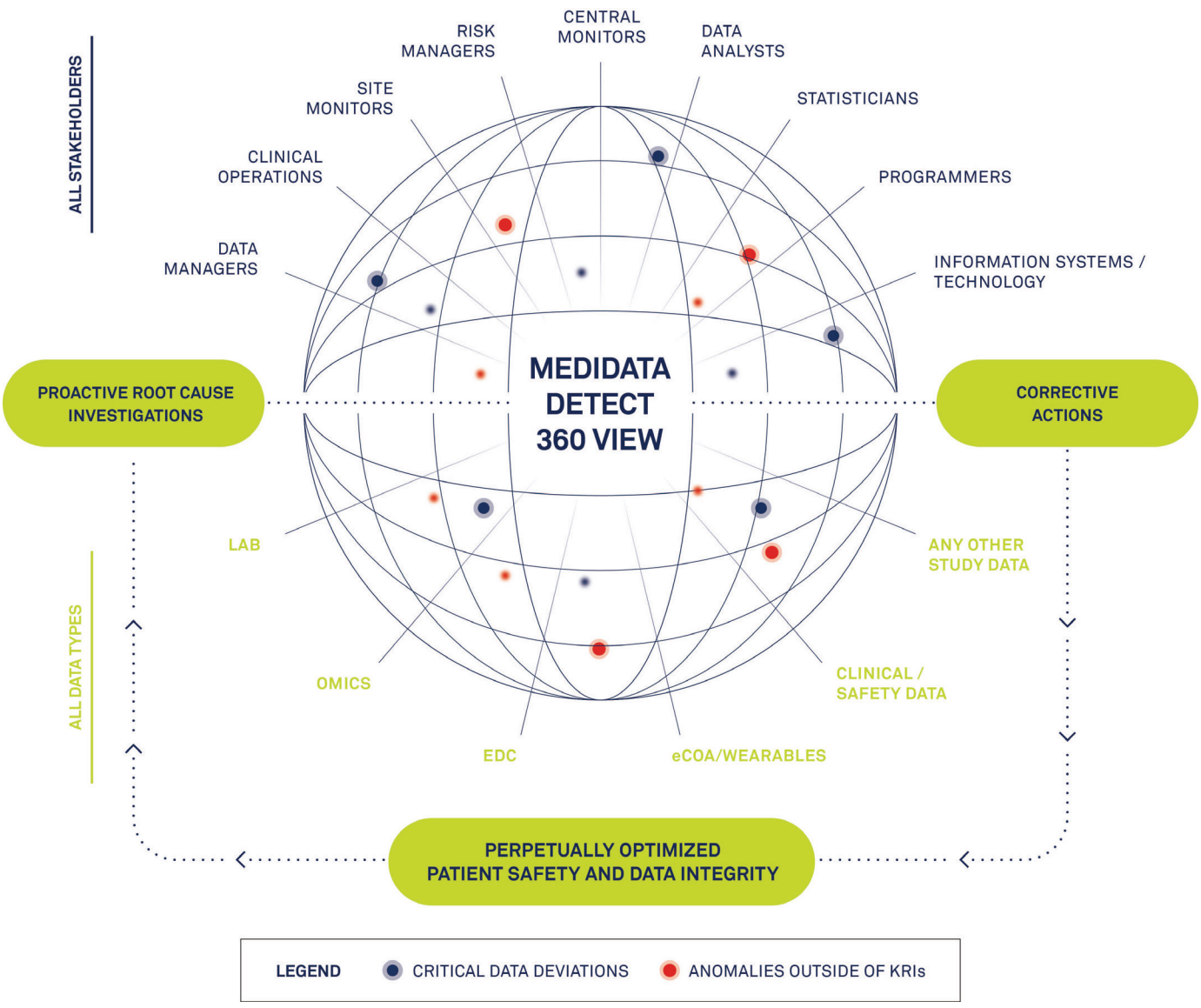
24%
applications that require one or more resubmissions before approval[1]

52%
resubmissions that had inconsistent study results[1]

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

THE POWER OF MULTI-DIMENSIONAL OVERSIGHT TO IMPROVE YOUR STUDY DATA QUALITY AND ENSURE PATIENT SAFETY

With Medidata Detect, anomalies, outliers and trends across multiple variables are automatically detected, including unknown errors and risks outside of defined Key Risk Indicators (KRIs).



THE IMMEDIATE IMPACT OF MEDIDATA DETECT

20%-40%
reduction in number of edit checks

83%
reduction in case review time by medical monitors

50%-55%
of data reviews automated

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

On average **1 out of 6 trials are delayed by 3 months** because of quality issues. Medidata Detect is designed to minimize this risk.

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.**

Oversight

Automate flagging of data anomalies

Reduce risk of undetected anomalies

Compute KRIs and provide early indication of clinically significant trends

Efficiency

50%-55% of data reviews automated

20%-40% reduction in number of edit checks

Data Quality

Identify indications of potential misconduct

Reduce risks of submission delays by submitting cleaner data

Simplification

Reduction from 30 days to 5 days for database lock in critical studies

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

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

6.8M Trial Subjects

900K+ Sites

23,000+ Total Complete Trials

70+ Study Therapeutic Areas

Medidata, a Dassault Systèmes company, is leading the digital transformation of life sciences.

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