

PROTECT YOUR PATH TO APPROVAL WITH MEDIDATA EDGE TRIAL ASSURANCE

Machine learning improves data quality and scales to meet increasing demand

When analyzing data quality issues in

24 RECENT STUDIES

across

18 THERAPEUTIC AREAS

Edge Trial Assurance found

1479 AVOIDABLE DATA QUALITY ISSUES

spanning

13M+ DATA POINTS

and

22K PATIENTS

learning

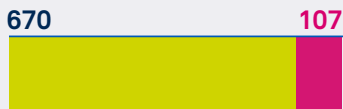
41K RULES

Former FDA Statistical Reviewers at Medidata indicated that

22%

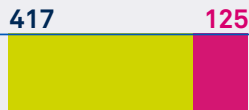
Of data quality issues found across 24 studies had potential to delay regulatory approval

Data Quality Issues Across 24 Studies

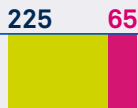


Anomaly Categories Detected

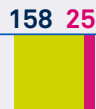
Inconsistencies in how sites evaluate or measure endpoints
24/24 STUDIES



Differences in the actions sites take with regard to an adverse event
24/24 STUDIES



Inconsistencies in how sites follow the protocol
22/24 STUDIES



Values that are impossible or highly unlikely due to data entry errors
9/24 STUDIES



Sites that make up data out of neglect or forgetfulness
3/24 STUDIES

■ Data Quality Issues Across Studies
■ Data Quality Issues With Potential to Impact Drug Approvals

A Top 25 Global Pharma

Data Quality Issues most likely to delay regulatory approval in
10 Studies in **6** Therapeutic Areas



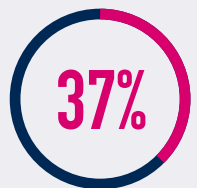
A Top Global Pharma with HQ in APAC

Data Quality Issues most likely to delay regulatory approval in
1 Study in **1** Therapeutic Area



A Top 10 Global Med-Device

Data Quality Issues most likely to delay regulatory approval in
2 Studies in **2** Therapeutic Areas



The difference between an FDA approval and an FDA letter:

Medidata Edge Trial Assurance

Sponsor 1

Medidata Edge Trial Assurance
Extra Analyses

FDA Approval

Q1' 2018 Launch

Sponsor 2

FDA Letter
Extra Analyses

Delay