

# 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

**30M+** DATA POINTS

and

**22K** PATIENTS

learning

**90K+** RULES

Former FDA Statistical Reviewers at Medidata indicated that

**22%**

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

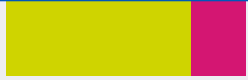
### Data Quality Issues Across 24 Studies

670 107



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

417 125



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

225 65



Inconsistencies in how sites follow the protocol  
**22/24 STUDIES**

158 25



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

9 3

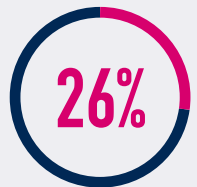


Sites that make up data out of neglect or forgetfulness  
**3/24 STUDIES**

■ 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



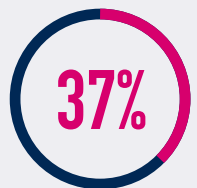
### A Top Global Pharma with HQ in APAC

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



FDA Approval

Q1' 2018 Launch

Sponsor 2

FDA Letter  
Extra Analyses

Delay