COVID-19 Risk Assessment of Clinical Trials: Medidata Guidance and Recommendations

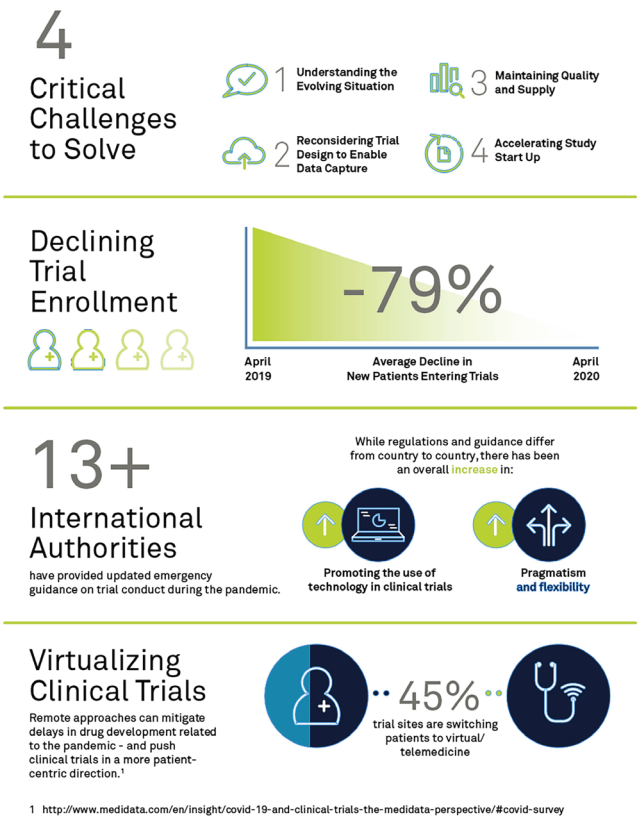
As noted in COVID-19 and Clinical Trials: The Medidata Perspective, regulatory agencies worldwide provided guidance on emergency measures to mitigate risks to clinical trial integrity and patient safety, with priority of these activities given to the impact of the pandemic on trial participants. This guidance emphasized the importance of clinical trial sponsors assessing new and/or elevated risks posed by the COVID-19 pandemic and appropriate mitigation strategies.

Medidata believes that clinical trial oversight responsibilities begin with risk management activities to ensure a methodical, consistent, and well-documented assessment. To assist you with this assessment, Medidata developed and made available a COVID-19 Risk Assessment Template.

To make it as easy for any company to use this template, whether a current Medidata client or not, we've developed it in a spreadsheet format so that it is quick and easy to download and use.

Conducting a risk assessment is the regulatory responsibility of the sponsor, however, both the sponsors and their CRO delegates need to ensure that the risk assessment is complete and accurate for each specific trial. The template should be tailored as needed to meet their risk assessment obligations.

COVID-19 Challenges



1 http://www.medidata.com/en/insight/covid-19-and-clinical-trials-the-medidata-perspective/#covid-survey

Medidata's Recommendations to Sponsors and CROs

In a complex, ever-changing crisis environment, it is important that assessment and mitigation of COVID-19 risks be methodical, consistent, and well-documented. Below are specific ways to create a formal risk management process and proper communications in the event regulatory agencies request this information.

Identify COVID-19 Risks

- Any common risks identified in the FDA Guidance on Conduct of Clinical Trials of Medical Products during the COVID-19 Pandemic (Appendix Q1) should be specifically addressed in a Sponsor and CROs' risk assessment

Site Monitoring Visits

- Given the disruption to site monitoring visits, it is recommended that sponsors and CROs use a central monitoring tool to proactively monitor for any patient safety or trial integrity risks.

Consolidated Risk Assessments

- COVID-19 specific risk assessments should be added to existing risk assessments and monitoring plans, with priority on patient safety

Remote Monitoring

- Sponsors and CROs can leverage site remote monitoring via uploaded images of source documents to ensure document review, if permitted by a country's regulatory agency

Risk Assessment Features

Built on the Medidata Clinical Cloud™

Offers end-to-end solutions for data capture, data management, trial planning, trial management, and analytics to support risk-based, central and remote monitoring across clinical trials for patient safety and data integrity.

Centralized Monitoring Tool

Scans millions of data points using machine learning to continuously learn proper and acceptable ranges for all data fields and identify statistical relationships between variables.

Powerful Risk Repository

Provides a Risk Management solution to evaluate risk across critical data and processes and ensure a well-documented risk assessment, that also includes a built-in COVID-19 Risk Assessment template.

Efficiency Tools

Creates efficiencies by using Targeted Source Data Verification (TSDV) while maintaining 100% coverage of critical safety or efficacy data and augment on-site monitoring through Remote Source Review.

Quality Tolerance Limits (QTLs)

Helps define corresponding risk control mechanisms and performance oversight metrics, such as Key Risk Indicators (KRIs) and QTLs, to make deviations easier to identify.

Professional Services

Supports risk assessment implementations, introduces best use of central analytics, and recommends data collection best practices.

Proven to Transform Your Study

COVID-19 has accelerated adoption of virtual capabilities as an urgent response. Is your technology strategy designed to accommodate further disruptions in the long term?

Medidata offers adaptability and operational agility needed to support virtualization of your clinical trials. Unifying virtualization capabilities on a single platform delivers fast adaptation and performance with the following benefits:

- All scenarios of virtualization have been pre-identified
- An end-to-end range of technologies delivers solutions across all sites, patients, and sponsors on one single platform
- Solutions are designed to improve patient experience, safety, and centricity
- All capabilities are synchronized to deliver real time insights for remediation and secure data integrity

Organizations using Medidata solutions have seen significant improvements to efficiency and cost*

64+%
REDUCTION IN STUDY BUILD TIME OVER INDUSTRY BENCHMARKS

35%
FASTER eCRFs DESIGN CYCLE TIME

50%
FASTER SUBJECT VISIT TO QUERY CLOSE CYCLE

~80%
REDUCTION IN DATA CORRECTION RATES

297K+
COST REDUCTION PER STUDY FROM REDUCED ON-SITE TRAVEL COSTS

*Source: *All data derived from internal analysis done by the Medidata Value Team, Oct 2020: "Value attainment proof points reflect performance improvements with clients."

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