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COVID-19 and Clinical Trials: The Medidata Perspective

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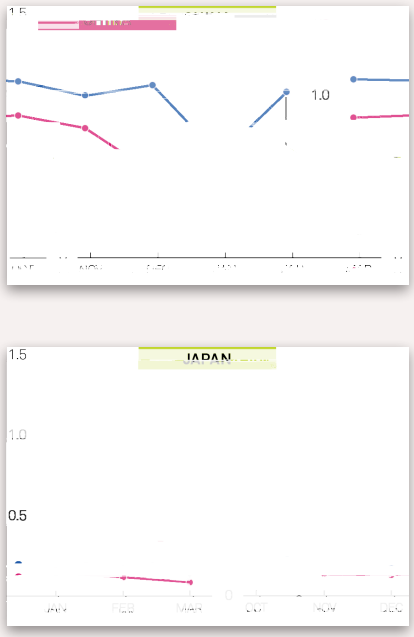
Introduction

As COVID-19 has spread, we have been monitoring its global impact on clinical trials. We see the profound impact on our industry, both at a global level but also at the site level. An analysis of the change in new patients entering clinical trials for actively recruiting studies demonstrates the significance of the impact as cities, regions, and countries have begun to restrict movement.[1] In China, for example, we saw an 83% decrease in new patients entering trials YoY in February 2020. We are now seeing similar trends in other affected countries. While the US didn't see a major decline in February, we've seen a decline of 62% in the first half of March. Similar declines are occurring across the EU, including France (61%) and Italy (see Exhibit 1).

Exhibit 1



Understanding what is happening on the ground is critical to define a path forward. Sharing this data is an important first step. We will continue to publish updated analyses on overall industry trends throughout this

1 Based on a review of 4,069 studies currently running on the Medidata Rave EDC platform.

Regulatory Response

As of March 21, the European Medicines Agency (EMA), U.S. Food and Drug Administration (FDA), Medicines and Healthcare Products Regulatory Agency (MHRA), National Health Service (NHS), Department of Health and Social Care (DHSC), the Association of Clinical Research Organizations (ACRO) and multiple IRBs (an example here) have provided emergency interim measures to that clinical trial monitoring is maintained during the COVID pandemic. In general, they agree on two critical points: that extraordinary measures must be quickly implemented, and that trials need to be adjusted as we adapt to this reality. The priority of these immediate activities must be given to the impact of the pandemic on the health and safety of the trial participant. Other key recommendations are that adjustments to clinical trial conduct should be based on a **risk assessment**, that there should be a transition to telemedicine and remote subject visits, and the use of central and remote monitoring to maintain oversight of clinical sites. An up-to-date summary by Ari Feldman, VP of Global Compliance and Strategy, of the evolving responses from clinical study regulatory agencies is available on the Medidata website here.

Impact to Medidata Customers, Patients and Trials

Real-time and detailed reporting and analytics are critical for sponsors and CROs to assess the day-to-day impact of the pandemic on a trial at the patient, site and country level and so they can quickly implement changes to mitigate the risk of trial failure.

Rapid and safe implementation of protocol amendments is vital to address both site closures and the fact that trial participants no longer receive or have access to the investigational product. Inaccessible sites mean that alternative, remote approaches to drug supply, monitoring study conduct, compliance, patient safety and data quality are needed. The more trials can be safely "virtualized," the more likely they will be able to successfully proceed.

Medidata Solutions to Assist Sponsors/Partners, Patients and Trials

Medidata has solutions that can be immediately leveraged by our customers to both better understand the impact of the pandemic on their trials, and to mitigate the challenges of patients unable to visit sites for their drugs and protocol-directed clinical and patient-reported data capture.

There are three main categories of challenges facing clinical trials. The following is a high level summary of these challenges and the solutions that Medidata is prepared and ready to provide:

CHALLENGE 1: UNDERSTANDING THE EVOLVING SITUATION

Solutions:

- Study/sponsor level metrics and dashboards to understand impact on enrollment, patient visits, data collection, query response rates, and additional metrics to help diagnose risk areas
- Industry-wide dashboards and analysis to understand trends globally and areas of greater or lesser disruption

CHALLENGE 2: RECONSIDERING TRIAL DESIGN TO ENABLE DATA CAPTURE

Solutions:

- Shift to more virtualization - reduce patient visits; minimize site burden
- Shift site mix to lower-impacted countries / regions
- Consider Synthetic Controls to reduce patient enrollment needs

CHALLENGE 3: MAINTAINING SUPPLY AND QUALITY

Solutions:

- Closely monitor patient volume and drug supply to minimize supply disruptions
- Centralize data oversight and monitoring activities, bringing identification of patient anomalies earlier in the process

Details on Medidata's Solutions

The following tables provide details around the Medidata's solutions available now to assist with your trial challenges. Since some aspects of the three challenges are not mutually exclusive, some solutions may be applicable to more than one challenge.

CHALLENGE 1: UNDERSTANDING THE EVOLVING SITUATION

Acorn AI Intelligent Trials

CHALLENGE	SOLUTION
Understanding the impact at site / country level across industry	Weekly updates at industry level (cross-sponsor) on trends in enrollment, data entry, and trial volume Considering alternate countries / sites to ramp up

Rave RBQM

CHALLENGE	SOLUTION
Regulatory risk assessment & documentation activities	To support regulatory oversight responsibilities Medidata offers 2 solutions within a Risk Based Quality Management (RBQM) framework.
Travel restrictions impacting ability of site staff and monitoring resources to perform oversight responsibilities to ensure subject safety and data quality	The Risk Assessment Categorization Tool (RACT) supports risk assessment activities in the development and documentation of monitoring strategies by collecting critical to quality data and risk control mechanisms. Centralized Statistical Analysis (CSA) supports the sponsors oversight responsibilities to ensure safety and data quality by next-generation analytical tools and algorithms. Medidata believes Rave CSA can bring incredible value to support the current landscape by: • Real-time data availability for earlier data oversight • On-demand data refreshes, enabling analyses to best comply with evolving best practices • Real-time event incidence analysis for earlier insight into patient safety data •

CHALLENGE 2: RECONSIDERING TRIAL DESIGN TO ENABLE DATA CAPTURE

Rave eCOA

Acorn AI Synthetic Control Arms/Trial Design

CHALLENGE	SOLUTION
Improving understanding of safety in experimental treatments (e.g., Chloroquine) that are now under review for cross-indication use.	Support research by providing aggregated data (e.g., SCD) to support understanding of expected and unexpected AEs for products being studied for COVID-19. These drugs are already marketed with a mature safety pro□le, but an SCD might improve the analyses above what published

About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,700 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data. Medidata, a Dassault Systèmes company (E Ne (ec)7j-O510t)T3(a DassMed.106 -10 Tdtic17TnM3tCptt)10 (j1 0 0 1 5.Tm Dassl