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Introduction

As COVID-19 has spread, we have been monitoring its global impact on clinical trials. Our rst data and insights impact report was released on March 23. Medidata's analysis of the change in new patients entering clinical trials for actively recruiting studies demonstrates the signi cance of the pandemic's impact on cities, regions, and countries with increasingly tighter laws and guidelines restricting movement by anyone outside of the home [1].

An update to the March 23 analysis was performed on April 3, 2020, which now includes impact on trial enrollment by therapeutic area (TA) shown in Exhibit 1 below. The global data shows a 65% decrease in the average number of new patients entering trials per study-site YoY during March [1]. Most geographic regions have been heavily impacted. All of the countries analyzed experienced accelerated decreases in new patients entering trials YoY, except two. For example, during March there were enrollment decreases YoY for the US (67%), France (68%), Italy (52%), Germany (32%), Spain (68%), UK (80%), Japan (43%), India (84%), and South Korea (61%). The two countries that improved between February and March were Argentina and China. In China, we saw a 68% decrease in new patients entering trials YoY during March, but the silver lining was that March was 240% higher than February in terms of new patients added, which could be a leading indicator of China returning to normalcy.

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		YoY Difference (%) Mar 2020 vs. Mar 2019
All Countries, All TAs	All	-65.1%
Country Breakdown	China	-67.5%
	United States	-66.7%
	Japan	-43.5%
	Indar 20a7 231 582nTw 7 0 MC 3.2 347i.5 (k)14 ETE17 39E221.75 475.157.5 q 17 39E221.75 475.157.16.50.008 Tf-0.007 Tc	

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.

As of April 3rd, several large pharma (P□zer, Bristol Myers Squibb and Eli Lilly)[2] and smaller Biotech companies (Moderna Therapeutics)[3] have publicly announced that they are modifying their R&D plans - part of that modi□cation is some form of temporary delay in site activation and/or patient enrollment in certain trials. The impact of COVID-19 on trial success is already an issue as evidenced by Aveo Pharmaceuticals Inc. citing COVID-19 as a reason for the study failure of □clatuzumab in acute myeloid leukemia.[4] These few but growing examples of trial delays or stoppage by biopharma to mitigate the cost and impact of the pandemic dramatically highlight the need for rapid, innovative solutions to help trials successfully start, continue and □nish.

Medidata Solutions to Assist Sponsors/Partners, Patients and Trials

[2] https://www.□ercebiotech.com/biotech/covid-19-prompts-p□zer-to-stop-enrollment-most-studies. Accessed April 4, 2020

[3] https://www.□ercebiotech.com/biotech/covid-19-causes-moderna-to-pause-a-clutch-clinical-trials. Accessed April 4, 2020.

[4] https://www.reuters.com/article/brief-aveo-oncology-and-biodesix-to-disc/brief-aveo-oncology-and-biodesix-to-discontinue-cy□-2-study-of-□clatuzumab-idUSFWN2BK1LR. Accessed April 4, 2020

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 SUPPL AND QUALIT

Solutions:

- Closely monitor patient volume and drug supply to minimize supply disruptions
- Centralize data oversight and monitoring activities, bringing identi□cation of patient anomalies earlier in the process and away from onsite identi□cation.

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 E OL ING SITUATION

Acorn AI Intelligent Trials

CHALLENGE	SOLUTION
Understanding the country/ site/disease area impact across the industry, and developing risk mitigation and recovery plans	Data and analytics to develop industry tracking, forecasting and deep dives for priority studies to support client's COVID-19 impact assessment, risk mitigation and recovery decisions. **Situation Tracking** • Deploy standard reports to track impact of COVID-19 • Data tracked - measures of enrollment and data collection • Views at study, portfolio, geography level **Impact Forecasting** • Overlay trends in COVID-19 testing and infection rates with impact on trials to understand leading indicators of slowdown • Identify markers of recovery at a country and region level **Recovery Planning** • Develop views on likely volume of re-starts post-recovery by geography and indication • Develop recovery plan and scenarios for acceleration post-recovery across portfolio

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	1. The Medidata Risk Assessment Categorization Tool (RACT) supports risk assessment activities

CHALLENGE	SOLUTION
Sites are closed and patients need a dispensation	Some of the methods above can also be used to allow a direct to patient shipment when the site is closed. Alternately, subjects may be transferred to sites that are open. We have a "How-to" procedure ready to share with you.
Subjects are able to have an onsite visit but future visits are questionable	Multiple dispensing visits can be made in Rave EDC at the same time, providing additional IMP for the subject. If this will become standard, DND dates should be updated so that the drug does not expire over the longer time period between dispensations. Our Services team can provide specific steps that can be utilized to ensure off-cycle/unscheduled visits can be conducted without issue.
Supply chain concerns make sites want to have more buffer stock on hand or less (depending on if the concern is availability of drug or availability of shipments)	Update supply plans — here is basic learning information for supply plan settings. The supply plan can be instantly adjusted to ensure that the site is stocked with additional drug, such as calculating drug needed for additional visits. Depending on the individual study design, these methods can be combined to address any challenges faced by the study.

Summary

Medidata is working around the clock to identify enhanced and innovative ways to assist you in analyzing the impact of the pandemic on your trials and leveraging current and developing technologies to mitigate risk through increased use of virtual capabilities, advanced analytics for operations and oversight, managing supplies and innovations like synthetic control arms to reduce the number of patients needed for evidence creation, centralization of data oversight, and identification of alternatives in supply management.

While the virus and uncertainty continue unabated, what is certain is that we continue unrelentingly to live and deliver our shared imperative to bring safe and effective therapies to market. Medidata is here for our sponsors, partners and patients throughout this remarkable and challenging time. Our mission has never been more critical than it is right now — Conquering Diseases Together.

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 1,400 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data. Medidata, a Dassault Systèmes company (Euronext Paris: #13065, DSY.PA), is headquartered in New York City and has offices around the world to meet the needs of its customers. Discover more at **www.medidata.com** and follow us **@medidata**, The Operating System for Life Sciences™.

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