COVID-19 and Clinical Trials: The Medidata Perspective

Release 3.0

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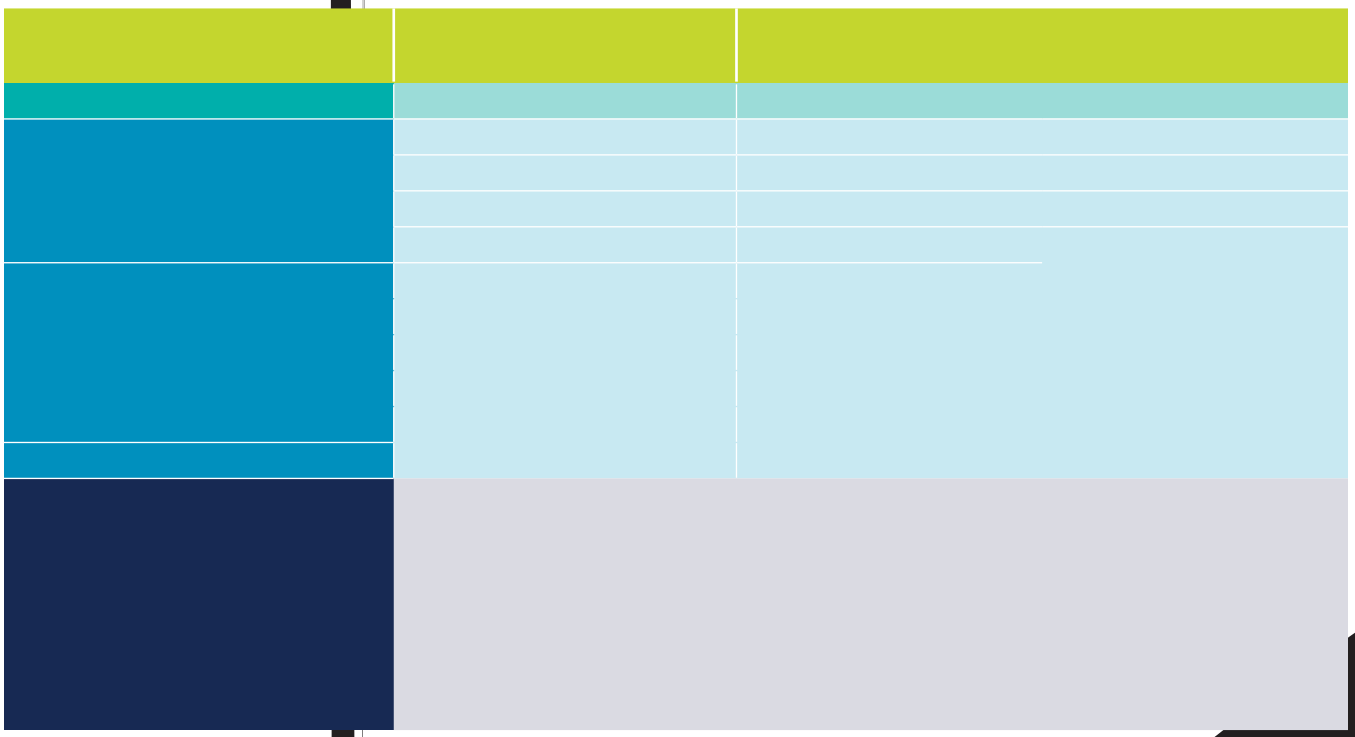
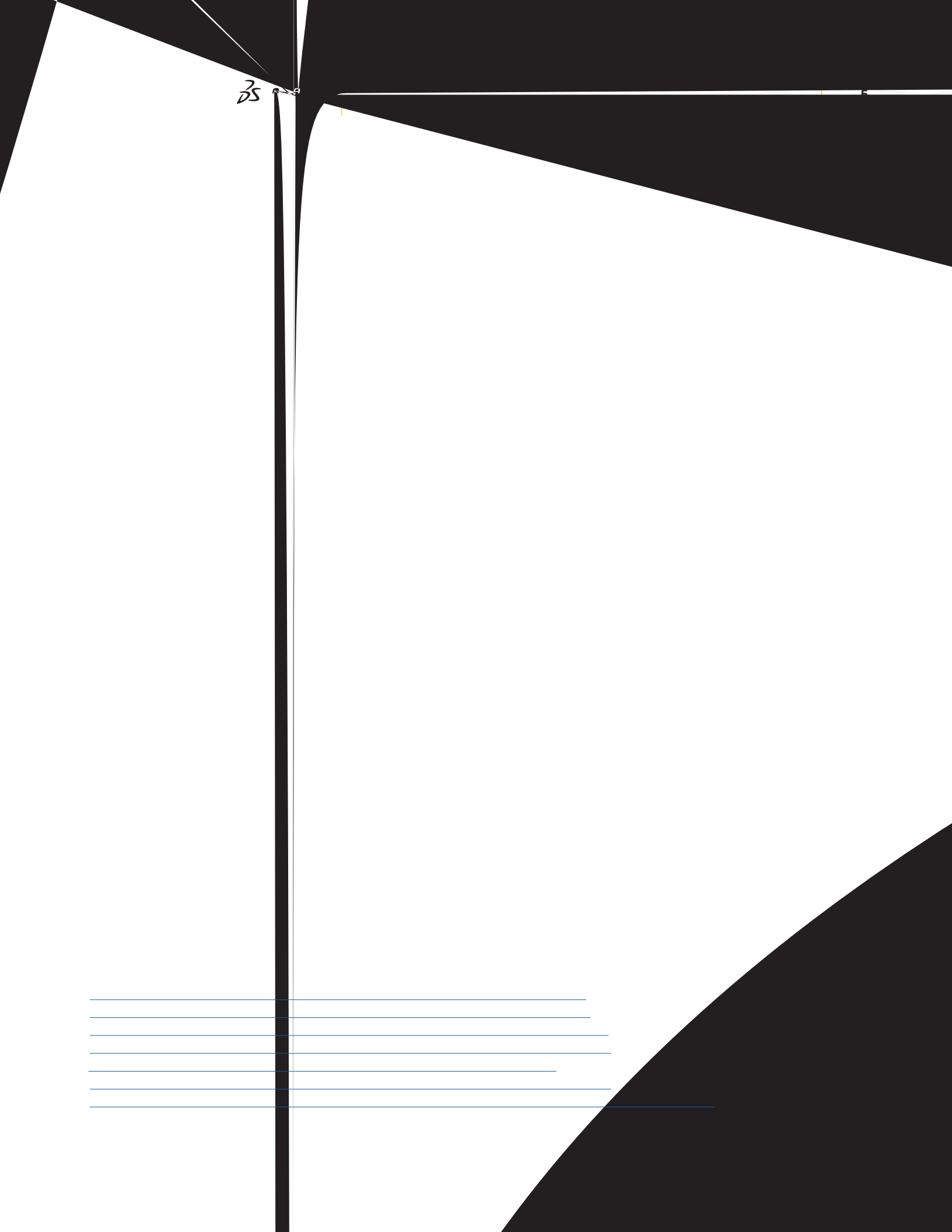
Introduction

As COVID-19 has spread and, in some Asian countries, begun to recede, we have been monitoring the global impact of the virus on clinical trials. Our first data and insights impact report was released on March 23 with subsequent updates on April 3rd and April 17th. Medidata's analysis of the change in new patients entering clinical trials for actively recruiting studies demonstrates the growing significance 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 April 3 analysis was performed on April 17, 2020 and the results for the first two weeks of April are shown next to the March results (See Exhibit 1), The global data now shows an 75% decrease in the average number of new patients entering trials per study-site YoY for the first two weeks of April compared to the same time frame last year.[1] This compares to a 65% decrease we saw in the month of March. The data clearly indicate that the impact of the pandemic on patient enrollment in most countries continues to grow. Only China, South Korea and Italy sawa decrease in impact.

Exhibit 1





Rave eCOA

CHALLENGE	SOLUTION
Provide ways for missed or riske visit forms to be remotely lled o t by patients on existing studies.	Medidata's eCOA solution can be used to convert site-based data forms to remote data forms. If study modi cations are made to accommodate this approach, patients can download the patient cloud app from the app store and provide urgent data forms as needed for missed visits. Any Rave EDC study using eCOA can have additional data forms pulled into the eCOA app and made available to patients. Any Rave EDC studies not using eCOA can add eCOA to the project and immediately begin converting forms to remote-enabled forms.

Rave eConsent

CHALLENGE	SOLUTION
Providing remote eConsent on trials that are underway or are starting up.	Currently, our iPad based consent is not set up for BYOD with a patient device. However, remote consent is possible through the use of the legacy Engage (Rave Virtual Trials/Patient Portal) platform and can be supported as a standalone activity. Some integration with Rave EDC is possible, although different usernames and passwords are used for the legacy Engage platform. The primary use case for this technology would be ongoing studies where a remote consent is required to keep the study up and running. In this case, a special instance of the Engage technology could be launched allowing patients to remotely log in and provide consent.

Rave Patient Portal / Rav Virtual Trials

CHALLENGE	SOLUTION
Prepare for COVID-19 studies with self-quarantined patients globally.*	Medidata and 3DS are launching a COVID-19 Screening app as part of Medidata's Patient Portal that can be used as a remote patient symptom tracker in France and the US. This app will function as a registry (in an MVP version) and will allow hospital staff to remotely review symptoms and triage patients to the hospital only when medically necessary. Subsequent versions will enable patients to nd trials and to consent remotely before entering a site that may be performing a study.
***New Medidata Solution**	
Provide rescue and/or new study designs that enable virtualizatio of visits and data capture.	In ongoing studies and/or new study designs, the Rave Patient Portal can be used to virtualize more aspects of the study design. New generation versions of the portal will be released later this year but our existing technology is used today on ongoing virtual trials managing thousands of patients and is a fully functional and validated system for clinical research. In many cases, this version can be modi ed for a study that needs to accommodate r consent, remote randomization, remote data capture, reporting and site access. P app is web-based, it is also easily available for all patients on all types of plat

Acorn AI Synthetic Control Database / 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., Synthetic Control Database (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 profile, but an SCD might improve the analyses above what published literature can provide. In addition, historical trial data can be compared against real-world data from claims or EMRs to provide confidence and validation in trial design, better understand inclusivity of patients populations to better reflect real world clinical practice, and potentially decrease sample size requirements for event-driven trials.
Closing out on-going studies given barriers completing visits.	Leveraging historical clinical trial data to augment or replace control arms of trials that are in danger of high dropout or unfulfilled enrollment due to COVID-19; reduce scientific uncertainty to advance to the next phase, reduce patient enrollment burden or increase statistical power.

Rave Imaging Critical*

CHALLENGE	SOLUTION
As a result of global restrictions, most sponsors are unable to monitor their active studies on site, and may not be able to manage critical document management activities. Some sponsors have turned to FTP, Box, Webex and Email to manage these critical documents. Without the ability to securely manage these documents, patient safety and data integrity are at risk and studies may not progress. **Regulatory guidance allows for sponsors to find ways to perform critical document management and SDR remotely in certain regions, excluding EMEA.** ***New Medidata Solution**	Medidata has tailored its Rave Imaging workflow to enable certain clients to rapidly and remotely deploy a method to assist monitors in their critical document management workflows and Source Document Review (SDR). **Rave Imaging Critical** is a streamlined and quick-to-implement solution (2 weeks go-live) that helps fill the gap when studies have critical timelines and no secure option to collect, manage, review and verify critical study documents. **Rave Imaging Critical:** • Acquires documents, via secure browser-based uploads, routes and manages document workflows to support source document review and verification • Is a 21 CFR Part 11 compliant system that includes the ability to de-identify and redact Personally Identifiable Information (PII) and Protected Health Information (PHI) • Mitigates risk due to site monitoring and patient visit disruption for some studies with no secure option to manage critical documents

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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 shipm… site is closed. Alternately, subjects may be transferred to sites that are open. We have a "T… 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 speci□c steps that can be utilized to ensure off-cycle/unscheduled visits can be conducted without issue.
Supply chain concerns make site want to have more buffer stock o 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.