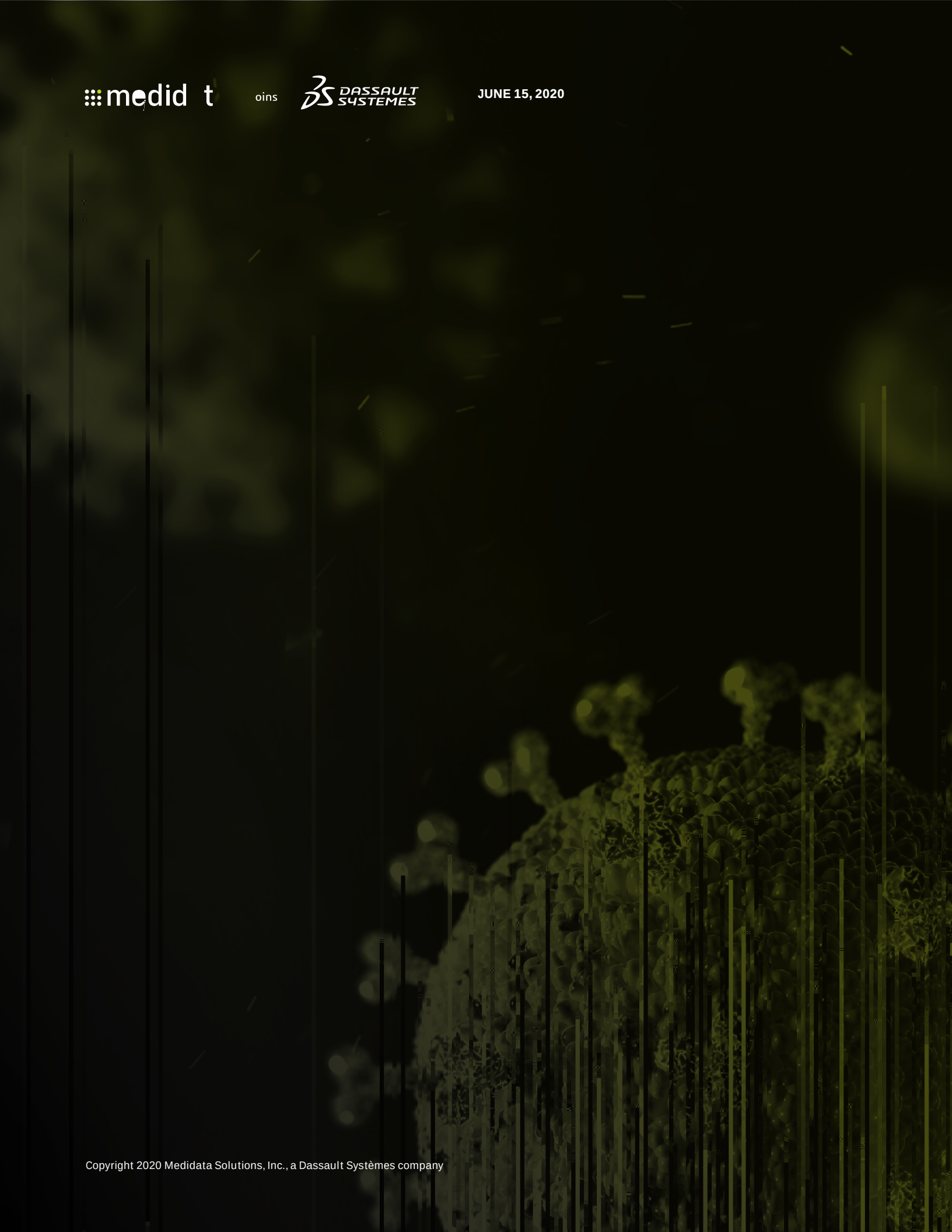

Figure 1: Impact of COVID-19 on New Patients Entering Trials

Regulatory Response

As of June 12, 2020, multiple authorities, including those below, have issued emergency guidance on trial conduct amidst COVID-19. Technology enablement topics including those in Figure 2 and many other topics including protocol deviation management, investigational product handling, protocol amendments, ethics committee review, etc are common areas of discussion by the authorities. As these are updated frequently and are not uniform in scope, duration, and approach, see the applicable guidance for speci□c expectations.

Figure 2: Key Technology Topics Addressed by Regulatory Authorities

Frequently discussed topics include telemedicine/decentralization (see FDA Question 19), consent and eConsent (See FDA FAQ 10 & 11), expectations on electronic records/signatures rules (See FDA FAQ 23), and remote monitoring including remote source data veri□cation (rSDV). Note that while the US FD , aUK MHRhgiuTes(F)35 a-yd7as0H MHRhgiHealth CanaurF,Singapoincludi HSs(

Figure 3: The 10 COVID-19 Vaccines in Clinical Development

Type of Candidate Vaccine	Developer	

Solutions:

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

Solutions:

- Sponsors focused on developing vaccines against, and treatments for COVID-19, must safely and effectively accelerate study start up times through faster investigator budgeting, so cures and treatments can get to market faster

Details on New and Adapted Medidata Solutions

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

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Rave eCOA

CHALLENGE	SOLUTION
Provide ways for missed or risked visit forms to be remotely □lled out 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

myMedidata/ Rave Virtual Trials

CHALLENGE	SOLUTION
Quantify the impact of trial participants with COVID-19 symptoms on ongoing research studies. ***New Medidata Solution**	In late April, Medidata and 3DS launched the **COVID-19 Symptom Tracker*** as part of **myMedidata*** (the Medidata Patient Portal), which will be used as a remote patient symptom tracker. This Tracker will function as a registry (in an MVP version) and will allow sites to remotely monitor and report symptoms of patients in their trials. Learn more about myMedidata and the COVID-19 Symptom Tracker here.

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 pro□le, 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 con□dence and validation in trial design, better understand inclusivity of patients populations to better re□ect 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 unful□lled enrollment due to COVID-19; reduce scienti□c uncertainty to advance to the next phase, reduce patient enrollment burden or increase statistical power.

Rave Coder

CHALLENGE

The coronavirus pandemic has prompted an urgent need for a harmonized, standardized approach to coding and reporting the infection as a global health issue.

SOLUTION

MedDRA Maintenance and Support Services Organization (MSSO) has released an updated version of MedDRA 23.0 with new COVID-19 terms and revisions. The updated MedDRA dictionary will allow organizations to capture, share and analyze scienti□c and medical information for pre-marketing and post-marketing data. Approximately 70 new COVID-19 related terms and revisions were implemented including new High-Level Term (HLT) Coronavirus infections to group relevant COVID-19 infection terms in System Organ Class Infections (SOC) Infections and infestations.

The updated MedDRA 23.0 dictionary is now available to clients using Rave Coder.

Rave RBQM

CHALLENGE

As shelter-in-place requirements

SOLUTION

CHALLENGE	SOLUTION
Restrictions of access to sites by staff and patients has affected the investigators' ability to maintain medical oversight. This has impacted, among other key processes, completion of trial assessments, completion of trial visits, and the provision of Investigational Medicinal Products (IMPs). ***New Medidata Solution**	As the monitoring landscape continues to evolve, ongoing risk assessment should be performed and corresponding modi□cations to existing risk control mechanisms and monitoring strategies a risk assessment should be performed to continually assess the risk to trial participants, data quality, and data ef□cacy. To support industry in performing risk evaluations, Medidata is offering at no charge a **Risk Assessment Template*** to support the development and documentation of monitoring strategies by collecting critical to quality data, mitigation strategies, and risk control mechanisms. A revised version of the Risk Assessment Template has been created following revised regulatory guidance and can be accessed here.
Travel restrictions have impacted the ability of site staff and monitoring resources to perform oversight responsibilities to ensure subject safety and data quality. ***New Medidata Solution**	**Rave CSA Critical*** (Centralized Statistical Analysis) is a customized solution to support sponsor oversight responsibilities by incorporating next-generation analytical tools and algorithms into a quickly implemented solution (<2 weeks go-live) providing: ••

Medidata Remote Source Review*

CHALLENGE

As a result of global restrictions, sponsors are experiencing an inability to adequately monitor their active studies on site, and may not be able to manage critical document acquisition and source document review (SDR) activities. Some have turned to less secure, antiquated, risky tools to manage these critical documents such as fax, email, video and □le sharing software.

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 □nd ways to perform critical document management and SDR remotely via a secure cloud-based viewing portal in certain regions, excluding EMEA

***New Medidata Solution**

SOLUTION

Based on the current FDA Guidance, Medidata has tailored its Rave imaging work□ow tool to enable clients to rapidly and remotely deploy a method to assist monitors in their critical document acquisition, work□ows, and Source Document Review. **Medidata Remote Source Review***

CHALLENGE	SOLUTION
With COVID-19 investigator-initiated studies, there are budget negotiation delays due to the gap between the site's and sponsor's individual cost benchmarks. Disparate data sources for clinical procedure activities and other direct costs at the investigator and site-level can undermine decision-making. There is a need for an independent industry benchmark..	**Rave Grants Manager COVID IIS** enables Sponsors to negotiate investigator-initiated studies quickly using a single, reliable fair market value data source as well as a complexity analyzer. The complexity analyzer calculates benchmarks with industry averages, along with a site's work effort required by the procedures, visits and protocol. This helps sponsors determine fair site payments based on relative study complexity.
Compliance and auditing risks. Lack of internal COVID-19 related data to establish FMV to ensure Sponsors are not overpaying or underpaying sites. *** New Medidata Solution**	Medidata's deep fair market value data provides auditable defensible rates. An audit trail of negotiation activity is retained for reference and compliance with fair market value regulations.

Rave EDC and Rave RTSM

CHALLENGE	SOLUTION
COVID-19 studies need to be up and running quickly.	Rave RTSM with basic EDC forms can be up and running in two weeks for a randomization only study and three weeks with basic trial supply management. Medidata has had multiple COVID-19 studies go from kick-off to live in 3 weeks or less with randomization and trial supply management.

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