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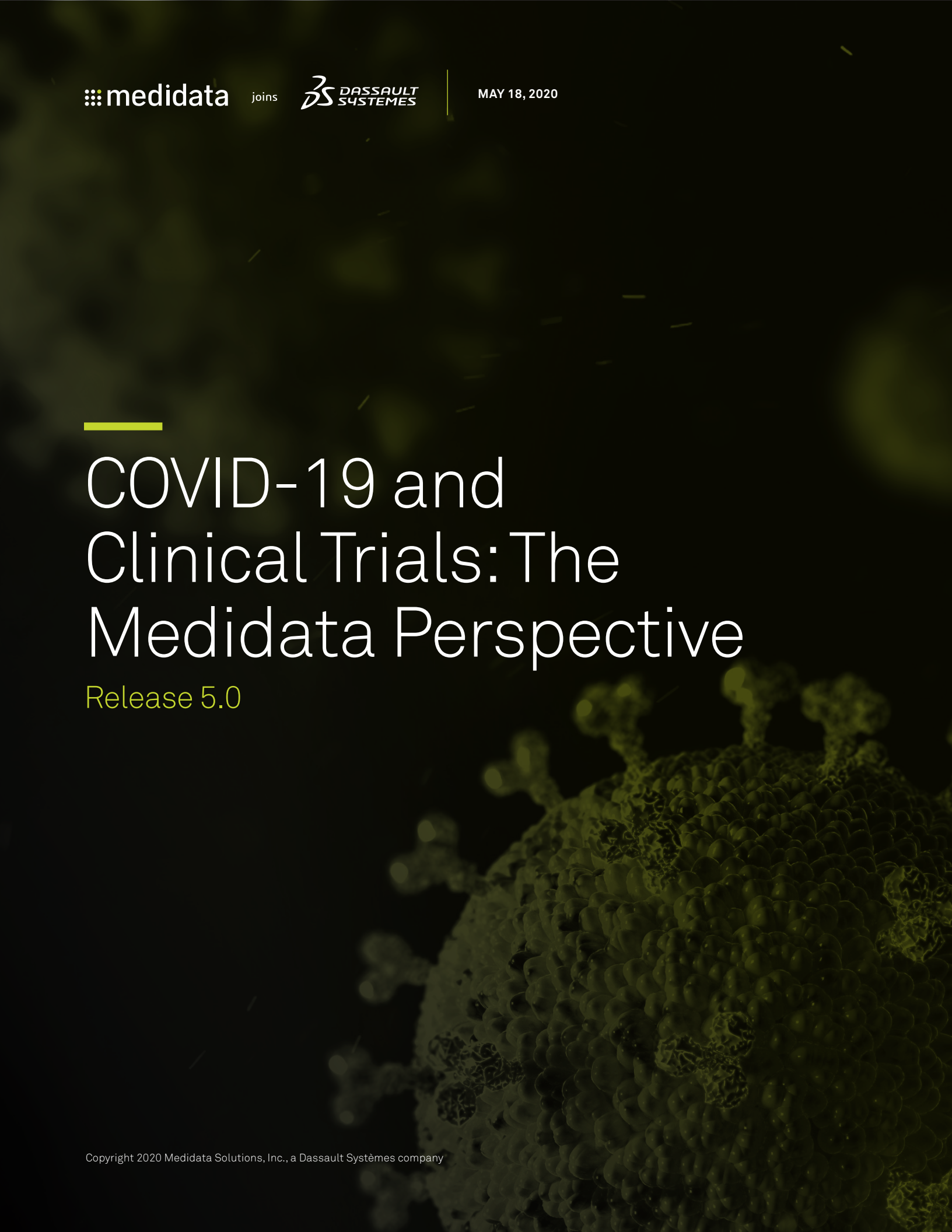
COVID-19 and Clinical Trials: The Medidata Perspective

Release 5.0



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What's New/What's Significantly Updated in Release 5.0

- Updated: Metrics on new patients entering trials by country and therapeutic area (full month data for March and April and first 2 weeks of May
- Updated: Metrics on new patients entering trials by country and therapeutic area (full month data for March and April and first 2 weeks of May
- Updated: Review of the regulatory response/guidance
- Updated: Summary table of the current 8 vaccine clinical trials for COVID-19
- New: TSDV Critical Solution
- Updated: Summary

Insights to Ongoing Data Capture in Clinical Trials

Medidata is continuously monitoring the global impact of COVID-19 on clinical trials. Our first data and insights impact report was released on March 23, with subsequent releases on April 3, April 17 and May 4. Medidata's analysis of the decline 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.

Updates to the April 3, April 17 and May 1 analyses were performed on May 15, and the results for the first two weeks of May are shown next to April (See Figure 1). Currently, the global data shows a 74% decrease in the average number of new patients entering trials per study-site year-over-year during the first two weeks of May compared to the same time frame last year.[1] The impact year-over-year for the first two weeks of May as compared to April is similar, and shows the pandemic continues to have an effect on trial activity and new patients entering trials.

[1] Analysis across 4,667 studies and 186,807 study-sites

Figure 1: Impact of COVID-19 on New Patients Entering Trials (n=385 companies)

		YoY Difference (%) Mar 2020 vs. Mar 2019	YoY Difference (%) Apr 2020 vs. Apr 2019	YoY Difference (%) May 2020 vs. May 2019*
All Countries, All TAs	All	-65.%	-79%	-74%
Asia	China	-68%	-33%	-49%
	India	-84%	-97%	-95%
	Japan	-44%	-69%	-72%
	South Korea	-61%	-42%	-54%
Europe	France	-68%	-81%	-76%
	Germany	-33%	-77%	-81%
	Italy	-53%	-49%	-65%
	Spain	-68%	-82%	-68%
	United Kingdom	-80%	-95%	-100%
North America	United States	-66%	-83%	-73%
Therapeutic Area	Cardiovascular (n=207)	-69%	-95%	-91%
	CNS (n=378)	-68%	-76%	-75%
	Dermatology (n=137)	-64%	-91%	-89%
	Endocrine (n=317)	-81%	-88%	-78%
	ID/Anti-Infectives (n=286)	-47%	-66%	-52%
	Oncology (n=2,190)	-48%	-60%	-58%
	Respiratory (n=110)	-34%	-86%	-81%

Additionally, we are adding an update to the **visit-per-study-subject** analysis in ongoing studies (see Figure 2). In line with the increased impact on new patients entering trials during April year-over-year vs. March year-over-year, we saw a continued decrease in visits per subject for April as compared to October. Overall, the visit rate decreased almost 30% from October to April. This decrease in visit rate is seen across trials, with the sharpest decline seen in the UK and the weakest in Japan. The change in visit rate for oncology and non-oncology participants in April vs. March was comparable.

Figure 2: Impact of COVID-19 on Site Visits

Understanding what is happening on the ground is critical to define a path forward. We will continue to publish updated analyses on overall industry trends throughout this pandemic and beyond.

Regulatory Response

As of May 15, many authorities including the European Medicines Agency (EMA), U.S. Food and Drug Administration (FDA),UK Medicines and Healthcare Products Regulatory Agency (MHRA), Germany (BfArM), France (ansm), Netherlands (ccmo), Ireland (HPRA), Denmark (Sundhedsstyrelsen), Switzerland (swissmedic), Japan (PMDA), South Korea (MFDS), Health Canada, Australia (DoH), and Singapore (HSA), have provided updated emergency guidance on trial conduct during the pandemic. In addition, multiple stakeholder organizations including the Association of Clinical Research Organizations (ACRO) and IRBs (an example here) have issued guidance documents as well. It is clear that regulations and guidance differ from country-to-country.

Activity promoting the use of technology in clinical trials has increased, due to the disruptions and challenges posed by COVID-19. Additionally, regulators and stakeholder groups are demonstrating pragmatism and flexibility in terms of mitigating issues when possible. Topics include: triggers for protocol amendments and deviation processes, risk assessment expectations, continuing or halting a trial, continued subject participation, telemedicine (FDA Question 19 May 11 Update), Consent and eConsent (FDA FAQ 10 & 11), and remote monitoring. Note that while the US FDA, UK MHRA, Australia DoH, Health Canada, and Singapore HSA suggest remote source data verification is possible, the EMA leaves it as an option in very limited circumstances (Section 11 and Annex). Centralized monitoring activities are suggested by most regulators, however.

For more detailed information on the global regulatory responses to the impact of COVID-19 on clinical studies, visit Medidata's blog 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.

As of April 3, several large pharmaceutical (Pfizer, Bristol Myers Squibb and Eli Lilly)[2] and smaller biotechnology companies (Moderna Therapeutics[3], Iveric Bio[4], Aslan[5], Provention Bio[6] and Addex[7]) have announced that they are modifying their R&D plans. Typical modifications in certain trials are some form of temporary delay in site activation and/or patient enrollment. The impact of COVID-19 on trial success is already an issue, as evidenced by Aveo Pharmaceuticals Inc., which cited COVID-19 as a reason for the study failure of ficlatuzumab in acute myeloid leukemia.[8] These growing examples of trial delays or stoppages by biopharma companies to mitigate the cost and impact of the pandemic dramatically highlight the need for rapid, innovative solutions to help trials successfully start, continue, and finish.

[2] https://www.fiercebiotech.com/biotech/covid-19-prompts-pfizer-to-stop-enrollment-most-studies. Accessed April 4, 2020
[3] https://www.fiercebiotech.com/biotech/covid-19-causes-moderna-to-pause-a-clutch-clinical-trials. Accessed April 4, 2020.
[4] https://www.fiercebiotech.com/biotech/iveric-bio-latest-to-be-hit-by-covid-19-as-it-delays-a-key-trial. Accessed April 19, 2020
[5] https://www.fiercebiotech.com/biotech/covid-19-outbreak-prompts-provention-to-pause-diabetes-trial. Accessed April 19, 2020
[6] https://www.fiercebiotech.com/biotech/covid-19-outbreak-prompts-provention-to-pause-diabetes-trial. Accessed April 19, 2020
[7] https://www.fiercebiotech.com/biotech/swiss-bio-addex-halts-parkinson-s-test-as-trial-delays-tick-up-covid-19-disruption. Accessed April 19, 2020
[8] https://www.reuters.com/article/brief-aveo-oncology-and-biodesix-to-disc/brief-aveo-oncology-and-biodesix-to-discontinue. Accessed April 4, 2020

The future of global public health is dependent on the scientific and medical communities' ability to develop readily available, accurate, and rapid virus and antibody tests and to discover highly effective vaccines to further prevent spread of the virus as well as mitigate the likelihood that it will reappear. As of May 15, according to the World Health Organization, there are 110 vaccine candidates in preclinical development and 8 candidate vaccines for COVID-19 in clinical evaluation. An abridged summary of these vaccines in clinical evaluation[9] is outlined in Figure 3 below.

Figure 3: The 8 COVID-19 Vaccines in Clinical Development

Type of Candidate Vaccine	Developer	Current stage of clinical evaluation/ regulatory status - Coronavirus candidate
Adenovirus Type 5 Vector	CanSino Biological Inc./ Beijing Institute of Biotechnology	Phase 2 ChiCTR2000031781 Phase 1 ChiCTR2000030906
LNP - encapsulated mRNA	Moderna/NIAID (*FDA fast track)	Phase 2 (IND accepted) Phase 1 NCT04283461
Inactivated	Wuhan Institute of Biological Products/Sinopharm	Phase 1/2 ChiCTR2000031809
Inactivated	Beijing Institute of Biological Products/Sinopharm	Phase 1/2 ChiCTR2000032459
Inactivated + alum	Sinovac	Phase 1/2 NCT04352608
ChAdOx1	University of Oxford	Phase 1/2 NCT04324606
3 LNP - mRNAs	BioNTech/Fosun Pharma/Pfizer	Phase 1/2 2020-001038-36 NCT04368728
DNA plasmid vaccine with electroporation	Inovio Pharmaceuticals	Phase 1 NCT043364101

[9] https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines. Accessed May 15, 2020.

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 **four** 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 QUALITY AND SUPPLY

Solutions:

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

CHALLENGE 4: ACCELERATING STUDY START UP

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.

CHALLENGE 1: UNDERSTANDING THE EVOLVING SITUATION

Acorn AI Intelligent Trials

CHALLENGE	SOLUTION
Understanding the country/site/ disease area impact across the industry, and developing risk mitigation and recovery plans	**COVID-19 Trial Impact Analytics***: 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. **Real-time Situation Insights:** Inform critical decisions on where to focus efforts by benchmarking impact of COVID-19 on own trials vs. industry • Assess impact of COVID-19 on own trials and compare to industry via standard dashboards • Understand weekly and monthly trends, and year-over-year performance for subject accrual, visits and data quality measures • Views at portfolio, study, country/region and site level **Impact & Recovery Forecasting:** Plan ahead by understanding leading indicators of slowdown and recovery at a country and site level • Track country/region and site level performance to understand countries and sites that are coming back on-line • Overlay trends in COVID-19 testing and infection rates with impact on trials to identify leading indicators of recovery at a country / region / site level

***New Medidata Solution**

CHALLENGE 2: RECONSIDERING TRIAL DESIGN TO ENABLE DATA CAPTURE

Rave eCOA

CHALLENGE	SOLUTION
Provide ways for missed or risked visit forms to be remotely filled 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 modifications 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 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 Coder

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

CHALLENGE 3: MAINTAINING QUALITY AND SUPPLY

Rave RBQM

CHALLENGE

As shelter-in-place requirements are relaxed and travel restrictions are lifted, the on-site monitoring activities that have been placed on pause will resume. Challenges with limited onsite capacity, limited site staff, safety precautions, and increased demand for onsite monitoring visits sites will inevitably have to limit the number of days that CRAs are allowed onsite.

Therefore, sponsors and CROs must quickly determine the current risks to subject safety and data integrity with as little impact to the site as possible.

***New Medidata Solution**

SOLUTION

The industry has traditionally relied heavily on on-site monitoring including significant amounts of Source Data Review (SDV) to ensure subject safety and generate quality data. This approach is highly resource intensive, costly, and has been found to have minimal impact on the quality of the clinical investigation when compared to less resource-intensive approaches.

It's well supported that 100% SDV has a negligible effect on data quality. A reduced SDV methodology has been increasingly encouraged by TransCelerate & global regulatory authorities. Applying a risk-based approach to reduced SDV enables sponsors and CROs to quickly navigate monitoring backlog resulting in earlier indications of potential subject safety, data quality issues, and study risks.

Medidata has enabled **targeted source data verification** through a new COVID-19 focused offering, **TSDV Critical***, to support sponsors and CROs in delivering quality data in a time effective and cost efficient method:

- Regulatory supported method for identifying critical data to perform reduced SDV
- Targeted critical data to focus attention
- Fully auditable solution
- Elimination of manual CRA determination of monitoring requirements
- Real-time reporting capabilities for sponsor and CRO oversight responsibilities
- Cost effective method for reduction in labor intensive onsite monitoring activities

Medidata offers consulting services to support to support a streamlined implementation process :

- COVID-19-specific Risk Management
- Streamlined Block/Tier plan based on study risk
- TSDV best practices guide
- Sample text for inclusion with monitoring (functional) plan for:
  - Supporting a reduced SDV approach
  - Guidance on training for monitors

Restrictions of access to sites by staff and patients may affect the investigators' ability to maintain medical oversight. This may impact, among other key processes, completion of trial assessments, completion of trial visits, and the provision of Investigational Medicinal Products (IMPs).

***New Medidata Solution**

Prior to making modifications to existing risk control mechanisms and monitoring strategies a risk assessment should be performed to establish the risk to trial participants, data quality, and data efficacy. 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.

CHALLENGE	SOLUTION
Travel restrictions are impacting the ability of site staff and monitoring resources to perform oversight responsibilities to ensure subject safety and data quality.	**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: • Real-time data availability for proactive early data oversight • Focused Key Risk Indicators (KRI) on areas of greatest risk • Remote management of site processes to mitigate risk • Detection of data patterns and anomalies • Automated insights into subject safety, data integrity, and site performance • Mitigation of risk due to site monitoring and patient visit disruption These allow for increased efficiency in data review and centralization of review activities and risk/issue detection - a critical capability that can maintain and support sponsor oversight responsibilities and allow earlier access to data and enhance key decisions making capabilities.
***New Medidata Solution**	

Rave Imaging

CHALLENGE	SOLUTION
As a result of global restrictions, most sponsors are experiencing an inability to adequately monitor their active studies on site, and may not be able to manage critical document acquisition and SDR activities. .Some have turned to less secure, antiquated, risky tools to manage these critical documents such as fax, email, video and file 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 find ways to perform critical document management and SDR remotely via a secure cloud-based viewing portal in certain regions, excluding EMEA.** ***New Medidata Solution**	Based on the current FDA Guidance, Medidata has tailored its Rave imaging workflow tool to enable clients to rapidly and remotely deploy a method to assist monitors in their critical document acquisition, t workflow, 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, de-identify, manage, review and verify critical study documents. Easy to get started with no software to download, is available at no cost to the sites, and can be used as a primary solution or alternative for sites. **Rave Imaging Critical:** • Acquires documents, via secure browser-based uploads, routes and manages document workflows to support source document review and verification remotely • 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

Rave EDC and Rave RTSM

CHALLENGE	SOLUTION
Patients can't get to the site for dispensation but the site is open.	Sites can process dispensation through Rave EDC as a visit and send the drug to the subject via a courier. Rave EDC could be updated to store the courier tracking number (collected as text data). Adding a new field would require a migration in Rave EDC.
Patients can't get to the site for dispensation - sites are open but do not have supply for dispensation.	There are several options to have drug sent to the patient from the depot or a central pharmacy. In Rave RTSM (randomization and trial supply management), the subject has to exist at the site where the drug supply is located. There are several options we are executing to manage transferring subjects and creating dummy shipments to allow a shipment to be sent to the patient's home from a location other than the site. We're able to work with study teams to help set up the best option based on the study design and logistic considerations.
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).	Supply plans can be instantly adjusted by end users to meet the changing needs of individual study sites. To ensure that the site is stocked with additional drug to service a larger number of visits, the maximum buffer can be increased or the long window extended. Alternatively, a supply plan can also be adjusted to maintain less inventory by shortening the long window or reducing the maximum buffer. The site can also be deactivated for shipping in the case of a closed site or dispensations occurring from alternate sites.

CHALLENGE 4: ACCELERATING STUDY START-UP

Rave Grants Manager

CHALLENGE	SOLUTION
Budgeting for the investigator-initiated studies (IIS) is different from a normal trial. IIS trial budgets are typically built as small cost buckets, with the sites (not the sponsor) indicating what the costs are and what they want the Sponsor to pay. This approach causes delays in getting approval from the sponsor as a more granular activity level budget is needed. The sponsor will also need reliable data to verify that the costs are fair.	Medidata has developed a COVID19 vaccination study budgeting solution, **Rave Grants Manager COVID IIS***, to help investigator- initiated studies develop detailed trial budgets for patient, procedure and site costs. Leveraging Medidata's deep fair market value data and our clinical trial budgeting expertise, Sponsors can streamline the budget build process for their sites.
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.	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.

*** New Medidata Solution**

Rave EDC and Rave RTSM

CHALLENGE	SOLUTION
COVID studies need to be up and running quickly.	Rave RTSM with basic EDC forms can be up and running in as little as two weeks for a randomization only study and as little as three weeks with basic trial supply management. We recently had a COVID study go from kick-off to UAT in 12 days with randomization and trial supply management.

Summary

At this moment in the COVID-19 pandemic, we find ourselves at an inflection point. After several months of lockdown, we're seeing nations, regions and municipalities begin to try to re-open their economies, while keeping a watchful eye on disease progression. Some countries are reopening while the infection rate continues to rise; others are moving with greater caution. Countries including South Korea, Lebanon and Germany are reintroducing lockdowns, after attempts to reopen led to more outbreaks. The U.S. is a patchwork, with widely different reactions and responses across the country.

What to Watch: This newly complex picture makes it even more vital that we at Medidata continue to monitor clinical trial activity by country and by site, and provide up-to-date information to our customers and partners. Time – and data – will tell us how the efforts to relax quarantines will impact drug development and discovery.

We are committed to providing this data to our stakeholders, along with relevant updates from a regulatory perspective. And you can count on us to continually innovate to identify new solutions designed to help further clinical research.

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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