
COVID-19 and Clinical Trials: The Medidata Perspective

Release 6.0

Table of Contents

What's New/What's Significantly Updated in Release 6.0	3
Insights to Ongoing Data Capture in Clinical Trials	3
Regulatory Response	5
Impact to Medidata Customers, Patients and Trials	6
The Race for a Vaccine	7
Medidata Solutions to Assist Sponsors/Partners, Patients and Trials	9
Details on New and Adapted Medidata Solutions	10
Summary	17

What's New/What's Significantly Updated in Release 6.0

- Updated: Metrics on new patients entering trials by country and therapeutic area (March, April and May)
- Updated: Regulatory Response
- New section: The Race for a Vaccine.
- Updated: Summary table of the current 10 vaccine clinical trials for COVID-19
- New: Graphical Representation of COVID-19 Vaccination Trials
- 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, May 4, May 18, and June 15. After an initial steep decline in clinical trial activity, both in terms of new patients entering clinical trials and visit rate per subject for ongoing trials, we are now starting to see a leveling off of the impact and regional fluctuations. We expect COVID-19 to continue to impact trials, at different times and with varying force across the globe. With that in mind, we will continue to monitor the impact on clinical trials.

Updates to the April 3, April 17 and May 1 analyses were performed on June 10 and the results for the full month 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 May 2020 compared to the same time frame last year¹. The impact year-over-year for May as compared to April is similar, with some countries experiencing an increased impact again in May (e.g., China, South Korea, Italy) vs. April, and some a slight recovery (e.g., France, Spain, US). This underscores the need to continue to track impact at a regional level to help decide when and where to focus trial efforts, as the pandemic continues to have an effect on trial activity.

¹ Analysis across 4,667 studies and 187,115 study sites

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

		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%	-47%
	India	-84%	-97%	-95%
	Japan	-44%	-69%	-74%
	South Korea	-61%	-42%	-56%
Europe	France	-68%	-81%	-71%
	Germany	-33%	-77%	-74%
	Italy	-53%	-49%	-58%
	Spain	-68%	-82%	-65%
	United Kingdom	-80%	-95%	-98%
North America	United States	-66%	-83%	-74%
Therapeutic Area	Cardiovascular	-69%	-95%	-92%
	CNS	-68%	-76%	-76%
	Dermatology	-64%	-91%	-91%
	Endocrine	-81%	-88%	-73%
	ID/Anti-Infectives	-47%	-66%	-64%
	Oncology	-48%	-60%	-53%
	Respiratory	-34%	-86%	-78%

Understanding what is happening on the ground is critical to define a path forward. Medidata will publish monthly updated analyses throughout this pandemic.

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 specific expectations.

Figure 2: Key Technology Topics Addressed by Regulatory Authorities

Authority w/Link	Monitoring	eConsent	Telemedicine / decentralization	Direct IP Shipment to Patients
Europe EMA (v3 28Apr)	✓	✓	✓	✓
U.S. FDA (03Jun)	✓	✓	✓	✓
U.K. MHRA (21May)	✓			✓
Germany BfArM (v3)	✓		✓	✓
France ansm (20May)	✓		✓	✓
Netherlands CCMO (26May)	✓			✓
Ireland HPRA (v6 28May)	✓			✓
Italy AIFA (7Apr)	✓			✓
Denmark Sundhedsstyrelsen (v5.1 24Apr)	✓		✓	✓
Switzerland swissmedic (v2.1 7Apr)	✓	✓	✓	✓
Japan PMDA (27May)	✓	✓	✓	✓
South Korea MFDS (26Mar)				
Health Canada (3Apr)	✓	✓	✓	✓
Australia DoH (9Apr)	✓	✓	✓	✓
Singapore HSA (27Mar)	✓		✓	✓
China CDE (30Apr- Draft)	✓	✓	✓	
Turkey TMMDA (31Mar)	✓		✓	

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 verification (rSDV). Note that while the US FDA, UK MHRA, Australia DoH, Health Canada, and Singapore HSA suggest rSDV is possible, the EMA leaves it as an option in very limited circumstances ([Section 11 and Annex](#)) and some outright discourage it including Germany and France. Centralized monitoring activities are suggested by most regulators, however.

The regulatory appetite for making COVID flexibilities extend beyond the pandemic is uncertain but there is reason to believe change is possible. For instance, US FDA Commissioner Hahn's June 1 [remarks](#) "The COVID-19 Pandemic — Finding Solutions, Applying Lessons Learned" indicated a desire to make some of the changes (i.e. accelerated receptiveness to trial decentralization, master protocols, real world evidence) endure beyond the pandemic.

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.

Large pharmaceutical (Pfizer, Bristol Myers Squibb and Eli Lilly)² and smaller biotechnology companies (Moderna Therapeutics³, Iveric Bio⁴, Aslan⁵, Provention Bio⁶ and Addex⁷) 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 impact of the pandemic on sites was well documented by a survey of over 1,000 clinical site personnel performed by Medidata in late April 2020. Not unexpectedly, the survey results clearly and dramatically show that most sites are feeling the negative impact of the pandemic on current and future trials, specifically around delays in patient enrollment and recruitment. They also are concerned about the impact of trial delays and cancellations on their financial well-being. Over two-thirds of respondents indicated that they have halted, or will soon halt, patient recruitment for ongoing trials, a third are halting randomization, and about half are now delaying or will be delaying their studies. Sites have shown flexibility and ingenuity in adopting new approaches. Over half of sites are switching site patient visits to virtual ones and/or are using telemedicine to interact with patients. The detailed results of the survey can be reviewed [here](#).

Other COVID-19 clinical trial impact surveys (mostly focused on oncology trials) by the Cancer Research Institute, IQVIA⁹ and The American Society of Clinical Oncology¹⁰ demonstrated similar results.

The Race for a Vaccine

The US federal government recently selected five companies as the most likely candidates to produce a vaccine for COVID-19, in an effort to start widespread inoculation of Americans by the end of the year. The project is called Operation Warp Speed.

The five companies are Moderna, which will enter Phase III trials targeting 30,000 subjects in July; the combination of Oxford University and AstraZeneca, on a similar schedule; and Johnson & Johnson, Merck and Pfizer. Each is taking a somewhat different approach.

Moderna, Johnson & Johnson and the Oxford-AstraZeneca group have already received a total of \$2.2 billion in federal funding to support their vaccine programs. Their selection as finalists, along with Merck and Pfizer, will give all five companies access to additional government money, help in running clinical trials and financial and logistical support for a manufacturing base. If all five companies reach Phase III trials, around 150,000 people, mostly Americans of all ages, some with underlying comorbidities, would ultimately be the trial subjects for a vaccine.¹¹

In addition to the United States, other countries, including China, are accelerating their own efforts to produce a vaccine.

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 June 12, according to the World Health Organization, there are 126 vaccine candidates in preclinical development and 10 unique candidate vaccines for COVID-19 in 15 clinical trials.¹² An abridged summary of these vaccines in clinical evaluation is outlined in Figure 3 below and represented graphically in Figure 4.

⁹ <https://www.nature.com/articles/d41573-020-00093-1>

¹⁰ <https://www.asco.org/sites/new-www.asco.org/files/content-files/blog-release/pdf/2020-asco-covid19-clinical-trial-site-survey-manuscript.pdf>

¹¹ <https://www.nytimes.com/2020/06/03/us/politics/coronavirus-vaccine-trump-moderna.html>. Accessed June 12, 2020

¹² <https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines>. Accessed June 12, 2020.

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

Type of Candidate Vaccine	Developer	Current stage of clinical evaluation/ regulatory status - Coronavirus candidate
ChAdOx1-S	University of Oxford/AstraZeneca	Phase 2b/3 2020-001228-32 Phase 1/2 2020-001072-15
Adenovirus Type 5 Vector	CanSino Biological Inc./ Beijing Institute of Biotechnology	Phase 2 ChiCTR2000031781 Phase 1 ChiCTR2000030906
LNP-encapsulated mRNA	Moderna/NIAID	Phase 2 NCT04405076 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 NCT04383574 NCT04352608
Full length recombinant SARS CoV-2 glycoprotein nanoparticle vaccine adjuvanted with Matrix M	Novavax	Phase 1/2 NCT04368988
3 LNP-mRNAs	BioNTech/Fosun Pharma/Pfizer	Phase 1/2 2020-001038-36 NCT04368728
Inactivated	Institute of Medical Biology , Chinese Academy of Medical Sciences	Phase 1 NCT04412538
DNA plasmid vaccine with electroporation	Inovio Pharmaceuticals	Phase 1 NCT04336410

Figure 4: Graphical Summary of COVID-19 Vaccine Candidates by Phase



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

Understanding the country/ site/ disease area impact across the industry, and developing risk mitigation and recovery plans.

***New Medidata Solution**

SOLUTION

Trial Impact Analytics*: COVID-19 tracking and forecasting powered by 6,000 active and 20,000 overall industry trials

Real-Time Situation Tracking: inform critical decisions by monitoring the impact of COVID-19 on enrollment, data collection and visits

- Standard reports to track impact of COVID-19 for customer and across the industry
- Trends and YoY comparisons, updated weekly
- Views at study, portfolio, country, region, and site level

Impact Forecasting: track leading indicators of slowdown and recovery to plan ahead

- Overlay trends in COVID-19 testing and infection rates with impact on trials
- Identify markers of recovery at a country and region level

CHALLENGE 2: RECONSIDERING TRIAL DESIGN TO ENABLE DATA CAPTURE

Rave eCOA

CHALLENGE

Provide ways for missed or risked visit forms to be remotely filled out by patients on existing studies.

SOLUTION

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

Quantify the impact of trial participants with COVID-19 symptoms on ongoing research studies.

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](#).

*New Medidata Solution

Acorn AI Synthetic Control Database / Trial Design

CHALLENGE

Improving understanding of safety in experimental treatments (e.g., chloroquine) that are now under review for cross-indication use.

SOLUTION

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

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 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 were placed on pause have resumed. Despite these changes to travel restriction, historical monitoring activities have not yet returned to what was seen pre-COVID. Challenges are seen with limited onsite capacity, limited site staff, safety precautions, and increased demand for onsite monitoring visits sites has resulted in a limited 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.

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 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

***New Medidata Solution**

CHALLENGE

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**

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**

SOLUTION

As the monitoring landscape continues to evolve, ongoing risk assessment should be performed and corresponding modifications 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 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](#).

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.

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 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

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, workflows, and Source Document Review. **Medidata Remote Source Review*** 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.

Medidata Remote Source Review:

- 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

Patients can't get to the site for dispensation - sites are open but do not have supply for dispensation.

*New Medidata Solution

Patients can't get to the site for dispensation but the site is open.

SOLUTION

Direct to Patient Supply Management*

Rave RTSM can now be configured to send investigative product directly from the Depot to the patient's home. Upon registering a dispensing visit, Rave RTSM sends a shipment request notification to the depot including the SubjectID, and the depot can send the dispensed items straight to the subject's home or office.

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.

CHALLENGE

Sites are closed and patients need a dispensation.

Subjects are able to have an onsite visit but future visits are questionable.

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).

SOLUTION

Subjects may be transferred to sites that are open, or if site users are able to work remotely they can register a visit in Rave EDC that is configured in RTSM to be Direct to Patient and have the dispensed items shipped from the Depot to the patient's home.

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 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 COVID IIS*

CHALLENGE

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.

SOLUTION

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.

CHALLENGE

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..

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

Rave EDC and Rave RTSM

CHALLENGE

COVID-19 studies need to be up and running quickly.

SOLUTION

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.

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.

SOLUTION

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.

Summary

We've reached a new phase in the COVID-19 pandemic, where many parts of the world are accelerating the reopening of their economies while the virus continues to rage. In many places the rate of new infections has declined; in others it continues to rise. Hospitalizations have been on the rise in at least nine U.S states just since the Memorial Day weekend holiday, and a facility in Maine that produces tests for Abbott Labs just became the site of a viral outbreak. Unpredictability and uncertainty have become the new norms. The World Health Organization (WHO) has had to clarify its statement about asymptomatic spread. Consistency in reporting continues to be a challenge across the globe. Brazil just resumed publishing their COVID-19 data after a court ruling. And the recent and extreme social unrest could potentially lead to a significant uptick in new cases; time will tell.

What to Watch: In the clinical trials ecosystem, we continue to see impacts on patient recruitment and retention as at-risk patients maintain quarantine while vaccines and therapies are in development.

The response to these challenges has been the increased use of and reliance on solutions like remote monitoring and trial virtualization. Interestingly and importantly, these may not be transitory solutions to an immediate problem; rather they may more and more become the standard.

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 1,500 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](https://twitter.com/medidata). The Operating System for Life Sciences™.

Medidata, Medidata Rave and Acorn AI are registered trademarks of Medidata Solutions, Inc., a wholly owned subsidiary of Dassault Systèmes. info@medidata.com | +1 866 515 6044