
COVID-19 and Clinical Trials: The Medidata Perspective

Release 9.0

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What's New/What's Significantly Updated in Release 9.0

- Updated: Metrics on new patients entering trials by country/region and therapeutic area by month
- Updated: Regulatory Response
- Updated and New: Ongoing Impact to Medidata Customers, Patients and Trials - Results of 2nd Site Survey on Impact of COVID-19 to Sites
- Updated: Discovering a Vaccine
- Updated: Summary Table of the current vaccine clinical trials for COVID-19
- Updated: Graphical Representation of COVID-19 Vaccination Trials
- Updated: New and Adapted Medidata Solutions to Assist Sponsors/CROs and Patients in Mitigating the Impact of the COVID-19 Pandemic on their Clinical 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, June 15, July 13, August 12 and now September 11. At the beginning of the pandemic, we were looking at year-over-year changes to understand and grasp the magnitude of COVID-19 on the impact on clinical trials in terms of trial activity, across geographies and therapeutic areas (TAs). As reported in Release 6.0, we had started to see a leveling off of the impact and regional fluctuations. After we aggregated several months of data, we pivoted to help the industry better understand the changes over time at the geographic and TA level, and enable real-time decision making.

Our data and methodology continues to be improved over time, and as such there may be some variability from report to report. Overall trends, however, remain the same. Below, you can find an updated analysis of trial activity as measured by the average number of new patients entering trials per study-site. As we mentioned in our last release, the negative effects of COVID-19 on new patients entering study-sites are likely understated as we are looking at trials that are still actively recruiting patients. 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 highlight insights from Medidata's cross-industry data. This analysis included 5,222 studies, 198,120 study-sites.

Globally, we saw a decline in new patients entering trials per study-site at the end of August, at -20% of pre-COVID baseline, as compared to about -10% for July. Recovery continues to vary greatly by geographic region and TA, due to the varying impact of the disease, and policies and responses adapted over time.

Within Europe itself, the UK saw some improvement, moving from -60% in July to -40% in August compared to its pre-COVID baseline. France and Spain have seen a continued worsening from July to August, with a sharp increase in case rates. Italy this month also experienced a reversal in recovery, with new patient flow at April/May levels.

In Asia, we have seen a reversal of the improvement we witnessed in July for China and Japan. Korea also has seen a dip in new patient flow in August. The exception is India, which is continuing a slow recovery.

In the US, we also saw a slight worsening in new patients entering trials as compared to July - this is despite a decrease in case rate as compared to July. For the first time in months, Oncology in the US experienced a decrease in new patient flow, with August at -10% of pre-COVID levels. See Figure 1 for more details.

Globally, from a therapeutic area (TA) perspective the impact has varied as well, with most TAs experiencing a downturn in August, including Oncology - similarly to what we saw in the U.S. Cardiovascular, however, saw an improvement in August, moving from -49% in July to -20% in August as compared to its pre-COVID baseline. Overall, non-oncology TAs are at -31% of their pre-COVID 2019 baseline.

The differing impact on TAs and geographic regions, as well as the continued fluctuations, underscore the need to continue to track impact real-time at a granular level, so that we can enable companies to make the best decisions on when and where to focus efforts, help them continue to run their trials and get treatments to patients. See Figure 2 for more details.

Figure 1: Change in new patients entering study-sites by region

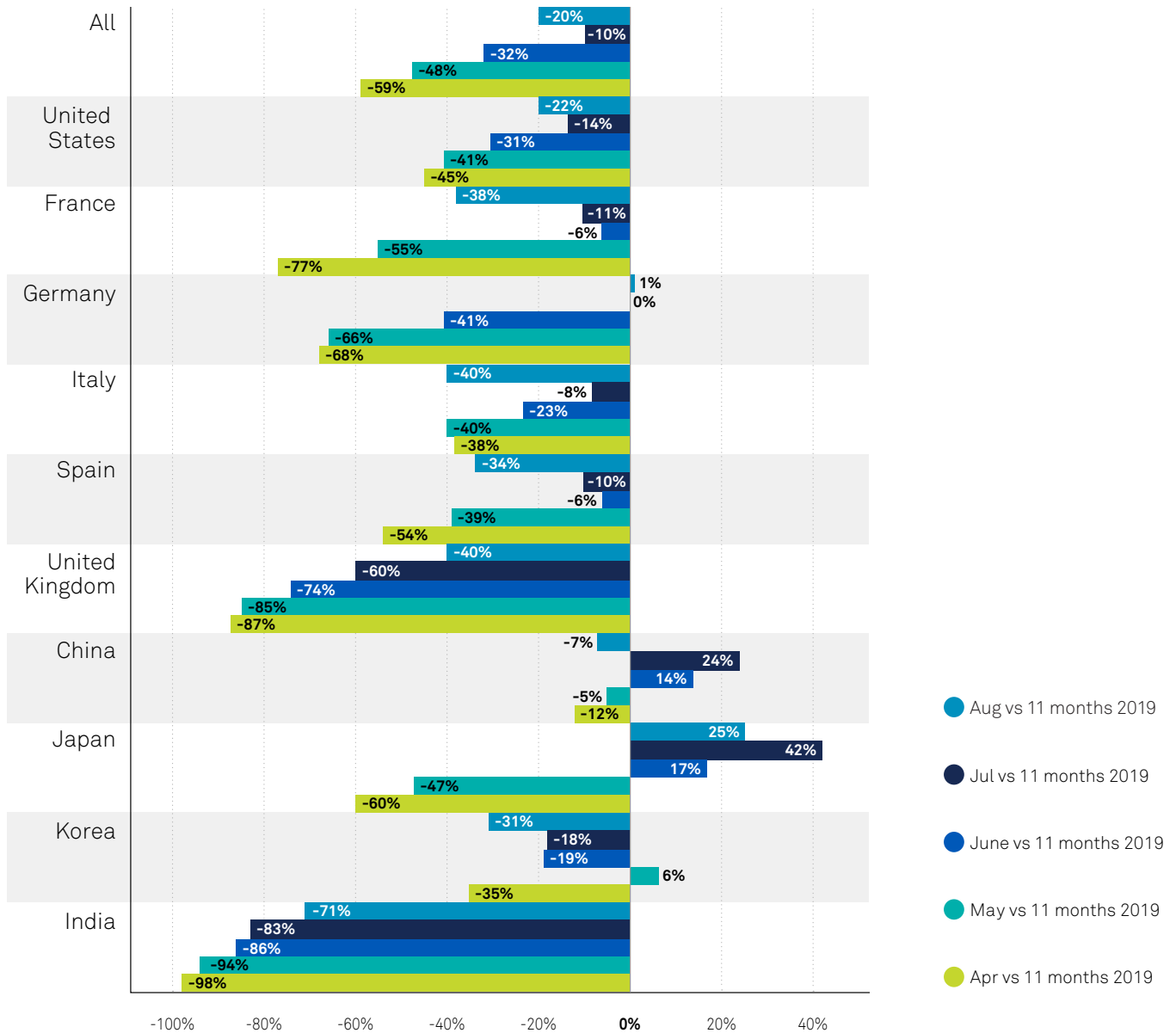
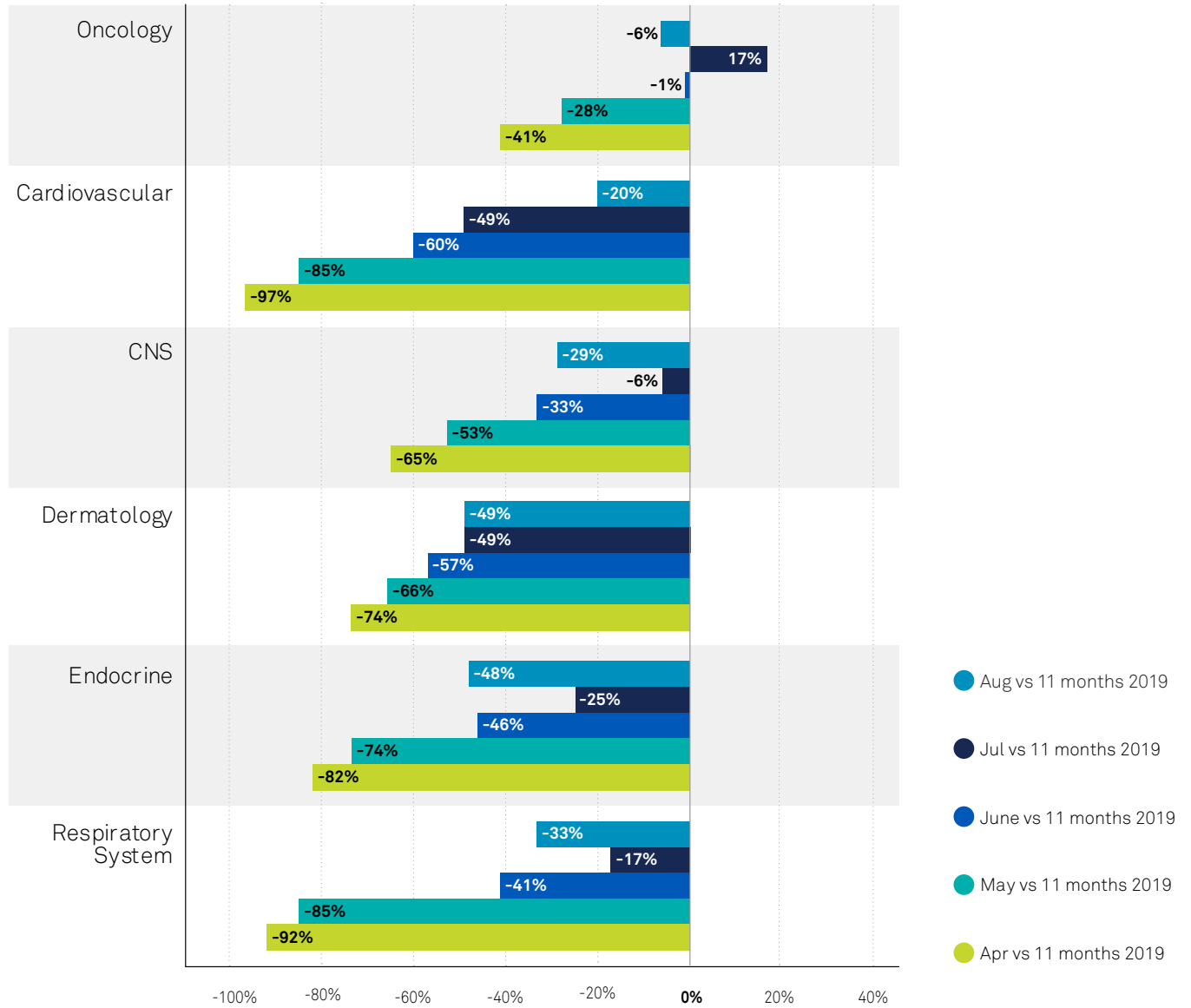


Figure 2: Change in new patients entering study-sites by TA



Regulatory Response

Over the past months multiple authorities, including those below, have issued emergency guidance on trial conduct amidst COVID-19. Technology enablement topics including those in Figure 3 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 3: Key technology topics addressed by regulatory authorities

Authority w/Link	Monitoring	Consent	Telemedicine / Decentralization	Direct IP Shipment to Patients
Europe EMA (v3 28Apr)	✓	✓	✓	✓
Denmark Jul 02: Sundhedsstyrelsen v 6.0)	✓		✓	✓
France ansm (08Aug)	✓		✓	✓
Germany BfArM (v3)	✓		✓	✓
Ireland HPRA (v6 28May)	✓			✓
Italy AIFA (7Apr)	✓		✓	✓
Netherlands CCMO (26May)	✓			✓
Switzerland swissmedic (v2.2 15Jun)	✓	✓	✓	✓
Turkey TMMDA (31Mar)	✓		✓	
U.K. MHRA (21May)	✓			✓
North America				
U.S. FDA (02Jul)	✓	✓	✓	✓
Canada Health Canada (05Aug)	✓	✓	✓	✓
Asia/Australia				
Australia DoH (9Apr)	✓	✓	✓	✓
China NMPA CDE (14July)	✓	✓	✓	✓
Japan PMDA (27May)	✓	✓	✓	✓
Singapore HSA (29July)	✓	✓	✓	✓
South Korea MFDS (26Mar)				✓

Frequently discussed topics include telemedicine/decentralization (see FDA Question 20), consent and eConsent (See FDA FAQ 10 and 11), expectations on electronic records/ signatures rules (See FDA FAQ 24), and remote monitoring including remote source data verification (rSDV) (See Question 14). 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. Additional information may be found in Medidata's regulatory [blog](#).

Ongoing Impact to Medidata Customers, Patients and Trials

COVID-19 SITE SURVEY 1.0 - APRIL 2020

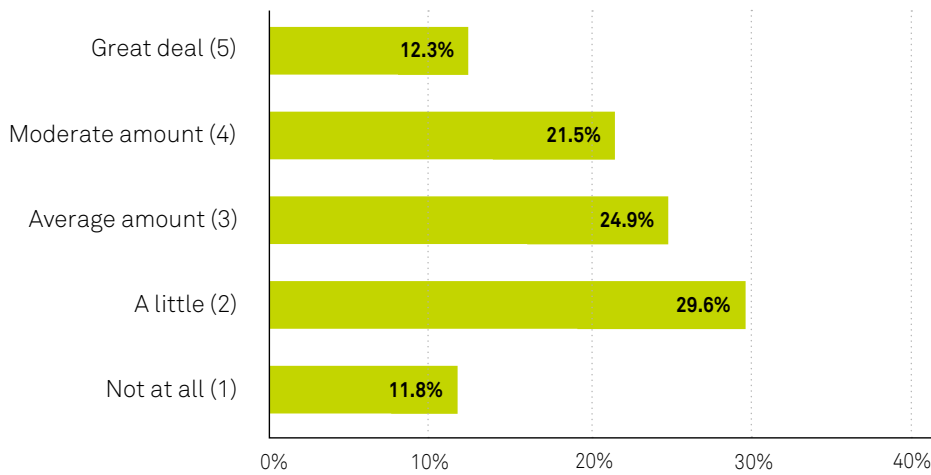
The impact of the pandemic on sites was well documented by a survey of over 1,000 clinical site personnel performed by Medidata in late April 2020. Not unexpectedly, the survey results clearly and dramatically show that most sites are feeling the negative impact of the pandemic on current and future 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](#).

COVID-19 SITE SURVEY 2.0 - AUGUST 2020

A follow up survey of sites was sent to over 7,000 sites during the first week of August 2020. Preliminary results of the 734 respondents indicate that sites are coping better with the pandemic now than when we surveyed them in April. Slightly over half of the respondents were from the United States and the vast majority of respondents were study coordinators or investigators.

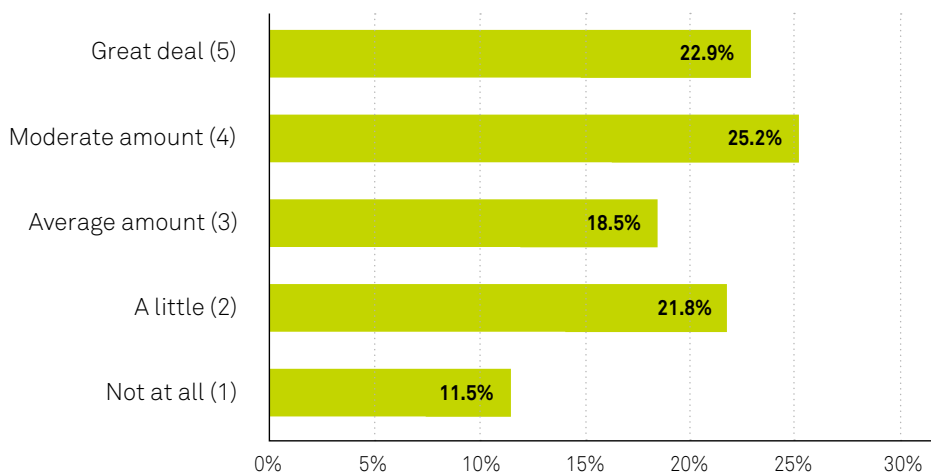
Medidata asked the sites again to weigh the impact of the COVID-19 pandemic on their ongoing trials with 5 being a great deal and 1 being not at all. The weighted average of respondents was only 2.93 with 41.4% of respondents stating that COVID-19 now had little to no impact on their ongoing trials. See Figure 4.

Figure 4: Impact of COVID-19 on ongoing trials



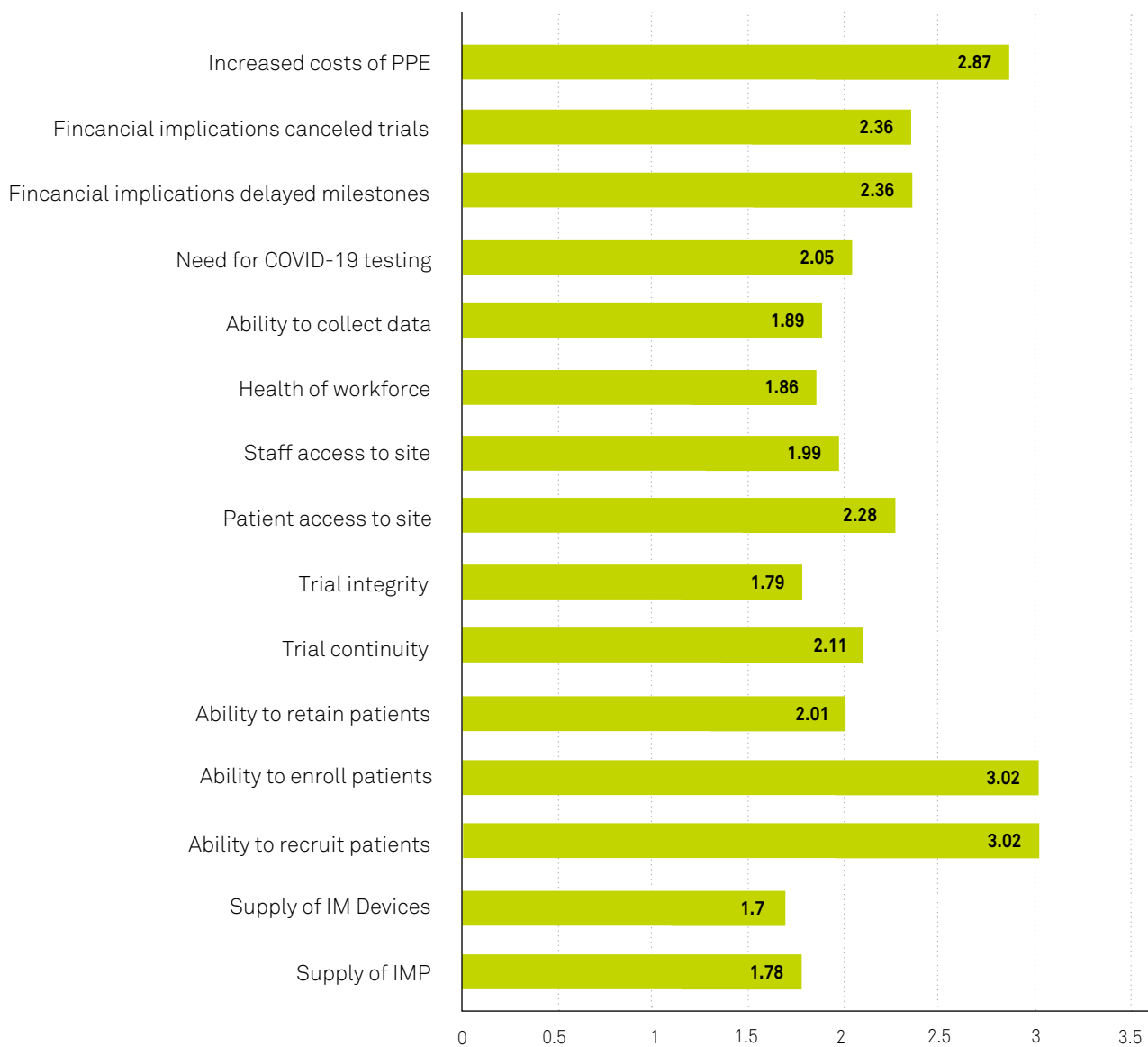
Again we asked sites to weigh the impact of COVID-19 on their ability to initiate new trials with 5 being a great deal and 1 being not at all. The weighted average of the responses was 3.26, higher than the impact for ongoing trials. Almost half of the respondents indicated that COVID-19 had significantly impacted their ability to start new trials, while one-third of respondents indicated that the pandemic had little to no impact on their ability to initiate new clinical studies. See Figure 5.

Figure 5: Impact of COVID-19 on initiating new trials



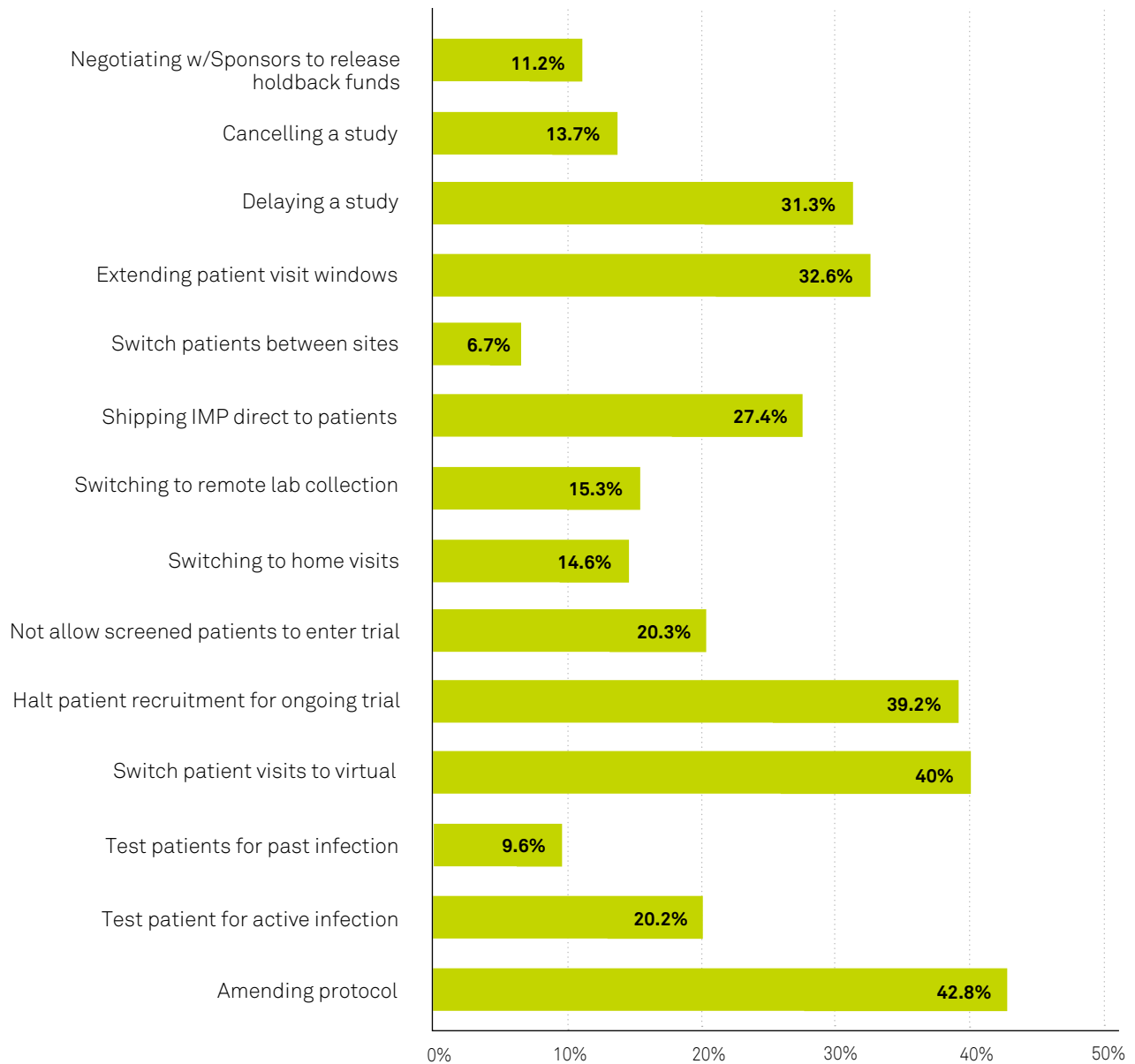
We once again asked sites to tell us how COVID-19 was impacted specific activities within their trial with 5 being severely impacted and 1 being not impacted at all. Generally, the results across all activities were better than what was reported in April with no weighted average results for any activity being moderately or severely impacted by COVID-19. The highest weighted averages for the impact of COVID-19 on ongoing trials were for the sites' ability to recruit patients (3.02) and enroll patients (3.02) and the increasing costs of personal protective equipment (a new question in this survey) was 2.87. The full results can be seen in Figure 6.

Figure 6: Weighted average of impact of COVID-19 by specific activity



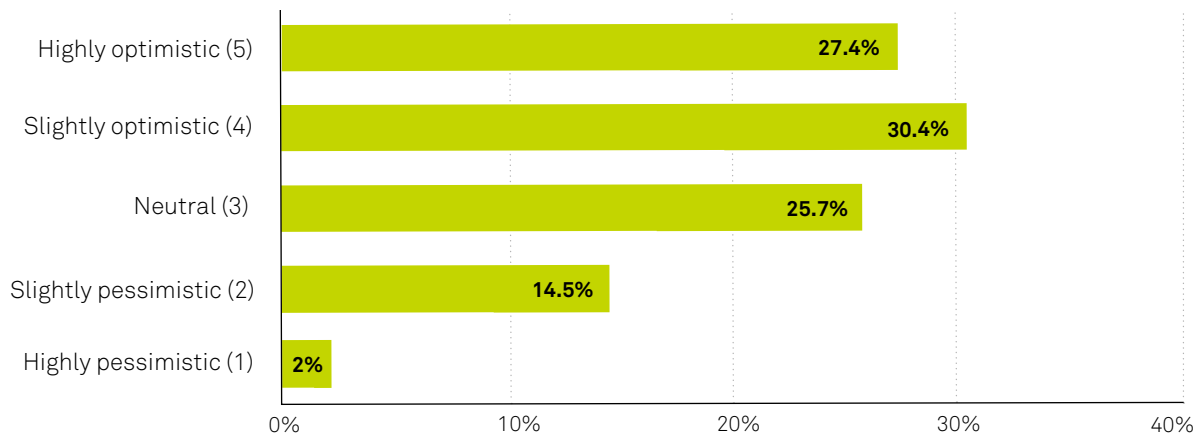
We also reasked the sites about how and when they would be responding to the impact of the pandemic on the trials. When looking at the results for activities that sites had already done, about 40% of respondents had implemented study protocol amendments, had halted recruitment for ongoing trials and 40% had switched patient visits to virtual. Of note, about one-third of respondents indicated that they had delayed a study and/or had extended patient visit windows. About one-fifth of sites test patients for active COVID infection but only about 10% test for past infection. See complete results in Figure 7.

Figure 7: Percentage of sites that have already implemented responses to COVID-19



In this survey we asked site respondents to think ahead 6 months and tell us how they would characterize their feelings about the future of their clinical trials with 5 being highly optimistic and 1 being highly pessimistic. The weighted average of the responses was 3.67 with almost 60% of sites being optimistic, while only 16.5% were pessimistic. See Figure 8..

Figure 8: Feelings about the future of clinical trials



More detailed results of Medidata’s second site survey will be published in the next month.

From the patient’s perspective, a survey of its Phase III patients by a Canadian CRO found that amid the changes COVID-19 has brought to its sites, patients were still committed to continuing their trials. When asked how the CRO could further support its patients, many mentioned medication deliveries and the option to have study visits in traditional, virtual, and hybrid forms, but what was most important was “someone asking us if we are okay.”

There were a variety of different ways patients wanted to stay engaged – updates on COVID-19, updates on their research trial, opportunities to ask questions about their trial, opportunities to discuss difficulties they are facing, etc. What was most important to them was “being informed, I can make better decisions” and “more awareness always is good – it provides hope.”¹

Discovering 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 September 18, according to the World Health Organization, there are 146 (8 more than last month) vaccine candidates in preclinical development and 36 (7 more than last month) unique candidate vaccines for COVID-19. Of these 36 candidates, 19 are in Phase I, 25 are in Phase I/II, 6 are in Phase II and 13 are in Phase III trials, for a total of 63 clinical trials (15 more than last month).² An abridged summary of these 36 vaccines in clinical evaluation is outlined in Figure 9 and represented graphically in Figure 10.

¹ https://www.clinicalleader.com/doc/what-patients-are-telling-sites-about-trial-participation-during-covid-0001?utm_source=OneSignal&utm_medium=pushnotification&utm_campaign=6-3-20

² <https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines>. Accessed September 18, 2020.

Figure 9: The 36 COVID-19 vaccines in clinical development

COVID-19 Vaccine developer/ manufacturer	Type of candidate vaccine	Clinical Stage			
		Phase 1	Phase 1/2	Phase 2	Phase 3
University of Oxford/ AstraZeneca	ChAdOx1-S		PACTR202006922165132 2020-001072-15 Interim Report	2020-001228-32	ISRCTN89951424 NCT04516746 NCT04540393
CanSino Biological Inc./Beijing Institute of Biotechnology	Adenovirus Type 5 Vector	ChiCTR2000030906 Study Report		ChiCTR2000031781 Study Report	NCT04526990 NCT04540419
Gamaleya Research Institute	Adeno-based (rAd26-S+rAd5-S)	NCT04436471 NCT04437875 Study Report			NCT04530396
Janssen Pharmaceutical Companies	Ad26COVS1		NCT04436276		NCT04505722
Sinovac	Inactivated		NCT04383574 NCT04352608 NCT04551547		NCT04456595 669/UN6.KEP/EC/2020
Wuhan Institute of Biological Products/ Sinopharm	Inactivated		ChiCTR2000031809 Interim Report		ChiCTR2000034780
Beijing Institute of Biological Products/ Sinopharm	Inactivated		ChiCTR2000032459		ChiCTR2000034780
Moderna/NIAID	LNP-encapsulated mRNA	NCT04283461 Interim Report		NCT04405076	NCT04470427
BioNTech/Fosun Pharma/Pfizer	3 LNP-mRNAs		2020-001038-36 ChiCTR2000034825 NCT04537949 Study Report		NCT04368728
Novavax	Full length recombinant SARS CoV-2 glycoprotein nanoparticle vaccine adjuvanted with Matrix M		NCT04368988 Study Report	NCT04533399 (phase 2b)	
Anhui Zhifei Longcom Biopharmaceutical/ Institute of Microbiology, Chinese Academy of Sciences	Adjuvanted recombinant protein (RBD-Dimer)	NCT04445194	NCT04550351	NCT04466085	

COVID-19 Vaccine developer/ manufacturer	Type of candidate vaccine	Clinical Stage			
		Phase 1	Phase 1/2	Phase 2	Phase 3
Curevac	mRNA	NCT04449276			NCT04515147
Institute of Medical Biology, Chinese Academy of Medical Sciences	Inactivated	NCT04412538	NCT04470609		
Research Institute for Biological Safety Problems, Rep of Kazakhstan	Inactivated		NCT04530357		
Inovio Pharmaceuticals/ International Vaccine Institute	DNA plasmid vaccine with electroporation		NCT04447781 NCT04336410		
Osaka University/ AnGes/ Takara Bio	DNA plasmid vaccine + Adjuvant		NCT04463472 NCT04527081		
Cadila Healthcare Limited	DNA plasmid vaccine		CTRI/2020/07/026352		
Genexine Consortium	DNA Vaccine (GX-19)		NCT04445389		
Bharat Biotech	Whole-Virion Inactivated		NCT04471519		
Kentucky Bioprocessing, Inc	RBD-based		NCT04473690		
Sanofi Pasteur/GSK	S protein (baculovirus production)		NCT04537208		
Arcturus/Duke-NUS	mRNA		NCT04480957		
ReiThera/ LEUKOCARE/ Univercells	Replication defective Simian Adenovirus (GRAd) encoding S	NCT04528641			
Clover Biopharmaceuticals Inc./GSK/Dynavax	Native like Trimeric subunit Spike Protein vaccine	NCT04405908			

COVID-19 Vaccine developer/ manufacturer	Type of candidate vaccine	Clinical Stage			
		Phase 1	Phase 1/2	Phase 2	Phase 3
Vaxine Pty Ltd/ Medytox	Recombinant spike protein with Advax™ adjuvant	NCT04453852			
University of Queensland/CSL/Seqirus	Molecular clamp stabilized Spike protein with MF59 adjuvant	ACTRN12620000674932p ISRCTN51232965			
Medigen Vaccine Biologics Corporation/NIAID/Dynavax	S-2P protein + CpG 1018	NCT04487210			
Instituto Finlay de Vacunas, Cuba	RBD + Adjuvant	IFV/COR/04			
FBRI SRC VB VECTOR, Rospotrebnadzor, Koltsovo	Peptide	NCT04527575			
West China Hospital, Sichuan University	RBD (baculovirus production expressed in Sf9 cells)	ChiCTR2000037518			
University Hospital Tuebingen	SARS-CoV-2 HLA-DR peptides	NCT04546841			
Institute Pasteur/Themis/Univ. of Pittsburg CVR/Merck Sharp & Dohme	Measles-vector based	NCT04497298			
Beijing Wantai Biological Pharmacy/Xiamen University	Intranasal flu-based-RBD	ChiCTR2000037782			
Imperial College London	LNP-nCoVsaRNA	ISRCTN17072692			
People's Liberation Army (PLA) Academy of Military Sciences/Walvax Biotech.	mRNA	ChiCTR2000034112			
Medicago Inc.	Plant-derived VLP adjuvanted with GSK or Dynavax adjs.	NCT04450004			

Figure 10: Graphical summary of COVID-19 vaccine candidates by phase



New and Adapted Medidata Solutions to Assist Sponsors/CROs and Patients in Mitigating the Impact of the COVID-19 Pandemic on their Clinical Trials

The following tables provide details about the Medidata’s solutions available to assist with COVID-19-related clinical 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.

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 on where to focus efforts by benchmarking impact of COVID-19 on own trials vs. industry

- Assess impact of COVID-19 through standard dashboards
- Understand weekly and monthly trends, and YoY performance
- Views at portfolio, study, country / region and site level

Impact Forecasting: Plan ahead by understanding leading indicators of slowdown and recovery at a country and site level

- Track performance at country and site level to understand which countries, sites 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

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. Learn more about Rave eCOA [here](#)

myMedidata/

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](#).

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 enhance 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 to group relevant COVID-19 infection terms in System Organ Class Infections (SOC).

The updated MedDRA 23.0 dictionary is now available to clients using Rave Coder. More information about Rave Coder is [here](#).

CHALLENGE 3: MAINTAINING QUALITY AND SUPPLY

Rave RBQM

CHALLENGE

As some on-site monitoring activities have resumed, early data are suggesting a return to early 2020 stages in the COVID-19 pandemic where clinical investigative sites are limited access to external parties. As we approach the winter period within the northern hemisphere establishing a remote monitoring strategy is critical in the application of lessons learned from early 2020 and proactively plan for a changing environment.

Challenges remain 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.

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

Often with limited or reduced access to clinical sites, Sponsors and CRO are faced with an urgent need to evolve their monitoring execution models, while ensuring patient safety and data quality. Medidata Remote Monitoring is a holistic solution to enable a hybrid on-site/off-site approach to study oversight, enabling the shift from 100% on-site monitoring to remote monitoring activities.

Medidata has developed a holistic remote monitoring solution encompassing three core activities, Centralized Statistical Monitoring, Central Data Monitoring, and Off-Site/ Remote- Site Monitoring.

Centralized Statistical Monitoring and Central Data Monitoring are supported via [Medidata Detect](#), which is driven by machine learning and automated algorithms to help unify and ingest study data, identify anomalies, and find risks in your study. Data flows in real time and can be refreshed on demand, supporting the dynamic requirements for safety and quality review.

Off-Site/Remote Monitoring is performed with the industry leading **Medidata Remote Source Review** technology, which provides a streamlined and quick-to-implement solution to collect, de-identify, manage, review and verify critical study documents. **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

It's well supported that 100% SDV has a negligible effect on data quality. Rave TSDV supports 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

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.

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

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

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. Learn more about Direct to Patient Supply Management [here](#).

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.

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. With budgets driven by the sites (and not the sponsor) there are often delays in getting approval from the sponsor as budget details are needed.

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. 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.

SOLUTION

Medidata has developed a COVID-19 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. Learn more about Rave Grants Manager COVID IIS [here](#).

[Rave Grants Manager COVID IIS](#) enables Sponsors to obtain a grant budget that allows them 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.

Rave EDC and Rave RTSM

CHALLENGE

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

SOLUTION

Rave RTSM with basic EDC forms for COVID-19 studies can be up and running in two weeks for a randomization only study and three weeks for Randomization and basic trial supply management. Medidata's robust capabilities and interoperability with Rave EDC can support the demand to deliver faster start-up timelines between study kick-off to database go-live and has supported multiple go-lives recently within 3 weeks or less.

Summary

All eyes are now on the COVID-19 vaccines in Phase 3 of trials. In an unprecedented and historic move 9 biopharma companies pledged to follow only the science in seeking approval. And the CEO of Pfizer communicated they will know about the safety and efficacy of their vaccine by the end of October. Regulatory bodies like the CDC are predicting longer timelines, likelier second or third quarter of 2021. And we see continued and increased investment in vaccine development; just in the last few days Germany announced an increase in funding.

The politicization of the clinical trial process has increased and is an ongoing cause of concern. And as those processes progress and move downstream other issues are bubbling to the surface. There's more discussion and planning for manufacturing and the infrastructure required for universal vaccine distribution. With that progress comes more issues; we are seeing vaccine hesitancy at a high level, even as high as 50% in the US according to polling.

Globally we are watching countries balance a return to normal while managing ongoing outbreaks. Restrictions are lifted, cases rise and restrictions are reimposed. In the U.S. cases continue to rise in all regions outside of the Northeast, and the anti-mask contingency is voluble. And across the globe testing at scale continues to present challenges; in the UK limitations on test processing are significant. The opportunity to use the lockdown period to upscale testing, tracing and treatment has been unevenly applied across countries. Rapid, reliable instant testing is the goal yet to be achieved.

In positive news, sponsors and sites continue to adapt to the new normal that COVID-19 has imposed. COVID-19 is enabling - actually, forcing - aspects of clinical trial management that have been in discussion for decades.

We will continue to monitor and share updates for the duration, and our support of our customers and partners in unwavering.

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