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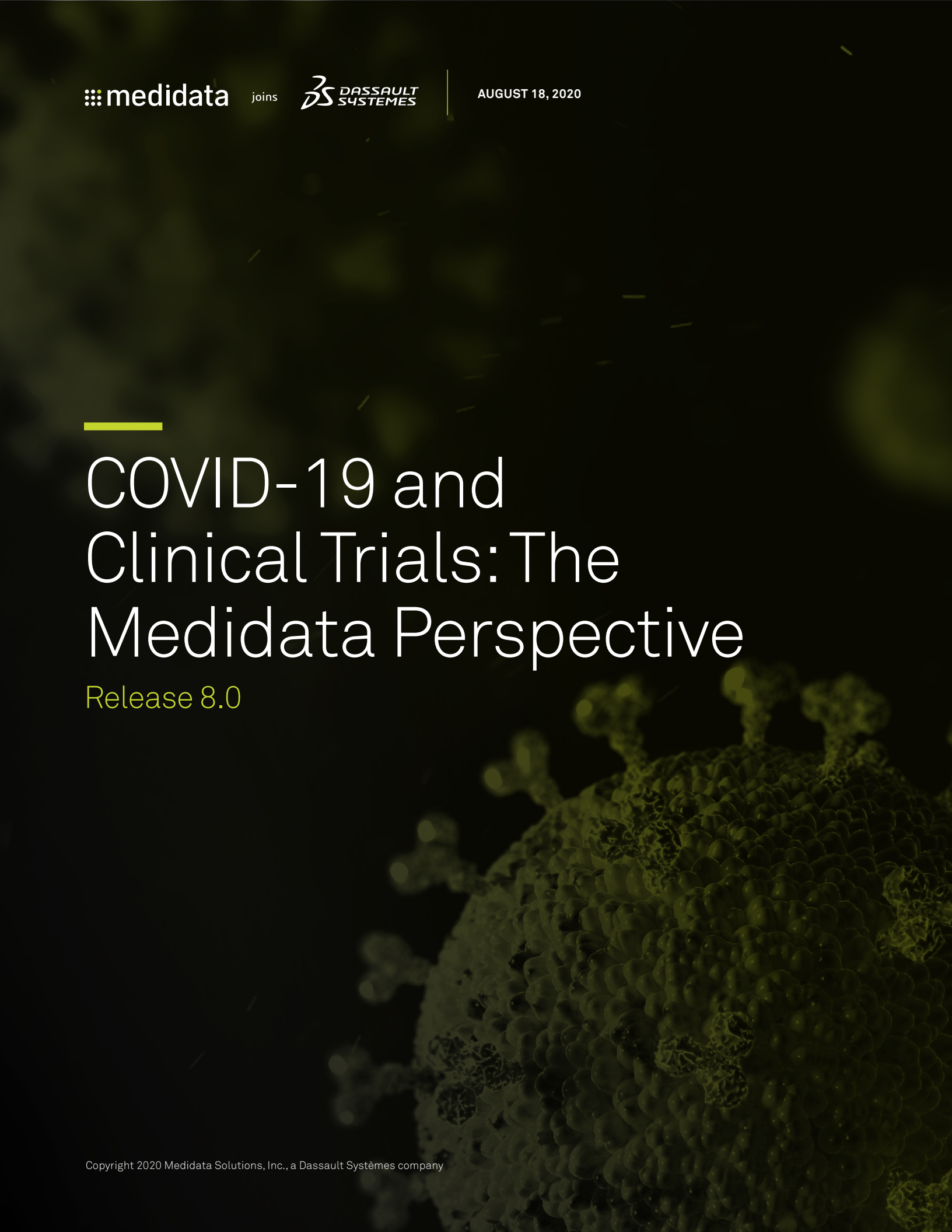
COVID-19 and Clinical Trials: The Medidata Perspective

Release 8.0



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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 and now August 12. 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. Now that we have several months of data, we are pivoting to help the industry better understand the changes over time at the geographic and TA level, and enable real-time decision making.

In this release, we are continuing to improve and refine our methodology. As such, we are changing our reference of a pre-COVID baseline to the first 11 months of 2019 rather than October 2019, in order to limit the variability that comes with comparing the data to a single month. Below, you can find an updated analysis of trial activity as measured by the average number of new patients entering trials per study-site. Note that 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 5,089 studies and 194,506 study sites.

Globally, we saw an improvement in new patients entering trials per study-site at the end of July, at -6% of pre-COVID baseline, as compared to about a -30% for June. As we noted in the last release, the recovery however varies 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 continues to be an outlier, at -55% of its pre-COVID baseline, but seeing an improvement from June as its case rate continues to decline. France has worsened from June to July, with an uptick in case rates.

In Asia, the picture remains varied. China and Japan continue to see an improvement in new patients entering study-sites. Korea has remained stagnant this month and India is slowly moving towards an improvement.

In the US, despite the increase in COVID-19 cases in July, we saw an improvement in new patients entering trials as compared to June. This is likely due to the limited return of lockdown measures and the differing policies across states. Oncology has even returned to above pre-COVID levels at +9% of 2019 baseline. Non-oncology continues to be negatively impacted, at -26%.

Globally, from a TA perspective the recovery has been varied. As we pointed out in our last report, oncology has made a recovery in June to its pre-COVID baseline and in July improved 20% over 2019 baseline levels. CNS has also made a marked improvement in July, at -7% of its pre-COVID baseline compared to -44% in June. Overall, non-oncology TAs are at -21% 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 realt-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.

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

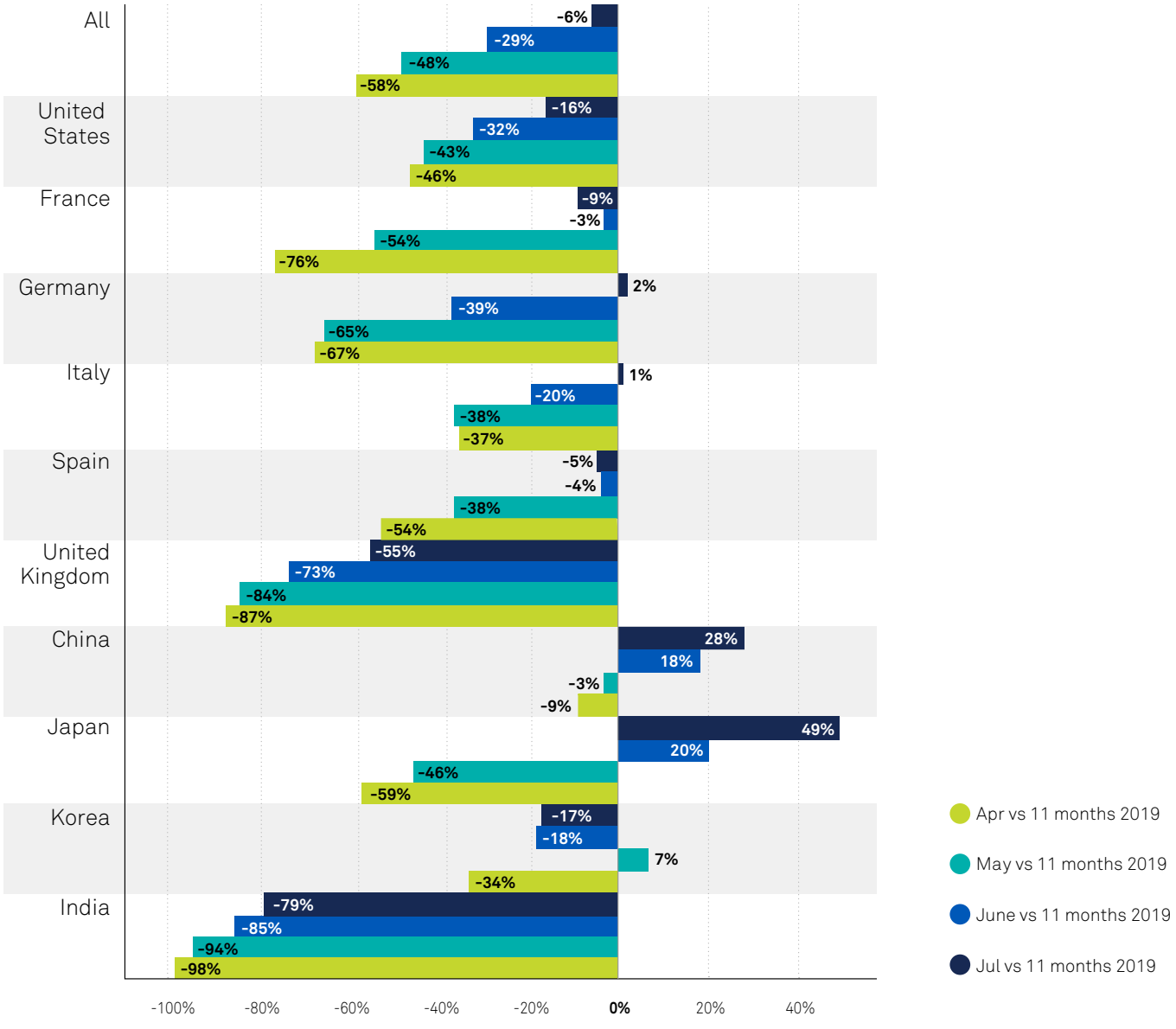
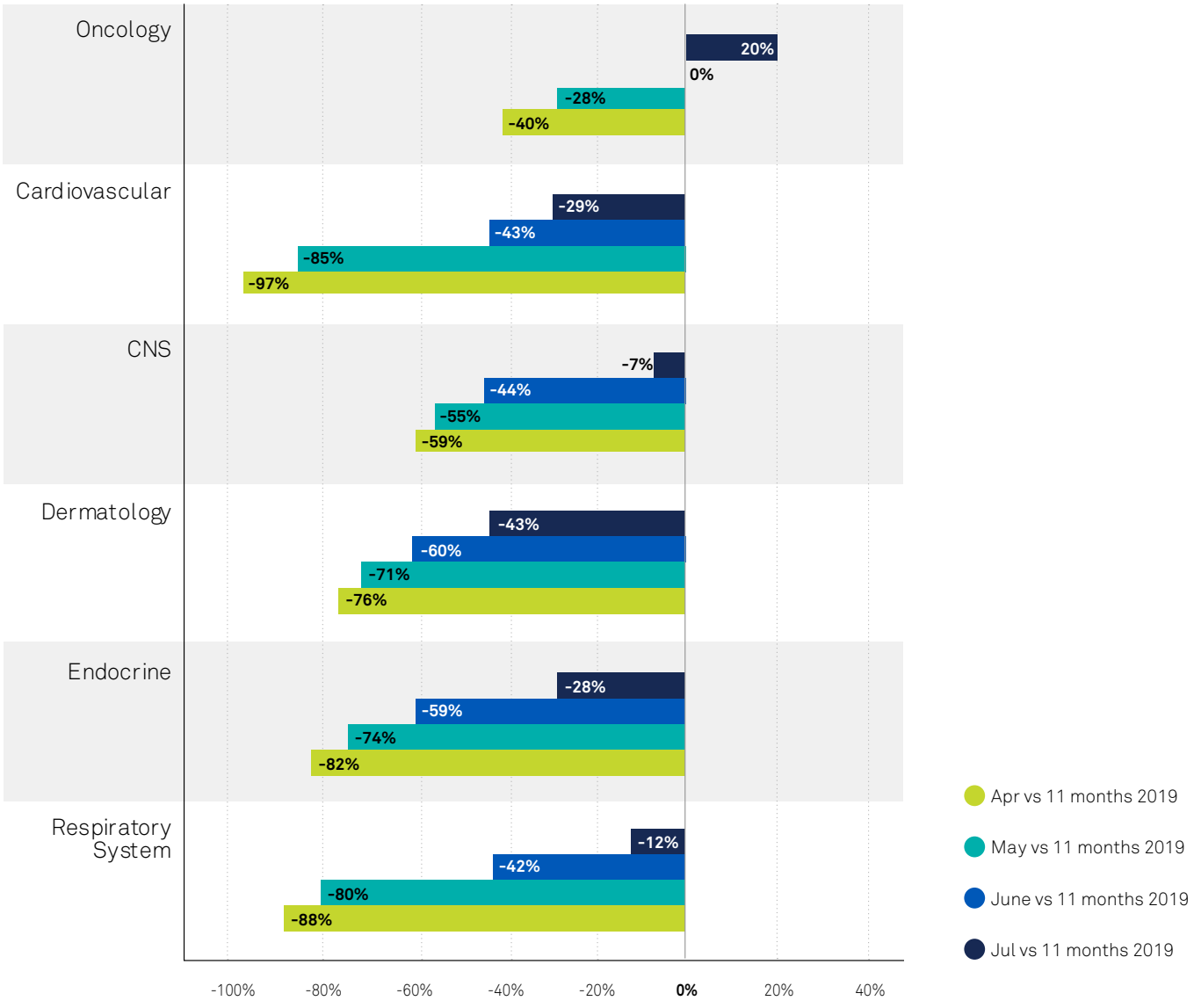


Figure 2: Change in new patients entering study-sites by TA



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	eConsent	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				
Canada Health Canada (05Aug)	✓	✓	✓	✓
U.S. FDA (02Jul)	✓	✓	✓	✓
Asia/Australia				
Australia DoH (9Apr)	✓	✓	✓	✓
China NMPA CDE (14July)	✓	✓	✓	✓
Japan PMDA (27May)	✓	✓	✓	✓
Singapore HSA (27Mar)	✓		✓	✓
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

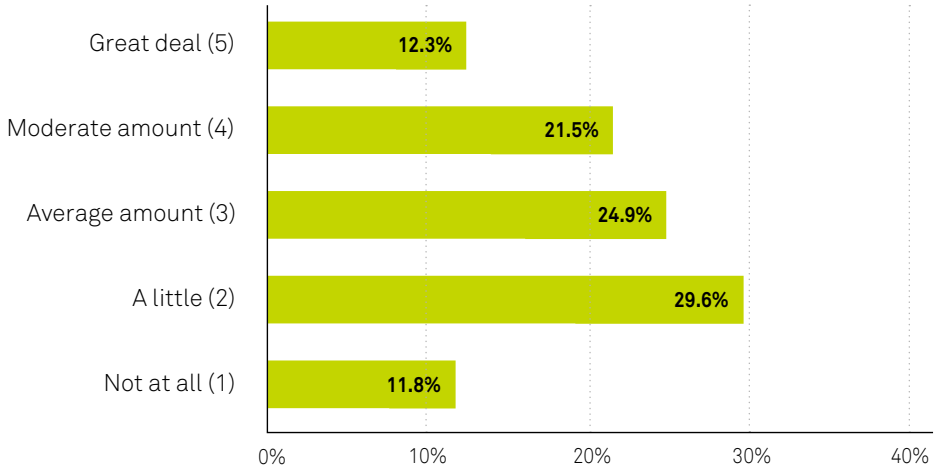
The impact of the pandemic on sites was well documented by a survey of over 1,000 clinical site personnel performed by Medidata in late April 2020. Not unexpectedly, the survey results clearly and dramatically show that most sites are feeling the negative impact of the pandemic on current and future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

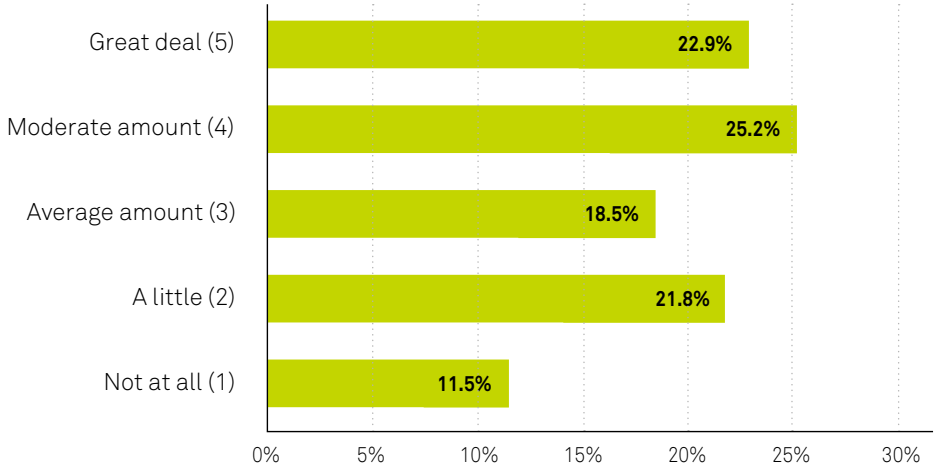
Medidata asked the sites again to weigh the impact of the COVID-19 pandemic on their ongoing trials with 5 being a great deal and1 being not at all. The weighted average of respondents was only 2.93 with 41.4% of respondents stating that COVID-19 now had little to no impact on their ongoing trials. See Figure 4.

Figure 4: Impact of COVID-19 on ongoing trials



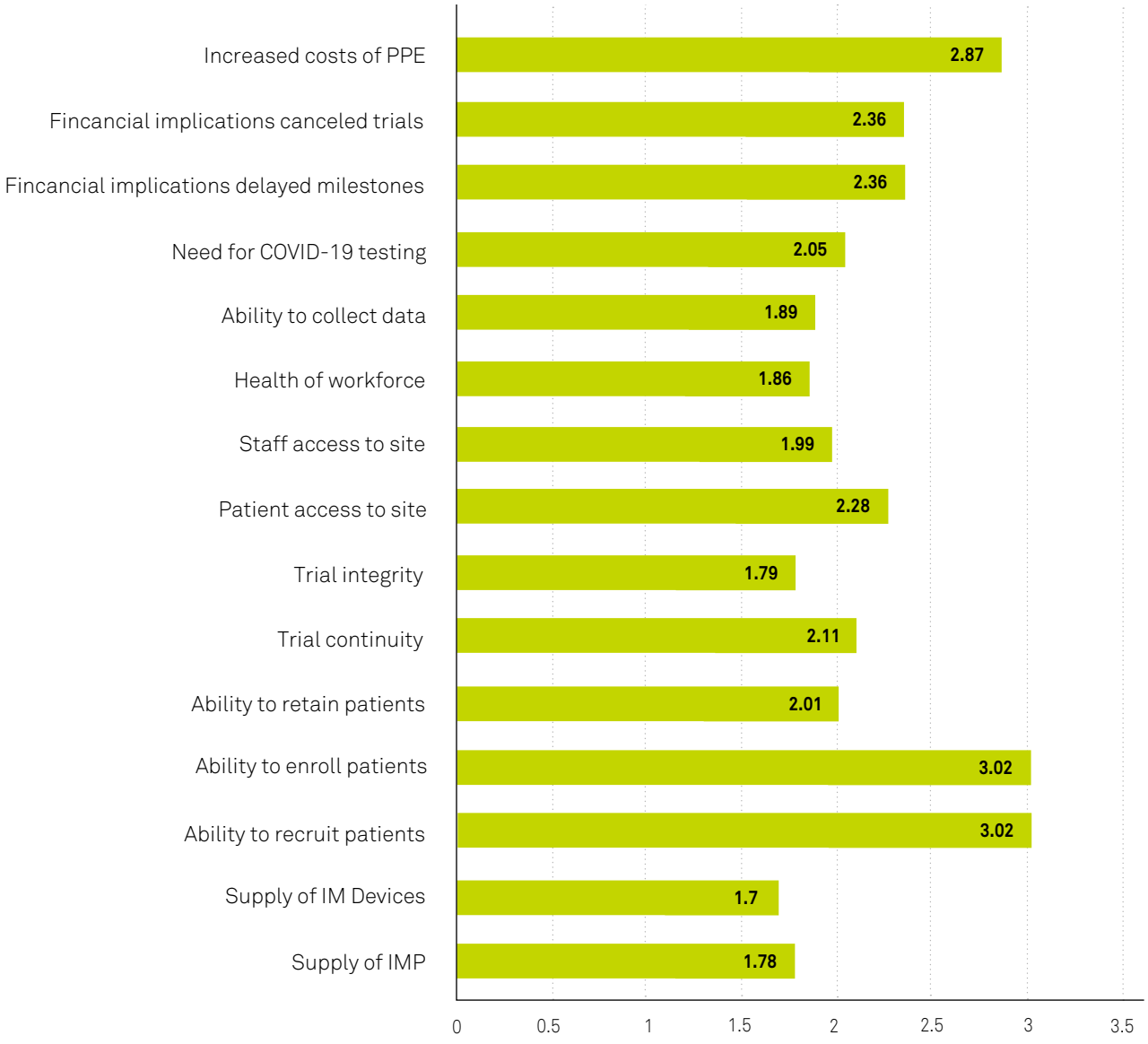
Again we asked sites to weigh the impact of COVID-19 on their ability to initiate new trials with 5 being a great deal and 1 being not at all. The weighted average of the responses was 3.26, higher than the impact for ongoing trials. Almost half of the respondents indicated that COVID-19 had significantly 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



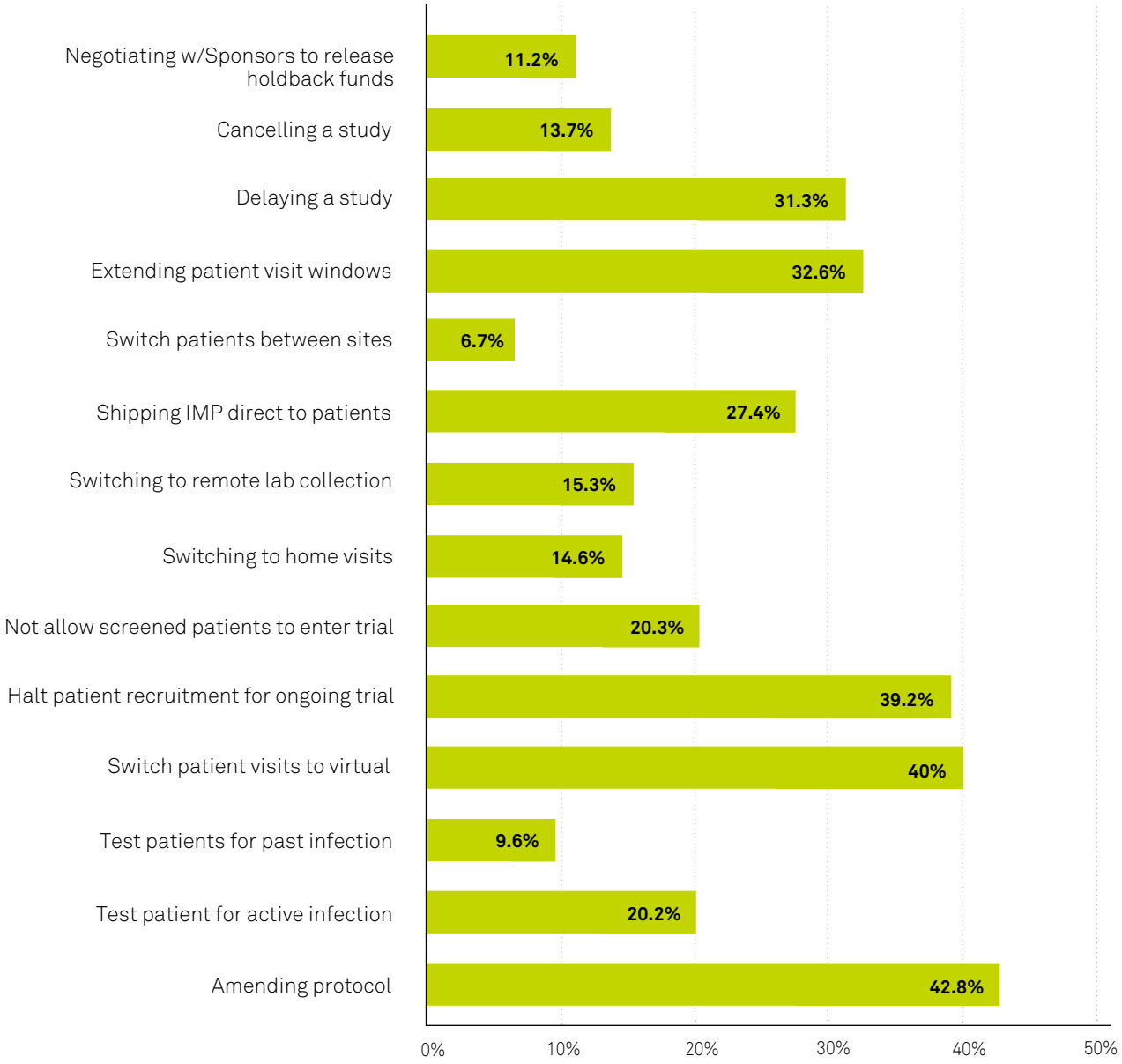
We once again asked sites to tell us how COVID-19 was impacted specific activities within their trial with 5 being severely impacted and 1 being not impacted at all. Generally, the results across all activities were better than what was reported in April with no weighted average results for any activity 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



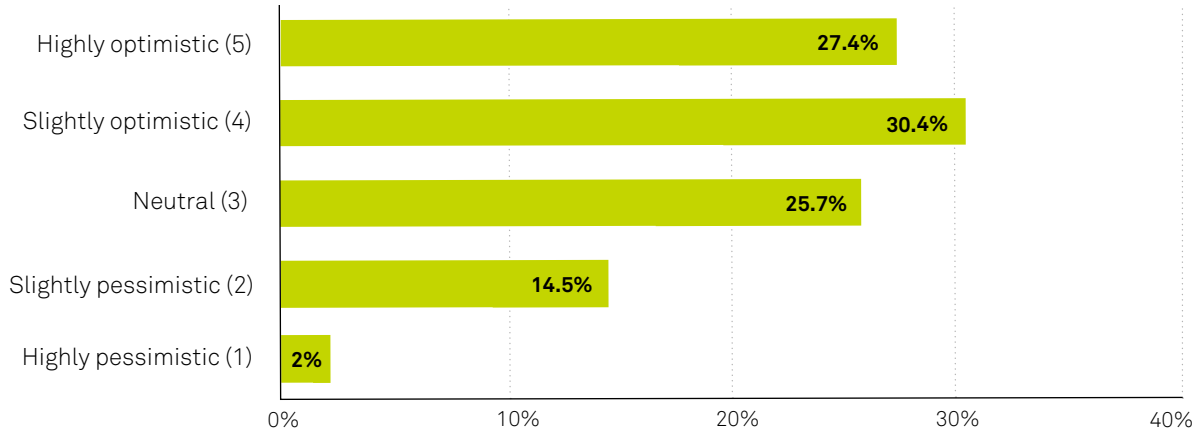
We also reasked the sites about how and when they would be responding to the impact of the pandemic on the trials. When looking at the results for activities that sites had already done, about 40% of respondents had implemented study protocol amendments, had halted recruitment for ongoing trials and 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 3 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 August 14, according to the World Health Organization, there are 138 (1 less than last month) vaccine candidates in preclinical development and 29 (8 more than last month) unique candidate vaccines for COVID-19. Of these 29 candidates, 16 are in Phase 1, 19 are in Phase I/2, 4 are in Phase 2 and 7 are in Phase 3 trials, for a total of 46 clinical trials (15 more than last month).[2] An abridged summary of these 29 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 August 14, 2020.

Figure 9: The 29 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
Sinovac	Inactivated		NCT04383574 NCT04352608		NCT04456595 669/UN6.KEP/EC/2020
Wuhan Institute of Biological Products/ Sinopharm	Inactivated		ChiCTR2000031809		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 Study Report		NCT04368728
CanSino Biological Inc./Beijing Institute of Biotechnology	Adenovirus Type 5 Vector	ChiCTR2000030906 Study Report		ChiCTR2000031781 Study Report	
Anhui Zhifei Longcom Biopharmaceutical/ Institute of Microbiology, Chinese Academy of Sciences	Adjuvanted recombinant protein (RBD-Dimer)	NCT04445194		NCT04466085	
Institute of Medical Biology, Chinese Academy of Medical Sciences	Inactivated	NCT04412538	NCT04470609		

COVID-19 Vaccine developer/ manufacturer	Type of candidate vaccine	Clinical Stage			
		Phase 1	Phase 1/2	Phase 2	Phase 3
Inovio Pharmaceuticals/ International Vaccine Institute	DNA plasmid vaccine with electroporation		NCT04447781 NCT04336410		
Osaka University/ AnGes/ Takara Bio	DNA plasmid vaccine + Adjuvant		NCT04463472		
Cadila Healthcare Limited	DNA plasmid vaccine		CTRI/2020/07/026352		
Genexine Consortium	DNA Vaccine (GX-19)		NCT04445389		
Bharat Biotech	Whole-Virion Inactivated		NCT04471519		
Janssen Pharmaceutical Companies	Ad26COVS1		NCT04436276		
Novavax	Full length recombinant SARS CoV-2 glycoprotein nanoparticle vaccine adjuvanted with Matrix M		NCT04368988		
Kentucky Bioprocessing, Inc	RBD-based		NCT04473690		
Arcturus/Duke-NUS	mRNA		NCT04480957		
Gamaleya Research Institute	Adeno-based	NCT04436471 NCT04437875			

COVID-19 Vaccine developer/ manufacturer	Type of candidate vaccine	Clinical Stage			
		Phase 1	Phase 1/2	Phase 2	Phase 3
ReiThera/ LEUKOCARE/ Univercells	Replication defective Simian Adenovirus (GRAd) encoding S	2020-002835-31			
Clover Biopharmaceuticals Inc./GSK/Dynavax	Native like Trimeric subunit Spike Protein vaccine	NCT04405908			
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			
Institute Pasteur/ Themis/Univ. of Pittsburg CVR/Merck Sharp & Dohme	Measles-vector based	NCT04497298			
Imperial College London	LNP-nCoVsaRNA	ISRCTN17072692			
Curevac	mRNA	NCT04449276			
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			
Medigen Vaccine Biologics Corporation/NIAID/ Dynavax	S-2P protein + CpG 1018	NCT04487210			

Figure10: 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-realted 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	SOLUTION
Understanding the country/ site/ disease area impact across the industry, and developing risk mitigation and recovery plans.	**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 visitsStandard 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	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. Learn more about Rave eCOA here.

myMedidata/

CHALLENGE	SOLUTION
Quantify the impact of trial participants with COVID-19 symptoms on ongoing research studies.	IIn 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 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 on-site monitoring activities are resuming we have yet to see a full return to pre-COVID state.

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

Throughout the pandemic global regulatory bodies have aligned on some common themes; a risk assessment should guide all protocol and monitoring strategy modifications and remote and central monitoring should be used to strategically target sites to enable risk based onsite monitoring activities.

To guide industry in the risk assessment process, 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. The Risk Assessment Template can be accessed here.

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 injest 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:

- 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:
  - 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	SOLUTION
Patients can't get to the site for dispensation - sites are open but do not have supply for dispensation.	**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.
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.
Sites are closed and patients need a dispensation.	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.
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 COVID IIS

CHALLENGE	SOLUTION
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.	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.
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.	**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.

Rave EDC and Rave RTSM

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

We've entered a new phase in the COVID-19 pandemic from a clinical trial perspective. There are now 6 vaccines in Phase III trials, and there's also progress in the development of therapies. Research on antibodies is similarly active and urgent. We've seen unprecedented investment in vaccine development, led by the US, Europe and China. Every part of the ecosystem is proceeding at a record pace to bring the vaccines and therapies to market quickly and safely. And sponsors are looking ahead to manufacturing and commercialization.

In addition, we're observing how sponsors, CROs and sites are adapting to the new normal that COVID-19 has imposed. The focus - by necessity - is on speedy, safe trials, and sites are finding ways to streamline their processes to accommodate this critical need. Many of the Medidata's COVID-19-related solutions mentioned above have supported this adaptation. From a patient point-of-view we're seeing a greater rate of new patients entering trials. While this varies by geography and therapeutic area (oncology trials are at pre-COVID levels), this provides hope that the ecosystem is not only adapting but evolving.

There continue to be areas of concern: continued virus spread in the US and persistent outbreaks even in countries where strict measures were taken and enforced; vaccine hesitancy, which persists, and according to sources may be increasing.

But from a clinical perspective we're reporting real and significant progress.

About Medidata

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