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The Impact of COVID-19 on Clinical Trial Sites

The Results of a Global Survey Performed by Medidata

April 2020

COVID-19 Impact on Clinical Trials:

NEW SITE SURVEY REVEALS

The COVID-19 pandemic has turned the world upside down; it's hard to think of an activity, business, or goal that hasn't been impacted. Clinical trial sites are no exception.

Globally, thousands of these sites are collectively the largest group of users of Medidata technology and solutions, which support the most efficient, safe, and accurate drug development process possible. To better understand how the pandemic is impacting their vital work and to gain insight into how they are adjusting to this new reality, we fielded a global online survey. Their responses paint a revealing picture of their concerns and flexibility.

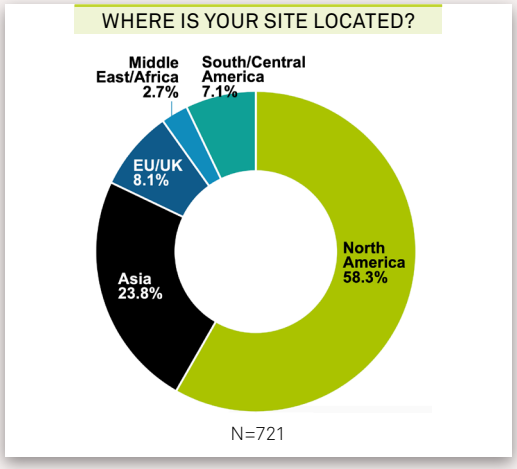
ABOUT THE SURVEY

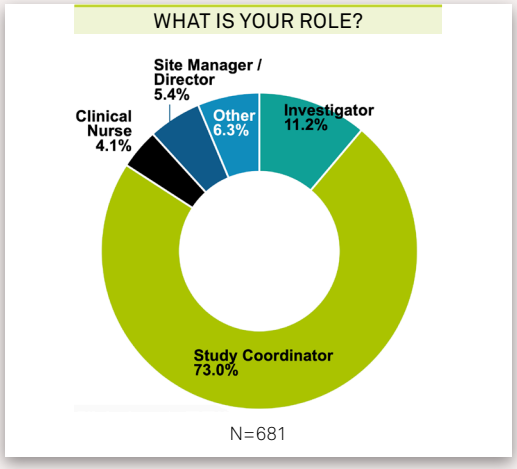
On April 23, 2020, Medidata successfully delivered 9,952 electronic surveys to personnel at investigator sites using our technology that supports their clinical trials. On April 27th, we sent an email reminder to 6,599 non-respondents. The survey was closed at 5pm EDT on April 29, 2020. The results are summarized below.

RESPONSE RATE BY WHOM AND FROM WHERE

There were 1,030 respondents who answered at least one question of the survey for a **response rate of 10.4 percent**. Of those who answered the questions, 58.3 percent were from the United States (North America) and 23.8 percent were from Asia. Of those who answered the question, 73.8 percent identified their role as Study Coordinator and 11 percent were Investigators. (See Figure 1).

Figure 1. Site Location/Respondent Role

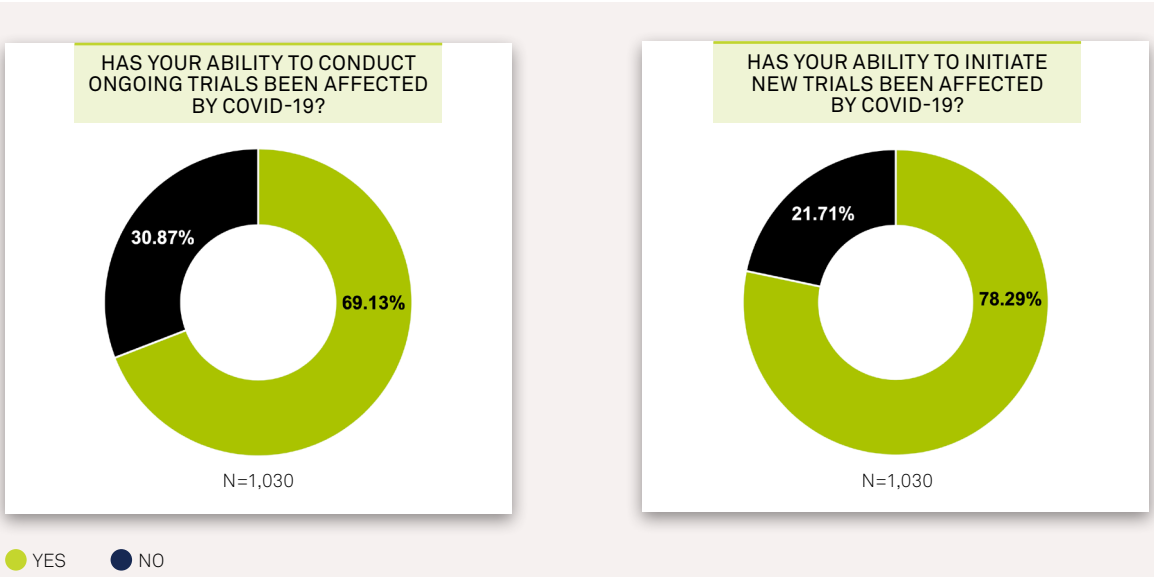




THE PANDEMIC IS A SIGNIFICANT FACTOR IN STUDY CONDUCT

The pandemic and various "lockdown" measures put in place around the world are impinging on sites' ability to both conduct existing trials and to initiate new trials. For **69 percent** of respondents, COVID-19 has affected their ability to conduct **ongoing** trials, while **78 percent** of respondents believe that COVID-19 has impacted their ability to **initiate new** trials. (See Figure 2).

Figure 2: Impact of COVID-19 on Ongoing Trails and Ability to Launch New Ones

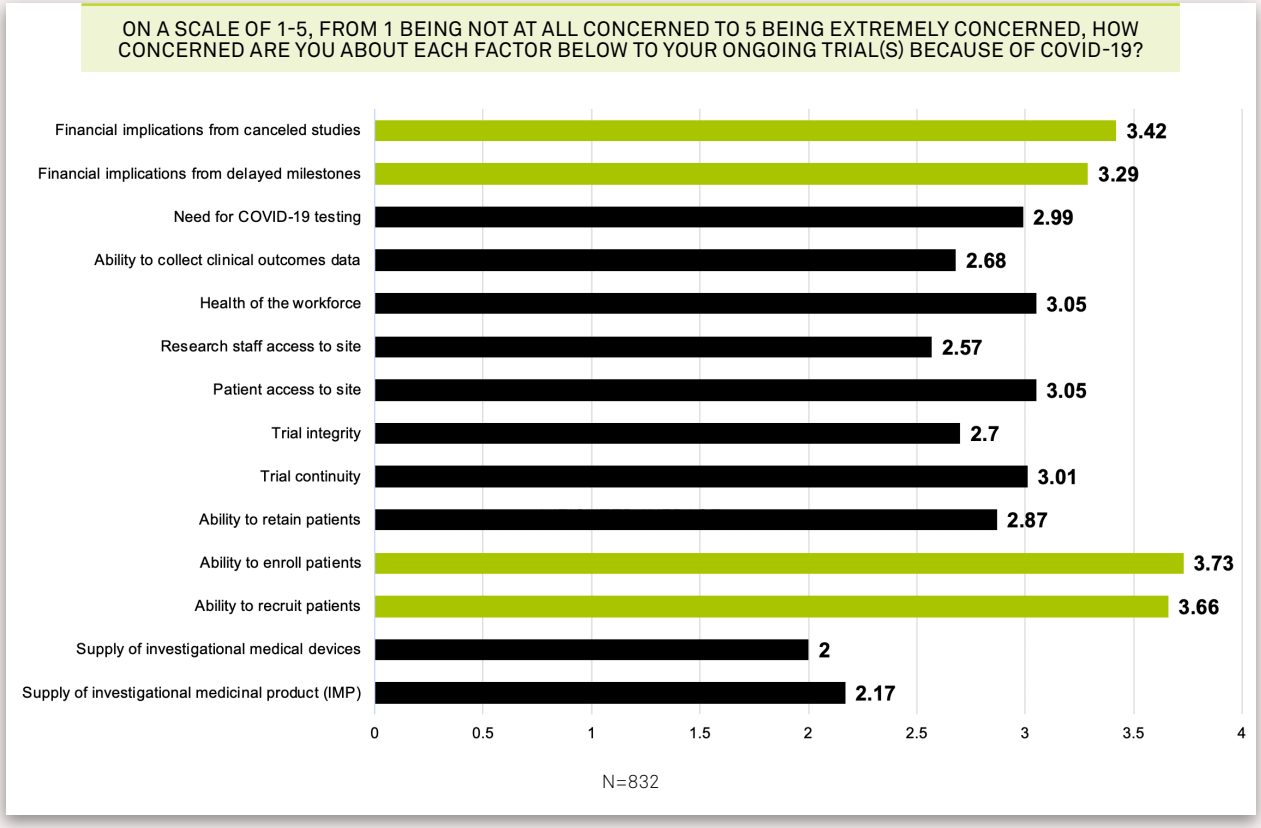


SITES ARE MOST CONCERNED ABOUT PATIENT RECRUITMENT/ENROLLMENT

Respondents were asked to rate their level of concern on a variety of factors ranging from the supply of investigational products… to their ability to recruit and enroll patients… to the health of the workforce and their ability to collect outcomes data. The scale was from one to five, with one being not at all concerned and five being extremely concerned.

The top four concerns expressed by the respondents based on the weighted average of the answers were: **ability to enroll patients** (3.73); **ability to recruit patients** (3.66); **financial implications for cancelled studies** (3.42); and **financial implication from delayed milestones** (3.29). Other noteworthy concerns were: **patient access to the site** (3.05); **health of the workforce** (3.05) and **the need for COVID-19 testing** (2.99). (See Figure 3). By far, respondents expressed the greatest concern over patient recruitment and enrollment; well over half rated their concern as a four or five for both of these topics. (See Figure 3).

Figure 3: Level of Concern of COVID-19 Impact on Trial-Related Activities



In looking behind the weighted average, we see that responses on trial continuity, trial integrity, the health of the workforce, and the need for COVID-19 testing were distributed widely across the spectrum from "not at all concerned" to "extremely concerned." Respondents indicated strong confidence in the **ongoing supply of investigational medicinal products** (IMP) as well as **investigational medical devices**. The percentages that described themselves as "extremely concerned" were **seven percent for IMP** and only **four percent for medical devices**.

Few were concerned about their **ability to collect clinical outcomes data**; only **11 percent** reported being "**extremely concerned**," while almost half (49 percent) described themselves as "not at all concerned" or only "somewhat concerned."

SITES ARE MITIGATING ISSUES IN A NUMBER OF WAYS

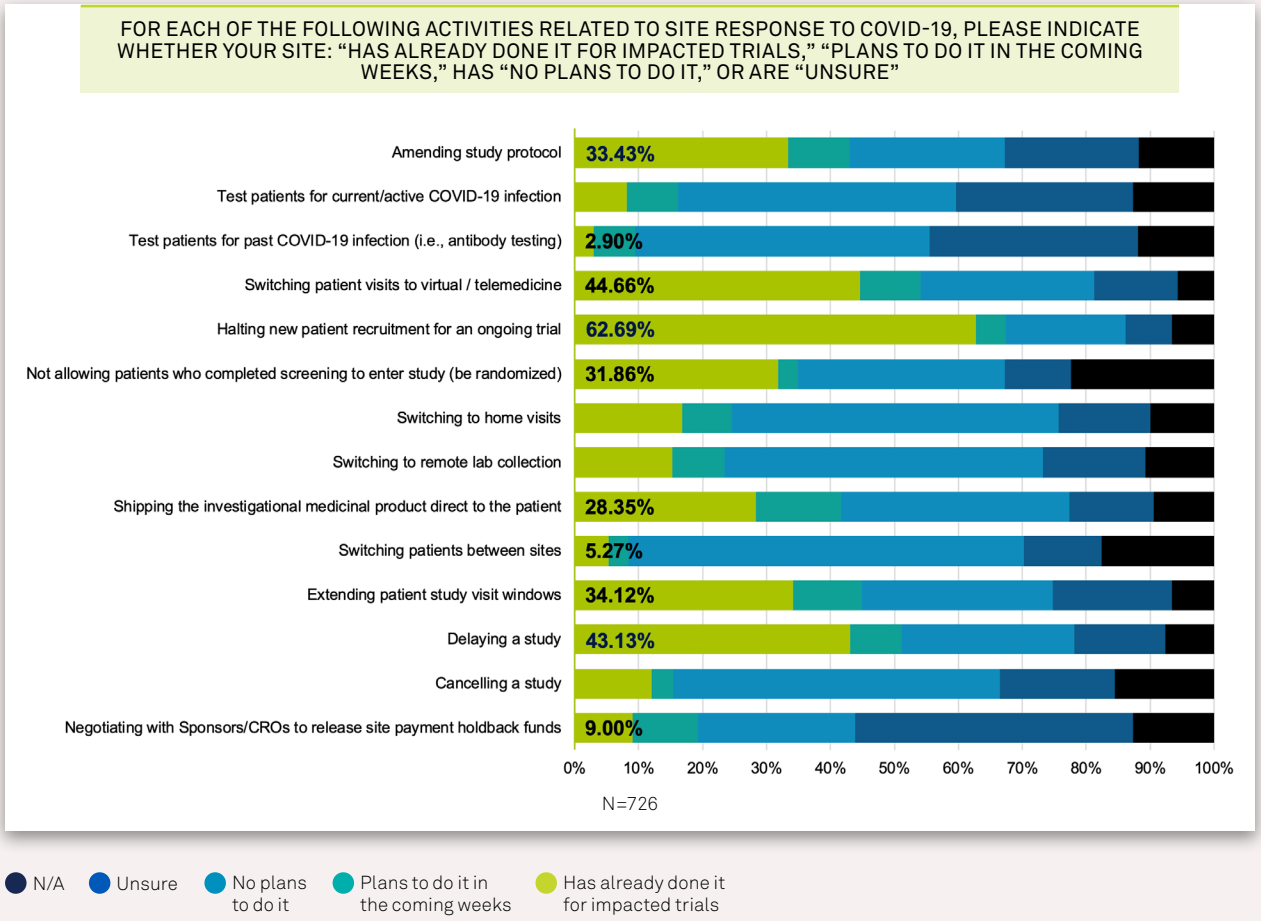
Given the health implications of the novel coronavirus and the practical considerations of managing patient contacts, sites have taken a variety of measures to limit patient exposure. Respondents were asked to indicate for a number of activities whether their site "Has already done it for impacted trials," "Plans to do it in the coming weeks," has "No plans to do it," or are "Unsure."

The top five activities already undertaken by sites in response to COVID-19 are: **halting new patient recruitment for an ongoing trial (63 percent), switching patients to virtual/telemedicine (45 percent), delaying a study (43 percent), extending patient study visit windows (34 percent)** and **amending study protocols (33 percent)**. (See Figure 4). Roughly a third **(32 percent)** have **not allowed patients who have completed screening to be randomized**.

Switching patients between sites has rarely been used as a solution, with only **five percent** having done so. And, the percentage of sites that has cancelled **studies (12 percent**) is relatively small.

Somewhat surprisingly, relatively small numbers have tested patients for current/active or past COVID-19 infection. Only **eight percent** have **tested patients for active infection** and only **three percent** have **tested patients for prior infection**. (See Figure 4).

Figure 4: Activities Done/Planned based on COVID-19



SUGGESTIONS FROM THE FRONTLINE

When asked to name the "one thing that could help you meet your clinical trial milestones that is currently not in place," respondents offered voluminous suggestions for Sponsor policies and support from Contract Research Organizations (CROs). Respondents appeared eager to share their ideas, which included:

- **Examine the global impact of decisions**
  Although COVID-19 is widespread, all parts of the world aren't impacted equally. Decisions to postpone a new study or to halt recruitment that apply universally around the globe, unnecessarily impact research in those areas where it is safe to continue screening and enrolling patients. Taiwan, for example, was mentioned as an area lightly touched by the virus.
- **Provide greater flexibility and understanding**
  Many sites wanted Sponsors and CROs to appreciate the fact that work cannot proceed under the rules of business as usual. Things must be done differently, or according to different timelines. For example, it may take longer to resolve data queries as staff may not be on site most of the time. And, to accommodate patients, study visit windows may need to be extended.
- **Adopt telemedicine**
  Sites suggested a number of solutions to accommodate patients who can't visit research centers. These included: using online questionnaires for patients, e-consent, amending protocols to include virtual visits and home-care nursing, sending investigational products directly to patients, reviewing and revising endpoints that require long-term, direct contact with patients, and adopting secure means for patients to communicate and share information with sites from home.
- **Provide additional financial support**
  Sites mentioned that when studies are suspended or when milestones are extended, their revenue is negatively affected, although they must continue to employ study coordinators. Suggestions ranged from making contract amendments for increased remote monitoring work to increasing overhead reimbursements.
- **Develop contingency plans**
  In light of how sites have had to respond to the emergency created by the pandemic, it was suggested that Sponsors and CROs develop study-specific contingency plans that can automatically be activated in the event of another outbreak. The plan should include provisions for transporting patients, for switching from a central lab to local labs, and for the proactive supply of PPEs, to name a few. This would prevent deviations from scheduled visit windows and outline systemic solutions without compromising patient safety.

RESEARCH, INTERRUPTED

Sites are on the frontline of experiencing the impact of COVID-19, and the pandemic has directly and dramatically impacted their ability to continue their work, which ultimately will impede development progress.

Not unexpectedly, 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 - most likely through protocol amendments.

The results are consistent with other data previously presented by Medidata and indicate the growing risks associated with new study starts, trial progression and completion as well as impact on the sites themselves from a financial and work safety perspective.