



# Clinical SCORE Report #3:

## The Impact of COVID-19 on Clinical Trial Sites After 3 Months

June, 2020

### Background

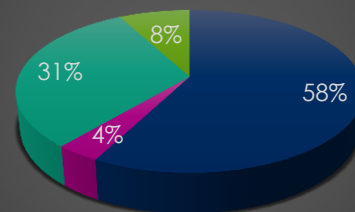
Starting in the last week of March 2020, Clinical SCORE began surveying trial sites globally to determine the impact of the COVID-19 pandemic on clinical trial operations. We repeated surveys of clinical trial sites in the first week of May, and now again in late June, 2020. Each survey is referred to as a “wave” in this report. This latest survey took a new direction: We asked sites about their prognosis for running trials in the near future, their impression of the financial impact of COVID-19 and how they believe trials need to change to adapt to that impact. Because the survey structure has changed, there are few trended data points in this wave of the survey.

# Sample Description

There was a total sample size of 255 site-staff respondents, from 46 countries spanning the globe.

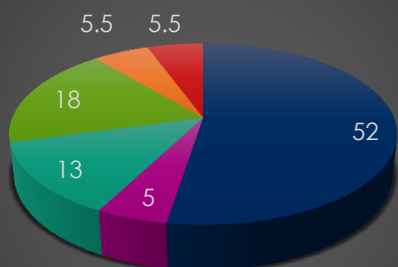
- Cognitive Specialties are Neurology, GI, and other non-surgical specialties
- Past Clinical SCORE surveys had roughly the same specialty breakout

## Specialty Segment of the Principal Investigator



■ Cognitive Specialties ■ ONC ■ Potential COVID ■ Other

## Regional Breakout (%)

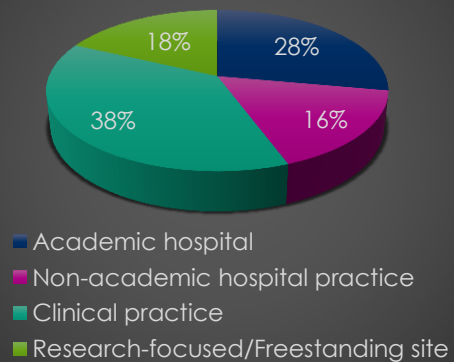


■ N.America ■ S. America ■ Western Europe  
 ■ Eastern Europe ■ Asia-Pacific ■ RoW

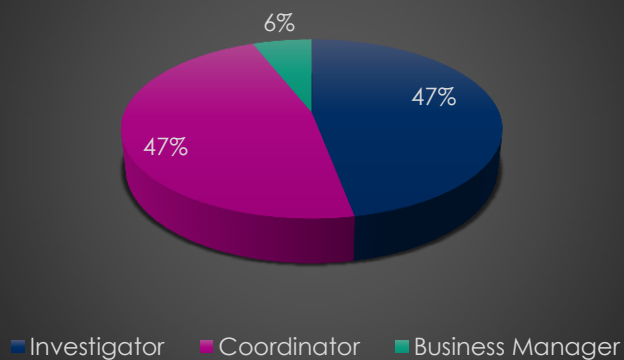
A similar breakout of regions was observed in survey waves 1 and 2

Survey waves 1 and 2 had a similar distribution of clinical trial settings

## Clinical Trial Setting



## Respondent Types

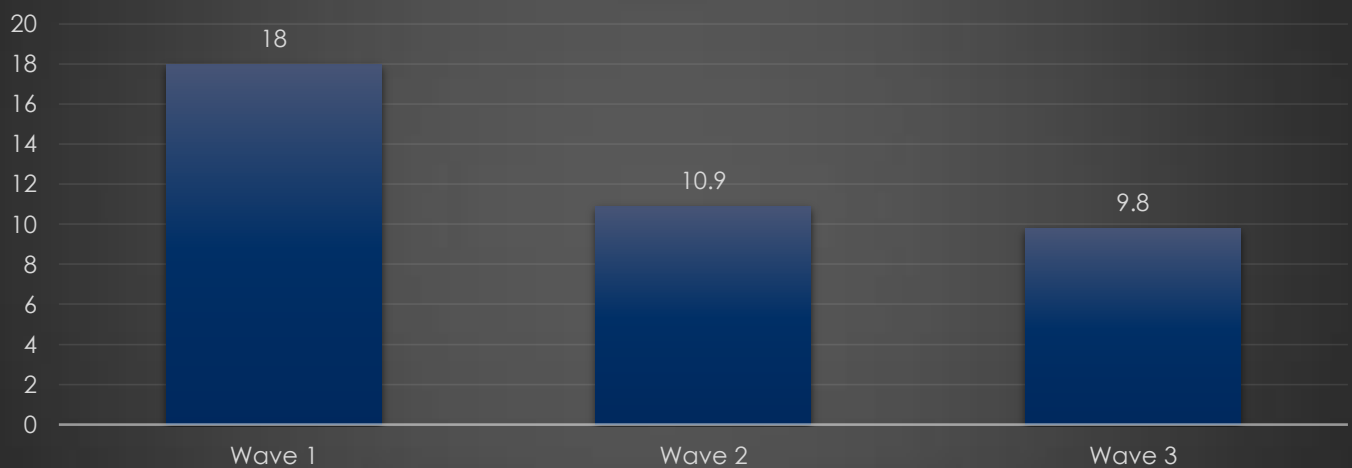


- Survey wave 1 also had equal numbers of investigators and coordinators
- However, wave 2, fielded in early May, had fewer coordinators complete the survey leading us to believe that some coordinators may have been furloughed in April

# Mean Number of Active Trials at Site

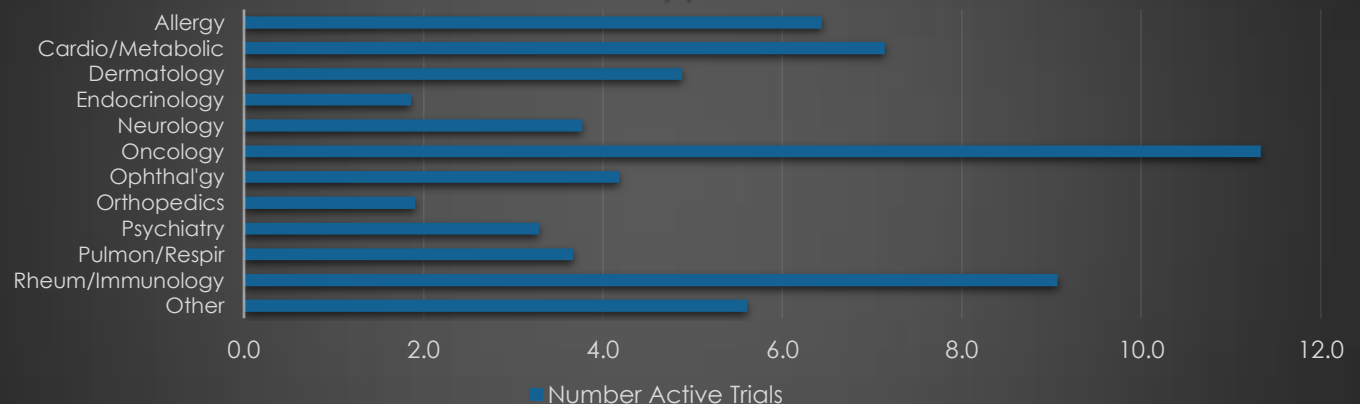
The mean number of trials active at each site continues to trend down, suggesting that sites are managing fewer active trials due to COVID-19. In wave 3 of this survey, sites were also asked the type (i.e., disease state) of trials they were managing.

## Mean Number of Active Trials at Site



Because trial type varies by specialty of the investigator of the site, the following disease state breakouts reflect those sites having at least one trial of each type:

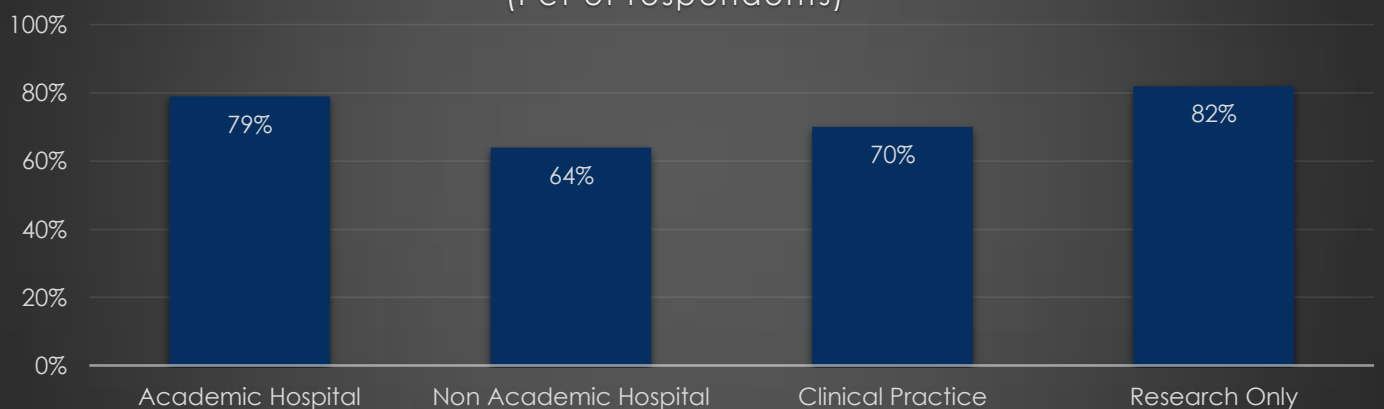
## Trial Types



# COVID-19 Impact on Trial Sites' Finances and Staff

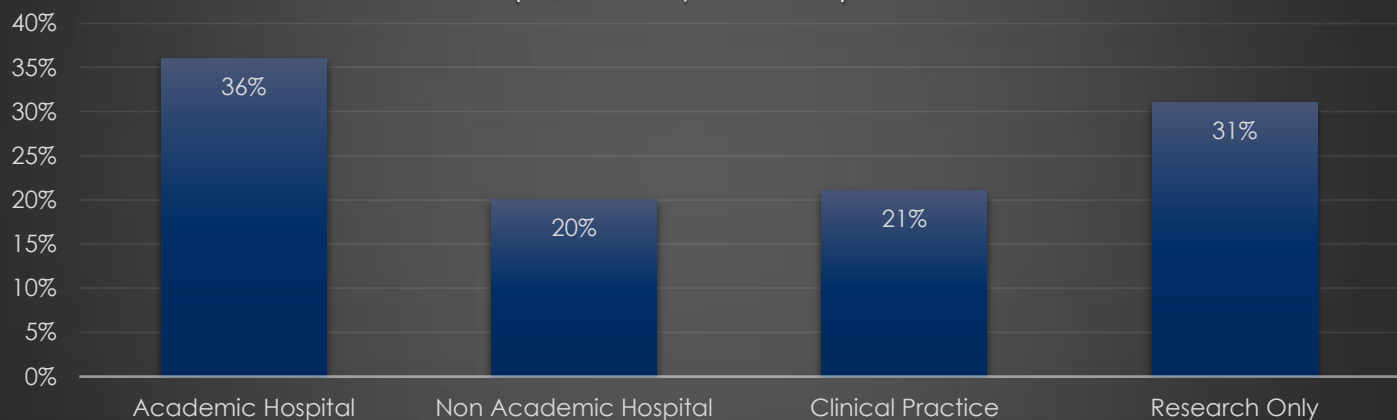
Site staff were asked to rate the degree of financial impact and staff impact experienced from the COVID-19 crisis. Unfortunately, 74% of clinical trial sites reported experiencing a financial decline because of the pandemic. Accordingly, 26% of respondents report that they have fewer staff than they had before COVID-19 hit.

## Financial Decline Since COVID-19 (Pct of respondents)



- Academic hospitals and free-standing research sites had the highest percentage of respondents reporting financial loss
- Only 3% of sites reported a financial increase since the COVID-19 crisis started. These were clinical practices and non-academic hospital sites who did NOT appear to be running COVID-19 trials.

## Decrease in Staffing Since COVID-19 (Pct of respondents)



### Impact on Staffing

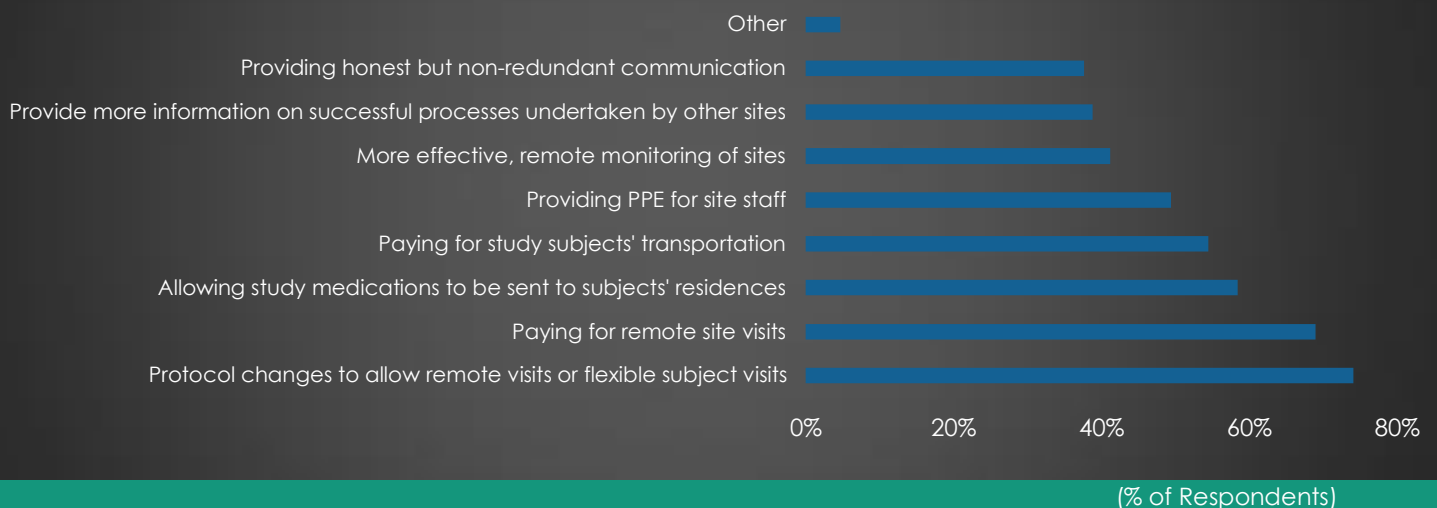
- As shown in the graph, academic and free-standing research sites experienced the largest cutbacks in site staff. Both rates are somewhat alarming, although they probably stem from different dynamics. Research-only sites do not have clinical practice obligations and revenues to offset slowed research revenues. The financial impact on large academic hospitals is no doubt multi-factorial but site staff were perhaps deemed less essential than other healthcare employees.



# What Support Do Staff Request?

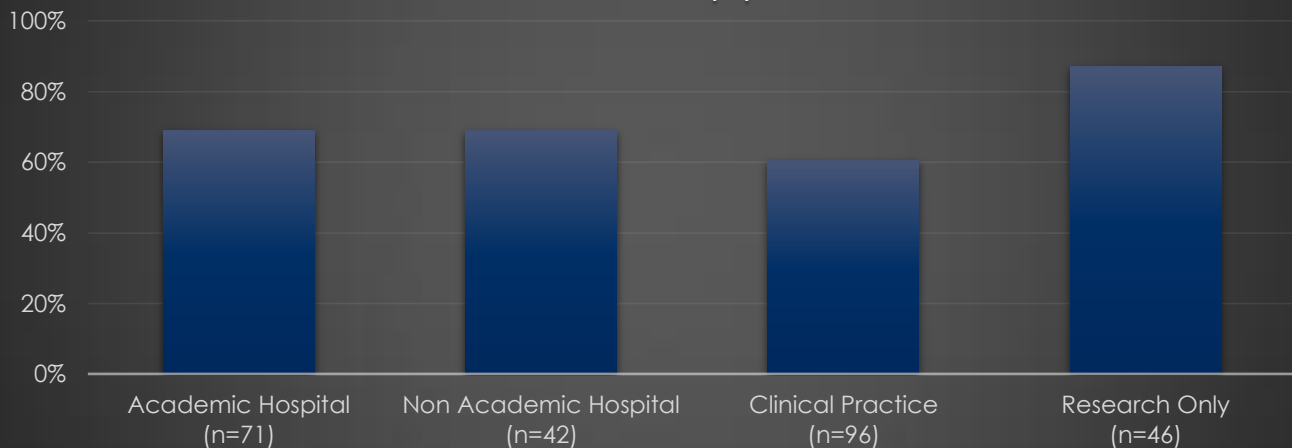
As with previous waves of the COVID-19 site survey, we asked site staff what support from sponsors would benefit them. Questions were asked on both a categorical basis and on an open-ended basis. Results of the closed-ended questions were consistent with the expectations for increasing use of remote patient monitoring (see next graph).

## Sponsor Support Requested



Fully three-quarters of site staff requested that sponsors provide protocol changes to allow for remote site visits – and this is a priority for hospital-based sites (87%) in particular. The desire to convert to remote visits was not affected by the number of active trials being conducted at a site. Most site staff requested the ability to have study medications sent directly to subjects' homes. Academic sites are significantly more likely to want study medications to be sent to subjects' residences (72%) than other site types

## Seek More Financial Support for Remote Visits



- Overall, 69% of site staff desired financial support from sponsors for remote visits. Research-only sites were significantly more likely than other site types to want financial assistance for COVID-related impact, and desire PPE provided by Sponsor (78%, not shown in graph) for their staff.

### When respondents were asked to write open-ended suggestions to sponsors for support, the following trends were noted:

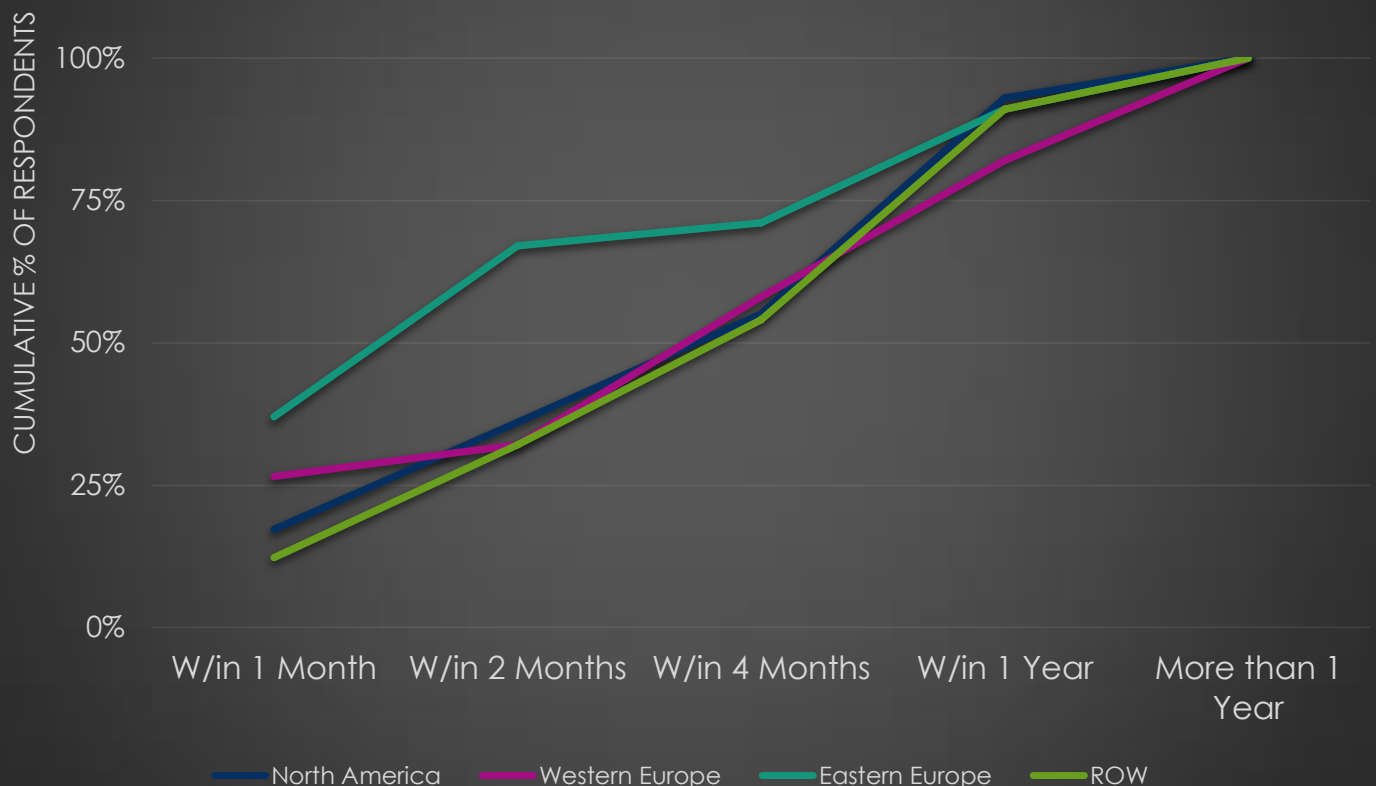
- Academic (68%) and non-academic hospital site staff (61%) were significantly more likely than other site types to request that sponsors allow non-onsite visits. The fact that nearly 70% of academic respondents wrote this as an open-ended response is itself quite remarkable.
- Overall, 26% of respondents requested an increased budget for remote monitoring
- Twenty percent (20%) of site staff requested more flexibility from sponsors
- Fourteen percent (14%) of respondents requested more COVID-19 supplies for site staff (such as tests and PPE)
- Only 5% of sites indicated they would like more communication with sponsor.



# When do Staff Believe Things Will Get Better?

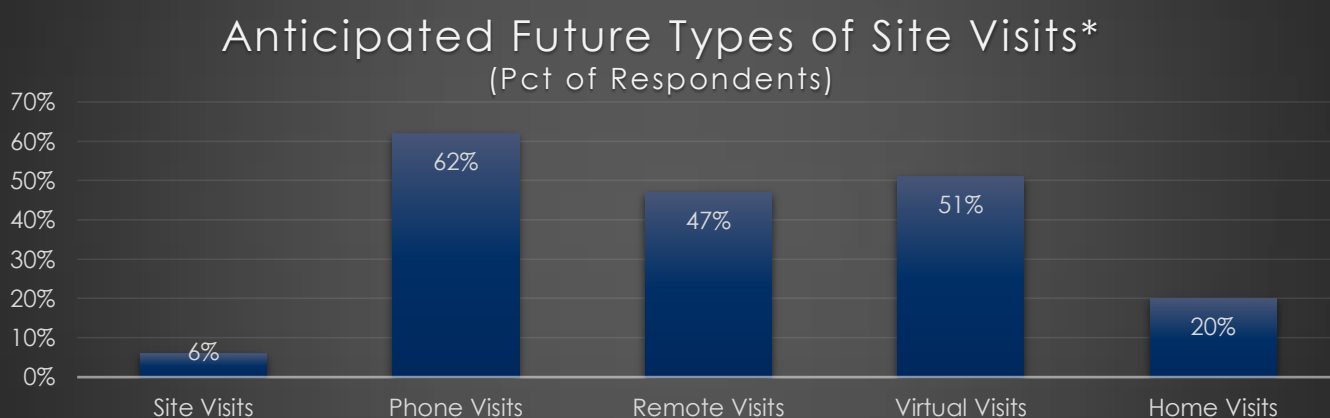
Site staff in Eastern Europe expect the number of trials activated to return quickly to pre-COVID levels. In contrast, site staff from all other regions expect a slower return of activated sites. In all regions, there is great variability as shown in the next diagram:

Estimated Time Until # of Trials Activated Returns to Baseline



# How do Site-staff See Trials Evolving to Cope With COVID-19?

Given the COVID-19 pandemic, site staff expect that upcoming clinical trials will utilize more virtual and/or remote visits. Across all site categories, most study site staff believe the number of in-person site visits will decline. In fact, over 50% of site staff requested sponsors minimize on-site visits (see next section).



\*Virtual visits include web-based video. Remote visits occur at medical facilities other than the site.

- One-half of site staff believe there will be fewer in-person site visits in the future due to the COVID-19 crisis. Only 7% of respondents indicated they believe regular site visits will increase over the next 12 months. Across site types, academic hospitals predicted the greatest decrease in in-person site visits.
- Fifty-one percent (51%) of respondents think virtual study visits (i.e., over the web) will increase in the future. Academic hospital staff predict the greatest increase in virtual visits.
- Alternately, 62% of site staff project that telephone visits will increase in the future
- Nearly half of respondents, 47%, believe remote visits are likely to increase post-COVID. More free-standing research facility staff (63%) than staff from other site types predict a rise in remote visits.
- Only 20% of site staff believe home-visits will increase as a viable option for flexible clinical trial visits

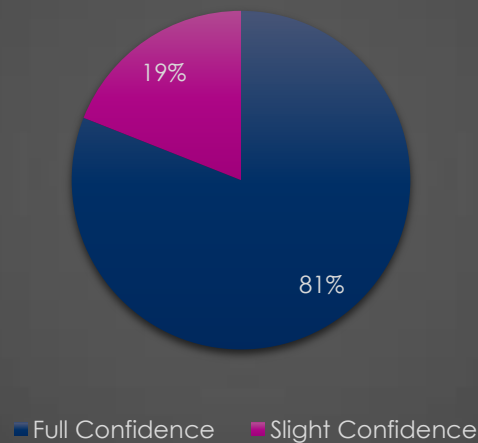
## Confidence in Data Quality Obtained from Non-traditional Site Visits

Because an increase in remote monitoring and site visits places a greater demand on technology, we asked a set of technology and data integrity questions of respondents who projected an increase in non-traditional site visits (n=158). Indeed, these participants reported they expected to use more automation and technology going forward. Overall, 64% of respondents indicated they will be using an increased amount of technology where academic hospital site staff (75%) and research-only site staff (74%) predicted the highest future use of technology.

- Sites with >10 active trials also have a significantly higher expectation level for technology use than do smaller sites

A potential concern from increased use of technology and remote monitoring is the quality and integrity of the data generated. Of site staff who expect an increase in non-traditional site visits, the vast majority (81%) felt fully confident in the quality of the data obtained from remote and virtual visits. There were no differences among site types.

## Confidence in Data from Remote Visits

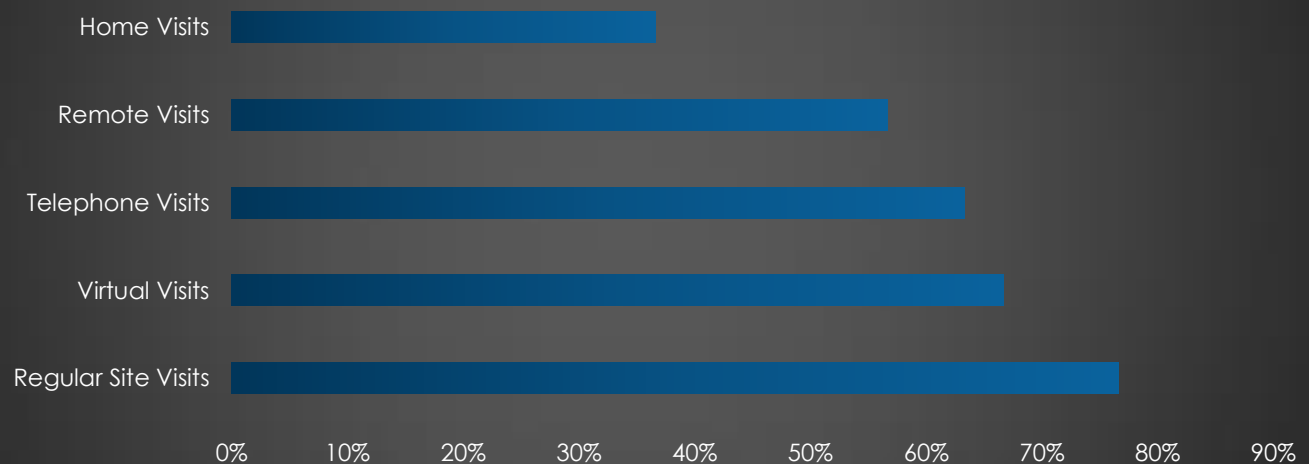


Although no site staff indicated they were “not” confident in remote monitoring technology, the results show that 19% are only slightly confident in existing data collection for remote monitoring. Although these 19% simply may be a more skeptical group of site-staff, sponsors should keep them in mind when recruiting sites for new trials.

# Running or Planning to Run Covid-19 Trials

Finally, site staff from “Potential COVID” sites (n=79, i.e., respiratory/pulmonary sites) were asked if they were running, or planned to run any trials for COVID-19 vaccines and therapeutics. Thirty-eight (38) % of these sites are running or plan to run a trial focusing on COVID-19. Of these 30 sites, most appear to desire hybrid types of study visits:

## Expected COVID-19 Study Designs



- These sites expect a mix of managing site visits for these trials, with regular site visits (77%) being the most mentioned, more than virtual or remote visits



For Further Information, or Questions:

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