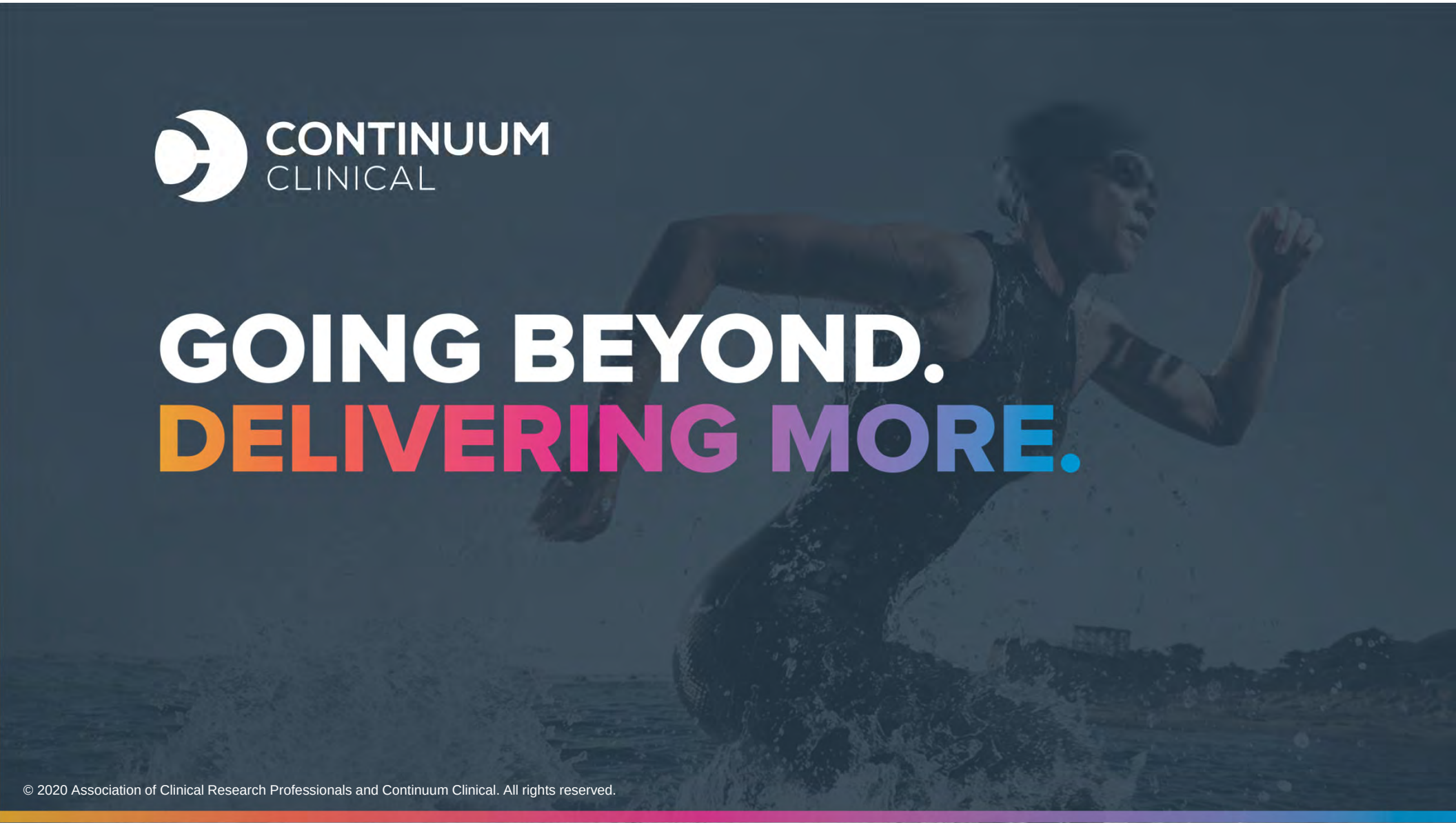

CONTINUUM CLINICAL

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# The Impact of COVID-19 on U.S. Clinical Trials

1 June 2020

# The Impact of COVID-19 on U.S. Clinical Trials: A Market Research Study Conducted by ACRP & Continuum Clinical

## About ACRP

ACRP supports clinical research professionals through membership, training and development, and certification. Founded in 1976, ACRP is a Washington, DC-based non-profit organization with more than 13,000 members who work in clinical research in more than 70 countries.

## About Continuum Clinical

Continuum Clinical is a global clinical trial enrollment company, providing fact-based patient recruitment solutions that deliver results. With over twenty-five years of experience, Continuum Clinical provides sponsors and CROs with patient recruitment and retention planning, study and site support, patient recruitment campaigns, patient advocacy and diversity & inclusion services, retention solutions, and reporting and analytics. We specialize in identifying and solving challenges that can impact successful clinical trial enrollment, from protocol development through study completion. Headquartered in the US, Continuum Clinical has more than 100 employees in the US and Europe and an expanded network of resources worldwide.

# Table of Contents

# Objectives, Areas of Learning & Study Design

# Objectives

- Association of Clinical Research Professionals (ACRP) and Continuum Clinical have partnered to conduct online surveys among clinical trial sites to obtain insights into to the Coronavirus (COVID-19) outbreak, the impact on patient enrollment and retention in clinical trials and how clinical trial sites are adapting.
- Insights will help clinical trial industry professionals assess and track changes that are impacting study sites.

# Areas of Learning

**How the impact of COVID-19 on clinical trial sites has changed over the past six weeks**

- Number of sites that have some or all of their clinical trials on hold due to COVID-19
- Likelihood of sites needing to close in the coming weeks
- Issues sites are facing with their employees
- Factors that have negatively impacted patient willingness to continue participating in clinical trials
- Percentage of sites that have had patients drop out of their studies since the onset of COVID-19; Percentage of patients at their site that have dropped out to date; Percentage of patients that sites anticipate will drop out of their clinical trials in the future
- Factors contributing to patients discontinuing from clinical trials
- Prevalence of COVID-19 clinical trials

**Solutions & Support:**

- How sites plan to maintain patient engagement on studies that are currently on hold or disrupted
- Technology solutions that would minimize disruptions
- Patient recruitment and retention support that would be helpful
- Patient willingness to permit in-home visits from clinical trial staff

**New areas of learning to the Wave II Study**

- Communication methods preferred by sites
- Patient safety procedures at sites
- Regulatory approval process
- Additional areas of site support

# Study Design & Sample Composition

- **Online surveys (US Only)**
  - Wave I: April 1-3, 2020
  - Wave II: May 14-26, 2020

- **Number of respondents**
  - Wave I: 297
  - Wave II: 274

- **Sample composition:**
  - ACRP members that conduct clinical trials

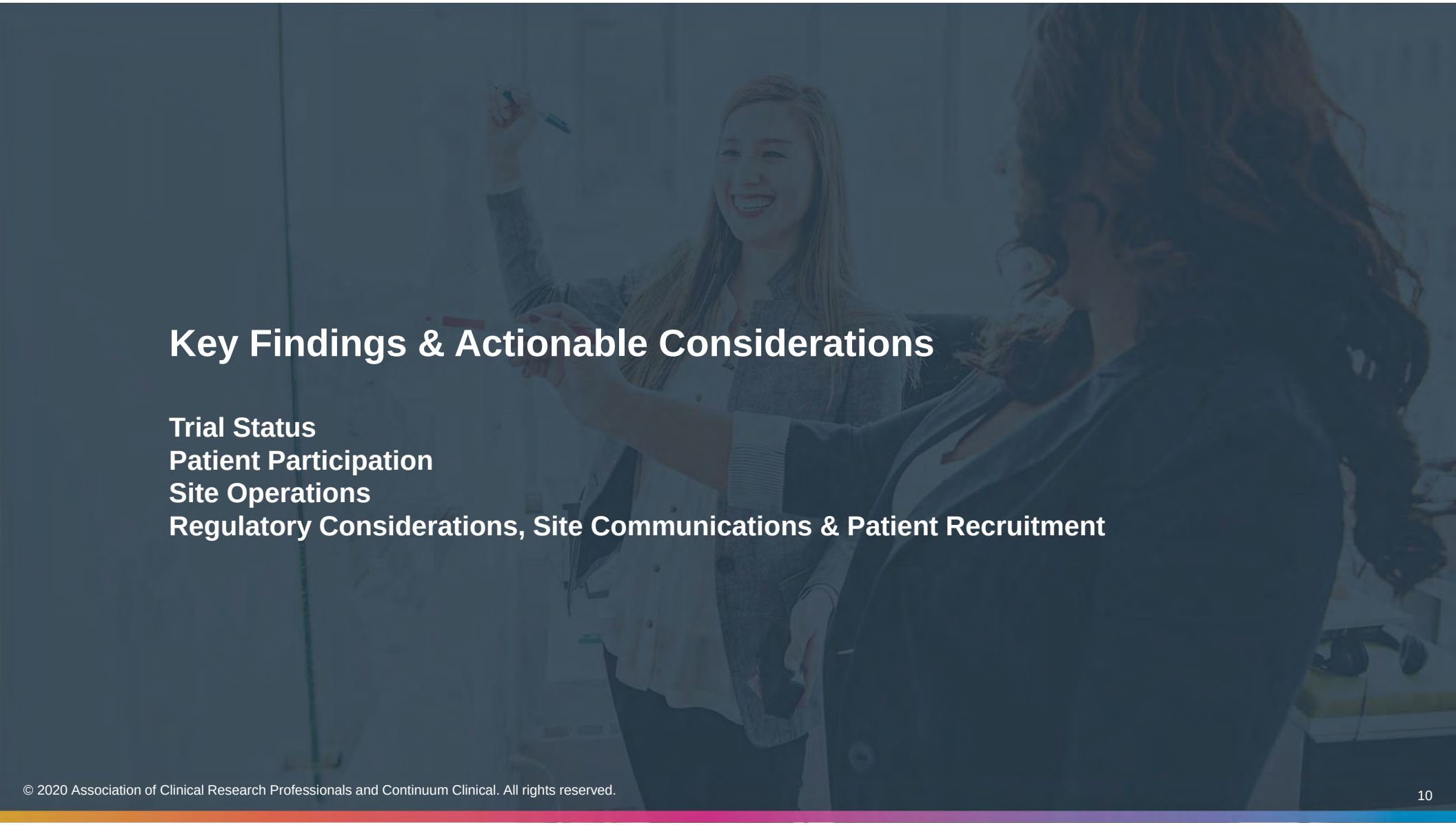
- **Notes about data tables:**
  - For certain questions, column totals may exceed 100% due to respondents having the ability to select multiple answers
  - Due to rounding, certain column totals may not equal 100% exactly

- **Statistical significance (Wave I versus Wave II)**
  - Statistically significant differences are indicated at a 95% confidence level are indicated in RED CAPITAL LETTERS.
  - Statistically directional differences are indicated at a 90% confidence level in red lower-case letters.

# Reader Note: Data Segmentation

**Data in this research study can be sub-segmented across the following criteria to create custom reports:**

- Type of clinical trial site
- Job description
- Number of sponsors and clinical trials enrolling prior to COVID-19
- Therapeutic areas of focus
- Location (Region of US)
- Whether or not sites are conducting clinical trials for COVID-19 related drugs



# Key Findings & Actionable Considerations

**Trial Status**
**Patient Participation**
**Site Operations**
**Regulatory Considerations, Site Communications & Patient Recruitment**

# Key Findings & Actionable Considerations: Trial Status

| Key Findings | Actionable Considerations |
|---|---|
| **Since Wave I of the ACRP & Continuum Clinical US survey (April 1-4, 2020), sites report a slight increase in trials continuing as planned and a decrease in the number of trials on hold.** | While many sites continue to have trials on hold, the forecast for more widespread resumption of clinical research operations is favorable. This aligns well with the approach states are taking to phased re-openings.<br><br>We believe that the favorable trends we are seeing will **accelerate** in the coming weeks. As such, time is of the essence for sponsors to be ready to move quickly. This includes ensuring that well-trained staffing is fully prepared to manage increased patient counts in concert with COVID safety procedure execution and enforcement.<br><br>Clearly articulated, comprehensive and fully vetted plans are imperative as the industry adapts to and defines the ever-changing definition of the 'new normal'.<br><br>Finally, sponsors should be sensitive to the widespread conduct and urgency of COVID trials at many sites. |
| **Sites are significantly more optimistic that they will <u>not</u> need to close in the coming weeks.**<br>• 75% indicate that it is very unlikely they will need to close vs. 36% in Wave I. | |
| **There has been a tremendous increase in the percentage of sites conducting COVID-19 related research, from 18% in Wave I to 43% in Wave II.** | |

# Key Findings & Actionable Considerations: Patient Participation

| Key Findings | Actionable Considerations |
|---|---|
| **The positive trend regarding the conduct of trials is further evidenced in an overall improvement in patients choosing to continue participating.**<br>• 66% of sites indicate that patients have <u>not</u> discontinued compared to 63% in Wave I.<br>• The vast majority of sites where any patients have discontinued indicates that relatively few patients have discontinued (25% or less of all patients currently enrolled in a study).<br>• The concerns that drive patient discontinuations have declined significantly.<br>  • These include fear of contracting the virus, willingness to visit the site, shelter-in-place requirements/social distancing and fear of interaction with medical professionals who are in close physical contact with other study subjects. | While the outlook among site personnel is far more positive than just six weeks ago, the rapidly changing nature of the pandemic underscores the need to be ready with contingency plans based on alternative scenarios.<br><br>While these are unprecedented times for everyone, patients and their family/friends/loved ones are experiencing the pandemic through an entirely different lens. And for healthcare professionals, the demands on these front-line essential workers are numerous and complex.<br><br>An understanding of the patient journey, their concerns, needs and wants specific to their healthcare condition is more important than ever. Sponsors should initiate proactive market research to unearth insights that will improve both patient retention and recruitment. |
| **The outlook for patient participation in the the future is even more optimistic.**<br>• 84% of sites say they expect 10% or fewer patients to discontinue compared to 74% in Wave I.<br>• While patient concerns about contracting COVID and visiting a site for appointments remain ongoing issues, the overall level of worry has not increased and is showing signs of improvement. | |

# Key Findings & Actionable Considerations: Site Operations

| Key Findings | Actionable Considerations |
|---|---|
| **Issues surrounding site staffing and engagement have declined, further buoying the prospects for patient participation and engagement.**<br>• Employees are somewhat less distracted, more engaged, and less concerned about working at their site due to health risks. There is also an indication that the challenges of working from home are lessening. | Sponsors cannot assume that COVID-related precautions are being universally implemented at sites. Nor can it be assumed that comprehensive training and enforcement is assured. This market research study indicates that there are sites that may not yet have comprehensive procedures established, or at least procedures that are fully and clearly communicated to site personnel.<br><br>Best practices for collaboration and communication with site personnel and CROs/CRAs should be established and continuously updated/improved as the reality of the pandemic and other societal issues changes, real-time.<br><br>The expectations and demands placed on site personnel are immense. Sponsors should evaluate the ability of each site to meet the demands of the pandemic in the context of each trial. Consideration should be given to augmented site manpower. |
| **Sites have implemented many of the newest COVID-related healthcare safety precautions for site visitors.**<br>• However, it is surprising that adoption has not been universal.<br>• In fact, there is not even one single accepted process that has been implemented universally. | |
| **The desire for operational support services remains very strong, especially telehealth (91%).**<br>• Interest in E-Consent has increased.<br>• The most important increase is the desire for assistance with patient transportation.<br>• In addition, sites are asking for PPE supply.<br>• Only 26% indicate that their site does not need any additional support. | Sites have a very strong need and desire for a greater depth and breadth of support services, from PPE to digital technology and fundamental necessities like patient transportation which is more challenging and complicated than ever. Sponsors can be more responsive by asking and listening to the unique needs of each site. Again, market research with site personnel is urged. |
| **Sites are somewhat more confident that patients will permit in-home visits by clinical trial staff (from 19% to 26%).**<br>• Still, over half remain uncertain patients will approve. | As in-home healthcare becomes increasingly important, sites will benefit greatly by understanding and addressing patient concerns, worries or fears. |

NW1
BK53

**Slide 13**

**NW1** [@Bob Klein] given the request for PPE, maybe we should suggest that sponsors should consider providing to sites as a consideration
Neil Weisman, 6/1/2020

**BK53** [@Neil Weisman] Thanks Neil. Good suggestion. I have revised. [@Ken Shore]  Do you have any feedback? Am I approved to change from 'draft' to
'final' and advise ACRP accordingly? When you provide final approval, will you be communicating with Marcie how you want to release to abbvie?
Bob Klein, 6/1/2020

# Key Findings & Actionable Considerations: Regulatory Considerations, Site Communications & Patient Recruitment

| Key Findings | Actionable Considerations |
|---|---|
| **62% of sites report that the IRB/CA/EC is continuing to function as normal during the pandemic.**<br>• 26% of sites believe that additional IRB approval will be required prior to re-activating studies postponed/placed on hold due to COVID-19.<br>• 48% do not believe additional approval will be required while another 26% don't know or are not sure. | Not unlike all businesses, there is some level of disruption in the regulatory environment. Sponsors will benefit by keeping a finger on the pulse as it pertains to changing requirements and timing for reviews/approvals. |
| **In terms of ongoing communication, Email is the method sites most prefer sponsors/CROs utilize.**<br>• Phone calls and videoconference are also welcomed by many sites.<br>• Text messaging is not well regarded; it may be viewed as personally intrusive.<br>• Not surprisingly, in person visits are not desirable during the pandemic. | With the added burden on site personnel, being sensitive to the best form(s) of site communication will be necessary for effective operations and, at the same time much appreciated. The varying familiarity and comfort with communication technology deserves special consideration. |
| **Overall, it's clear that sites are looking for greater recruitment and retention support.**<br>• There has been a significant increase in the desire for two key patient recruitment support services: physician referral networks and secondary telephone screening by telephone of patients referred via media and/or physician referral networks. | The burden of the pandemic on sites extends to the ability to recruit and retain patients.<br><br>It's abundantly clear that sites need and want added recruitment and retention support.<br><br>Sponsors can be most effective when armed with knowledge of and actionable insights into the trial-specific, condition-specific and site-specific needs that are changing daily as the pandemic runs its unpredictable course. |

# Detailed Findings:

# Profile of Sites & Survey Respondents

## 75% of the sites who responded to the Wave I and Wave II surveys conduct clinical trials and also provide other healthcare services unrelated to clinical trials.

| Which ONE of the following best describes your site? | US Wave 1 (A) | US Wave 2 (B) |
|---|---|---|
| Total | N=297 | N=274 |
| Our site conducts clinical trials only | 25% | 25% |
| Our site conducts clinical trials AND provides other healthcare services unrelated to clinical trials | 75% | 75% |

# The largest single segment is academic sites.

| Which ONE of the following best describes your site? | US Wave 1 (A) | US Wave 2 (B) |
|---|---|---|
| Total | N=297 | N=274 |
| Academic institution | 41% | 47% |
| Non-academic hospital, health system or affiliated office | 28% | 27% |
| Independent clinical trial study site | 22% | 17% |
| Other, please specify: | 9% | 9% |

# Sites that responded to the surveys cover much of the US.

| In what state is your site located? | US Wave 1 | US Wave 2 |
|---|---|---|
| Total | N=297 | N=274 |
| Alabama | 1% | 1% |
| Alaska | 0% | 0% |
| Arizona | 2% | 2% |
| Arkansas | 0% | 1% |
| California | 5% | 8% |
| Colorado | 2% | 1% |
| Connecticut | 2% | 1% |
| Delaware | 0% | 0% |
| District of Colombia | 1% | 0% |
| Florida | 11% | 13% |
| Georgia | 2% | 2% |
| Hawaii | 0% | 0% |
| Idaho | 2% | 1% |
| Illinois | 4% | 2% |
| Indiana | 2% | 2% |
| Iowa | 0% | 0% |
| Kansas | 2% | 1% |

| In what state is your site located? | US Wave 1 | US Wave 2 |
|---|---|---|
| Kentucky | 1% | 2% |
| Louisiana | 1% | 1% |
| Maine | 1% | 0% |
| Maryland | 1% | 1% |
| Massachusetts | 0% | 0% |
| Michigan | 3% | 3% |
| Minnesota | 1% | 1% |
| Mississippi | 0% | 0% |
| Missouri | 3% | 3% |
| Montana | 0% | 0% |
| Nebraska | 1% | 1% |
| Nevada | 0% | 1% |
| New Hampshire | 0% | 0% |
| New Jersey | 2% | 1% |
| New Mexico | 1% | 1% |
| New York | 7% | 6% |
| North Carolina | 4% | 4% |
| North Dakota | 0% | 0% |

# Sites that responded to the surveys cover much of the US.

| In what state is your site located? | US Wave 1 | US Wave 2 |
|---|---|---|
| Ohio | 4% | 5% |
| Oklahoma | 1% | 0% |
| Oregon | 1% | 0% |
| Pennsylvania | 5% | 7% |
| Rhode Island | 1% | 0% |
| South Carolina | 2% | 1% |
| South Dakota | 0% | 0% |
| Tennessee | 3% | 1% |
| Texas | 9% | 8% |
| Utah | 3% | 2% |
| Vermont | 0% | 1%a |
| Virginia | 3% | 2% |
| Washington | 1% | 2% |
| West Virginia | 1% | 1% |
| Wisconsin | 4% | 4% |
| Wyoming | 0% | 0% |

# Over half of those who responded are Site Coordinators or Study Nurses.

| Which job title best represents your current role? | US Wave 1 (A) | US Wave 2 (B) |
|---|---|---|
| Total | N=297 | N=274 |
| Study Coordinator or Study Nurse | 59% | 53% |
| Principal/Site Investigator/Owner | 5% | 4% |
| Marketing or Outreach Coordinator | 1% | 0% |
| Office Manager | 7% | 10% |
| Other, please specify: | 27% | 33% |

# The sites conduct clinical trials across a broad range of therapeutic areas.

| In which of the following therapeutic areas does your site conduct clinical trials? | US Wave 1 (A) | US Wave 2 (B) |
|---|---|---|
| Total | N=297 | N=274 |
| Cardiovascular | 40% | 43% |
| Oncology | 34% | 31% |
| Endocrinology | 32%b | 26% |
| Gastroenterology | 30% | 28% |
| Respiratory | 29% | 28% |
| Neurosciences | 25% | 26% |
| Infectious Diseases | 24% | 28% |
| Pediatrics | 23% | 23% |
| Vaccine | 23% | 21% |
| Central Nervous System | 22% | 22% |

| In which of the following therapeutic areas does your site conduct clinical trials? | US Wave 1 (A) | US Wave 2 (B) |
|---|---|---|
| Hematology | 21% | 23% |
| Dermatology | 20% | 19% |
| Women's Health | 19% | 18% |
| Nephrology | 19% | 17% |
| Immuno-inflammatory | 18% | 19% |
| Gynecology | 18% | 18% |
| Urology | 17% | 15% |
| Other, please specify: | 17% | 22% |
| Ophthalmology | 15% | 12% |
| Rare Diseases | 14% | 14% |
| Rheumatology | 14% | 21%A |

# Nearly half of sites were contracted with more than 10 sponsors prior to the onset of COVID-19.

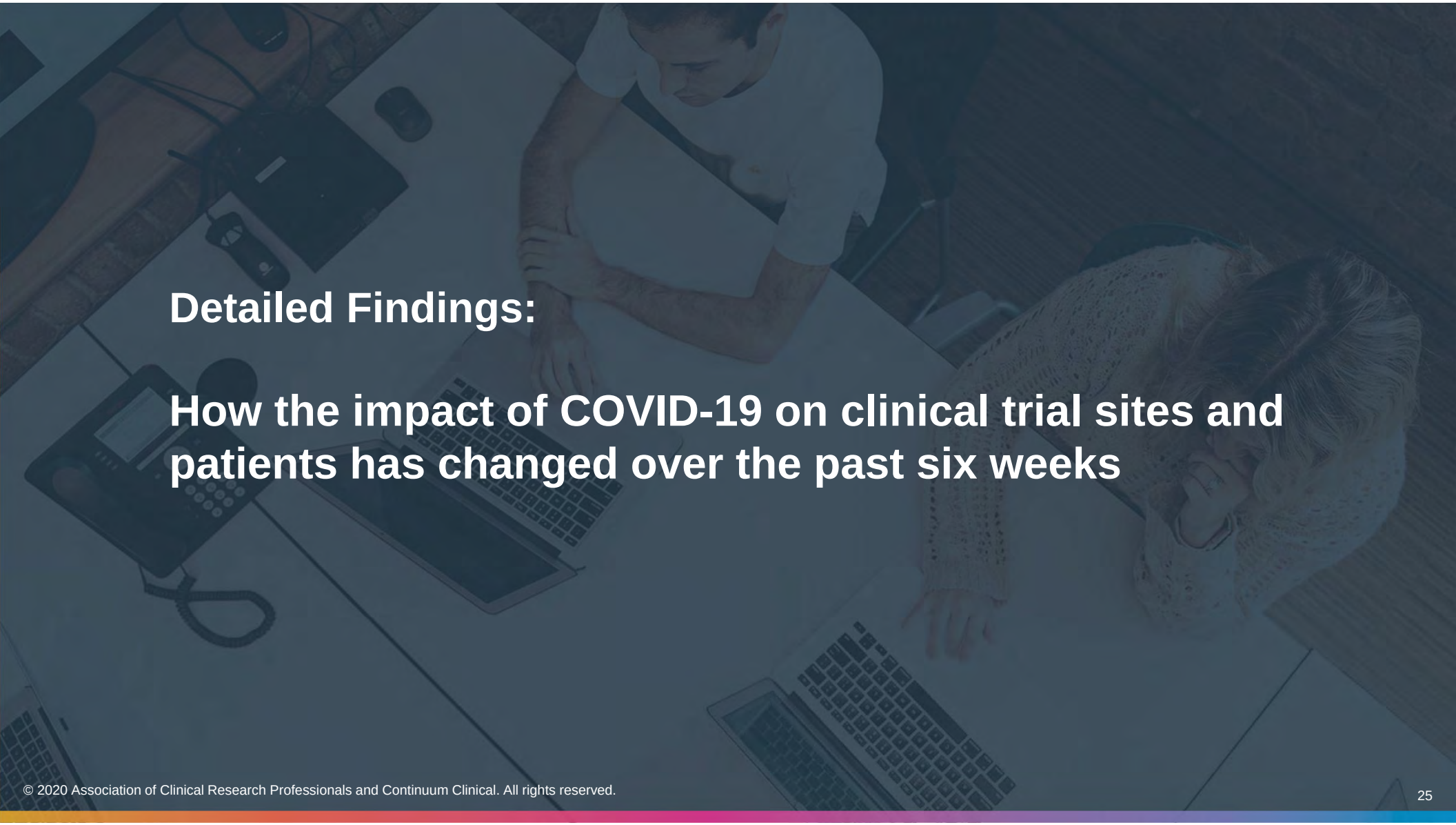
| How many different clinical trial sponsors was your site contracted with prior to the onset of the COVID-19 pandemic? | US Wave 1 (A) | US Wave 2 (B) |
|---|---|---|
| Total | N=297 | N=274 |
| 1-2 sponsors | 6% | 9% |
| 3-4 sponsors | 12% | 12% |
| 5-6 sponsors | 15% | 15% |
| 7-8 sponsors | 11% | 9% |
| 9-10 sponsors | 11% | 9% |
| More than 10 sponsors | 44% | 46% |

# Nearly half of sites were enrolling more than 10 trials prior to the onset of COVID-19.

| How many different clinical trials was your site enrolling prior to the onset of the COVID-19 pandemic? | US Wave 1 (A) | US Wave 2 (B) |
|---|---|---|
| Total | N=297 | N=274 |
| 1-2 trials | 9% | 11% |
| 3-4 trials | 11% | 14% |
| 5-6 trials | 13% | 14% |
| 7-8 trials | 11% | 9% |
| 9-10 trials | 9% | 7% |
| 11-15 trials | 10% | 8% |
| 16-20 trials | 8% | 8% |
| 21 or more trials | 29% | 30% |

# There has been a tremendous increase in the percentage of sites conducting COVID-19 related research, from 18% in Wave I to 43% in Wave II.

| Is your site currently conducting clinical trials for a COVID-19 related drug? | US Wave 1 (A) | US Wave 2 (B) |
|---|---|---|
| Total | N=244 | N=223 |
| Yes | 18% | 43%A |
| No | 82%B | 57% |



## Detailed Findings:

# How the impact of COVID-19 on clinical trial sites and patients has changed over the past six weeks

# Since the first wave of the site survey April 1-4, 2020, sites report a slight increase in trials continuing as planned and a decrease in the number of trials on hold.

| Which ONE of the following best describes the current status of clinical trials at your site? | US Wave 1 (A) | US Wave 2 (B) |
|---|---|---|
| Total | N=297 | N=274 |
| All clinical trials are continuing as planned prior to the COVID-19 pandemic | 5% | 8% |
| Some clinical trials have been put on hold due to the COVID-19 pandemic | 77% | 74% |
| All clinical trials have been put on hold due to the COVID-19 pandemic | 18% | 19% |

## There has been a slight increase in the intent to use telemedicine to maintain patient engagement for trials that are currently on hold. Phone calls continue to be the predominant method sites intend to utilize.

| How do you plan to maintain patient engagement on studies that are currently on hold or disrupted? | US Wave 1 (A) | US Wave 2 (B) |
|---|---|---|
| Total | N=282 | N=253 |
| Phone calls | 85% | 85% |
| Email | 51% | 52% |
| Telemedicine | 50% | 54% |
| Other, please specify | 15% | 11% |
| We do not plan to re-engage with patients until the studies resume | 7% | 7% |

## Sites are significantly more optimistic that they will not need to close in the coming weeks. 75% indicate that it is very unlikely they will need to close vs. 36% in the first wave of the study.

| Based on what you know today about the COVID-19 pandemic, how likely is it that your site will need to close in the coming weeks? | US Wave 1 (A) | US Wave 2 (B) |
|---|---|---|
| Total | N=244 | N=223 |
| Bottom 2 | 69% | 91%A |
| Very unlikely | 36% | 75%A |
| Somewhat unlikely | 32%B | 17% |
| Somewhat likely | 20%B | 5% |
| Very likely | 11%B | 3% |
| Top 2 | 31%B | 9% |

## Issues surrounding site staffing and engagement have declined. Employees are somewhat less distracted, more engaged, and less concerned about working at their site due to health risks. There is also an indication that the challenges of working from home are lessening.

| Which of the following issues are you facing with staffing at your site since the onset of the COVID-19 pandemic? | US Wave 1 (A) | US Wave 2 (B) |
|---|---|---|
| Total | N=297 | N=274 |
| Employees experience difficulties working from home | 38% | 35% |
| Employees are not fully engaged due to COVID-19 related disruptions | 33% | 28% |
| Employees unwilling to work at the site due to health risks | 22% | 20% |
| Employees are ill and not able to work | 10%B | 5% |
| Employees unable to arrange transportation to the site | 2% | 3% |
| Employees demanding higher pay | 0% | 1% |
| Some of the employees at our site have been furloughed | 0% | 28%A |
| Other, please specify: | 18% | 18% |
| None of the above | 31% | 29% |

## While patient concerns about contracting COVID and visiting a site for appointments remain ongoing issues, the overall level of worry has not increased and is showing signs of improvement.

| Which of the following have impacted patient willingness to continue participating in clinical trials since the onset of COVID-19? | US Wave 1 (A) | US Wave 2 (B) |
|---|---|---|
| Total | N=244 | N=223 |
| Fear of contracting COVID-19 | 63% | 60% |
| Fear of interaction with medical professionals at the site who are in close physical contact with other study subjects | 40% | 39% |
| Not willing to visit the site for appointments | 55% | 57% |
| Desire to maintain social distancing | 57% | 55% |
| Local shelter-in-place or stay-at-home regulations | 57% | 53% |
| Lack of access to transportation to and from the site | 12% | 12% |
| Non-compliance to medication regimen | 2% | 3% |
| Insufficient stipend for participation given the severity of the pandemic | 4% | 6% |
| Other, please specify: | 6% | 5% |
| None of the above | 15% | 17% |

## These positive trends are further reflected in a slight overall improvement in patients choosing to continue participating. 66% of sites indicate that patients have not discontinued.

| Have patients chosen to discontinue from any of your clinical trials since the onset of COVID-19? | US Wave 1 (A) | US Wave 2 (B) |
|---|---|---|
| Total | N=297 | N=274 |
| Yes | 15% | 16% |
| No | 63% | 66% |
| I don't know/I'm not sure | 22% | 19% |

## The vast majority of sites where any patients have discontinued indicate that few patients have discontinued (25% or less of all patients currently enrolled in a study). The percentage of patients discontinuing has declined since the first wave of the survey.

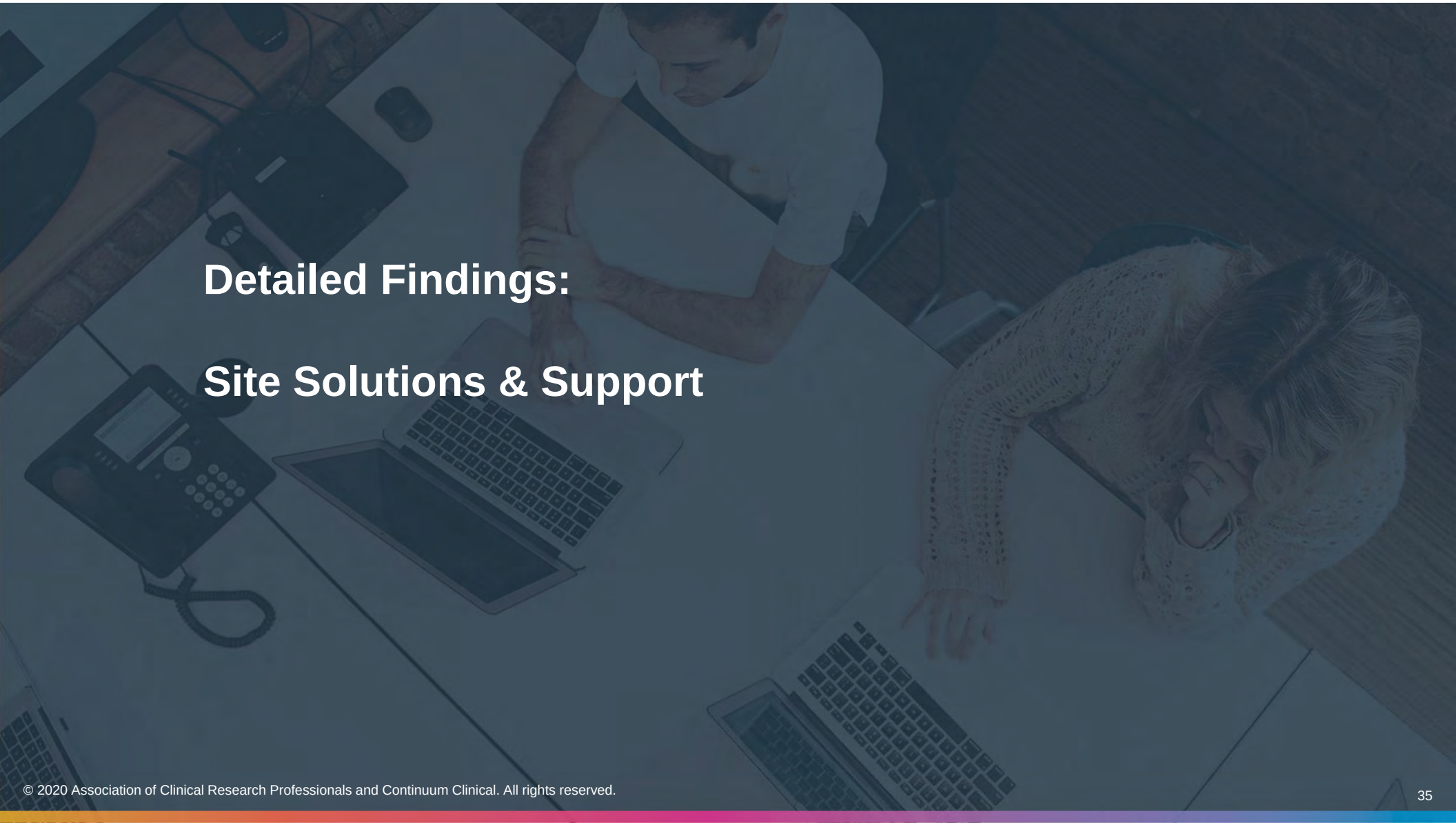
| Thinking about all studies being conducted at your site, approximately what percentage of patients have discontinued since the onset of COVID-19? | US Wave 1 (A) | US Wave 2 (B) |
|---|---|---|
| Total | N=44* | N=43* |
| 10% or less | 73% | 72% |
| 11 - 25% | 9% | 14% |
| 26 - 50% | 5% | 0% |
| 51 - 75% | 0% | 5% |
| 76% or more | 2% | 5% |
| I don’t know/can’t answer | 11% | 5% |

## The outlook for patient discontinuations in the the future is significantly more optimistic. 84% of sites say they expect 10% or fewer patients to discontinue compared to 74% in the first wave.

| While the future is impossible to predict, approximately what percentage of patients do you anticipate will discontinue from clinical trials at your site due to COVID-19? | US Wave 1 (A) | US Wave 2 (B) |
|---|---|---|
| Total | N=297 | N=274 |
| 10% or less | 74% | 84%A |
| 11 - 25% | 19%B | 10% |
| 26 - 50% | 5% | 4% |
| 51 - 75% | 1% | 1% |
| 76% or more | 0% | 1% |

## The concerns that drive patient discontinuations have declined significantly. These include fear of contracting the virus, willingness to visit the site, shelter-in-place requirements/social distancing and fear of interaction with medical professionals who are in close physical contact with other study subjects.

| Which of the following have contributed to patients discontinuing from clinical trials being conducted at your site? | US Wave 1 (A) | US Wave 2 (B) |
|---|---|---|
| Total | N=44* | N=43* |
| Fear of contracting COVID-19 | 82% | 67% |
| Not willing to visit the site for appointments | 80%b | 63% |
| Local shelter-in-place or stay-at-home regulations | 75%B | 49% |
| Desire to maintain social distancing | 64% | 53% |
| Fear of interaction with medical professionals at the site who are in close physical contact with other study subjects | 52% | 44% |
| Lack of access to transportation to and from the site | 14% | 16% |
| Not wanting to remain compliant with medication regimen | 2% | 9% |
| Insufficient stipend for participation given the severity of the pandemic | 2% | 0% |
| Other, please specify: | 7% | 16% |
| I don't know/I'm not sure | 0% | 2% |



# Detailed Findings:

# Site Solutions & Support

## The desire for support services remains very strong, especially telehealth (91%). Interest in E-Consent has increased. The most important increase is the desire for assistance with patient transportation.

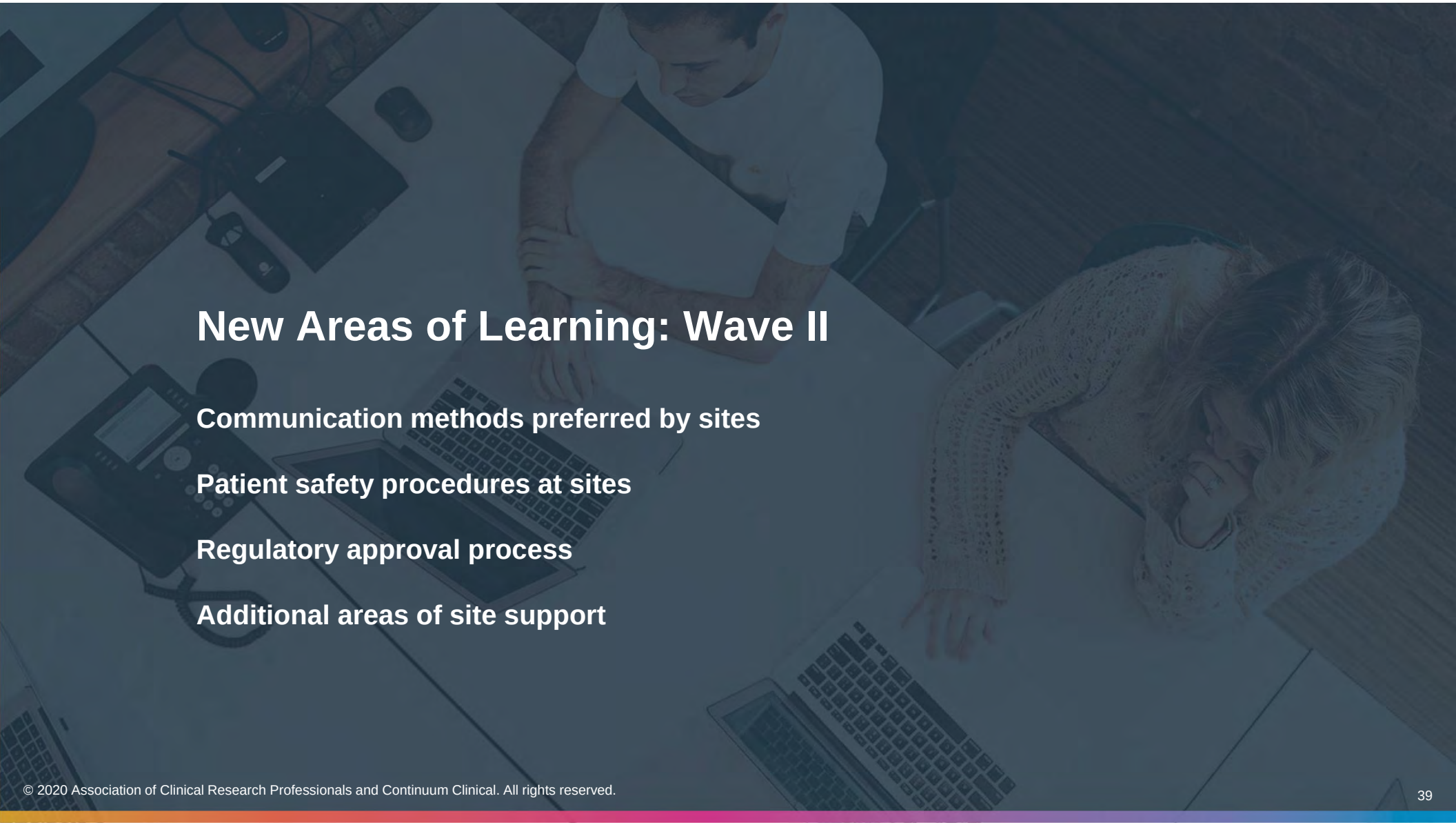
| Thinking about the clinical trials that are currently being conducted at your site, how helpful would the following technologies be in minimizing disruptions? | US Wave 1 (A) | US Wave 2 (B) |
|---|---|---|
| Telehealth (video visits with site staff for assessments and answering patient questions) | 92% | 91% |
| Patient Chat (technology that automatically engages with patients to answer frequently asked questions and provide study tips and reminders) | 79% | 79% |
| Medication Compliance (in-home technology or phone apps to remind and monitor patients taking study treatments) | 78% | 78% |
| E-Consent (patients complete all study related paperwork and consenting documents at home) | 75% → | 80% |
| Transportation (enabling the patient to order their transportation electronically) | 56% → | 68%A |

## Sites are somewhat more confident that patients will permit in-home visits by clinical trial staff (from 19% to 26%). Still, over half remain uncertain patients will approve.

| Considering the impact of COVID-19 now and in the future, do you think your patients will permit in-home visits by clinical trial staff? | US Wave 1 (A) | US Wave 2 (B) |
|---|---|---|
| Total | N=297 | N=274 |
| Yes | 19% | 26%A |
| No | 26%b | 20% |
| I'm not sure/I don't know | 56% | 54% |

## There has been a significant increase in the desire for two key support services: physician referral networks and secondary telephone screening by telephone of patients referred via media and/or physician referral networks. Overall, it's clear that sites are looking for greater support.

| Thinking about the clinical trials that are currently active or on hold at your site due to COVID-19, how helpful would each of the following types of patient recruitment and retention support be over the coming weeks and months? | US Wave 1 (A) | US Wave 2 (B) |
|---|---|---|
| Provide tools (e.g., information on how important it is to participate in and stay in a clinical trial) to maintain engagement with referred and/or enrolled study patients | 68% | 73% |
| Provide you a list of highly qualified potential study subjects for you to contact | 59% | 64% |
| Provide secondary screening by telephone of patients referred via media and/or physician referral network | 57% | 64%a |
| Development of physician referral network (nearby treating physicians) that can quickly generate a steady stream of highly qualified referrals | 54% | 65%A |



# New Areas of Learning: Wave II

**Communication methods preferred by sites**

**Patient safety procedures at sites**

**Regulatory approval process**

**Additional areas of site support**

**Email is the communication method sites most prefer sponsors/CROs utilize. Phone calls and videoconference are also welcomed by many sites. Text messaging is not well regarded; it may be viewed as personally intrusive. Not surprisingly, in person visits are not desirable during the pandemic.**

| During this time, which of the following are your preferred methods of communication with sponsors/CROs? | US Wave 2 |
|---|---|
| Total | N=274 |
| Email | 96% |
| Phone calls | 53% |
| Videoconference | 41% |
| Text | 5% |
| In person | 3% |
| Other, please specify*: | 2% |
| None of the above | 1% |

*Other (open-end): TriNetX

## Sites have implemented many of the newest COVID-related healthcare safety precautions for site visitors. It seems surprising that adoption of *all* these processes have not been implemented universally. In fact, there is not even one single process that has been implemented universally.

| What new site processes related to COVID-19 have been implemented to ensure safety of clinical trial subjects entering your facilities? | US Wave 2 |
|---|---|
| Total | N=274 |
| All staff is required to wear a mask and gloves | 84% |
| We take the temperatures of all patients entering our facility | 82% |
| We enforce social distancing | 81% |
| All patients are provided with a face mask | 77% |
| We prescreen our subjects over the phone prior to a clinical trial visit | 72% |
| We limit the number of patients permitted to enter the site at a single time | 70% |
| All patients are required to use hand sanitizer | 59% |
| Other, please specify*: | 20% |
| None of the above | 1% |

*Other (open-end) responses are included in the appendix

## 26% of sites believe that additional IRB approval will be required prior to re-activating studies postponed/placed on hold due to COVID-19. 48% do not believe additional approval while another 26% don't know or are not sure.

| Will your site require additional IRB approval prior to re-activating studies postponed/placed on hold due to COVID-19? | US Wave 2 |
|---|---|
| Total | N=253 |
| Yes | 26% |
| No | 48% |
| I don't know/I'm not sure | 26% |

# 62% of sites report that the IRB/CA/EC is continuing to function as normal during the pandemic.

| Is the IRB/CA/EC for your site continuing to function in a standard way or has the activity level decreased as a result of COVID-19? | US Wave 2 |
|---|---|
| Total | N=274 |
| IRB/CA/EC is not currently meeting (scheduled meetings have been cancelled) | 1% |
| IRB/CA/EC activity is focused only on active studies or COVID-19 new studies | 11% |
| IRB/CA/EC is continuing to function in the normal way | 62% |
| IRB/CA/EC is meeting more frequently (additional meetings added) | 7% |
| I don’t know/I’m not sure | 19% |

## 40% of sites believe that their IRB/CA/EC will return to normal business in the next four months. However, 49% say they don't know.

| When do you anticipate that the IRB/CA/EC will return to normal business? | US Wave 2 |
|---|---|
| Total | N=53* |
| May 2020 | 4% |
| June 2020 | 17% |
| July 2020 | 13% |
| August 2020 | 6% |
| September 2020 | 4% |
| October 2020 | 2% |
| November 2020 | 0% |
| December 2020 | 0% |
| 2021 or later | 6% |
| I'm not sure | 49% |

## In terms of additional support due to COVID, sites most want PPE supply. Only 26% indicate that their site does not need any additional support.

| As a result of COVID-19, what additional clinical trial support is your site in need of? | US Wave 2 |
|---|---|
| Total | N=274 |
| PPE Supply | 54% |
| Remote Access Systems/Platforms | 38% |
| COVID-19 Testing | 36% |
| Our site does not need any additional clinical trial support | 26% |
| Resources (Staff) | 22% |
| Subject Outreach | 20% |
| Technology Support | 19% |
| Medical Equipment | 5% |
| Other, please specify: | 4% |

*Other (open-end) responses are included in the appendix

# Appendix: Open-end responses

Please describe the processes that your site has put in place for the proper oversight of subjects with presumed or confirmed COVID-19.

How do you plan to maintain patient engagement on studies that are currently on hold or disrupted?

Which of the following issues are you facing with staffing at your site since the onset of the COVID-19 pandemic?

In addition to the technologies mentioned in the question above, are there any other technologies that you would recommend?

What new site processes related to COVID-19 have been implemented to ensure safety of clinical trial subjects entering your facilities?

As a result of COVID-19, what additional clinical trial support is your site in need of?

Do you have any suggestions to help overcome patient objections to home visits by clinical trial staff?

Are there any other thoughts or comments that you would like to share related to the onset of the COVID-19 pandemic as it relates to your site?

# Appendix: Open-end responses

**Please describe the processes that your site has put in place for the proper oversight of subjects with presumed or confirmed COVID-19.**

# Please describe the processes that your site has put in place for the proper oversight of subjects with presumed or confirmed COVID-19.

- Pre-screen by phone prior to appointment  Take temperature prior to entering clinic  -require subjects to wear masks and sanitize hands
- 1. Ask the presumed or confirmed subject to stay at home.  2. encourage the subject to contact the health care immediately.  3.
- 1.Contacted by phone, check emergency contact info with patients  2. Medical history and concom med list by email or teleconference  3. Confirm diagnosis 4. Check eligibility for studies on place  5. Complete AE and notify Sponsor  6. Follow protocol for COVID-19 precautions as FDA and CDC precautions .  7. Monotonize subject remotely every other day
- A separate clinic team that is responsible for COVID-19, with a hotline. Once called patient is directed to their car and can be tested by car from the back of the building.
- AE to be reported to Sponsor within 24 hours of site being notified and subject will be given instructions on status of study medication based on PI and Sponsor guidance, Subject not allowed to come to the site for study visits, site will continue to contact the subject to follow up with the AE reporting guidelines.
- All confirmed or rule-out COVID patients coming into the ER are put in single rooms with [negative air pressure], (when available). Critical patients are in the intensive care unit, and others on floor with appropriate rooms. All staff in contact with patient has PPE. This continues until patient has a negative COVID result.
- All follow ups are done over the phone
- All must go through the ER for testing
- All newly admitted trauma and burn patients receive a rapid COVID-19 test.
- All outpatients are required to have COVID19 testing prior to their visit
- All participants on studies are tested prior visit this triggered unwanted deviations depending when the test is resulting  Multiple phone calls from providers and research staff prior visits to participants  Multiple teams are prescreening New participants to see if the benefit of IP treatment is outweigh the risk.  Sponsors approvals to skip “nonessential” visits, usage of local labs, shipping oral IP, this will affect the data integrity but some will be gathered than nothing
- All patients are asked questions about COVID-19 symptoms, travel, etc.  All patients must wear face mask and gloves as do employees.  All patents and employees have their temp taken.
- All positive pts are only seen at our infectious disease clinic--we are trying to keep all  hot  patients there in an effort to keep our clinic  cool .
- All required precautions.

# Please describe the processes that your site has put in place for the proper oversight of subjects with presumed or confirmed COVID-19.

- All subjects are asked COVID screening questions during their reminder calls and asked to wear a mask. if they do not have one, they are provided one at their visit.
- Any confirmed cases will need to follow-up with their healthcare provider/local hospital. Site will maintain weekly contact with subject if possible. Subject must be at least 3 weeks symptom free before performing onsite study visit. Partial remote visits will be done if possible, with special considerations given to IP dispensing, on a per-study basis (potentially drop off IP, drive by pick up, pick up from family member, etc)
- Any patient that tests positive for COVID will not come into the office unless they are still receiving treatment. If it is necessary to come in for treatment, then patients will be scheduled at the end of the day after all other patients are gone. Staff will use full PPE and double mask during visit. Once patients are checked out all rooms will be cleaned and sanitized.
- Any visits that can be done remotely are completed that way. we are also performing drive-by appointments.
- As much as possible is postponed or done remotely
- Asked to reschedule appointment
- Chart review of hospitalized pts, discuss pt. condition w treating physicians, cont. follow up after discharge
- Clinical research has not restarted at our institution yet
- Clinical trials have not yet resumed at our site.
- COVID tracker via phone app
- COVID unit
- COVID-19 testing ordered
- Curbside or telehealth visits
- Depends on how severe their COVID-19 disease is at the time of visit. If acutely ill, in hospital and/or ICU PPE are required. If out of hospital but necessary visit - subject must mask and maintain social distancing - visit is limited to only the minimum needed tests. For subjects recovering from COVID-19 we generally require two negative PCR's before scheduling a test or visit.
- Depends on the study. Our site is doing a lot of COVID trials.

# Please describe the processes that your site has put in place for the proper oversight of subjects with presumed or confirmed COVID-19.

- Designed area for screening all subjects
- Enrolling is currently on hold for all studies per IRB
- Entrance through back door of the office, One dedicated exam room, proper PPE for staff interacting with the patient.
- Entrance to ER or related departments for suspected patients. Other hospital entrances are not open for them.
- Everyone is screened at the entrance. Anyone who screens positive is not allowed in the facility and offered testing outside or in the negative pressure room. Our practice has not had any patient's report positive for COVID-19 at this time
- Follow clinical processes for our institution
- Follow hospital guidelines
- Follow hospital protocol for testing
- Following local and state health regulations. If a subject is confirmed to have a positive result of COVID-19, anyone in contact will be asked to quarantine.
- For our inpatient studies we are isolating participants in their rooms
- Have not entered the site for visits
- Have not had any
- Haven't had any
- Hospitalized if appropriate. Cohorted in same area of hospital.
- I am not sure of this process and do not have access to the information at this time.
- I do not know - we have not had any presumptive or positive research subjects on my team
- I do not know since the research department is not currently working.
- I do not work directly with this trial. My understanding is that we have remained in phone communication with our subjects with all study visits being paused. If there was any concern for COVID-19 we would direct them to their primary care physician and follow. We have not been granted any exemptions to our protocol to allow in person visits.

# Please describe the processes that your site has put in place for the proper oversight of subjects with presumed or confirmed COVID-19.

- How to manage study participants who are interview screen positive  Research participants with possible exposure or symptoms of illness should be scheduled (or rescheduled) for a future appointment and monitored for illness progression. Future appointments should  be made after the participant has clinically recovered or been medically cleared. Participants must  comply with all home quarantine recommendations and requirements.  In the instance that a participant screens positive for COVID-19 exposure or potential illness and must  be seen for clinical reasons or safety concerns, please follow all current infection prevention guidance,  including the following:  Staff and faculty at highest risk should not come into contact with a potentially infected COVID-19  patient. High risk faculty and staff includes adults over the age of 65, and anyone with cardiovascular or  pulmonary disease, or who is immunocompromised.  1. Precautions to minimize patient risk to others  a. The patient will wear a mask  b. If available, the patient should be isolated in a single-patient, negative pressure room,  with the door closed. Otherwise, patients will be placed in a single-patient room with  the door closed.  c. Limit patient movement and transport throughout the facility. Notification and preparations for safe transport of the patient must occur prior to transport.  d. All clinicians in contact with the patient must comply with current infection prevention  precautions (i.e. gown, gloves, face mask).  2. Utilize Personal Protective Equipment  a. Gloves  i. Perform hand hygiene, then don clean, non-sterile gloves before entry to the  patient's room. Change gloves if they become torn or heavily contaminated.  Remove and discard gloves and perform hand hygiene before leaving the room.  b. Gowns  i. Don a clean disposable gown before entry into the patient room or area.  Change the gown if it becomes soiled. Remove and discard the gown before  leaving the patient room or care area.  c. Respiratory Protection  i. Don an "ordinary" face mask before entry into the patient room or area for  routine assessments.  d. Eye Protection  i. Don eye protection (e.g., goggles, a disposable face shield that covers the front  and sides of the face) before entry to the patient room or care area. Remove  eye protection before leaving the patient room or care area.  e. Aerosol-Generating Procedures  i. Procedures that are likely to induce coughing; e.g., nasopharyngeal specimen  collection, sputum induction, and open suctioning of airways should be  performed cautiously and avoided if possible.  ii. If these procedures must be done, they should be performed in an Airborne  Infection Isolation Room. Individuals present should be limited to only those  who are essential.  f. For explicit instructions for donning and doffing PPE, follow the included links to  resources provided by the CDC and BJC Healthcare.  i. https://www.cdc.gov/hai/pdfs/ppe/ppe-sequence.pdf  ii. https://www.youtube.com/watch?v=YXNVcnxuMmA  3. Patient room disinfection  a. Rooms should be cleaned using virucidal treatment, then left unoccupied with all doors  closed for a minimum of 30 minutes.  b. Gowns, gloves and other PPE should be deposited into biohazard safety bags and in  medical waste containers per EH&S and CDC guidelines: https://fpp.wustl.edu/covid-19-  information/.  4. All equipment used in handling specimens of screen-positive patients should be disinfected,  placed in a bag, and transported to processing facilities/labs using current EH&S guidance.

# Please describe the processes that your site has put in place for the proper oversight of subjects with presumed or confirmed COVID-19.

- I'm not sure as I am not part of that team
- I'm unsure if you are asking about existing subjects already enrolled that may have contracted COVID-19 or if you are asking about subjects who are enrolled into COVID trials because they already have the disease. We have not yet experienced having to deal with an existing patient contracting COVID while on trial. For patients being enrolled into COVID trials, we are following the FDA guidelines for consent (electronic or finding other ways to document consent without paper forms leaving the patient room) and minimizing in person contact by utilizing video and phone to interactions.
- If a patient is presumed positive for COVID-19, they are isolated and get a COVID-19 test. If confirmed positive, they are taken to our hospital COVID-19 ICU ward and treated as necessary per protocol.
- If fail screening on site (this does not mean patient is symptomatic of CPVOD), isolated in closed room then contact the central command center who gives further instructions. Investigator, may or may not carry out study visit. Patients were referred to follow up with their primary care MD.
- If in office placed in exam room specifically set aside for COVID. If positive patients would be followed by telephone
- If patients come to clinic and are suspect for COVID due to temperature taken at door they are isolated in a separate room. it is Standard of Care from there and the clinic responsibility.
- If phone visit- report AE (some studies requiring SAE for any report of presumed or confirmed positive COVID-19). For anyone coming into clinic for a procedural visit, if they have a fever they are turned away and asked to reschedule visit.
- If presumed or confirmed COVID-19, a telemedicine visit will be done in lieu of in-clinic visit.
- If presumed: CXR & to PCP for testing. if confirmed: unknown
- If they present with a fever or answer yes to any of the screening questions - they are asked to return home and contact their primary care MD
- Immediate quarantine and testing implemented, including for anyone who had contact.
- Immediate referral to COVID19 command post
- Increased cleaning schedule. Delay of some study activities to decrease the number of people required to interact with the subject and/or study partner.
- Inform providers prior to the clinical appointment. Testing all patients with COVID symptoms.
- Isolation rooms in clinic, PPE for both patients and staff must be followed

# Please describe the processes that your site has put in place for the proper oversight of subjects with presumed or confirmed COVID-19.

- It would be our hospitals policy that would be used. Currently Research is not allowed to have any face to face contact with any research subjects.
- Keeping in mind that our subjects require surgery, they are tested for COVID-19 prior to surgery/screening. The current studies (2) are performed while the subject is in the hospital (3-day stay) and then a couple of visits to the office over a 3 week period.
- Leave in room, contact/droplet precautions for person
- Limited facilities to support COVID+ patients. Drive through testing for suspected COVID+ patients.
- Most visits are being done remotely when possible. No new subjects are being screened nor enrolled. No new studies are being actively opened or evaluated
- Move to a separate section of the hospital
- N/A.  Subjects are not allowed on campus.
- N/A. We are not conducting in-person visits at this time. Processes are per University guidelines and they are very dynamic. When study allowed to start in-person visits we will follow the guidelines that are in place at that time
- NA - not allowed onsite if presenting symptoms
- No clinical trial subjects at our site have had presumed or confirmed COVID-19
- NO current plan announced yet. Partial opening of trials June 1st
- No in person visits. Telecommunications
- No patients with positive or confirmed COVID-19 will be seen.
- No plan in place.
- No presumed or confirmed subjects with COVID-19 are allowed on site.
- Not allowed in office will be assessed from their car
- Not allowed into facility
- Not allowed into the hospital
- Not allowed on site. PI has oversight.

# Please describe the processes that your site has put in place for the proper oversight of subjects with presumed or confirmed COVID-19.

- Not allowed to come on site
- Not allowed to enter building.  Staff sent home that come to work with a fever.  We have positive pressurized rooms for suspicious patients/staff
- Not applicable for our studies, no known positive subjects at this time.
- Not enrolled right now
- Not seeing these patients on site
- Not seen and referred to PCP for immediate phone contact for direction. Withdrawn from study
- Notify sponsor, wait for instructions on how to proceed with study visits.
- Once the subject has been determined COVID-19 positive the PI is informed and instructs the CRC on how they would like this patient followed. The the sponsor is informed within 24 hours, the patient is contacted and given instructions on how to proceed with their treatment.
- One examination room utilized in clinic isolated from remainder of cancer treatment center areas and patients if patient deemed presumed positive upon arrival.  Cleaning room thoroughly after each use.  New patient referrals to our center are screened by phone prior to scheduling.  If presumed positive or confirmed COVID-19 positive, appointment delayed until cleared.
- Our group practice has sent up a  tent  for persons with symptoms of COVID-19.  Any person who answers the questions about their symptoms or associations that sound suspicious are required to go to the tent for further evaluation by a healthcare provided and possible testing.
- Our research unit is separated from the general clinical. We have halted any study procedures that are done in the general population clinic area.
- Our site has not had any subjects with presumed or confirmed COVID-19
- Our site is located in a hospital that treats COVID19 patients. We are still working from home and unable to resume our study until the Stay At Home order has been lifted. Our study will need to change drastically to move from in-person data collection to virtual data collection.
- Our site will not see these subjects, so they will not be allowed to enter the facility.
- Our system flags subjects that have been to an ED or UC in system. Follow up calls are initiated to monitor the subject
- Participants are pre-screen over the phone and asked question regarding their new COVID-19 symptoms. Participants are then scheduled 5-weeks from the date that their COVID-19 symptoms resolved.

# Please describe the processes that your site has put in place for the proper oversight of subjects with presumed or confirmed COVID-19.

- Patient that may have COVID or were around someone with it are being asked to call our COVID hotline to schedule a virtual visits, and come to the clinic for a curbside test if applicable.
- Patient visits are postponed or done telehealth
- Patient visits are through telemedicine unless they are receiving treatment or procedures that require a hospital visit. I an not certain specifically where critically ill COVID patients are isolated. Patients testing COVID positive at screening pre-visit are rescheduled if possible.
- Patient w/flu-like s/s calls Access center of practice to be seen. Call triaged to determine course of care (telehealth, in-person, phone). Severe S/S > Y > Call nearest ED and self-transport; Severe S/S > N > Asses for telehealth appropriateness. After evaluation, order COVID testing as clinically indicated. Patient to self-isolate for 5 days if negative and at least 14 days if positive. Contact provider if s/s worsen on self-isolation. For negative patients >= 65 yo or w/chronic illness or immunocompromised, practice to f/u daily via telehealth. If s/s become severe, follow pathway.
- Patients are asked to reschedule their appointment if they contract any COVID-19 symptoms. If they arrive at our site with symptoms, they will be asked to reschedule and will not be seen.
- Patients are followed remotely.
- Patients are not allowed to come to site for visit if presumed or confirmed COVID-19 infection. Site conducts phone visits and IP drop-off/pickup in parking lot if needed.
- Patients are screened via phone prior to appointments then are screened at the door of the hospital. If suspected, patients are escorted to our urgent care for further work up. If patients are at home/confirmed we encourage them to see their PCP or go to their local emergency room or testing center.
- Patients have telephone visits until they test negative for COVID and have self quarantined for 2 weeks.
- Patients who are being followed remotely at this time have been asked to call and inform the site if they contract COVID. Patients who fail the pre-screen call are told not to come in to the site and to follow-up with their family doctor.
- Patients with COVID-19 are handled per the institutional standard for treatment of that condition. The occurrence is appropriately documented in accordance with study protocols as an AE/SAE.
- Patients with presumed or confirmed COVID are not allowed in the facility until they have cleared the infection. In the interim visits are conducted virtually if possible.
- Per CDC recommendations
- Phone and/or email contact, medical records release from treating physician and documentation of Aes, SAEs
- Phone or teleconference consenting has been implemented.
- Place mask on subjects and sent to the ER for evaluation.

# Please describe the processes that your site has put in place for the proper oversight of subjects with presumed or confirmed COVID-19.

- PPE
- PPE
- Pre-screen survey is taken. Temperature is checked at specified entry points. Only essential visits are taking place at this time. Remote consent and follow-up are being allowed but only essential COVID-19 and respiratory research is allowed at this time.
- Pre-screen with phone call; Delay visit for 2 weeks if presumed COVID-19; Have patient wear gloves and masks and ensure social distancing; limit time exposed to staff.
- Prescreened for symptoms by phone when they are in the parking lot. Directed to their health care provider if symptomatic.
- Prescreening questions asked on the phone. participants are then asked to reschedule
- Prescreening, limited visitors, immediate isolation
- Presumed or confirmed COVID - 19 subjects will not be seen in a clinic setting until 14 days after resolution of symptoms or a negative COVID test. Follow up will be via the phone until those criteria are met.
- Quarantine and transfer to ER
- Recommend that subjects contact primary care physician for guidance/treatment.
- Referred to a local provider for testing.
- Referred to the hospital
- remote consenting & dat collection
- Remote eConsent or new consent processes for patients in isolation where bedside nurse takes consent form in and process conducted over Zoom. Papers discarded, POC and witness sign attestations to consent process.
- Remote monitoring
- report to PHD, mandatory quarantine or admission to hospital, if needed.
- Reporting to the Sponsor. Not currently doing in person patient visits.
- Required PPE for all providers. Unable to see in-person visits for research only
- Research site is closed at this time . we are not seeing research patients
- Research visits are currently on hold.

# Please describe the processes that your site has put in place for the proper oversight of subjects with presumed or confirmed COVID-19.

- Research processes are aligned perfectly with Clinical policies of the University hospitals and clinics, including strict Universal Masking and Eye Protection for COVID + patients (N95 or better). AGPs for research visits are allowed only in the hospital or in Ambulatory clinics with HEPA filters and appropriate air circulation. Currently we are in Orange status, locally that means tight restrictions on many research activities and expanding non-essential research visits only in inpatient populations who have been isolated from contracting COVID (existing inpatients like neonates). We are currently conducting an in-home trial for 400 COVID + patients; that study required a great deal of PPE training, and many revisions to our normal processes.
- Routed at the door to different clinic, asked questions regarding symptoms
- Screen at check in and anyone with any symptom at all is turned away.
- Screening, isolation, testing before general clinic
- Send to COVID Clinic
- Sent them to our screening tent.
- Since we have cancer patients, these patients are not coming to the clinic unless absolutely necessary, not for trial, but for their treatment and care. We then do televisits and mailing medications to patients if possible. If infusion visits, we have limited these.
- Site does testing, will follow-up with patient
- Site follows sponsor specific guidelines
- Site pre-screens subje4ctsprior to their arrival onsite and due to being a dedicated research site, we would then refer to a local testing center for follow up care and recommend quarantining asap. For subjects requiring remote visits, each trial has guidelines for this to be executed and staff is prepared for hybrid or remote visits with subjects.
- Site transferred active subjects to sister site.
- Site visit cancelled or done by telemedicine. Referral to primary provider or local testing site, etc.
- Special quarantined rooms
- Specific operating procedures are followed based on known positive. PPE, cleaning of area, limited interactions with staff members, restricted testing/procedures.
- Staff are stationed at elevators to 'badge' patients to needed floor to limit roaming. Hand sanitizers are available throughout public spaces. PPE provided to patients and staff. Elective procedures have been canceled or rescheduled to limit onsite presence.
- Staff at each entrance

# Please describe the processes that your site has put in place for the proper oversight of subjects with presumed or confirmed COVID-19.

- Study Staff will report any presumed or positive COVID-19 subjects. PI and Sub-I will oversee care. One study sponsor has given instruction surrounding subject care during COVID-19.
- Study subjects are called prior to their appointments and questions about their health and contact with persons suspicious of COVID 19 are made. Subjects are allocated in special room wearing face masks, gowns and gloves. Staff members using PPE and CDC guidelines are followed.
- Subject's with presumed or confirmed COVID-19 subjects are asked not come to the office. Sponsor/ CRO is notified of subject status. Safety follow up with Subject will be done over the phone. IP continuation and/ or Study IP will be shipped to the subject per Sponsors guidelines.
- Subjects admitted to hospital undergo COVID testing. Subjects requiring anesthesia undergo COVID testing within 24 hours.
- Subjects are not allowed on site until two consecutive PCR tests for COVID are negative, unless they are enrolled in a a COVID inpatient trial conducted in a COVID specific work unit )eg ICU or medical ward dedicated to treating COVID positive patients.
- Subjects are not being seen for purposes of the research. Any testing or screening of symptomatic or asymptomatic patients is handled in accordance with established standard COVID-19 screening procedures.
- Subjects are prescreened over the phone. They are not allowed to return to site if answered yes to any of the questions. Must get clearance from pcp if c/o symptoms indicative of COVID19
- Subjects are screened when entering clinic. If COVID-19 is presumed, patients are referred for testing prior to appointment. Subject would need to isolate for 14 days with no symptoms prior to returning for a study visit.
- Subjects in treatment are remaining on treatment but we are unable to do some of the required procedures because they are not coming to the office but having a telemedicine visit instead.
- Subjects should be tested for COVID 19 before they participate in the study
- Subjects who are symptomatic are not allowed into the facility for research at this time
- Subjects who may test positive will be assessed for best options with regard to continuing treatment. We have not had this occur at my site.
- Subjects with confirmed COVID-19 are not allowed to come to site for any clinical trial activities until COVID-19 testing comes back negative and has clearance from their PCPs to resume study activities. Subjects with presumed COVID-19 upon arriving to site will be transferred to inpatient COVID-19 unit for further investigation.
- Subjects with confirmed COVID-19 is quarantined according to their PCP. Subjects will be retested with negative results prior to engaging in any in-person activities.
- Subjects with possible COVID-19 are not allowed on site. We follow the guidance of the CDC and the sponsor of each study.

# Please describe the processes that your site has put in place for the proper oversight of subjects with presumed or confirmed COVID-19.

- Subjects with presumed or confirmed COVID-19 will be urged to seek medical advice and care from their PCP. We would continue to follow-up on the health of the subject and any outcomes, reporting any SAE as required.
- Telemedicine
- Telemedicine
- Telemedicine visits are being conducted. Coordinator and physician contact to the patient and thorough questioning. At this time none of the active research subjects have presumed or confirmed COVID-19
- Telemedicine visits, phone call upon arrival for COVID-19 dedicated entry, COVID-19 specific exam room, drive in medication pick up, drug accountability/compliance document by phone.
- Temp check, symptom questions, if any positive, we do not let into facility
- Temporary tent set up outside of ED to triage, drive up testing sites at several entrances and dedicated COVID-19 unit for admissions.
- Test at alternate off site lab, if positive patient is not allowed in office until 2 negative tests > 14 days for positive test. Conduct Telemedicine as needed.
- Testing, isolation
- The healthcare system has implemented policies reviewed and approved by the state government.
- There is a designated area for anyone diagnosed with COVID 19. Only workers permitted in area. Full protective garments must be worn at all times.
- There is now a COVID unit where patients who are positive or suspected of are seen and treated
- These subjects are discontinued from the study and referred to their physician for testing and / or care.
- These subjects are not seen in the clinic until they have negative test result
- These subjects will not be seen.

# Please describe the processes that your site has put in place for the proper oversight of subjects with presumed or confirmed COVID-19.

- They are being referred to their PCP. We are not seeing any subjects in person at this time.
- They are directed to the COVID center for screening and if positive either admitted or quarantined at home.
- They are directly referred the hotline for assessment.
- They are immediately provided a mask and placed in isolation. The appropriate medical care is determined and they are moved to the location to get that care.
- They are isolated within the center and action according to institutional policy are enacted.
- They are not allowed onsite. Contact to determine the severity of illness would be done over phone or video teleconference. We would mail/email records request forms as needed to complete AE/SAE forms. Luckily, to my knowledge, no subject has had COVID 19 infection they have told us about.
- They are on isolated units
- They are only seen the ER
- They are quarantined for the guided amount of time. If they are in the hospital then they are sent to our COVID floor.
- They are referred to a testing site for confirmation and encouraged to follow-up with their general practitioner.
- They are referred to an off site  tent  that our group practice has set up for evaluation and testing.
- They are to be symptom free for 14 days after testing positive for COVID-19.. If unknown and symptomatic, they are scheduled for testing at a testing site.
- They do not come to the office.
- They enter the clinic through a separate entrance and put in a contained area.
- They follow the institutional policy of notifying their primary care provider who manages the patient through testing and any COVID related care.
- They will be provided information to contact provider of their choosing for follow-up care
- They will not be seen by research at this time
- They will not come to clinic and medication will be dropped off to them
- They would not be allowed in outpatient centers or private practices. Treatments shift to the hospital.
- This has not come up yet.
- This is difficult to address as we do not test for Coronavirus, as such the only information we might gather is from the subject. If we ascertain during a call that the subject in indeed infected or suspected of being infected.
- We refer the subject to seek immediate medical care, preferably to go to their closest ER unit.

# Please describe the processes that your site has put in place for the proper oversight of subjects with presumed or confirmed COVID-19.

- This is done by clinical staff, not research staff unless the research is COVID-19 specific. No patients are allowed on site if they report active respiratory symptoms. If a clinical trial patient reports symptoms, we are delaying their study visits until sxs resolution.
- This subject would not be permitted to attend clinic visits at the site. The patient would be referred to local healthcare providers that could direct and manage their care for COVID-19. This would be treated much the same as when a subject participant has an intercurrent illness that requires medical attention while they're in a study.
- Those patients will not be seen in the office but can elect for telehealth visit.
- Too lengthy to list all. Isolation with pre-assigned rooms for their arrival/treatment. Only come in if clinically necessary
- Too numerous to mention! From electronic medical records, triaging via phone, three city testing sites, screening, screening and screening at every point of care from scheduling appointments, entering the building to checking in for appointment.
- Trial subjects not yet permitted to site
- Two negative tests prior to returning to site.
- Universal precautions
- Unknown at this time
- Use of PPE and disinfecting protocols for every subject seen in our office or interacting with clinical research staff. This includes remote/home based visits.
- Video or phone visits will occur. If needed pt. go to ED for labs.
- Visits are conducted via telephone or virtual visits.
- We are a specialty clinic. Subjects are referred to the PCP for COVID-19 care of any kind
- We are conducting COVID related trials. Staff must use PPE and avoid ICU areas if possible. PIs have had to assume some responsibility for RC tasks.
- We are currently shut down. Once we begin, they will not enrolled. If not currently under a physician's care, they are directed to their PCP. If positive while enrolled, they will be withdrawn.
- We are doing home visit if requested by sponsor. If not we are doing safety calls
- We are in a hospital so any subject presenting with COVID-19 symptoms would be sent for testing.
- We are not conducting any in-person clinic research visits at this time. We are contacting our patients by phone and email. We hope to go back to in-person study visits on June 1. At that time we will probably implement taking temperatures and asking questions about any travel or contact with COVID persons.
- We are not equipped to see them due to lack of PPE
- We are not seeing patients if they indicate they have or presume to have COVID-19

# Please describe the processes that your site has put in place for the proper oversight of subjects with presumed or confirmed COVID-19.

- We are on hold by ORD, not seeing subjects
- We are still working out these issues and it depends on the patient needs.
- We ask if they have quarantined for 14 days, or when they were tested for the virus. We inquire about any current health issues and then our medical staff convenes and determines if it is safe for the subject to come to our site
- We contact the infectious disease team in the hospital to deal with them.
- We continue to have patients on site for treatments and use telehealth and phone calls for follow up patients and those that oral drug can be delivered to their homes
- We currently do not have any cases of trial subjects in this situation but would direct them to their Primary Care Doctor or suggest one if they don't have one.
- We do not enter the rooms of our subjects with confirmed COVID19 that are hospitalized unless absolutely necessary. We are using a telephone consent process to maintain distance
- We do not have patients with presumed or confirmed COVID-19, but oversight would be same as SAE
- We do not nor will not work with anyone that is presumed or confirmed with COVID 19.
- We do PCR testing if positive we don’t proceed with visit or surgeries
- We follow site SOP
- We have a tent set up outside our office to see potential COVID-19 patients (symptomatic, fever, exposure).
- We have implemented a remote reconsenting process for one of our studies to get the information to the sponsor in a timely manner. It is for an extended follow up for on of the studies so the patients are already familiar with the study and our staff.
- We have none. None will have an office visit pending sponsor guidance for protocol compliance and clinical care.
- We have not experienced this, but if a subject contracts COVID-19 we would follow them just as we would any other subject with an AE of this magnitude. We would not allow the subject to enter our facility until 2-4 week after symptoms have resolved.
- We have not had a confirmed case, one possible exposure found on screening and subject was provided resources and transportation for testing.
- We have not had one subject with COVID
- We only communicate with subjects via email/phone who are suspected

# Please describe the processes that your site has put in place for the proper oversight of subjects with presumed or confirmed COVID-19.

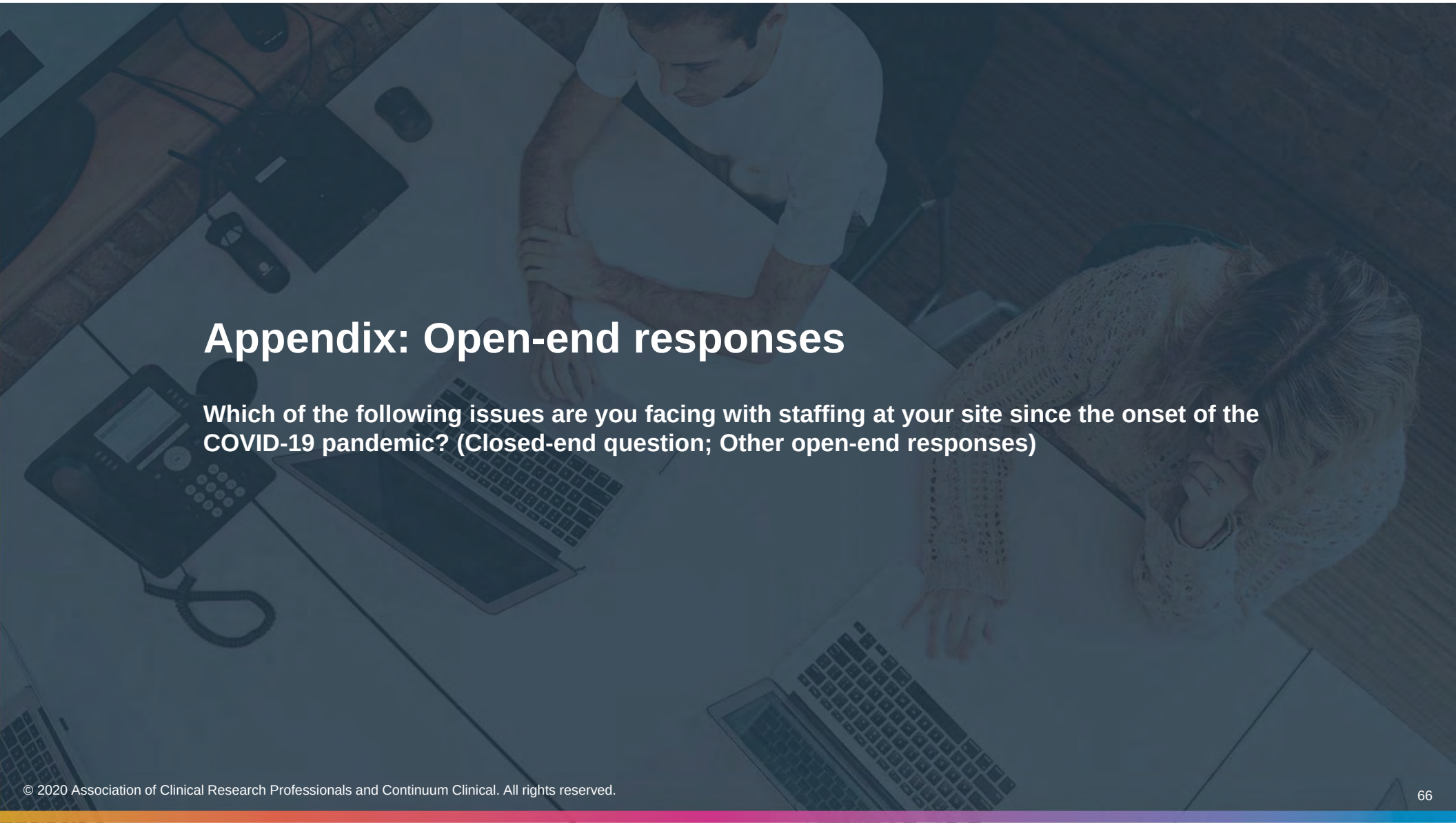
- We have not yet had this scenario play out at our site but are set up for telemedicine in the event that an enrolled patient is confirmed to have COVID-19. They will not come into the clinic. If there are essential data points that we feel we need to collect for PATIENT SAFETY that can only be done in person a home health nurse or CRC will be sent to the patient's home with proper PPE to collect that data. We will follow them via telemedicine until their recovery. In the event they are hospitalized due to COVID-19 we will request medical records for their stay.
- We reschedule patients or cancel their visits if they are ill. We have not had the situation come up yet but patients with presumed or confirmed COVID-19 who require immediate ophthalmic attention will be considered on a case by case basis. Doctors would maintain communication with the patient in order to monitor their symptoms/health and heightened precautions would be taken if the patient were to come in for a visit. Precautions would include examining the patient when no other staff are on site, minimizing patients movement within the site, and extra sanitary measures after the visit.
- We will not be conducting any research visits or procedures with COVID- 19 patients.
- We're a COVID center - oversight is paramount. Individuals who've tested positive are quarantined in house. Individuals who are possible and undergoing testing are in house quarantined.
- Weekly or biweekly phone visits with subjects.
- Weekly safety check in calls with all participants who are not scheduled for a telemedicine visit for every week they are “enrolled” in the study. Option to delay treatment or restart medications with approval from medical monitors
- When patients is screened before entering the office if they are experiencing symptoms or admit to being exposed they are asked to return home. Then they are to call their Primary Care physician and get instructions on how to be tested.
- When the hold is lifted up, screening and wearing masks.

# Appendix: Open-end responses

**How do you plan to maintain patient engagement on studies that are currently on hold or disrupted? (Closed-end question; Other open-end responses)**

# How do you plan to maintain patient engagement on studies that are currently on hold or disrupted?

- As of last week, we can perform elective surgeries, which allows subject visits
- Clinic visits
- During visits regularly schedules with Rheumatologists
- Follow-up study visits have not been put on hold, they continue without disruption
- I have no studies that have been suspended, but our site does
- In office visits
- Limited in person scheduled visits that correspond with well child checks
- Mail, if necessary
- Mailers via USPS
- Most have continued onsite visits as usual
- Must wait until sponsor reopens trial
- Ongoing studies are moving forward but recruitment stopped for several studies to new participants, we are doing in office visits for open studies
- Per protocol (in person visits, phone, text and email)
- Postal mail
- Qualtics
- Social media
- Some home health visits
- Some patients are being seen at time of clinical visits or treatment, such as oncology patients.
- Text
- Text
- Text
- Text
- Texts
- Therapeutic studies  - all patients on study still coming to hospital for oncology treatment
- Unclear. On furlough and no idea if job is still available
- Varies by study/discipline
- Video Conferencing
- We are still seeing our patients that are enrolled in a trial if they are comfortable coming to our office.



# Appendix: Open-end responses

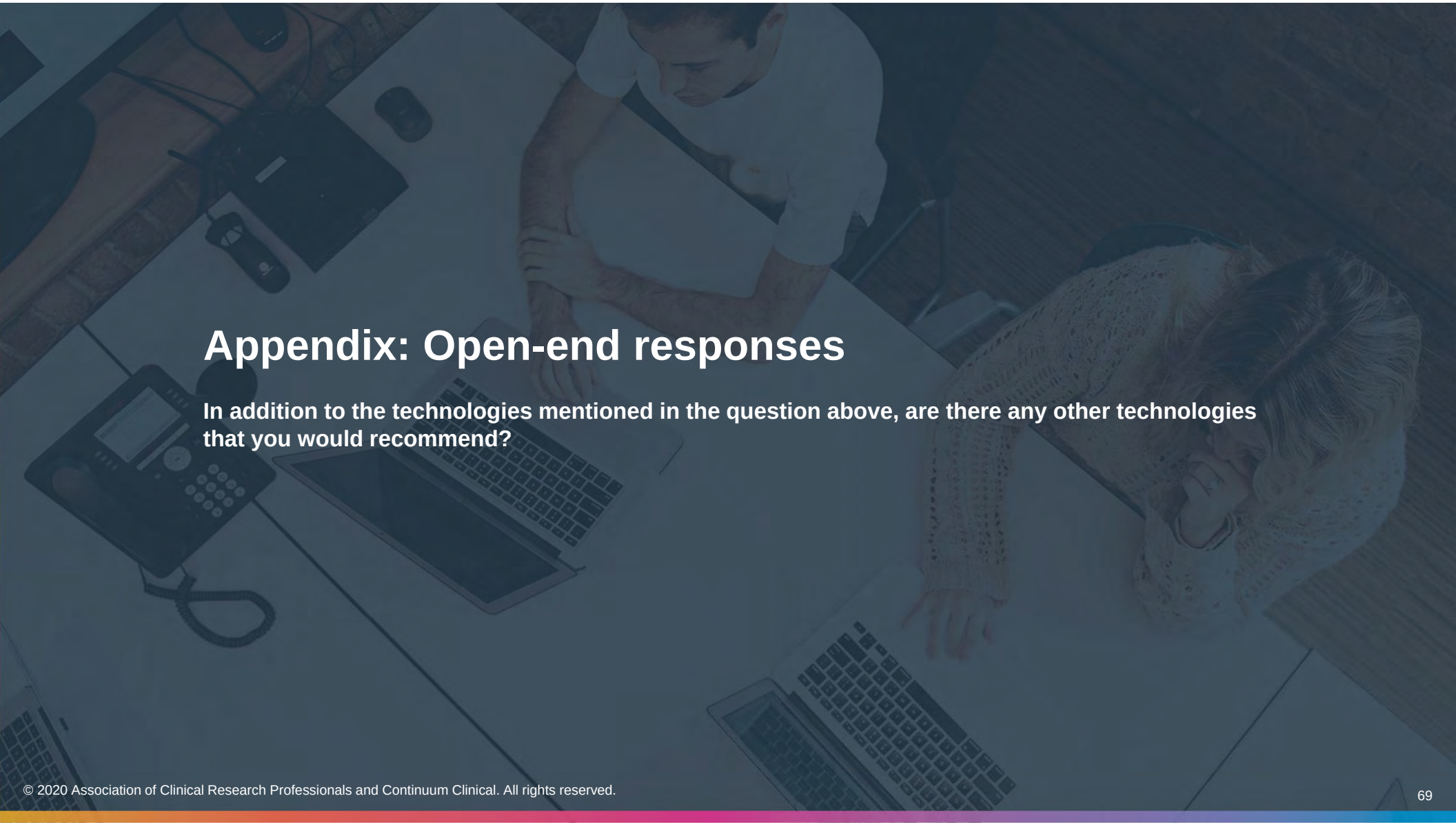
**Which of the following issues are you facing with staffing at your site since the onset of the COVID-19 pandemic? (Closed-end question; Other open-end responses)**

# Which of the following issues are you facing with staffing at your site since the onset of the COVID-19 pandemic?

- 2 part time staff have stayed home due to health concerns for elders they care for
- 20% of our staff was laid off due to the hospital losing money during pandemic
- A few employees are splitting working from home to coming into the office
- Accommodating resources employees need when working from home (monitors, printers, etc)
- All of the research staff are partially furloughed
- During COVID-19 Restrictions: Employees other than the research director with cut hours. One working strictly from home. Basically one person trying to keep up with everything as part time employees are not fully engaged.
- Employee hours cut drastically
- Employee's reluctant to be in office full time.  Come in to see patients already enrolled in study but then leave and work from home.
- Employees are  fearful  but not unwilling to work at the site; employees are requesting time off for mental health breaks, to care for family members, and to conduct home-schooling
- Employees are working on COVID-19 trials
- Employees are worried about getting exposed to COVID 19
- Employees having issues with childcare due to schools closing.
- Employees required to take four furlough days over a four-month period/one day per month
- Employees required to work from home per state regulations
- Employees taking advantage of the system
- Employees who cannot telework and ride public transit at increased risk to self and site
- Employees with Child care issues due to schools being closed
- Employees working reduced hours and/or re-assignments as needed.
- Executive order-stay home
- institutional salary reductions for staff, some staff redeployed for clinical activities due to COVID
- No difficulties.  We remained fully staffed and operational
- None, we have been able to continue operations
- None, we transitioned to working remotely and have been grateful for this option.

# Which of the following issues are you facing with staffing at your site since the onset of the COVID-19 pandemic?

- Nurses serving as bedside nurses
- Only essential employees are allowed at the hospital
- Part-time coordinator left to pursue medical training. Position will not be refilled.
- Reduced employee hours due to COVID-19 due to decreased number of patients coming into the office
- Reduced hours
- Reduced in hours
- Required to work from home
- Research staff reassigned
- Restrictions on conducting non essential treatment research at the AMC
- Shortened hours but not furloughed
- Site has closed.
- Some employees are having child care issues due to COVID-19
- Some employees are not allowed on site
- Some employees are not fully engaged due to the disruption.
- Some employees have been redeployed
- Some of our employees are required to work from home
- Staff has been reduced to a bare minimum, due to travel restrictions and stay home orders per Florida Governor.
- Staff Redeployed to patient care
- Taking sick/PTO day per week to mitigate financial burden
- Teleworking
- Time off to care for children who are out of school
- Unable to fill vacancies due to hospital hiring freeze
- We have all received a partial furlough over the next 6 months. The amount is dependent on salary level.
- We have been asked to work from home unless we have patient visits
- We have had few subject visits in all, so some investigators have chosen to work from home, doing emails, signing eCRFs, protocol reviews, etc.



# Appendix: Open-end responses

**In addition to the technologies mentioned in the question above, are there any other technologies that you would recommend?**

# In addition to the technologies mentioned in the question above, are there any other technologies that you would recommend?

- Centralized faxing
- Direct to patient delivery of IP.  Sponsor-supported wearable monitoring devices.
- E- Regulatory  E- Source
- E-monitoring
- E-Regulatory systems and 21 CFR Part 11 compliant esignature systems
- Electronic diaries
- Electronic questionnaires or patient medication diaries, Part 11 compliant electronic signatures
- Electronic signature process meeting 21 CFR 11 requirements.
- ePRO
- esource
- Full fledged e-source that would integrate with above systems
- HIPAA compliant platforms for contacting participants from personal devices (phone, texts, etc.).  Electronic survey platforms.
- Home lab services for some patients
- Home testing
- How much taxpayer funded resources for transportation, internet access and computer/device provisions exist in the state that study participants can utilize to communicate with study staff, participant visits and exams/testing/pharmacy?
- I do not feel any additional technology is needed at our site.
- In home testing / venipuncture / ultrasound
- Increase stipend cards to engage patient easier
- It would be useful to have some at-home equipment for taking vitals (digital thermometers, bp cuffs, pulse ox, etc).  Often these are the only data points we miss when we need to conduct a visit via telemedicine.  While they're in the protocol they are a deviation when we can't collect them but, with the portable devices we have today, shipping these to study participants so even these data points can be collected would be helpful.

# In addition to the technologies mentioned in the question above, are there any other technologies that you would recommend?

- It's noteworthy that this site has implemented a Part 11 compliant cloud-based system for eReg and eSource review. This initiative was already in progress for quite some time (~2+ years). A vendor was identified in Jan 2020 and the pandemic significantly catalyzed the initiative at our site. During a 7-week period, SOP and procedural guidelines for eReg & eSource review have been adopted and migration of files is in progress. The site has not represented to existing Sponsors that this capability has been launched but that is the short-term objective. Furthermore, it is believed that this capability will be indispensable (if not required) going forward.
- On call coordinator support apps.
- Our hospital has implemented most of these strategies already
- Our site already telephones and emails subjects/caregivers frequently as a standard prior to COVID-19.
- Platforms to help with remote monitoring
- Providing patients with the ability to check vitals from home based on the protocol - digital scale, BP cuff, easy to use thermometer, pulse oximeter, etc.
- Some of these are already in place but the research participants also have to have the technology and access to Internet for some of these to work.
- Studies on hold to recruitment should be using this time to advertise for their studies at sites that are staffed to handle recruitment and put those interested candidates on a list to bring in after speaking with them about the study.  This way, when the study opens up sites will be able to bring in more rapidly to make up for the lost time.
- Study questionnaires
- System integration and intense training/education on how systems interact with other systems and data bases.
- This might not be possible, but I would really like an instant messaging option that allows us to contact patients via social media when they won't answer their phones.
- We have already implemented telehealth.
- Wearables for gathering data remotely from subjects

# Appendix: Open-end responses

**What new site processes related to COVID-19 have been implemented to ensure safety of clinical trial subjects entering your facilities? (Closed-end question; Other open-end responses)**

# What new site processes related to COVID-19 have been implemented to ensure safety of clinical trial subjects entering your facilities?

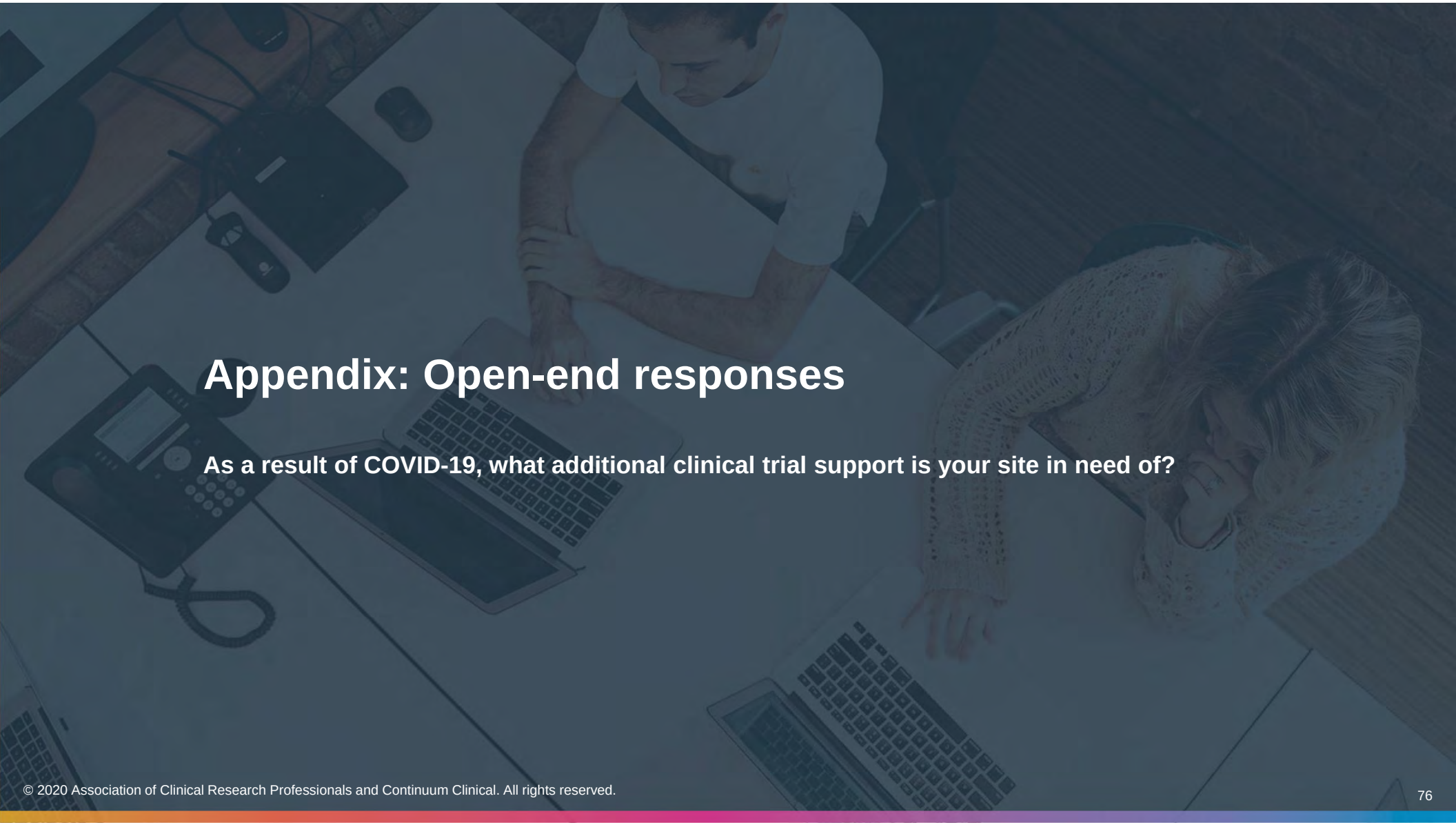
- Adult subjects must come alone and minors can only have 1 guardian present.
- All non-essential visits are performed remotely, if a patient responds positively to any of the screening questions and is coming for an in-person visit will be provided a mask
- All patients and visitors required to be prescreened but we are still on hold
- All patients are required to wear a mask, but they are not provided to them
- All patients are required to wear face coverings and are screened upon arrival
- All patients are tested for COVID-19 before procedures or admission.
- All patients required to wear mask in the facility
- All staff are required to frequently wash hands, wear masks, and wear safety goggles
- All staff are screened at the beginning and end of each shift; persons accompanying participants are limited
- All staff required to wear mask and googles or face shield when interacting with patients/participants, no handshaking
- All staff wear masks
- All staff wear masks and all patients required to have negative testing prior to hospital procedures
- All study staff wear face shields as well as mask and gloves
- All surfaces disinfectant before and after each subject visit
- All visits have been performed remotely by phone

# What new site processes related to COVID-19 have been implemented to ensure safety of clinical trial subjects entering your facilities?

- Changed protocol for minimal contact (bp taken at home with monitor we provided); curbside pickup of study products and drop off of urine samples
- Clinical trials have not restarted yet
- Clinical trials have not yet resumed at our site
- Drive by dispensing and mailing IP to subjects
- If patients don't have to come to site for a visit, we try to do visit by phone or mail medication.
- Limiting visitors
- No new patients; only patients on drug continue to be seen
- No one may accompany patient to clinic visit unless a new diagnosis
- No visitors, only patients
- Non life sustaining trials are paused
- Not seeing study pts
- Our trials were healthy volunteer studies, our site is closed currently  except for COVID studies (the current one is being done in the hospital) We are talking about all these as options to implement when we do reopen
- Patients are encouraged to wear a face mask.  putting straight into an exam room rather than sitting n waiting room.
- Protocols will be implemented when subjects are permitted to facility
- Rapid COVID-19 testing for new Trauma/Burn patients
- Required mask but not gloves
- Research site is closed
- Research subjects are not allowed on campus yet.
- Some patients are doing video visits rather than in-person visits
- Some procedures are deferred until more liberal easing of research restrictions  (PFTs for example)

# What new site processes related to COVID-19 have been implemented to ensure safety of clinical trial subjects entering your facilities?

- Staff is also required to wear a face shield when interacting with patients.
- Staff masking (no gloves)
- Staff required to wear full PPE
- Staff required to were masks when SD cannot be maintained
- Staff wear a mask and other PPE as clinically indicated
- Staff wear masks have temperatures taken on entrance to work
- TeleHealth visits when appropriate
- Transition all active studies to eRegulatory platform
- Unable to answer - site not widely open for research visits at this time
- Visitors are limited
- Visits are being done by telemedicine whenever possible.
- We also wear face shields and there is a lot of extra cleaning between patient visits
- We are conducting phone only data collection with hope for in-person data collection at a later date
- We are currently not allowed any face to face with research subjects
- We are not holding face to face visits as this is not permitted by institution
- We are still operating under COVID restrictions- no in-person research visits at our site until June 1
- We ask series of health questions before bringing in patient
- We have not returned back to work. Teleworking
- We haven't begun any visits
- We provide mask if patients don’t have their own.

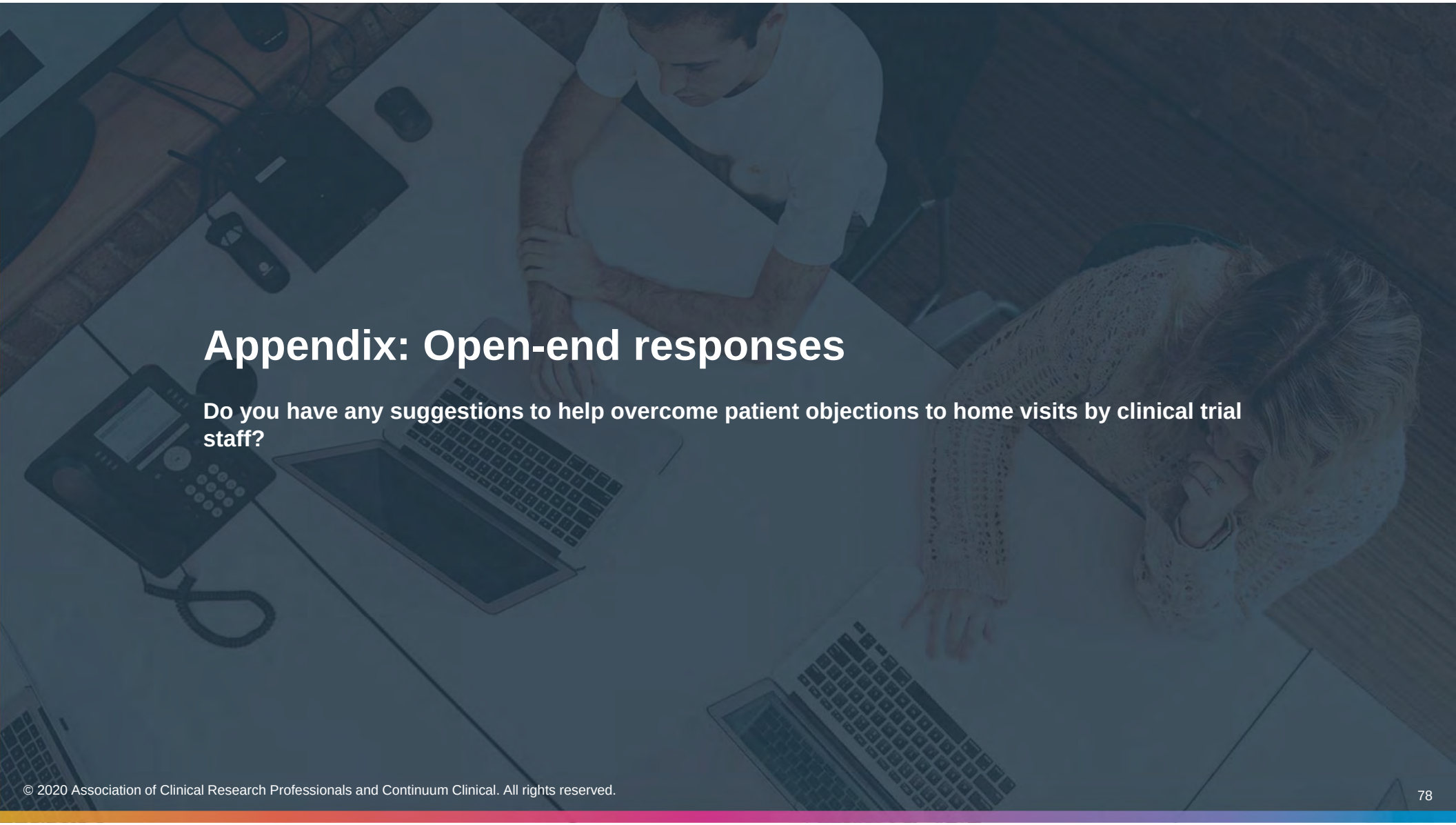


# Appendix: Open-end responses

**As a result of COVID-19, what additional clinical trial support is your site in need of?**

# As a result of COVID-19, what additional clinical trial support is your site in need of? (Closed-end question; Other open-end responses)

- Additional work for remote monitoring and remote source verification
- Budgetary reviews to accommodate changes
- Childcare
- Cleaning supplies - we have to shuffle between offices at this point
- I don't know. Clinical trials have not yet resumed at our site.
- MASKS!
- Monitors can be granted remote access to EHR if necessary.  No in person monitoring visits since March 18 through June 30, 2020 at this time.
- Monitors need to return to work or remote monitoring/sdv that does not require site staff.
- Our site is not permitting visitors which means we can't have monitors on site. Most sponsors won't allow us to enroll new patients without monitoring, and we've had challenges with getting our research infrastructure accessible remotely.
- Space and physician availability
- We are in need of eSignature of Logs, eRegulatory and eSubject binders.
- We are Non-essential on campus and therefore cannot be physically there to screen or interact with the pt's currently in the hospital. We do not recruit outside of current in-patient admissions therefore we cannot recruit at all.



# Appendix: Open-end responses

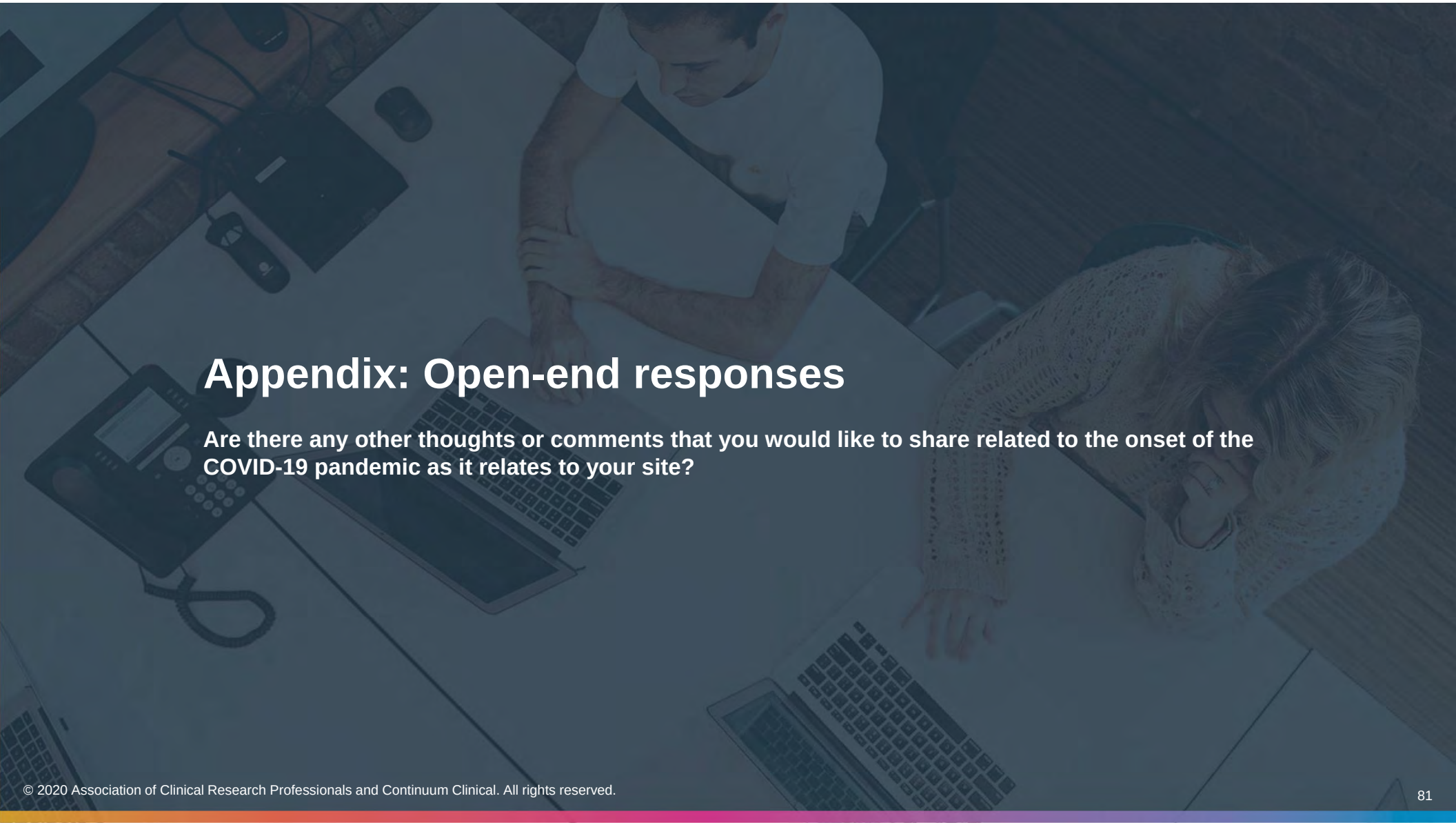
**Do you have any suggestions to help overcome patient objections to home visits by clinical trial staff?**

# Do you have any suggestions to help overcome patient objections to home visits by clinical trial staff?

- An educational approach may be the best remedy. Subjects should be assured that the visit staff has all the required PPE, staff will maintain social distancing guidelines. Furthermore, if the subject could be reassured that the visit staff will not enter the subject living space. The visit could conclude in the garage or outdoor patio or yard without compromising subjects family and their living space.
- By keeping our clinic cool we assure pts we are free of COVID and we have tested all of our staff..not sure how often we will do this going forward..all still in the air--too new
- Continue the use of technology such as electronic consents and telehealth visits
- Create a pathway that allows data collection to be collected by the patients themselves at home, not by a staff member coming to their home.
- Hand out or script with information about the benefits and risks of a home visit compared to a site visit
- I do not have any suggestions other than proper PPE
- I think the patients may be fine with it but the legal liability of our center staff going to a patients home is not possible. We would need, a home health service in order to see patients and it should ideally be provided by the sponsor so that they do the CRFs and whatnot, as it's not reasonable to verify CRFs from visits site study staff didn't perform.
- I think they would prefer to have telehealth visits over in home visits. When someone else is coming into their home they may not feel like they can control their environment. The anxiety of not knowing where all that person has been. Where when they go in for an appointment they can control what they touch etc.
- If we can do telecommunications that is the best. If patients need emergency treatments then only should visit the hospital
- In our area, this would likely only be relevant for 5-10% of the potential subjects. Taking a CRC resource out of an office with additional SOPs, Protocol changes and opportunity cost of having them gone from the office may sacrifice more than it is worth. I believe having a proper set up in an office will make the subjects comfortable. Sending a staff member to someone's home may only put our staff at risk in an environment that we can't confirm is kept sanitary, thus putting our other staff members at risk upon return.
- It is not the patients per se, but this is not something that I believe our site or site staff would be interested in.
- It is really not up to the patient here, it is the policy of the VA and research patients.
- Liabilities
- Make the visit less frequent

# Do you have any suggestions to help overcome patient objections to home visits by clinical trial staff?

- No- I don't want anyone in my home, so I don't blame patients if they don't want anyone in theirs.
- No, high risk individuals
- None.  Not interested in exposing clinical staff to the subject's home environment.  If subject does not come to clinic for visit, we conduct tele-med visit and get as much done as can be done.
- Not helpful for orthopedic studies
- Our site does not have the resources to send staff into subject homes.  Site would require sponsor to hire, train, manage homecare company.
- Our site has multiple oncology clinical trials, and staff is divided into teams by disease site. My team's patient population is in the high-risk category (most are >65 yo), so research coordinators are not even allowed to be face to face with patients at this time. Home visits are not feasible nor a good idea for our subjects or clinical trial staff. Moreover, home visits would be a burden for clinical trial staff in terms of getting reimbursed for travel as this will have to be approved by the sponsors as well.
- Patients are afraid of getting COVID. They are more likely to come to the site where they can limit what they touch vs letting someone in their home, potentially contaminating is. Plus, site staff can't do home visits, so this would need to be contracted work and patients would probably be concerned to have someone they don't know entering their home during a pandemic. At least, with clinic and research staff, we have pre-existing relationships with them.
- Patients get IV chemo, cannot be administered at home.
- Safety labs importance
- Some patients are comfortable with others coming to the home and some are not, even before the current issues.  i just think that since people have been made paranoid, they are less likely to let someone come to the house
- Somehow regaining caregiver's confidence that provider will not carry-in COVID-19 into their home.
- This would need approval first and many of our patients live far away from the hospital
- We are in ophthalmology and cannot do the testing needed in a patients home
- We as a site would not do that unless through a 3rd party such as Hawthorne Effect
- We do not do in home visits
- We don’t offer home visits. PPE worm by all parties
- You will have to really assure that the clinical trial staff going to other people's homes are doing this safely.  They can be spreading to each home and that is not very safe.  It is also leaving he clinical trial staff open to getting it themselves.



# Appendix: Open-end responses

**Are there any other thoughts or comments that you would like to share related to the onset of the COVID-19 pandemic as it relates to your site?**

# Are there any other thoughts or comments that you would like to share related to the onset of the COVID-19 pandemic as it relates to your site?

- 85% of our efforts have shifted to COVID research
- Apprehensive about getting back to work with regard to keeping my family safe and healthy ie. exposure of child going back to daycare, me coming home after a day seeing subjects.
- COVID 19 pandemic is a big challenge and also an opportunity to adapt us to new technologies and ways to perform our jobs.
- COVID-19 changes the staff work flow. Staff usually works Monday -Friday 40 hours a week And now works everyday 16 hours a day to run the COVID-19 trials. We had to change our scheduling to allow for Research coordinators to get time off during this pandemic.
- Dealing with patients who don't want to wear a mask has been hard at some specific times. sponsors were not really clear during this pandemic, or know themselves, that changes to protocols must be IRB-approved. Some conducted telehealth visits without IRB approval. I think in the future, a more proactive response to something like this is needed, but understandably, this is an unprecedented time. Most of the response seems to be delayed reaction to sites making actions on their own.
- Due to the nature of the diseases, our clinical research activities are minimally impacted by COVID-19. Some new technologies are helpful as I checked. New ways for patient engagement are unlikely helpful since we are the only Children's Hospital in our region.
- Even though we are still following subjects, we can't begin any new trials until we are allowed to see the patient's in person. There is no clear answer when that might be.
- For me in seeing cancer patients we have to evaluate each type of study and each patient individually. there is no easy answer. In NY we needed to close all new enrollments to cancer studies given the widespread nature in my region.. I feel this was responsible. We cannot risk these fragile patients lives. I had many patients who had cancer and lost their life to COVID, not cancer. I always feel that the patient is more important than the study and in this unusual circumstance that is what should guide the decisions about interruptions to study procedures.
- Funding is needed for non COVID-19 studies to continue.
- I am not involved
- I have an amazing team of investigator's and staff, this has been the hardest of times, yet my work family makes this all much easier to endure.
- Increased work for research staff now conducting COVID-19 studies, increase stress, ongoing consent issues w pts in isolation, no visitors allowed in hospital, increase risks of exposure to staff, limited PPE.
- It has become more of a burden for the site to perform remote monitoring visits and expectations of access and documents needing to be submitted by an already reduced work force. The research sites that are a part of a general clinical practice have scrambled to have new guidance and directives regarding patient care and procedure functions due to the pandemic which then has taken time to implement as well.
- It has been a challenge, but opportunities are always available to those who can adapt.

# Are there any other thoughts or comments that you would like to share related to the onset of the COVID-19 pandemic as it relates to your site?

- It has been tough to put staff on the front line seeing COVID + pts--there has been great fear and some of my staff are in the vulnerable population which limits who we can send--there is a lot of fear. It didn't help we had a nurse turn up + not work related that we can tell--but it added to the fear factor. We have PPE but that has done little to ease the fear. The other issue is these studies have come so fast and furious that some of them have not been well planned or organized which has added a lot of unnecessary stress--my coordinators have been overwhelmed with this aspect--myself included.
- It has completely disrupted the usual patient flow in our clinic and scheduling subjects is extremely challenging as we move week to week. Space will be more limited due to distancing and cleaning requirements. Most of our subjects are comfortable with the idea of coming to our clinic.
- It would be very helpful if someone created a program/website that monitored the availability of PPE, cleaning supplies, and paper products on other sites. For example, I could open this page and there would be Lysol wipes available at Target, masks at McKesson, and the next day when those sites are showing inventory of zero, it would populate whatever sites did have product availability. It is very exhausting trying to find this stuff!
- It's a shame that so many clinical trials will be affected as well as the closure of so many sites permanently from this situation. It will be interesting to see how the next 3 months plays out and I hope the sponsors re-open enrollment soon at sites that are open for business.
- It's hard to believe that I was tasked with making a list of ways I would keep myself occupied during pandemic. So optimistic! We're a small office. We're exhausted and overwhelmed. I speak for the IRB, but the same holds true for our coordinators and regulatory people. Many of whom are leaving healthcare post-COVID.
- Lack of trials even available, Our site personally had 3 new studies that were in line to start in the past 2 months and they were retracted due to COVID-19. Our site personally is in need of clinical trials that are still on course to start.
- Luckily for me where I work we have numerous tools to utilize for research study recruitment, screening, enrollment and retention. Our Cancer Ctr even has access to utilize Watson--who may ultimately replace me some day; like the way the computer replaced ward/unit clerks in the late 90s, and then took it a step further with providers entering their own orders and intializing coding via EHRs.
- Monitoring visits are on hold. This is a huge disruption to the normal work flow, especially when a new patient is put on a pharma trial. We don't have the capability to remote access our EMR.
- Most of our studies take place in the operating room, so until the PPE shortage lets up we will not be allowed to recruit patients for studies.
- Need more experienced staff and resources. Stressful situation with constantly shuffling processes. Need new SOPS.
- Non-essential research paused during pandemic. Working on process to restart research with preference given to interventional studies with the prospect of benefit.
- Not really. Just that I really don’t know if I will even have a job. I’ve worked over 20 years in research. I’ve tried seeking a CRA position but all the companies want experienced people in CRA. So how do get experience if you can’t get hired? Plus it’s difficult finding other kinds of work because now I’m over qualified. Now what do you do? I belong to this organization which I can’t afford now and losing the certification is at stake. What was it all for?

# Are there any other thoughts or comments that you would like to share related to the onset of the COVID-19 pandemic as it relates to your site?

- One of the challenges as a site that is open and conducting all study visits and regular clinic visits is managing sponsor/CRO expectations in regards to remote monitoring. Most sponsor/CRO representatives such as CRAs are currently unable to travel to the site. We are already spending extensive amounts of time on maintaining safety for our staff and subjects while causing as little disruption to the subjects and study schedule as possible. The burden on the site is enhanced with all the additional requests for remote monitoring, extra calls, and emails for work that would normally be completed in person. It'a been a relief when a sponsor has been understanding and has just let us focus our efforts right now on conducting the study in a safe and effective manner.
- Our hospital and research section has done an awesome job of quickly implementing changes.
- Our Institution's response has been impressive - both safely and expeditiously in providing clinical trial options for our patients.
- Our major problem is that new patients are all being seen via Tele health and it is hard to discuss clinical trials with them. One of our biggest accruing trials has been suspended until the pandemic is over.
- Our research center was shut down for four weeks from April 8 - May 12. We maintained our patients through phone calls and one coordinator attended the site for 4 hours per week to stay on top of patient care. The only reason we returned was because the company received money from the Payment Protection Program so they had to bring us back
- Our site is a university and hospital. Our research team have been doing COVID studies so most coordinators were very busy, some on-call 24/7. More COVID study feasibility forms are coming in for new studies.
- Patient recruitment is reduced or stopped due to risks being higher than any benefits related to the trial unless its COVID related drugs. Staff is working from home due to increased risk of exposure and lack of PPE.
- Please know that our department has little involvement with any aspect of patient recruitment or follow-up. We work with the IRB and facility to ensure all hospital policies and procedures are adhered to before and during the clinical trials.
- Primary site issues are related to most research related staff working from home. Do to volume of those working from home (most of university) and many living in rural areas quality of internet connectivity and caring for children at home while working are issues. That said research activities such as startup activities are continuing as usual. Studies not deemed as essential treatment are put on hold after IRB approval.

# Are there any other thoughts or comments that you would like to share related to the onset of the COVID-19 pandemic as it relates to your site?

- Provide transportation for patients for on site visits
- Since almost all of our studies involve imaging COVID-19 has been a great impact on our site since we can't bring in subjects for scanning.
- Thankfully, we have not been effected as much as other sites and locations.
- The cardiology office of 5 cardiologists is the main activity. They have transitioned to 90% telemedicine. Enrollment was paused by sponsor for 4 clinical trials Sponsors have been unwilling to allow implementation of e-Consent for active studies, or even for new enrollment into registry studies, even one which is a medical-records review registry study. One study sponsor has allowed for telephone visits and direct to patient shipment of IP. But they will not allow e-consent for a new protocol amendment.
- The constant barrage of COVID-19 webinars, surveys, and special requests is mind numbing.
- The necessity of equipment like -70 °C freezer, expensive and backorder equipment its limiting to be selected in many protocols We are new site and ready to work with years of experience Ana L Gutierrez 8326468468
- The pandemic was the issue that pushed us into remote monitoring. I wish we could have arrived at remote monitoring much sooner because the technology made it possible, and not the pandemic.
- The primary focus of the site is to save lives and treat individual clinically. Research is a mission but saving lives comes first.
- The sponsor guidance for COVID-19 policies varied tremendously. The site was overwhelmed with reviewing all of the e-mails and various mandates. Some sponsors did ask for site feedback regarding our ability to see subjects. Other sponsor were not interested in our ability to see subjects and we were forced to ET subject because we were not allowed to see subjects on site and completed safety procedures.
- The unemployment monetary increase has hampered employees from returning to work. Often the amount is over what they would earn if they were to return to work.
- There has been an extraordinary burden on our site with multiple sponsor/CRO and regulatory updates. some of the sponsors have had knee jerk reactions. Additionally questions raised by our site about new processes and lack of information frequently go long periods of time without answers. It's been difficult to manage the mountain of information, train site staff, and document it all. In my opinion a once per week approach would be more efficient and helpful. Have sites submit questions all week and the following week send out the answers?
- This has been very eye opening to the need to move to a more digital format. Specifically moving to e-regulatory binders as a first step, but also thinking about trials in a remote/virtual format. Not everything can be done through a computer or phone but knowing what can be done that way and having plans in place are crucial.

# Are there any other thoughts or comments that you would like to share related to the onset of the COVID-19 pandemic as it relates to your site?

- Trials that are trying to demonstrate efficacy of a product are typically reliant on endpoints obtained by performing procedures. Procedures cannot be done via telemedicine. Yet telemedicine seems to be the primary suggestion moving forward. This is not realistic.
- VA as its own rules and regulations that have to be followed plus we follow the local VA IRB submission/approval policies. Thank you
- VA has its own system and doesn't allow outside networks, thank you.
- We are being considered for COVID vaccine and prophylaxis studies. We are hoping that sponsors will employ mostly virtual options for patients who may have been exposed or infected.
- We are concerned that we have no studies in our pipeline and that 1 study was put on hold and 1 discontinued due to COVID-19. Hoping for a COVID 19 vaccine very soon and better times for all.
- We are continuing to do business as usual as much as possible. Only a few of our staff need to work from home due to a compromised family member or compromised themselves. We continue to screen new patients and are planning to start about 4 new studies in the next 1-2 months.
- We are operating as usual
- We have been working remotely due to the stay home order.
- We have not had to do study visits via video as of yet and we have not had to visit any subjects' homes or get labs done locally or other alternative measures for safety etc. We have prepared with the study instructions kept in a binder, but have not used any of these measures.
- We have not seen large number of cases. All research has been placed on pause with all staff working remotely from home.
- We lost a few studies, but gained more COVID-19 studies. There is so much we do not know about this disease and a great public interest in funding - this should present opportunities for additional clinical research.
- We will get through this together.
- When technology is offered it comes with a price. It's expensive, time consuming and inconvenient to train and implement new technologies that are demanded by sponsors. sponsors always think more technology is better but they don't support what they demand. Instead we're sent to help desks that are overwhelmed and under trained. The pandemic is NOT the right time to institute new technology and procedures. Sites are already burdened by protocol adherence, missed visits, new reporting guidelines, multiple sponsor memos and emails, and new consents to name a few.

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