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

A Market Research Study Conducted by ACRP & Continuum Clinical

Executive Summary

4 June 2020

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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.

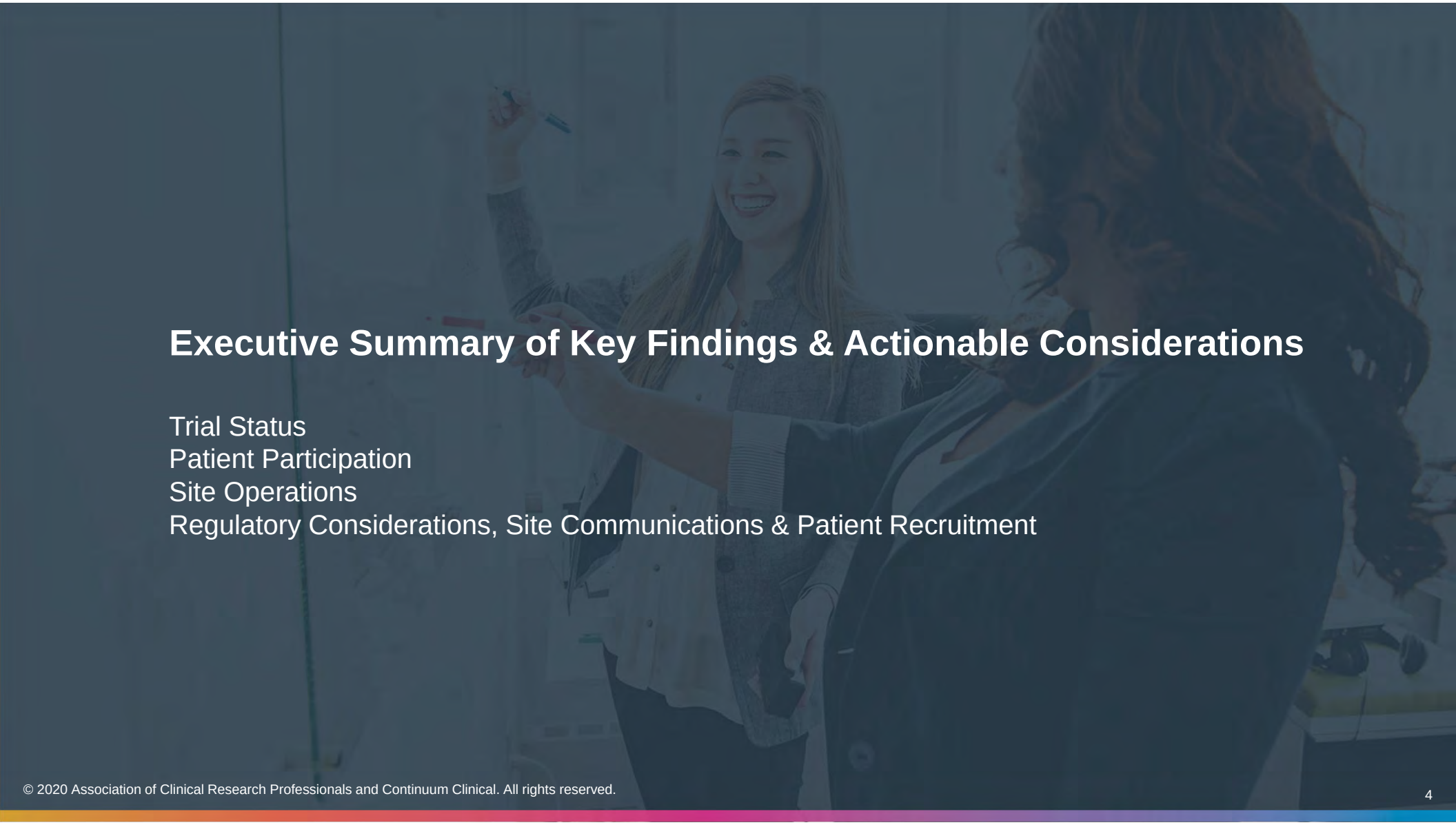
Objectives & Methodology

Objectives

- The Association of Clinical Research Professionals (ACRP) and Continuum Clinical have partnered to conduct online surveys among United States 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.

Methodology

- Online surveys among ACRP members in the United States that conduct clinical trials
  - Wave I: April 1-3, 2020
    - 297 respondents
  - Wave II: May 14-26, 2020
    - 274 respondents



Executive Summary of 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. 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. Clearly articulated, comprehensive and fully vetted plans are imperative as the industry adapts to and defines the ever-changing definition of the 'new normal'. 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. • 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. • 66% of sites indicate that patients have <u>not</u> discontinued compared to 63% in Wave I. • 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). • 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.	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. 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. 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. • 84% of sites say they expect 10% or fewer patients to discontinue compared to 74% in Wave I. • 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. • 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. 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. 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. • However, it is surprising that adoption has not been universal. • 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%). • Interest in E-Consent has increased. • The most important increase is the desire for assistance with patient transportation. • In addition, sites are asking for PPE supply. • 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%). • 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 7

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. • 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 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. • 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.	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. • 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. It's abundantly clear that sites need and want added recruitment and retention support. 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.

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To download a copy of the full report visit:

https://acrpnet.org/special-report-the-impact-of-covid-19-on-u-s-clinical-trials/

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