COVID-19 COMPENDIUM

WHITE PAPER

Expanded Role of Patient Engagement in Clinical Research During the COVID-19 Pandemic

DENIS CURTIN, PHD
PRINCIPAL, SCIENCE & MEDICINE,
Signant Health

COVID-19 COMPENDIUM

This informational white paper is part of a compendium intended to share best practices and ongoing learnings related to the impact of COVID-19 on ongoing and planned clinical trials. Content is authored by a dedicated team of experienced scientists, clinicians, technologists, and data quality experts. To read other white papers in the series, please visit **www.signanthealth.com/covid**

Over the past several weeks, the COVID-19 crisis has triggered profound changes in societies around the world, forcing the global community to continually adapt to new challenges set by this crisis. The impact of this crisis on healthcare is visible, as hospitals and clinics have transformed to triage and care for COVID-19 patients. As a result, regularly scheduled visits, surgeries and treatments for other disease areas have been rescheduled as telehealth or telemedicine visits, or have been moved to a time "to be determined" by government and state restrictions. This transformation has had a dramatic effect on clinical research, as trial sites have put hundreds of trials on hold and sponsors and research institutions have reprioritized existing resources toward addressing the needs of the crisis. Patients in active trials are thereby left in need of greater support and information as to the status of their trial, risks of discontinuing (or continuing) with visits, and the potential impact of COVID-19 on their health due to their existing conditions.

MEETING THE NEEDS OF THESE TRIAL PATIENTS IS CRITICAL AND IS BEING ADDRESSED THROUGH DYNAMIC, MULTILAYERED PATIENT ENGAGEMENT.

Patient support systems in clinical trials have evolved over the last decade as new solutions designed to keep patients "on-track" to meet trial protocol obligations have become common features in most studies. Mobile phone applications, community websites, and wearables are among the many patient focused tools that create unique opportunities to engage not only patients but also their care partners to improve the trial experience. Since these patient engagement tools are currently deployed in many trials around the world, they have proven to be foundational in linking patients and their families with critical information regarding in impact of COVID-19 on their trial. For instance, patient engagement tools have been used to communicate the status of patients' trials, revised safety information, changes to any visits, or shifts to other trial activities.

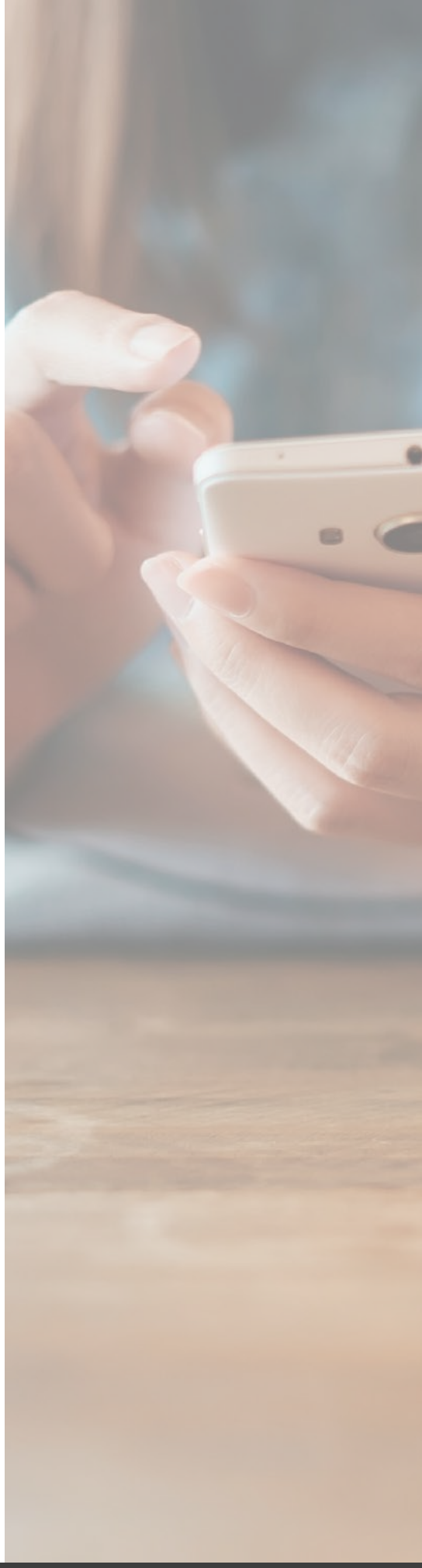
For example, Signant Health's TrialGuide, a tablet and phone-based application facilitating patient participation in hundreds of active trials with information, reminders, eDiaries, PRO instrument data collection, and protocol driven features has highlighted a path for sponsors and sites to follow for communicating crisis driven decisions to patients. The list of TrialGuide's patient engagement features that have been utilized in active and enrolling studies during the COVID-19 crisis include:

- **Study updates**

  Notifying patients regarding COVID-19 mandated suspension of their trial or altered study processes. Directions for site location changes and office hours, visits, data collection, etc.

- **Prescreening surveys**

  To identify potential COVID-19 symptoms and directions for patients who may have the coronavirus or have been exposed



- **Reconsent information FAQs**
- **Appointment/visit rescheduling if demonstrating virus symptoms**
- **Retention messages to help patients in a COVID-19 environment in multiple formats**

  Video, images, and positive text outreach from the site team

- **Trial instructions**

  Updates for patients regarding revised study obligations including visit frequency, data collection and assessments, instructions for care partners transporting to and from appointments, and related logistics for family members

- **Resources for managing safely during the COVID-19 crisis**
- **Online social communities**

  When integrated within the retention programming of the trial or ex-trial disease area offerings, patients are not only able to obtain critical information tied to COVID-19, but can also foster a sense of belonging and encouragement in this time of physical isolation.

THE IMPORTANCE OF VIDEO

Another key element to patient engagement that has seen exponential growth in importance and broad applicability during the COVID-19 crisis is the use of video software for real time, remote patient interactions with physicians or other health professionals. This is true across multiple types of healthcare interactions from symptom consultations with primary care physicians to regularly scheduled visits with psychiatric specialists as many patients and care providers are finding effective health management via remote video visit.

Video has had a similar effect on clinical research. Trials that would have been placed on hold or discontinued due to site visit safety concerns and healthcare resource reallocation driven by the COVID-19 crisis have overcome these challenges by employing video visits. It should be noted that shifting trial visits to video requires additional planning by the sponsor and site in order to comply with the recent guidance issued by the FDA and EMA.[1,2]

However, once in place, video visits that are integrated with other trial engagement features offer a seamless conversion of study visits to remote interactions without rescheduling. One example of this integration is in TrialGuide where in addition to scheduling and retention programming, it provides integrated video to create real time, virtual interactions between clinicians and patients in a secure environment.

While clear and reliable communications with patients are always critical, this is especially true in clinical research. The current global COVID-19 crisis further raises the stakes for patients in active trials due to the uncertainty of this disease and the added risk to trial participation it creates. Patient engagement solutions described here can help manage patient anxiety by providing consistent and reliable messages about their treatment and study status. Trial sites and sponsors can endeavor to provide rapid updates to active and enrolling studies through institution and study websites, frequent social media posts, and even engaging influencers such as principle investigators or patient advocates who are important in each specific trial environment to drive the impact of individual posts. In time, as the COVID-19 crisis abates, the effectiveness of these engagement tactics to support the needs of patients will be measured through regulatory review of trial data, sponsor and institutional assessments, and survey of patients completing these research programs.

REFERENCES

1. FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic, Guidance for Industry, Investigators, and Institutional Review Boards, March 27, 2020.

2. Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) pandemic. Version 2 (27/03/2020) European Medicines Agency.

WHO IS SIGNANT HEALTH?

The best technology succeeds in the background. Signant Health provides solutions that simplify every step of the patient journey to make it easier for people to participate in, and for sites and study teams to run, clinical trials. Signant unites eCOA, eConsent, Patient Engagement, IRT, Clinical Supplies and Endpoint Quality into the industry's most comprehensive patient-centric suite – an evolution built on more than 20 years of proven clinical research technology. Our intense focus on the patient experience, deep therapeutic area expertise and global operational scale enable hundreds of sponsors and CROs (including all Top 20 pharma) to extend the reach of drug development, expand patient opportunities and improve data quality – helping them bring life-changing therapies to our families and communities around the world. Take a significant step toward patient-centricity at signanthealth.com.

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