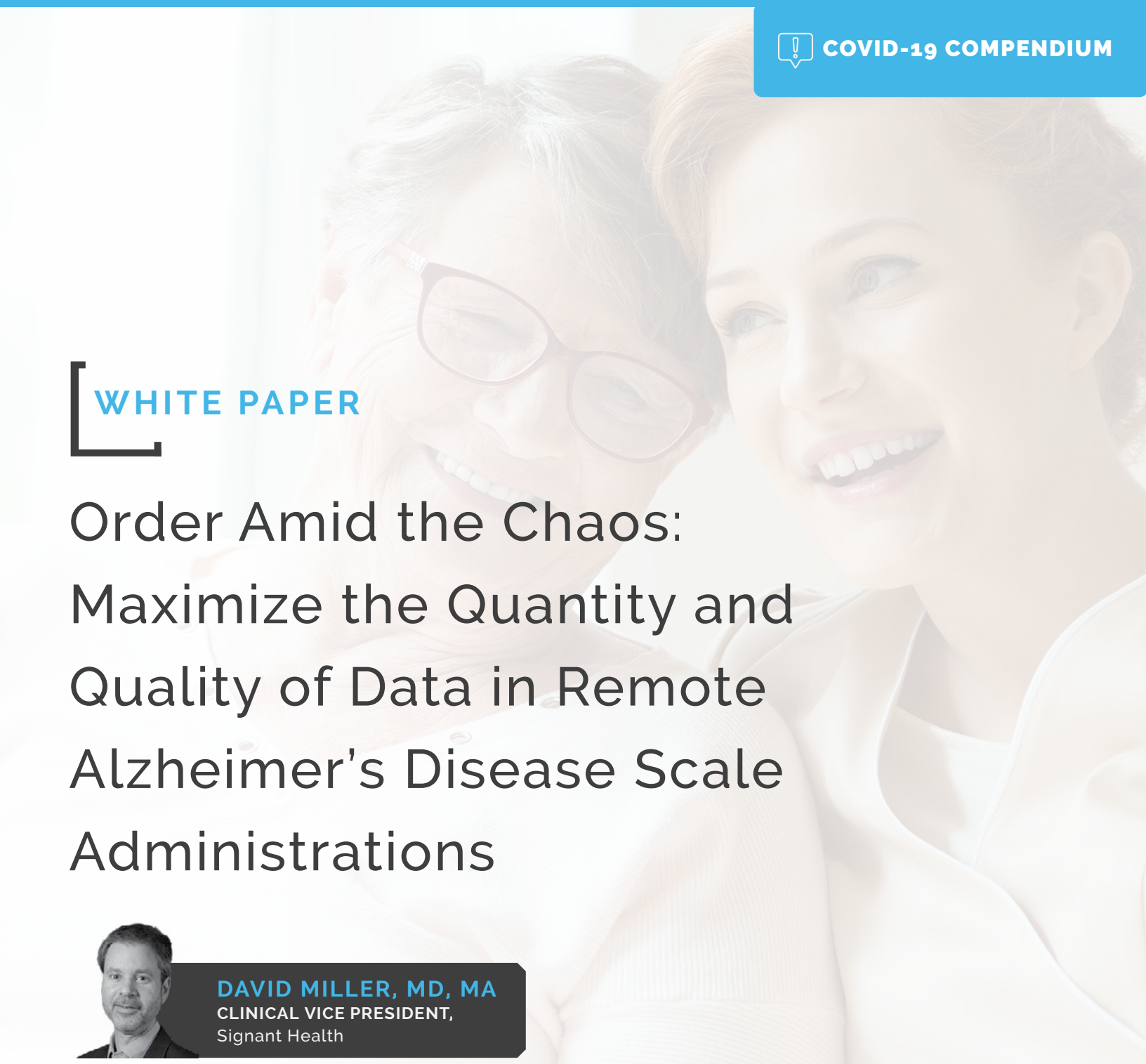
COVID-19 COMPENDIUM



WHITE PAPER

Order Amid the Chaos: Maximize the Quantity and Quality of Data in Remote Alzheimer's Disease Scale Administrations

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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**

WITH THE RAPIDLY EVOLVING NATURE OF THE CORONAVIRUS (COVID-19) PANDEMIC, CONFIGURABILITY AND ADAPTABILITY ARE KEY FOR IRT SYSTEMS IN ORDER TO MINIMIZE THE IMPACT TO CLINICAL TRIAL PATIENTS. OVER THE PAST FEW WEEKS, SIGNANT HEALTH HAS MET WITH SEVERAL CUSTOMERS TO HELP THEM MITIGATE THE INCREASING CHALLENGES AND AVOID INTERRUPTIONS TO THEIR ONGOING TRIALS. NOW, WE'RE SUMMARIZING OUR FINDINGS AND BEST PRACTICES BELOW, IN ORDER TO SHARE WITH THE INDUSTRY AT LARGE.

In all indications, but perhaps even more so in Alzheimer's Disease, time is of the essence as we try to overcome years of failed clinical trials. Each trial is important, and each patient and caregiver or study partner is precious.

With that background, it is no surprise that a variety of study sponsors are actively engaged to try to find creative and innovative solutions to capture as much study data as possible for trials that are in progress. To support their efforts, it is essential to ensure that assessments are conducted in a manner that most closely approximates what would have occurred had they been administered in person. While there is much uncertainty and fear related to the Coronavirus pandemic, our collective responsibility is to help restore some semblance of order amid the chaos.

Many issues require consideration as potential solutions are developed. Among them are:

Have the scales in a study already been validated for audio and/or video administration? If not, sponsors should consult with scientific and clinical experts to adapt them as much as possible to maximize the amount of data that can reasonably be collected.

Does the scale require input from the subject alone, or is the caregiver also required to provide information? Protocols often define a minimum amount of time a caregiver should spend with the patient per week. During the pandemic, especially in instances where the caregiver and patient do not live together, this requirement may not be met. This issue will need to be evaluated and followed to see what, if any, impact that has on the scale data.

In order to successfully conduct remote assessments, it is crucial to ensure that all participants – the site rater, the patient and/or caregiver – are well versed in what is expected of them. For example, do the patients and/or caregivers understand how to set up or utilize existing technology in their homes to make

remote assessment feasible? If not, they should be trained well in advance of the visit. We must be mindful that there will be instances when the patient and/or caregiver do not own the requisite technology to facilitate video assessments. Should this be the case, only scales that could be administered by phone would be possible. While this may mean that not all scales can be administered for that particular study visit, it still may allow for the collection of relevant information.

In instances when the study drug is given as an infusion, rather than in pill form, a potential solution could be recommending that an infusion nurse visit the patient's home to ensure that they receive the study drug on schedule. Should this option be chosen, it provides an opportunity to ask the infusion nurse to serve as a boots on the ground assistant, and training them to ensure that items that can't be completed remotely are actually and accurately completed. This would result in less "missing" data. If they agree to serve in this additional role, they too would require training as to how the scale and the particular items they will assist with are administered.

There are differences between private sites and those that are part of a university (ie – academic sites). For example, at academic sites, investigators might not be able to evaluate / treat subjects because the university may limit who is allowed on campus during the Coronavirus pandemic. Private sites may be more flexible, have fewer restrictions, and therefore may be able to evaluate patients if all parties are comfortable with this arrangement.

Given the uncertainty regarding the Coronavirus, not all patients and/or caregivers will be amenable to having someone enter their home to administer or assist in the administration of the various assessments. In these instances, sponsors may have to rely solely on those assessments that can be administered over the phone.

If there is not someone in the patient's home who can assist with scale administration (preferably someone other than the caregiver or a relative to serve in this role), not all items from certain scales will be able to be administered/completed. The reason for this is that when the caregiver or relative is present, there is the tendency on the patient's part to seek out their help, for the caregiver to want to provide that help, and for each to become frustrated. If any of these were to occur, the patient's performance would be impacted. Therefore, the preferred outcome would be that some items would not be administered, and therefore would need to be counted as "missing data."

These are just some examples to consider when devising solutions to continue clinical trials in the midst of the Coronavirus pandemic. Additionally, these solutions are not determined in a vacuum. Rather, because each study is different, potential solutions need to be discussed and decided upon in concert with the sponsor's clinical and operational teams as well as their statisticians. It is important to collaborate with other key stakeholders, such as CROs, as well.

Every provider should focus on ensuring sponsors that site raters administer and score assessments correctly, and that the highest data quality is achieved. In this way, the current COVID crisis simply means that providers should continue to do what we always have done, and work closely with sponsors to identify new, different, and creative ways to do our job together.

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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