How Digital Technology and Remote Assessment Strategies Can Aid Clinical Trial Research

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The COVID-19 pandemic has created widespread uncertainty in our industry, which is clearly demonstrated by the number of clinical trials that have stopped, slowed, failed to start or are otherwise impacted. While there has been some hopeful news around the margins from our industry on treatments and vaccines, it is important to consider that COVID-19 related issues are expected to continue into 2021.

Regulators have provided guidance for patient safety and study conduct during COVID-19. A core safety risk mitigation strategy for study sponsors and the industry has been replacing face-to-face clinic visits with remote visits, where telemedicine and other technologies allow a participant to complete study activities from their home or other remote location. Particularly, patients in active trials need support and information as to the status of their trial, risks associated with discontinuing or continuing with scheduled appointments, and the potential impact of COVID-19 on their health due to existing conditions.

Collection of electronic patient-reported outcomes (ePROs) in a decentralized trial model has been widely adopted and accepted across the industry prior to changes brought about by the pandemic. Mobile phone applications for ePROs, eDiaries, and sensors and wearables are among the patient-focused tools that create opportunities to engage not only patients but also their care partners to improve the trial experience. Because of the pervasiveness of technological devices, designing trials around bring-your-own-device (BYOD) strategies is becoming not only accepted but appreciated by participants. Additionally, the remote administration of clinician reported outcomes (ClinRos) in a decentralized model was less established than PROs prior to COVID.

With this in mind, as we look to the future of the clinical trial landscape, with several months of trials run during the COVID-19 pandemic, the question isn't if, but how, digital technology will contribute to enabling reliable and feasible remote data collection of outcomes, including ClinRos, PROs, sensors and other reliable and feasible for all stakeholders.

Some considerations when navigating this landscape are listed below:

- **Protocols and study visits:** Three general categories of remote visits have been included in re-started or new protocols launched during the COVID-19 pandemic, including pre-specified remote visits, with options for remote or in-clinical visits, and high-level contingency procedures that are not identified with specific visits. These distinctions in a protocol help define the infrastructure requirements listed below for remote visit implementations or emergency planning.

- **Equipment and logistics:** The varying requirements of ClinRos, and lack of robust remote administration equivalence data for many outcomes and scales, present issues of validity, mode of administration, technology requirements and acceptance by patients. Physical hardware and broadband requirements should be discussed and ideally standardized across the study prior to it beginning. Additionally, the living situation for all participants, including a suitable location to conduct an interview, should be considered. For example, a ClinRo measure that includes visual interpretation of symptoms by a clinician may need minimum

bandwidth and device quality requirements. Other ClinRos, such as those evaluating Alzheimer's or pediatric disorders, may require interviews with both a participant and a caregiver.

- **Remote healthcare:** The requirements for study activities such as laboratory or drug delivery can create a necessity for in-home healthcare professionals. For example, if the treatment requires specialized delivery from an injection, mobile nurses may be required. Patient populations like the elderly are also a consideration for these types of solutions because they are more vulnerable to COVID-19.

- **Training:** For ClinRos, clinicians may require additional training for administration of remote assessments or scales require modifications in the administration. Adequate identification procedures and safety protocols also must be addressed in the training and remote assessment processes. The FDA highlighted these issues in a FAQ section of guidance issued on May 14, 2020.

- **Standardization:** These procedures should be integrated into standardized processes across site and remote visits. Strategies can include device agnostic web-based delivery, a provisioned personal device or BYOD applications for participants.

Sponsors and other stakeholders should plan to discuss necessary strategies and contingencies at the outset of new studies or re-opening of halted studies. The considerations described can help sponsors and researchers manage uncertainty and engage with patients effectively as we navigate the pandemic together. As an industry, the opportunity to proactively address patient safety and access to studies can be a silver lining to the pandemic, bringing broader participation to current and future clinical research.

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