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VIRTUAL TRIALS AND REMOTE MONITORING

The current clinical research environment is moving towards a "new normal". Study sponsors, regulatory agencies, investigator sites, service providers, and patients alike have a new awareness and appreciation for conducting clinical trials in a decentralized manner. The focus on patient safety and convenience, coupled with new technologies and partner models, is driving the industry towards an increase in decentralized or virtual trials.

ProTrials leverages virtual trial technology solutions and remote monitoring strategies to improve safety and help put lifesaving clinical trials into action.

Fully Virtual Trials - all trial activities conducted virtually

- Patient-centric approach where all procedures are done remotely (i.e., at home)
- Determined through initial protocol assessment/input and site training
- Telemedicine or in-home consult conducted by primary investigator or medical staff
- May incorporate eConsent, eDC, eISF, drug/device shipment directly to patient
- Bring Your Own Device (BYOD) app for "visits", video/text chats, reminders
- Secure (256-bit dual encryption) cloud-based environment, HIPAA compliant, 24/7/365 support
- Centralized provisioning of required supplemental devices/systems (e.g., wearables, ePRO, eDiary) and study materials

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Hybrid Trials - selected trial activities conducted virtually

- Patient-centric approach to replace some select in-clinic visits with visits done remotely
- Determined through initial protocol assessment/input and site training
- Same virtual technology and processes used as needed to reduce the number and/or length of site visits

Remote Monitoring Strategy

ProTrials often recommends a blended remote monitoring strategy to provide supplemental support to on-site monitor (CRA) visit time. This is beneficial for the following types of scenarios:

- Real-time monitoring to meet data cleaning timelines and deliverables for data cuts
- Sites that may have limited capacity (e.g., monitoring "seats") for on-site monitoring
- Proactive data monitoring for high-enrolling sites
- Travel restrictions that may limit or prohibit on-site monitoring
- Realize efficiencies through reduced monitor travel (travel time and expense)

ProTrials' remote monitoring SOPs, guidelines, and visit report templates support these efforts.

ProTrials has extensive experience incorporating decentralized study management techniques and related technologies across multiple therapeutic areas to drive safe, efficient, and cost-effective delivery of clinical trials.