

Elite Research Network

Coronavirus Response & Capabilities

Sites within Elite Research Network are working diligently to respond to the constantly changing COVID-19 pandemic. Below is a summary of proactive steps being taken for ongoing studies and new, upcoming studies.

Patient-centric approach:

In an effort to maximize patient compliance and retention, sites are taking unprecedented steps to recruit and retain patients in ongoing and upcoming studies. Sites are implementing a “hybrid” approach to minimize the amount of time the patient spends at the site. This is accomplished by reviewing medical records and concomitant medications prior to screening visit along with eConsent. With IRB approvals, sites are offering flexible visits, including 7 days a week and nights, through a variety of options, including, but not limited to:

- On-site visits utilizing extra safety precautions
- Home visits
- Telemedicine visits
- Phone visits
- “Mobile” visits
- eConsent

Remote Monitoring:

Sites within Elite Research Network are familiar and prepared for remote monitoring of current and future studies. Utilization of e-Regulatory and e-Source will allow for widespread remote monitoring practices during the COVID-19. These systems allow the monitor(s) direct access to the 21 CFR Part 11 platforms, enabling SDV to be performed remotely. Paper source can also be prepared with various 21 CFR Part 11 compliant options to meet our clients’ needs.

Financial:

During the pandemic, we are requesting that all sponsors and CROs reconsider holdback payments to investigator sites to help with cash flow. Monthly (vs quarterly) payments are also preferred.

Phase I-III Capabilities

Coronavirus Vaccine Sites: up to 40 investigator sites

Coronavirus Treatment (Out-patient): up to 18 investigator sites

Coronavirus Prophylactic (Healthcare Workers): 18+ investigator sites

Coronavirus (Hospitalized Patients): 8+ Affiliated Hospitals / Networks

Coronavirus Diagnostic / Specimen Collection Studies: up to 40 investigator sites

Expedited Study Start-up: Central IRB / Centralized Budget (5-10 business days).

Phase I sites (including PBMC) capabilities

Related Links:

<https://www.worldometers.info/coronavirus/#countries>

<https://www.fda.gov/media/136238/download>

<https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html>

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application>

<https://myscrs.org/uncategorized/scrs-calls-on-sponsors-to-release-holdback-funds-in-response-to-covid-19/>

<https://www.acrohealth.org/wp-content/uploads/2020/03/ACRO-Statement-on-Monitoring-Oversight-FINAL-3.13.20.pdf>

<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#COVID19ivd>