WORLDWIDE CLINICAL TRIALS

COVID-19 CLINICAL TRIALS: STUDY DESIGN AND CONDUCT

Plan wisely to turn challenges into opportunities for productive, innovative clinical trials.

STUDY DESIGN

Effective study design for COVID-19 clinical trials must take into account the burden on sites, potential supply chain weaknesses, remote monitoring needs, and a variety of other factors — before the study even begins.

PATIENT POPULATION

Tailor your operational strategy to the severity of the patient population that the study is serving:

MILD OR MODERATE VS **SEVERE**

Design eligibility criteria to safeguard data integrity and protect against design flaws:

1. How will COVID-19 diagnosis be confirmed?
2. How will healthy controls be monitored for infection?
3. When and where will eligibility be assessed?
4. Will compassionate/emergency use criteria be proposed?
5. How will missing medical histories be dealt with?

FEASIBILITY ASSESSMENTS

GEOGRAPHIC

Leverage **real-time data on geographic hotspots** and predictive analytics to select study sites by country or locality.

STUDY SITES

Use preferred vendor partners to coordinate study efforts among staff in emergency departments, ICUs, wards, and technical services.

- Does the site have access to a qualified local laboratory?
- Can they support home healthcare activities?
- Are patients treated at a standard ICU or ad hoc centers?
- Does the site have an adequate supply of ventilators?

LEAD INVESTIGATORS

Build an investigator database to enable rapid identification of investigators with the resources and experiences required for COVID-19 studies.

RISK ASSESSMENT

Identify operational challenges and anticipate monitoring difficulties

- Can the sponsor provide home healthcare nurses to reduce site burden?
- How will the study deal with patients lost to follow-up
- How will the protocol stratify groups and implement monitoring for patients without a known medical history?
- How will adverse event information or IP-specific risks be communicated to study sites?
- How might additional social distancing regulations affect site or medical monitoring?

STUDY EXECUTION

Ensure that study conduct meets regulatory and compliance standards, despite the novel environment.

INFORMED CONSENT

Know your governing body's rules on acceptable consent for isolated patients:

- **FDA:** For isolated, infectious patients, written consent is ideal, but electronic methods are acceptable.
- **EMA:** Get regional advice. When physical records are not possible, oral consent with an impartial witness usually suffices.

PATIENT RECRUITMENT

Provide assistance to enhance recruitment and minimize study staff burden.

- Give local testing sites study information to share with patients with COVID-19.
- Offer information via a study recruitment phone number or website.
- Require and financially support pre-screening of patients.

MONITORING

Enable HIPAA-compliant transmission and remote review of electronic medical records, electronic data capture and related electronic patient-reported outcomes, as well as query resolution and data entry at the site.

PATIENT RETENTION

BOOST RETENTION BY:

- **Making it convenient:** Provide IP delivery to the home or to centers conducting laboratory testing, and use telehealth visits when feasible.
- **Using wearable devices:** Bluetooth-enabled technology can monitor health data or track compliance.
- **Remembering the basics:** Send thank-you notes, acknowledge study milestones, offer nominal compensation, and give updates on study progress.

DATA MANAGEMENT

Provide assistance to enhance recruitment and minimize study staff burden.

- Collect only data that is absolutely necessary.
- Consider what can be tracked centrally rather than locally.
- Allow sites to scan lab reports for central data entry on their behalf.
- Offer site-specific support for locations struggling with data entry.

CONCLUSION

COVID-19 has forced the development of new approaches to operationalizing clinical trials, in ways that may permanently change the world of clinical research.

At Worldwide, we've taken a step-by-step approach to offset negative impacts of COVID-19 on clinical trial operations and become a proactive leader in the development of COVID-19 studies.

Learn more about how you can minimize research disruption and speed progress in search of a vaccine or therapy. **Download our COVID-19 Guidebook** or **contact one of our experts today**.