

Customized Trial Design for COVID Studies

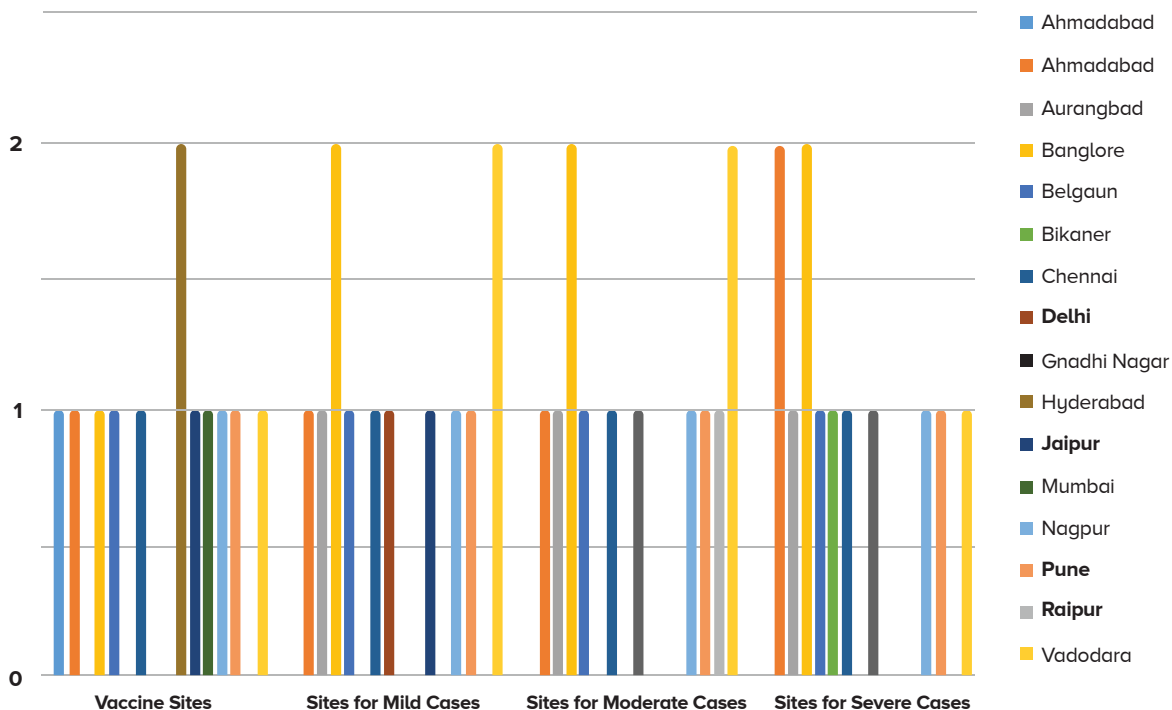
We at Veeda are armed with a number of traditional and digital assets to conduct COVID trials for our global sponsors. Depending on the trial's need , we are offering traditional and hybrid model services for your COVID trials.



Methods & tools for enabling Hybrid COVID Trials at Veeda

- Telemedicine - It is the safest interactive system which enables virtual study visits using video calls through the patient's smartphone
- eConsent- Validated and secure electronic system for patient consent
- Oral Consent- This is for patients who are in isolation & may not be able to provide written consent. Oral consent can be taken by an impartial witness according to the applicable regulations. The impartial witness must sign and date the consent document
- Direct to Patient drug shipment- Study drug delivered direct to the patient's home (in most cases, from site to patient's home)
- Home Nursing- Trained healthcare professionals, including nurses and phlebotomists, conduct home health visits to perform lab work, infusions, or other home care needs study tests also provided at patient's home
- eSource: Tool to enable sites to document the various assessments & interactions while conducting a remote visit
- Clinical Trial Management System- One centralized database for all study data. Real time visibility into study milestones & metrics. Interactive reporting feature allows users to report on trial data promptly





Balancing risks and benefits

- Access to a secure shared drive to store trial documents so they can be accessed remotely and securely
- Electronic patient-reported outcomes (ePRO) in a clinical trial allow patients to answer questions and report on their health through an electronic device, such as a smartphone or tablet
- Automated alerts to trial participants and researchers through ePRO, faster access to patient's PRO data and real-time monitoring for significant changes in their health status or symptom thresholds
- Virtual meetings via Webex/Zoom/MS Teams for study training sessions and for sharing continuous information to mitigate any risk during the course of trial

- ▶ Study specific Quality Management Plan
- ▶ Ongoing Protocol Deviation Analysis
- ▶ Pre Identification of Subjects: Use of Pre Screening Logs
- ▶ System Availability: Electronic Platforms, EDC, CTMS, ePRO, eConsenting and others
- ▶ Using Remote SDV model for monitoring
- ▶ Mandatory protocol training with knowledge assessment
- ▶ Strong Site Network of experienced sites for COVID study

Supporting sponsors beyond traditional trials

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