CASE STUDY

George Clinical
Science. Service. Solutions.

Major COVID-19 Trial at Height of Global Lockdown Implemented in Record Time

Extraordinary achievements under unprecedented conditions due to established global relationships and unflinching dedication.

SITUATION

Healthcare professionals worldwide were working under extreme conditions with limited resources at the height of the COVID-19 lockdowns. The global George Clinical team was no exception and was challenged with embarking on an investigator-initiated collaboration between a major pharma company, a private research institute and George Clinical to study the potential of a drug to give certain COVID-19 patients a better survival chance. With over-taxed healthcare systems and virtually everyone on the planet confined to their homes, it was seemingly impossible that a major time-sensitive multi-national clinical trial could overcome the barriers and achieve startup. But despite all of the adverse conditions including complete dependence on electronic communications, the George Clinical team hit the ground running, and was able to begin recruiting patients in warp speed time.

Full-services provided included Project Management, Operations, Regulatory, Medical Monitoring, Safety Management and Reporting, Data Management, Vendor Management of Central Lab, eCRF vendor, IP Supplier/Depots, Partner CROs and AROs.

"As CMO of George Clinical I am extremely proud of this team and the work they accomplished in these extraordinary times. As unusual as the circumstances were, this "can do no matter what" attitude is not at all unusual for a George Clinical team. Our people are absolutely our best asset because each and every one is invested in a very personal way. Every team member is willing to be as flexible, creative and available as the job requires. And we all at George Clinical are constantly and consistently working toward the goal of improving the health and quality of life of as many people in as many places as possible."
— Maria Ali, Chief Medical Officer

CHALLENGES

- Critical timing as study was associated with effects of COVID-10 on patients
- Limited resources, over-taxed healthcare systems, and everyone locked down
- Quick start-up needed to enroll >1,000 eligible COVID-19 patients at nearly 100 sites
- Regulatory approval, site identification, set up and recruitment all through remote communications from homes of investigators and teams
- Needed minute-by-minute COVID-19 information to best design study for maximum results in shortest time
- Highest quality of evidence required for "gold-standard" trial
- Ever-evolving dynamics of pandemic challenging for event-driven study endpoints
- Many protocol amendments and changes to process required

SOLUTIONS

- Fluid COVID-19 information used by scientific team to design study for maximum results ensuring scientific rigor and safety for patients
- Expedited and optimized study operations by teams accustomed to creative problem solving and efficient communications across time zones and continents
- Able to leverage on-the-ground relationships with local regulators and hospital investigators for strategic decisions in approvals, site identification and patient recruitment
- Scientific team maintained study integrity throughout amendments and process changes
- Developed personalized, considerate communications for home locked-down researchers and overtaxed healthcare workers

"I can't tell you how challenging this was. Every day was deadline day and you got up and chose to fight, and there were days you didn't feel like fighting anymore, but you did it anyway." Emily Akin, Project Director

RESULTS

Getting drug approval within a matter of weeks to begin enrolling patients at the height of the pandemic beat any timeline our team had ever seen. Systems were developed, sites recruited and patients enrolled within 22 days of study start. At nearly 100 sites in multiple countries, >1,000 patients were recruited in under eight months. These incredible efforts demonstrated the possibility of producing high-quality evidence even under extraordinary conditions. Of the hundreds of randomized, placebo-controlled, double-blind clinical trials begun in this time period to study COVID-19 treatments, this study was one of the few to be successfully completed. The quality, science, and study delivery were exemplary, allowing for a meaningful contribution to fight COVID-19.

To hear from the staff members who helped make this COVID-19 study a reality, click here.

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