



## COVID-19 CATO SMS OPERATIONS UPDATE

March 16, 2020

As the COVID-19 pandemic spreads across the globe, CATO SMS continues to take steps to address the challenges in study conduct that may arise due to illness, quarantine and restricted travel of study participants, clinical investigators, clinical site staff, and monitoring personnel. The events are unprecedented.

Our number one priority is the safety and well-being of trial participants, employees, and sponsors, and we recognize our responsibility to the communities in which we live and work.

### KEY HIGHLIGHTS:

- CATO SMS has assembled an executive-level, dedicated task force to continuously monitor the impact of COVID-19 in each country in which we operate, and to work in close collaboration with our sponsors to maintain the safety of trial participants, the integrity of study data, and compliance with GCP.
- We are developing project-specific Risk Mitigation and Contingency Plans, and our project managers will reach out to you shortly to discuss and mutually agree on measures to be taken for your project.
- We are exploring and deploying alternative solutions, including remote/centralized monitoring, to maintain oversight of clinical sites where planned on-site monitoring visits are no longer possible due to the implementation of COVID-19 control measures.
- We are coordinating with all stakeholders (i.e., the sponsor, clinical investigators, CATO SMS personnel, institutional review boards (IRB), ethics committees, and regulatory/competent authorities) to drive the best possible outcomes under the current circumstances.
- We are proactively soliciting and monitoring any relevant guidance from regulatory authorities around the globe regarding how to handle potential COVID-19 related study disruptions.
- CATO SMS is continuously assessing the situation in real-time, remaining vigilant, and following recommendations of the Food and Drug Administration (FDA), World Health Organization (WHO), U.S. Centers for Disease Control and Prevention (CDC), European Medicines Agency (EMA) and local authorities as appropriate.

We will make every effort to ensure that we continue to deliver the level of quality, excellence and timeliness that you have come to expect from us despite the challenges that we all face. Please feel free to contact us with any questions.

In the meantime, we send our best wishes to you and your loved ones during this difficult time.

Sincerely,

A handwritten signature in black ink, appearing to read 'Mark A. Goldberg', written in a cursive style.

Mark A. Goldberg, M.D.  
Executive Chairman