

SITE TRAINING AGILITY PUTS PATIENTS FIRST

Shifting the Clinical Trial Paradigm to Speed COVID Treatment

When COVID-19 changed everything, sponsors needed solutions outside of traditional clinical trial methodology to meet demands for speed and volume. A leading pharmaceutical company, partnering with the NIH, collaborated with training partner WCG on a groundbreaking process designed to accelerate lifesaving treatment for COVID patients.

The study protocol called for access to non-traditional sites such as emergency rooms and long-term care facilities as part of a global COVID clinical trial. The unique, rapid enrollment requirements did not allow for training sites prior to finding patients as patients were testing positive for COVID on a daily basis. In essence, WCG's InvestigatorSpace platform allowed the study teams to shift the paradigm by putting patients first in the process. This shift required agility for healthcare provider training to comply with the study protocol and audit preparedness.

"We shifted the paradigm by putting patients first. This change required agility for healthcare provider training."

"The training process took only two weeks, with 1,133 patients and 111 sites quickly enrolled in the clinical trial."

UNDERSTANDING THE CHALLENGES

- Quickly develop and implement training for fast, consistent online training of site staff.
- Enable site staff to provide immediate service to patients in need of treatment.
- Support the global enrollment goal and ensure site preparedness.
- Provide auditable training records to ensure and verify compliance.
- Ensure easy access to training and reports via mobile device, computer, tablet and applications with memorable URL.



ACCELERATING THE PROCESS

Speed was the name of the game in ensuring the best chances of survival when COVID patients required treatment. Training was provided and accessed in a just in time manner to ensure patient needs were met and sites could administer drug. We worked aggressively – to confirm a unique URL for ease of access and enabled the proprietary self-registration workflow via

InvestigatorSpace. This automation allowed for immediate training access healthcare providers in the field.

The NIH proactively communicated with emergency rooms: “If you have a COVID patient, we want to run this study to reduce the number of patients needing ventilators. Will you participate if you have a patient?” Access to the site was provided via a common URL. The system prompted them to enter metadata into a form using a security PIN.

In short.....providers would click on the link, register, take training, achieve certification, and administer the medication.

REALIZING THE OUTCOME

The training process took only two weeks, allowing lightning speed patient treatment and trial enrollment.

As a result of this game-changing process, 111 sites, accounting for 1133 patients, were able to be certified same-day, without deviating from established quality standards.

The approach accelerated the trial and application for regulatory approval while saving lives.

WCG remains committed to pioneering new ways to streamline clinical trial training via InvestigatorSpace. Lessons learned during the pandemic continue to support groundbreaking innovation.