Trial Recruitment at Warp Speed

How Citeline Connect Supported the Fastest-recruiting COVID-19 Clinical Trial in Operation Warp Speed History
A late-stage biotechnology company developing a next-generation vaccine against COVID-19 was set to conduct a large Phase III trial. The trial design was aligned with other Phase III trials conducted under the auspices of Operation Warp Speed, and planned with specific recruitment diversity goals and an enrollment target of 30,000 volunteers. Location of trial sites emphasized communities and demographic groups most impacted by the disease, including people over age 65 and those living with comorbid conditions that placed them at higher risk of complications from COVID-19.

“The full enrollment of [this trial] is another important step in building a body of evidence to demonstrate that [the vaccine] will be safe and effective across diverse, representative populations.”

PRESIDENT, RESEARCH AND DEVELOPMENT
COVID-19 TRIAL SPONSOR

ENROLLMENT GOALS AT LAUNCH:

≥ 25%
of the study population
65 years of age or older

≥ 15%
Black/African-American

10-25%
LatinX

1-2%
American Indian
Use Case | Trial Recruitment at Warp Speed

Citeline Connect Selected

Operation Warp Speed partners who had previously succeeded in recruiting for a high-profile Phase III COVID-19 trial with Citeline Connect introduced the solution to the study sponsor’s CRO. Citeline Connect was selected to support the trial’s 30,000-participant goal. The sponsor was now able to work with many of the same recruiting partners that had already responded to its RFP, simultaneously and without the burden and risk associated with selecting just one.

Within just days of launch, 20 recruitment partners across a variety of specializations and recruiting methodologies — each armed with IRB-approved assets co-created by the Citeline Connect team — mobilized to instantly begin referring patients to enrolling research sites at once.

SOME OF THE RECRUITMENT PARTNERS WHO ACTIVATED FOR THIS TRIAL

- patientriais
- LIFE LINE SCREENING
- CareONE Concierge
- SubjectWell
- Clinical Connection
- Genomelink
- Curify
- patient association
- epion HEALTH
- RARE PATIENT VOICE
- Medivizor
- CURES
Reinventing the Recruitment Model

Unlike traditional clinical trial recruitment models, Citeline Connect works as a collective, empowering over 100 different recruitment partners to refer patients to research sites concurrently using a pay-for-performance model. In this specific trial, recruiters were compensated for both referrals and randomizations, through a predetermined rate card agreed upon by the sponsor and CRO. This pay-for-performance model incentivized recruiters to directly optimize their outreach and performance.

Citeline Connect’s built-in content repository was used to provide all recruitment partners with the same IRB-approved copy and imagery, including email and call center scripts. Sample advertisements were also created to ensure proper use of recruiting materials across social channels such as Facebook, Twitter and Instagram.
In a study such as this one, with a large volume of prospective participants and accelerated startup timelines, creating processes to prevent catastrophic site congestion and streamlining the enrollment process through technology were key to success. First, a Trial Site Administration portal was established to allow local site staff to edit and confirm the correct contact details for their locations and, most importantly, change their site recruiting status in real time as needed to pause referrals during busy spurts.

The administration portal also allowed the sponsor and CRO teams to add or remove site staff users and oversee site-level analytics in a single web application. In the case of individual sites becoming bogged down with referral traffic, admins could re-route referrals to other local sites to ease congestion and ensure no leads were left behind.
Second, Citeline Connect created and launched new capabilities unique to this trial: A toll-free telephone support auto-attendant and an automated email responder for inbound inquiries. Working together to alleviate participant concerns and respond to common questions, these technologies buffered patient inquiries from reaching site personnel, while ensuring most pertinent questions were addressed.

Lastly, rather than allowing prospective trial participants to contact sites independently, Citeline Connect’s embedded prescreening solution was deployed across all recruitment partners, including the sponsor’s own trial website, to quickly prequalify patients. This prevented more than 130,000 unqualified referrals from contacting already busy sites.

“Your campaign has been extremely successful for us! We are receiving many [Citeline Connect] referrals which have been wonderful!”

SITE DIRECTOR
Through Citeline Connect, the sponsor and CRO teams were able to review recruiter-specific performance metrics such as prescreened patients and number of participants randomized, as well as campaign-specific details for their own advertising across social media channels such as Facebook. This level of detail is made possible by Citeline Connect’s technology coupled with daily IRT reports ingested into the platform.
Citeline Connect delivered **6,432 randomizations (22% of target)**, over 50% within the minority population, in a record-setting 48 days — reaching the enrollment goal **55% faster** than the next quickest Operation Warp Speed clinical trial.

“Working with [Citeline Connect] on this study has been a pleasure and very successful. It has turned out to be money well spent.”

DIRECTOR, CLINICAL OPERATIONS
COVID-19 TRIAL SPONSOR

Only Citeline Connect can help you rapidly find, refer and screen highly qualified patients for even the most challenging clinical trial.

**Broaden Your Recruitment Funnel**
Reach millions of patients from over 75 diverse data partners

**Improve Referral Quality**
Incorporate patient qualification earlier in your process

**Pay for Performance**
Set fees using an intelligent pricing recommendation engine

**Optimize in Real Time**
Gain confidence with analytics on all referral channels
Citeline, a Norstella company, powers a full suite of complementary business intelligence offerings to meet the evolving needs of life science professionals to accelerate the connection of treatments to patients and patients to treatments. These patient-focused solutions and services deliver and analyze data used to drive clinical, commercial and regulatory-related decisions and create real-world opportunities for growth.

Our global teams of analysts, journalists and consultants keep their fingers on the pulse of the pharmaceutical, biomedical and medtech industries, covering it all with expert insights: key diseases, clinical trials, drug R&D and approvals, market forecasts and more. For more information on one of the world’s most trusted life science partners, visit Citeline.com