

Use Case

# Trial Recruitment at Warp Speed

How Citeline Connect Supported the  
Fastest-recruiting COVID-19 Clinical Trial  
in Operation Warp Speed History

July 2023



## Recruiting with Scale, Speed and Diversity

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



# 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.

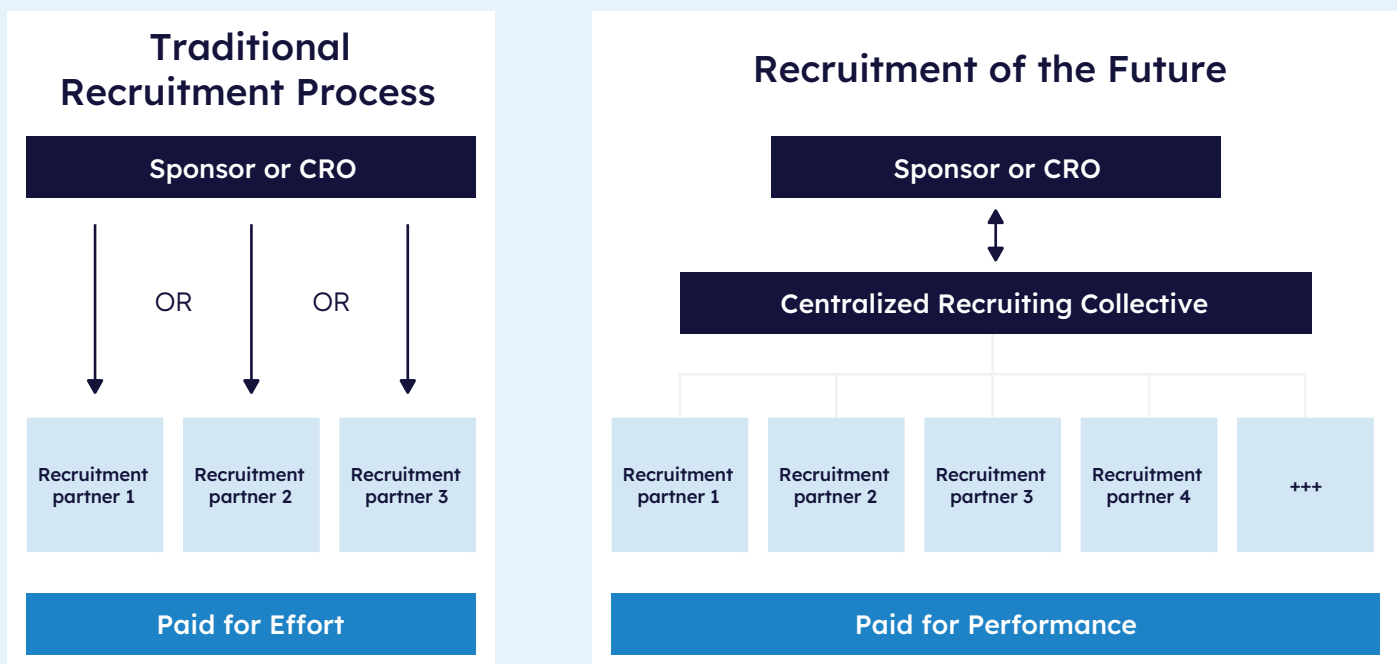
Within just days of launch, 20 recruitment partners across a variety of specializations and recruiting methodologies — each armed with IRB-approved assets co-created by the Citeline Connect team — mobilized to instantly begin referring patients to enrolling research sites at once.

## SOME OF THE RECRUITMENT PARTNERS WHO ACTIVATED FOR THIS TRIAL



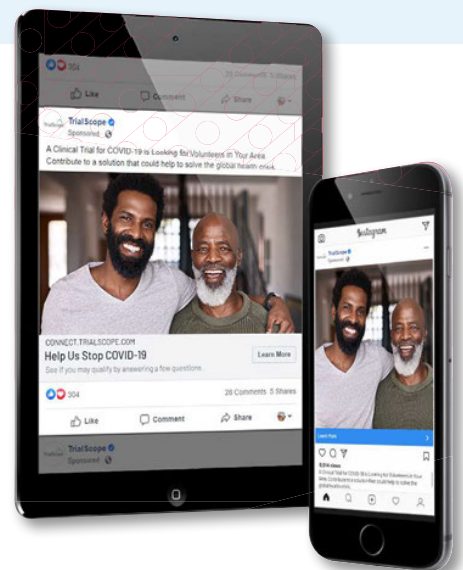
# Reinventing the Recruitment Model

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.



## Centralizing IRB-Approved Assets

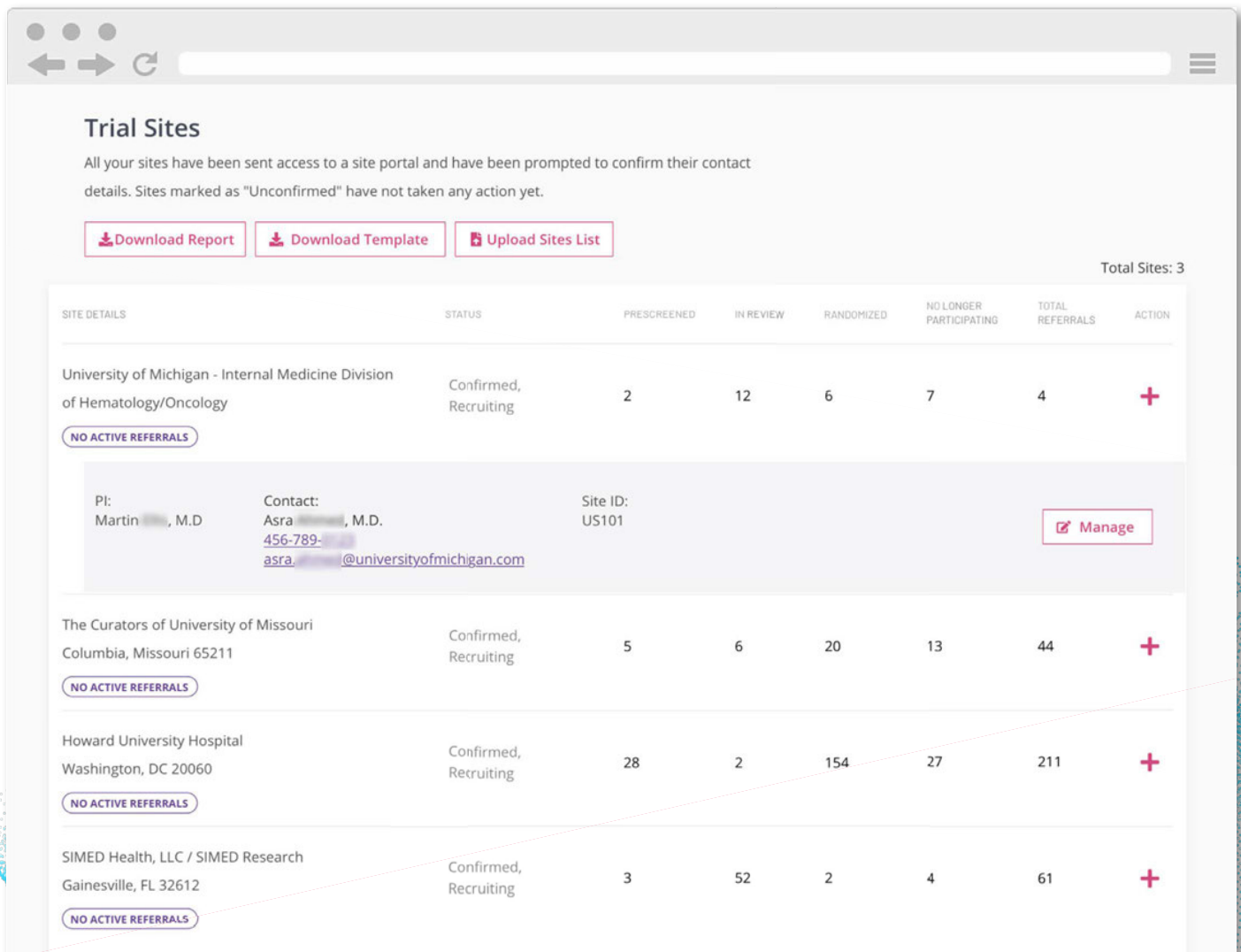
Citeline Connect’s built-in content repository was used to provide all recruitment partners with the same IRB-approved copy and imagery, including email and call center scripts. Sample advertisements were also created to ensure proper use of recruiting materials across social channels such as Facebook, Twitter and Instagram.



## Setting Sites Up for Success

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.



The screenshot displays a web application interface for managing trial sites. At the top, there are navigation buttons (back, forward, refresh) and a search bar. Below the navigation, the page title is "Trial Sites" with a sub-message: "All your sites have been sent access to a site portal and have been prompted to confirm their contact details. Sites marked as 'Unconfirmed' have not taken any action yet." There are three buttons: "Download Report", "Download Template", and "Upload Sites List". On the right, it says "Total Sites: 3".

SITE DETAILS	STATUS	PRESCREENED	IN REVIEW	RANDOMIZED	NO LONGER PARTICIPATING	TOTAL REFERRALS	ACTION
University of Michigan - Internal Medicine Division of Hematology/Oncology <b>NO ACTIVE REFERRALS</b> PI: Martin [redacted], M.D. Contact: Asra [redacted], M.D. 456-789-[redacted] asra.[redacted]@universityofmichigan.com Site ID: US101 <b>Manage</b>	Confirmed, Recruiting	2	12	6	7	4	+
The Curators of University of Missouri Columbia, Missouri 65211 <b>NO ACTIVE REFERRALS</b>	Confirmed, Recruiting	5	6	20	13	44	+
Howard University Hospital Washington, DC 20060 <b>NO ACTIVE REFERRALS</b>	Confirmed, Recruiting	28	2	154	27	211	+
SIMED Health, LLC / SIMED Research Gainesville, FL 32612 <b>NO ACTIVE REFERRALS</b>	Confirmed, Recruiting	3	52	2	4	61	+

## Setting Sites Up for Success continued

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**

The image displays three overlapping screenshots of the Citeline Connect eligibility screening interface. The top screenshot is a green-bordered box titled "Check Your Eligibility" with a "Get Started" button and the text "We'll check to see if you're eligible by asking you some questions." Below it, the "Question 1 of 6" screen asks "How do you identify your race or ethnicity?" with radio button options: American Indian or Alaskan Native, Asian or Pacific Islander, Black or African American, Hispanic or Latino, White or Caucasian, and Multi-Race. A "Next" button is at the bottom. The bottom screenshot is "Question 6 of 7" asking "Have you been diagnosed or treated for the following diseases or conditions:" with radio button options: Cancer, Chronic kidney disease, COPD (chronic obstructive pulmonary disease), Immunocompromised state (weakened immune system) including HIV, Obesity (body mass index [BMI] of 30 or higher), Serious heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies, Sickle cell disease, Type 2 diabetes mellitus, and None of the above. A "Next" button is at the bottom.

## Channel and Campaign Analytics

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.

The screenshot displays two overlapping web application windows. The top window, titled "Collective Referral Partners", shows a table of recruitment partners with columns for "COMPANY", "PRESCREENED", "IN REVIEW", "RANDOMIZED", "NO LONGER PARTICIPATING", "TOTAL REFERRALS", and "ACTION". The table lists companies such as CureClick, DirectDerm, Icon, CareONE Concierge, MMG, Clinical Connection, CoverMyMeds, Clinispan Health, Epiion Patient Services, Patientory Inc., PatienTrials, and Patiro. A legend indicates 26 Active, 10 Pending, and 2 Declined partners. The bottom window, titled "Analytics", features a "Filter by UTM" section with dropdowns for Source, Medium, and Campaign, and a "Filter" button. Below this is a "Prescreener Activity" section with three cards: "Prescreeners Completed" (20), "Disqualified" (10), and "Qualified" (10). The "Disqualified" card lists reasons such as "Have you ever had a positive test for COVID-19?" (4 disqualifications) and "How do you identify your race or ethnicity?" (3 disqualifications). The "Qualified" card lists "1 Participant Referred to Site(s)" and "9 dropped off without sharing contact details". At the bottom of the analytics window, a summary row shows values: 47, 6454, 14198, and 85513.

COMPANY	PRESCREENED	IN REVIEW	RANDOMIZED	NO LONGER PARTICIPATING	TOTAL REFERRALS	ACTION
CureClick						+
DirectDerm						+
Icon						+
CareONE Concierge						+
MMG						+
Clinical Connection						+
CoverMyMeds						+
Clinispan Health						+
Epiion Patient Services						+
Patientory Inc.						+
PatienTrials						+
Patiro						+

**Analytics**

Filter by UTM  
For information on setting up UTM campaigns please review the [Getting Started](#) tab

Source: All Medium: All Campaign: All Filter

**Prescreener Activity**

- Prescreeners Completed: 20
- Disqualified: 10
  - Have you ever had a positive test for COVID-19? 4 Disqualifications
  - How do you identify your race or ethnicity? 3 Disqualifications
  - Have you been diagnosed with any of the following medical conditions that puts you at increased risk for COVID-19 infection? 4 Disqualifications
  - Are you 65 or older? 0 Disqualifications
  - Do you plan to receive any vaccines in the next 1 month? 0 Disqualifications
- Qualified: 10
  - 1 Participant Referred to Site(s)
  - 9 dropped off without sharing contact details

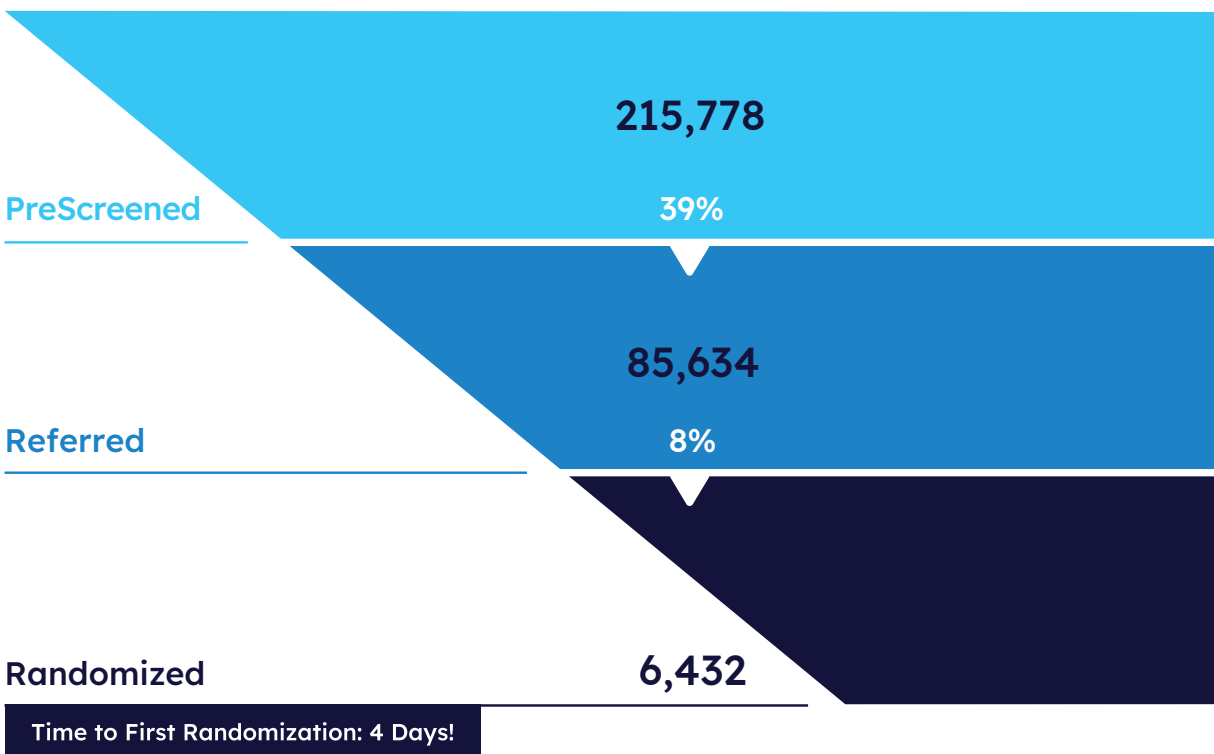
47 6454 14198 85513

# Achieving the Enrollment Goal in Record Time

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





## Connect. Refer. Screen. Enroll.

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





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