Covid-19 Rescue Study

A **Fully Decentralized Trial** (DCT) with Multi-Sourced Data Collection to Enable the Rapid Screening, Enrollment, and Diagnosis of 15,000 Participants

SUMMA

The engine that drives the advancement of complex digital trials.

Precision Digital Health

DIGITAL TRIALS AND CONNECTED DEVICES, *Simplified*

Challenge

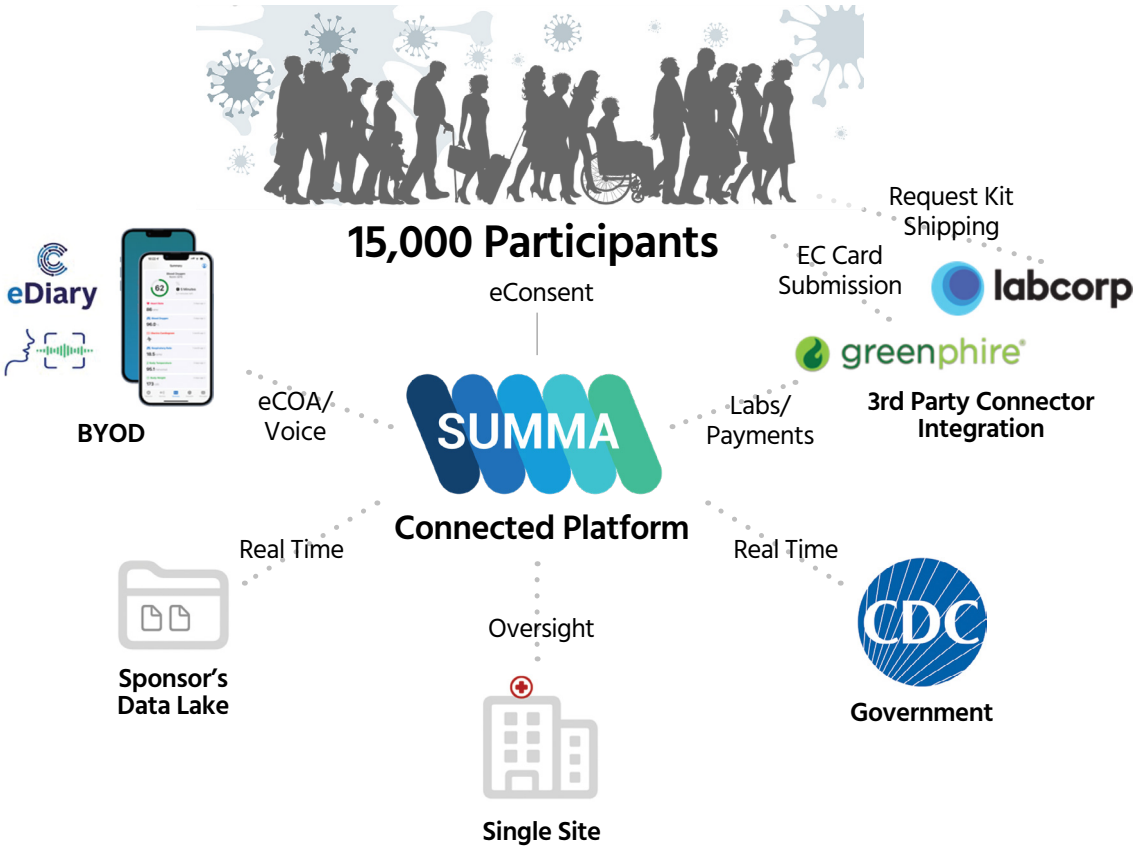
A top tier pharmaceutical company encountered operational and technical challenges while implementing a complex digital study involving 15,000 participants. The primary objective was to collect voice and diary data to develop an AI-based digital tool for detecting COVID-19. The study design required that a centralized digital solution collect and manage multiple data sources from 3rd party vendors while effectively supporting clinical workflows and downstream data analysis. The study team was faced with ongoing operational issues related to the trial design complexity.

Study requirements:

1. A single site, 100% decentralized participant approach
2. Participants were required to be enrolled via a mobile solution and then co-consented to enroll in the study
3. Enrolled participants required:
    a. E-Consent, automatic ordering of home-based diagnostics & eCOA diary entry
    b. Capture of voice recording for cough analysis
    c. E-card study payments directly to participants
    d. Two-way HIPAA compliant communication to participant and clinical staff
4. Mandatory state reporting to Center for Disease Control (CDC) state agencies (n=50) required Health Level Seven (HL-7) standard to report test results
5. Digital study design with centralized clinical oversight to manage unblinded participant data (HIPAA compliant)
6. Blinded study management and data management services to support CRO and sponsor operational requirements

Solution

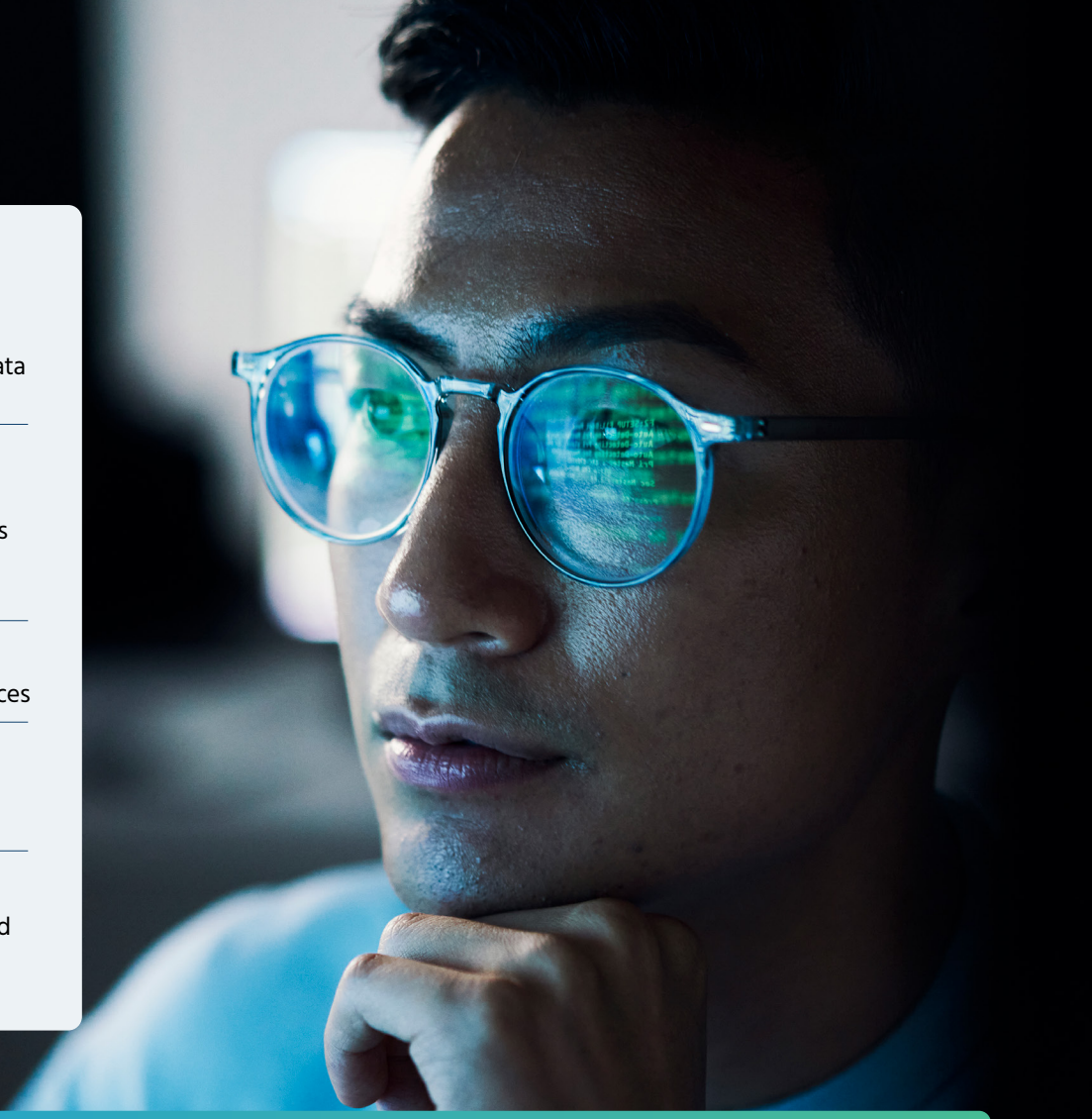
Precision Digital Health enabled the digital study in less than 45 days by implementing their highly configurable cloud-based platform, SUMMA, which orchestrated clinical workflows in a validated system across 5 (five) 3rd party vendors in regulatory compliant manner.



SUMMA's real-time data connectors and clinical portal provided a centralized "Data Hub" to manage and track the large, decentralized participant population. SUMMA provided a streamlined user experience to enable and support:

- A BYOD approach to capture participant consent, diary entries, voice recordings and adverse events
- The sharing of PHI (required for identity verification and shipping of kits) in a HIPAA compliant way
- Centralized oversight using a single health system's clinical resources to provide co-consent to enroll participants into the trial in a 21 CFR Part 11 compliant way
- The supply of Labcorp PCR kits shipped directly to participants following enrollment
  a. The creation of a tracking record (FedEx) entry to manage full workflow [: lab kit ordered —> participant records COVID Swab/ date on Diary —> Returns kit for processing —> Lab results provided to SUMMA
  b. Lab results notification: SUMMA reported in real-time COVID, Influenza and RSV testing to the participant, centralized oversight staff and 50 CDC agencies
  c. Chatbot driven secure lab results and downloadable PDF of the results that was HIPAA compliant
- Timely management of each participant lifecycle (screened -> completed), tracking of labs, Diary tracking (what components / days completed) and ecard payment to the participant
- Regulatory compliance through HL7 driven notifications to CDC agencies in each of the 50 states
- E-card Payment – payment connector was used to create subject accounts for payment SUMMA to calculate the payment based on diary metrics, tasks completed, and electronic payment process to pay the participant with electronic acknowledgement
- De-identified access to reporting, tracking and reconciliation activities.
- Voice analytics – voice data capture was also delivered 3 times a week and PDH data services provided all the data quality checks for the 60,000 voice recordings that were processed weekly.
  a. Weekly data size in excess of 1 TB of data

Covid-19 Rescue Case Study



100%
fully decentralized trial
(DCT) BYOD along with seamless data flow simplified participation

45 days
Our fully configured, tested, and implemented SUMMA platform was delivered ahead of schedule in an accelerated environment.

15,000 participants
Across five (5) third party data sources

3X weekly data imports
of over a tera byte of data to its data lake

HIPAA compliant
Through an automated de-identified process

Results

The Sponsor and the clinical oversight team followed participants daily for 15 months collecting the clinical and voice data to capture the study's digital endpoints. Data collection, integration, daily exports, and data analysis of this magnitude would not be possible using traditional clinical trial methods.

SUMMA

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Call **949-343-0079** or email **info@precisiondigitalhealth.com** to learn how SUMMA™ – combined with PDH's expertise and specialized services – can help your next trial realize its full potential.

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