mytrials

Clinical Trial Application Concept

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IRB Statement

This project is not a systematic investigation. It will not collect data from Cal Poly students or employees as subjects, and does not attempt to answer research questions. Therefore, this project does not need to be reviewed by the California Polytechnic State University Institutional Review Board.

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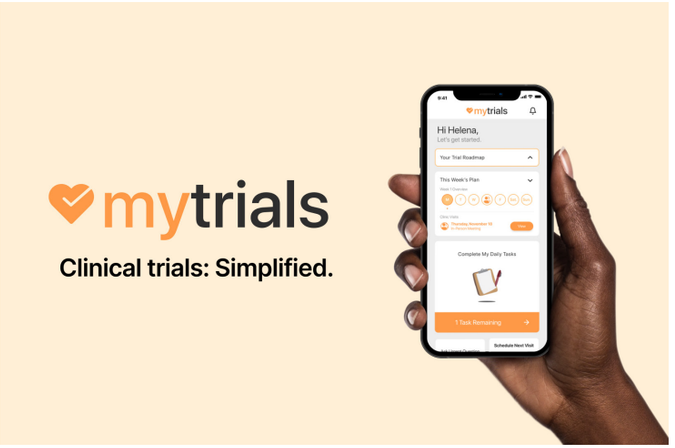
Abstract

A clinical trial's success is dependent upon whether a patient attends their highly-structured clinical trial visit schedule, which may include both in-person clinic visits and virtual check-in visits. MyTrials is a clinical trial journey app prototype that enables patients to schedule, reschedule, and attend join their in-person or virtual clinic visits. This product seeks to reduce the burden that scheduling places on the patient, and provides trial-provided resources and a daily and weekly timeline to help patients navigate their clinical trial journey.



About Katie

Hi there! I'm Katie Hollister, a Graphic Communication and English double major from Walnut Creek, California. I'm a student, designer, photographer and peer-educator (I enjoy wearing a lot of hats!).

I desire for the things I create and the work I do to improve other people's lives. I enjoy hosting UX design workshops at Cal Poly's User Experience Club, empowering other women in tech, and putting my user's experience ahead of my own.

After graduating, I'm excited to start my career at Veeva Systems as an associate product designer.

Timeline

Week 1
Clinical Trial Research

Week 2
Competitive Analyses

Week 3
Conduct Professional Interviews

Week 4
Branding and Design System

Week 5
Low Fidelity Screens

Week 6
High Fidelity Screens

Week 7
Revise High Fidelity Screens

Week 8
Prototype Screens

Week 9
Final Presentation

Week 9
Design Process Book

Problem Statement

Navigating a clinical trial journey requires the patient to schedule meetings within specific date ranges However, not all clinical trial patients are adept at reading clinical trial protocols and schedules.

As a result, clinical trial patients may find it difficult to manage their visit schedule and quit the clinical trial before they complete their required meetings. This nullifies their trial data, and as a result, researchers cannot use the data they learn from that patient.

Project Objectives

Design a mobile application that allows users to complete the following tasks:

View Schedule of Clinic Visits

- In Person vs Virtual Visit
- Type of Visit
  - Physical Exam
  - Swab
  - Blood Draw

Schedule Clinic Visits

- Confirm
- Reschedule

Join Virtual Clinic Meetings

- From In App
- From Notification
- From Text Message Reminder

Background Research

Clinical trials are a form of planned experiment with human participants that are designed to identify new and improved treatments for future patients with given medical conditions [1].

Trial patients could be from any age, background, ethnicity and other demographic criteria that the principal investigator wants to investigate. One type of clinical trial patient is healthy volunteers that want to advance medicine, to help others and to obtain better treatment; other patients are sick and seeking experimental treatments to save their life.

Each patient is subject to a high number of medical exams and tests as a part of their trial. It's common for patients to log their health data each day through questionnaires, which helps researchers monitor their symptoms and reactions to their treatment over time. In some cases, patients may even have to stay at a hospital for a period of time to be monitored by the research team.

A clinical trial's success is dependent upon whether a patient attends their highly-structured clinical trial visit schedule, which may include both in-person clinic visits and virtual check-in visits. Trial patients are responsible for managing their own scheduling of appointments and tests amidst their everyday life. They are required to meet with trial managers, principal investigators, trial coordinators healthcare

providers, researchers and social workers as a part of a strict patient schedule.

this is the day the vaccine was given

Table 14: Schedule of Events (Vaccination Phase, Day 1 – Day 57)

Visit Number	0	1				2				3
Type of Visit	C	C	SC	SC	SC	C	SC	SC	SC	C
Month/Weekly Timepoint		M0				M1				M2
Study Visit Day	D0[7] (Screening)	D1 (Baseline)	7 days after D1 D8	14 days after D1 D15	21 days after D1 D22	D29 [9]	7 days after D29 D36	14 days after D29 D43	21 days after D29 D50	D57 [9]
Window Allowance (Days)	-28		+3	+3	+3	-3/+7	+3	+3	+3	-3/+7
Days Since Most Recent Vaccination	-	0	7	14	21	28/0	7	14	21	28
ICF, demographics, concomitant medications, medical history	X									
Confirm participant meets inclusion and exclusion criteria	X	X								
Physical examination[2]	X	X				X				X
Pregnancy testing[3]	X	X				X				
Randomization		X								
Dosing										
Study injection (including 30-minute post-dosing observation period)		X				X				
Efficacy Assessment										
Surveillance for COVID-19/Unscheduled Visit[4]		X	X	X	X	X	X	X	X	X
Nasopharyngeal swab[5]		X				X				
Immunogenicity Assessment										
Blood for immunologic analysis[5]		X				X				X
Safety Assessments										
eDiary activation for recording solicited adverse reactions (7 days)[6]		X				X				
Review of eDiary			X				X			
Follow-up Safety[1]			X	X	X		X	X		
Recording of Unsolicited AEs		X	X	X	X	X	X	X	X	X
Recording of MAAEs, AE leading to withdrawal and concomitant medications relevant to or for the treatment of the MAAE[8]		X	X	X	X	X	X	X	X	X
Recording of SAEs and concomitant medications relevant to or for the treatment of the SAE[8]	X	X	X	X	X	X	X	X	X	X
Recording of concomitant medications and non-study vaccinations[8]		X	X	X	X	X	X	X	X	X

C = Clinic Visit
SC = Safety Call

This last visit would be 28 days after the vaccine (with a window of -3 to +7)

This last visit the patient should expect a physical exam and a blood draw

These are the sites activities - maybe not for sharing to the patient?

Abbreviations: AE = adverse event; C = clinic visit; D = day; eDiary= electronic diary; ICF = informed consent form; M = month; MAAE = medically attended AE; SAE = serious adverse event; SC = safety (phone) call.

An Example Clinical Trial Patient's Schedule

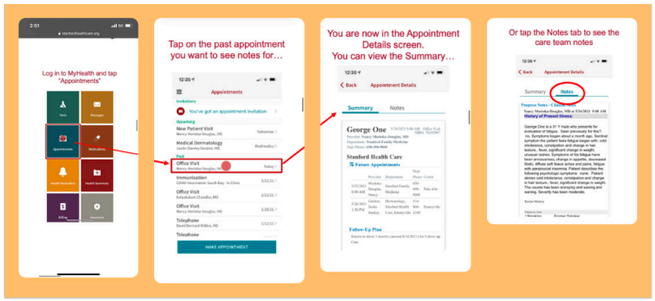
With the recent increase in the number of virtual visits, patients have to be clear on each of their visit's modality, location and requirements. However, clinical trial protocols and schedules (see example above) are difficult to interpret and are not displayed in a traditional calendar format, making it difficult for patients and their supporters manage their trial's schedule.

This may lead patients to quit their trial before they complete their required meetings, which nullifies their trial data that could have been used by researchers.

Competitive Landscape

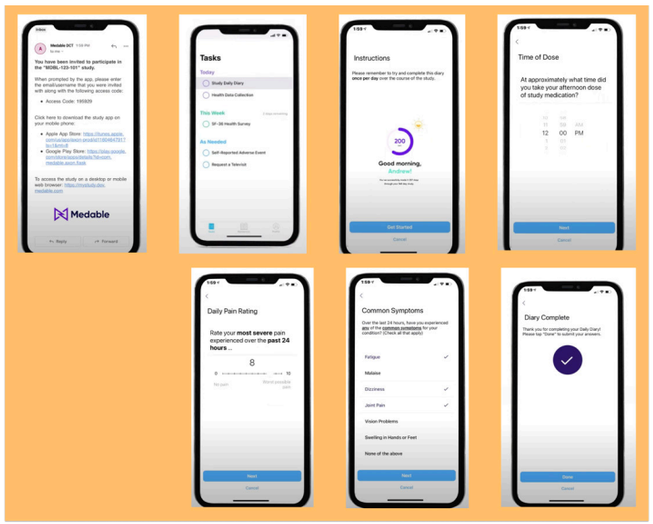
To understand current industry trends and reveal design opportunities for MyTrials, I reviewed the features and scheduling flows of two similar applications: Stanford MyHealth and Medable.

Stanford MyHealth



Stanford MyHealth helps Stanford patients manage their regular checkups and hospital stays, streamlining appointment scheduling and communication with doctors. It also allows users to view their test results, pay medical bills, renew prescriptions, and more.

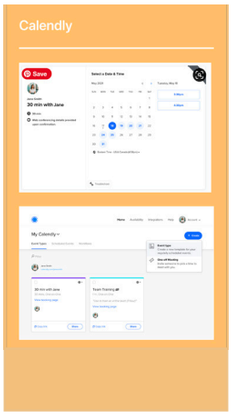
Medable

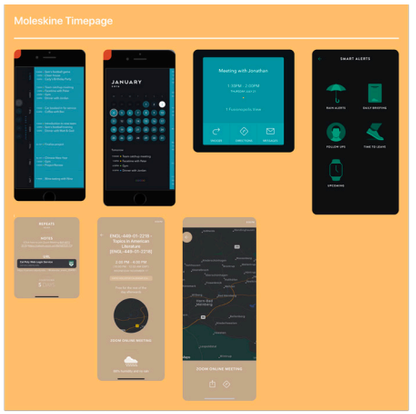


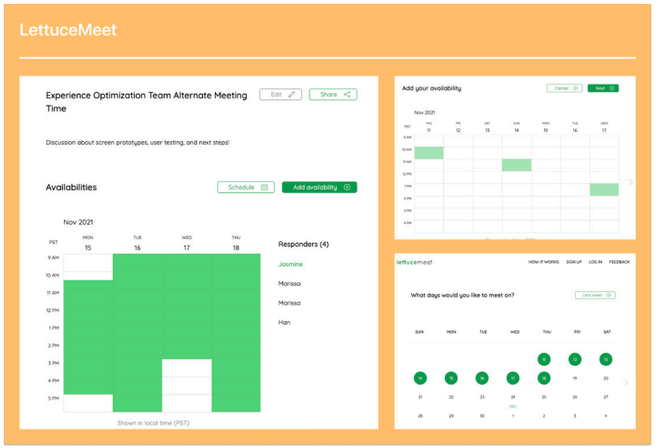
Medable is an application that seeks to streamline clinical trials. It allows for both patients and any other trial stakeholder to quickly and easily access and enter trial data at any time. Patients can easily access their task list and complete their daily surveys from the Tasks tab, and view trial-provided insights and updates on the Resources tab.

Analogies

Analogies, a common design thinking activity, are parallel platforms that can reveal design opportunities. To support MyTrials' scheduling feature, I visited three applications that emphasized scheduling and displaying upcoming meetings: Calendly, Moleskine Timepage and LettuceMeet.

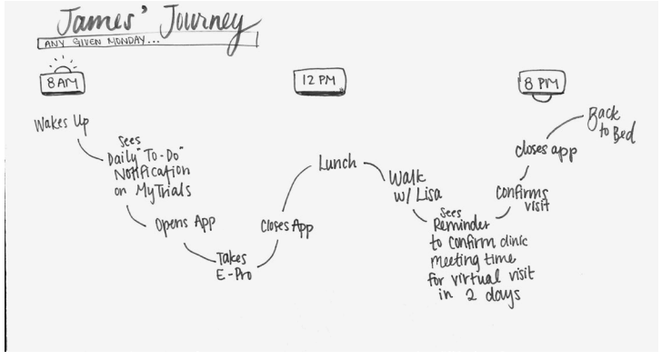




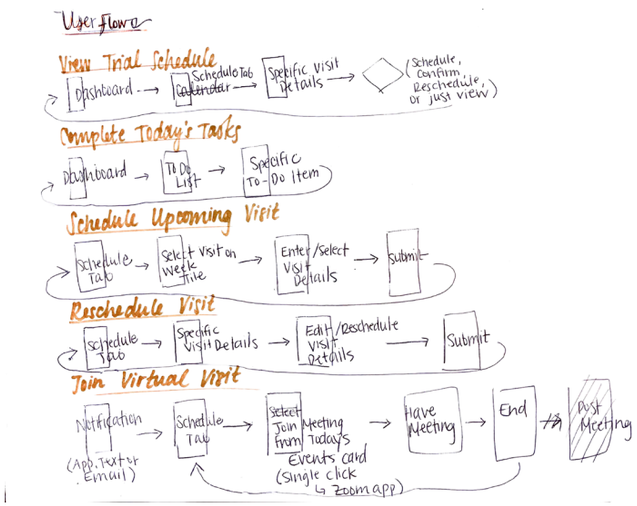


User Journey Maps

To better empathize with MyTrial's target user, I drafted a schedule for James, a persona I designed, where he used the app to fill out his daily trial form.

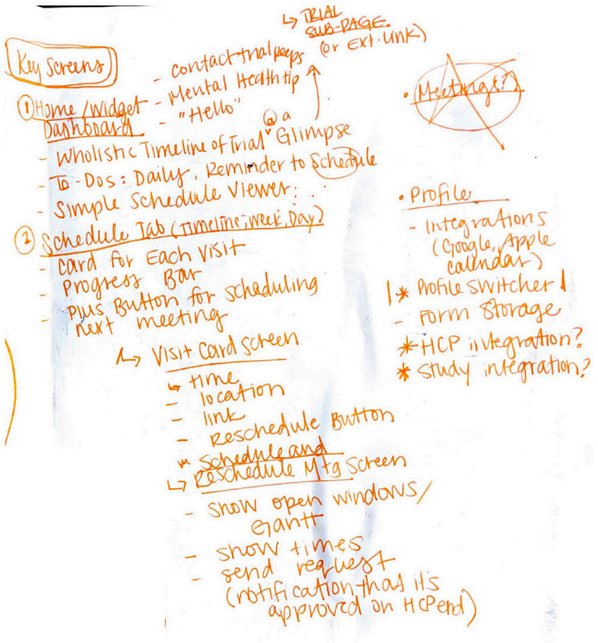


User Flow Sketches



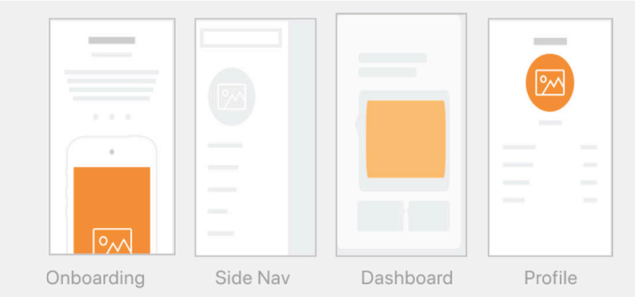
Next, I made a sketch of the screens needed to complete each user flow.

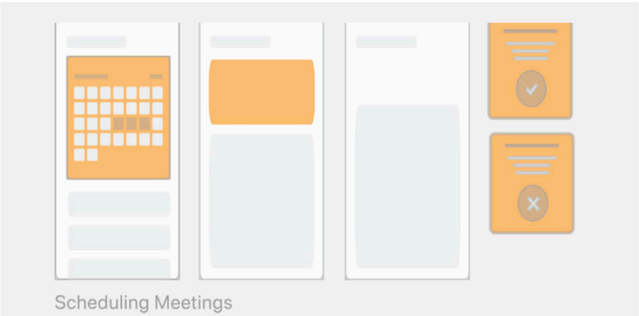
Feature Brainstorming Per Screen



Once I determined which screens I needed to design for each user flow, I brainstormed which features and capabilities should appear on each screen.

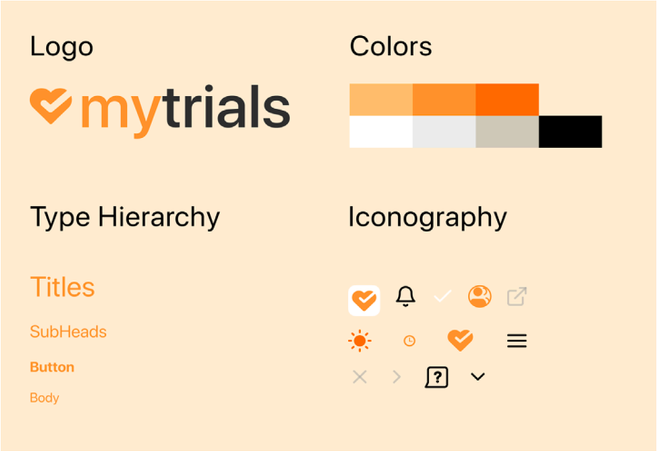
Wireframes





With the outline of the screens done, MyTrials needed a brand to centralize the design of the prototype. The brand uses colors similar to Veeva Systems and their products, as I originally started this project in an interview for the company, and I wanted the brand to fit in well with the rest of the company's UI to appeal to my interviewers. With that in mind, I made a choice to make the logo a heart shape with a check and schedule their tasks to improve their health and complete their trial.

Branding



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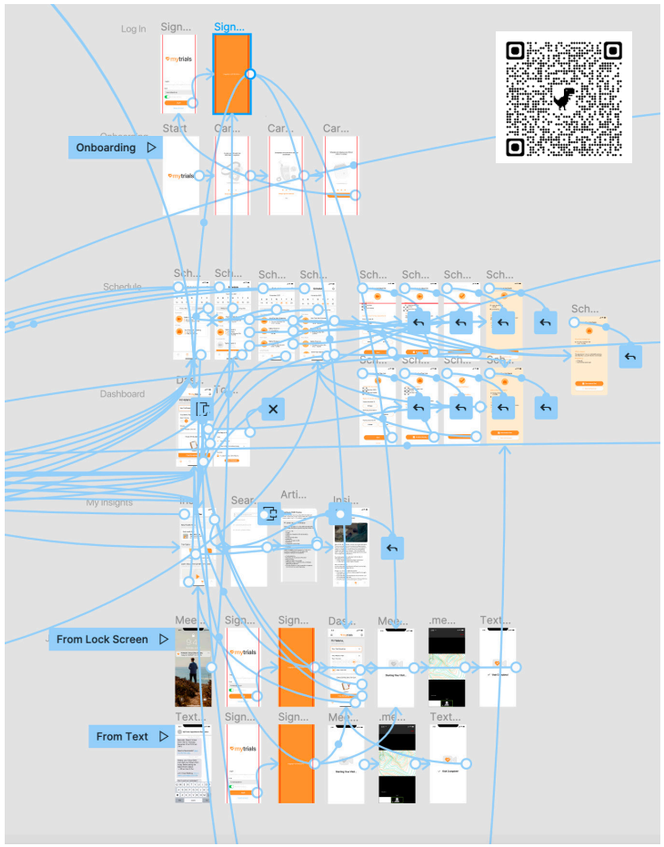
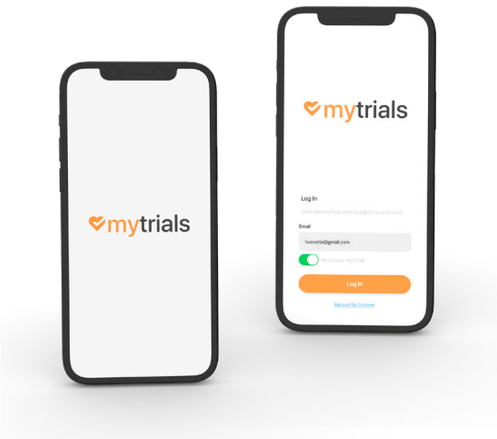
High Fidelity Prototype

Figma Flows



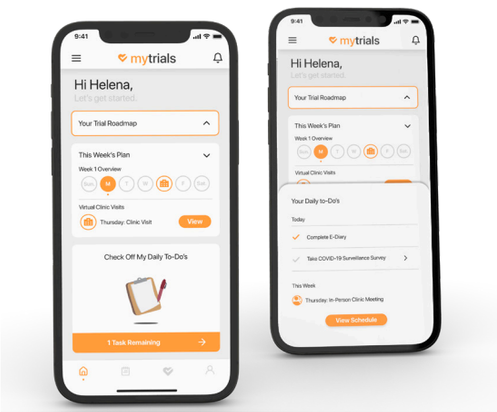
With the wireframes and branding completed, I moved on to the high fidelity prototype. Scan the QR code above to access the full view of these screens and prototype on Figma.

Loading and Login Screens



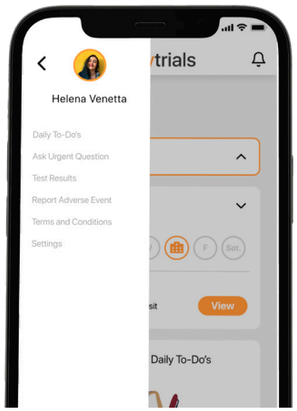
Upon opening the app, users will first see the logo loading screen, which then dissolves away to reveal the login screen. This design assumes that users already have an account associated with their personal email.

Dashboard



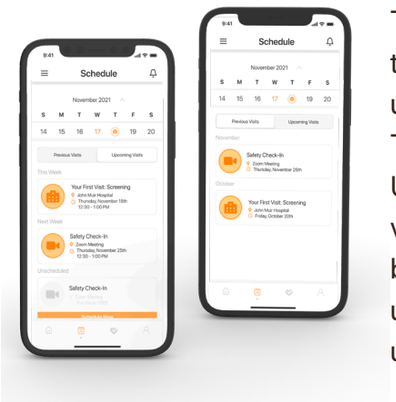
The Dashboard tab features three main cards: a Trial Roadmap, a Week Plan and a Daily To-Do's List. The Trial Roadmap and the Week Plan are collapsible menus, and tapping the To-Do's list pops up a sheet that allows users to access their daily tasks.

Side Menu



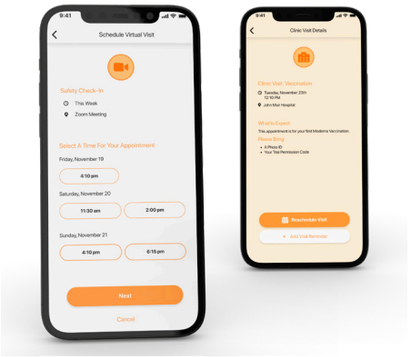
The side menu of the app is available across all four tabs, and allows users to quickly access their daily tasks, communication resources, and app settings.

Scheduling Tab



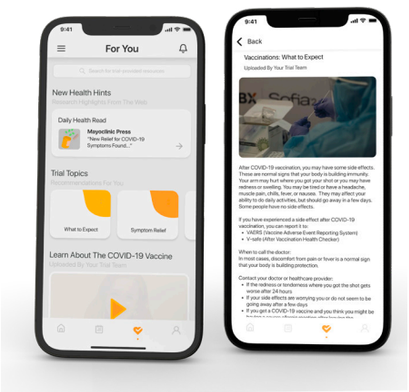
The Scheduling tab features the user's previous and upcoming clinic visits. Toggling the Previous and Upcoming allows users to view their meetings divided by week, and also prompts users to schedule their next upcoming meeting.

Visit Scheduling



The scheduling pages allow patients to select from a specific list of times that trial coordinators and researchers designate. Once a visit is scheduled, the visit details page turns a pale orange to indicate that it is confirmed.

For You Tab



The For You tab provides patients with personalized resources and information about their trial. Users can search for trial-provided articles and guides to help navigate their symptoms and side effects, while also learning more about their treatment during the trial.

Reflections

This project offered me an opportunity to put my product design abilities into practice, and allowed me to create a meaningful, empathetic application for patients. The largest struggle in this project was dealing with scope and feature creep over time, as I wanted to add more features and conduct user testing to complete my ideal vision for the project but was constrained by the ten week time-frame.

Despite the time constraints, I learned how to avoid creating information-heavy screens and how to combine Figma's Interactive Components and Smart Animate protoyping tools to bring my app's interactions to life exactly how I intended them to appear.

In the future, I would like to expand MyTrial's Profile Tab, conduct user testing and address the common pain points that the users experience. I believe MyTrials could also facilitate eConsent, and deliver medication and appointment reminders.

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