UC Health IN SCIENCE LIVES HOPE.

High Enroll Clinical Research Recruitment Services

Friday, August 6th, 2021

Learning Objectives:

1) Identify 2 consequences of slow enrollment into a clinical trialDescribe the impact of the COVID-19 pandemic on study recruitment and retention

2) Identify 3 barriers to provider engagement in clinical trial recruitment

3) Identify one action that would increase awareness of currently recruiting clinical trials.

Target Audience:

Clinical Research Professionals (CRPs) at UC/H and Cincinnati Children's Hospital Medical Center (CCHMC): including Principal Investigators (PIs), Research Nurses (RNs), Critical Care Unit Nurses (RNs), Pharmacy Technicians and Regulatory Specialists.

Off-Label Disclosure Statement:

Faculty members are required to inform the audience when they are discussing off-label, unapproved uses of devices and drugs. Physicians should consult full prescribing information before using any product mentioned during this educational activity.

Learner Assurance Statement

The University of Cincinnati is committed to resolving all conflicts of interest issues that could arise as a result of prospective faculty members' significant relationships with drug or device manufacturer(s). The University of Cincinnati is committed to retaining only those speakers with financial interests that can be reconciled with the goals and educational integrity of the CME activity.

Accreditation Statement for Directly Sponsored Activity

The University of Cincinnati is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The University of Cincinnati designates this live activity for a maximum of 1 *AMA PRA Category 1 Credit*™. Participants should claim only the credit commensurate with the extent of their participation in the activity.

CRPs, NPs, PAs, and RNs can count activities certified for *AMA PRA Category 1 credit*™ for professional credit reporting purposes. Other healthcare professionals should inquire with their certifying or licensing boards.

Disclaimer Statement

The opinions expressed during the live activity are those of the faculty and do not necessarily represent the views of the University of Cincinnati. The information is presented for the purpose of advancing the attendees' professional development.

Speaker Disclosure:

In accordance with the ACCME Standards for Commercial Support of CME, the speakers for this course have been asked to disclose to participants the existence of any financial interest and/or relationship(s) (e.g., paid speaker, employee, paid consultant on a board and/or committee for a commercial company) that would potentially affect the objectivity of his/her presentation or whose products or services may be mentioned during their presentation. The following disclosures were made:

Planning Committee Members:

- Maria Stivers, MS, CIP; Course Director – No Relevant Relationships
- Zachary Johnson, BS – No Relevant Relationships
- Nate Harris, BS, Course Coordinator – No Relevant Relationships
- Brandon Armstrong, CME Program Coordinator – No Relevant Relationships

Speakers:

Ginger Conway MSN, CNP

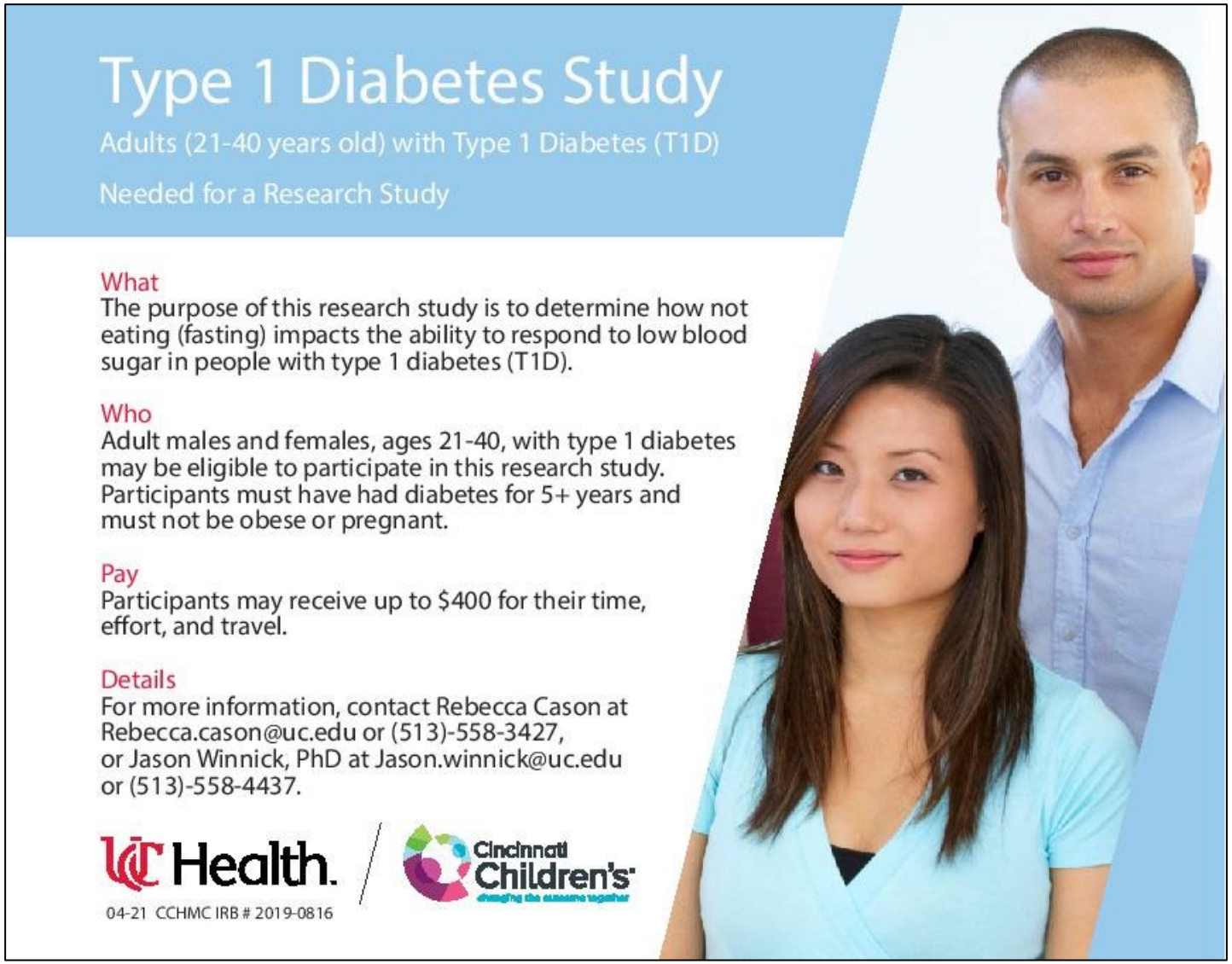
- **COO High Enroll, LLC**

Matt Vorst

- **CTO High Enroll, LLC**

No Relevant Relationships

August 2021 Study of the Month



OCR Announcements:

UC Health

New CDA and CTA Submission Process:

Effective 7/1/2021 all new clinical trial contracts are being processed by the Sponsored Research Services (SRS) Contract Management team at the University of Cincinnati.

Existing agreements that were executed through UC Health will continue to be managed at UC Health until their conclusion.

Important: An executed CDA between UC and the study sponsor before a CTA can be negotiated by UC.
If a CDA was executed at UC Health, but the CTA had not begun negotiation prior to July 1st, a new CDA must be executed between UC and the study sponsor.

All new CDAs should be sent to Geoffrey Pinski's team at UC-MTA@ucmail.uc.edu , where CDA questions and inquires can also be sent.

A new online submission process has been developed to support the new contracting process:
https://redcap.research.cchmc.org/surveys/?s=CLDDCECC84

All OCR SOPs are accessible from the UC Health intranet home page utilizing the Compliance 360 policy search function or reach out to the Office of Clinical Research with any questions or concerns.

OCR Announcements:

Thursday, August 19th, 2021, 12:00noon - 1:00pm
Virtual Presentation

The Consent Process for Central IRBs

Please join us and for an overview of reliance on commercial IRBs, including currently executed agreements, number of studies, requirements for reliance determinations, and completing the cover page, processes for changes to informed consent language and approval release for studies housed at Advarra IRB and the WCG Group IRB.

Kareemah Mills, CIP
Assistant Director
Human Research Protection Program
UC Office of Research Integrity

UC Health Clinical Research Orientation and Training (CRO&T)

Thursday, September 9th, 2021
9:00 am - 3:00 pm
Virtual presentation

The last day of registration is EOB Friday, September 3rd, 2021

Please contact Nate Harris
Nate.Harris@UCHealth.com
for information and registration

UC Health

Today's Presentation:

High Enroll Clinical Research Recruitment Services

Ginger Conway MSN, CNP,

COO, High Enroll, LLC

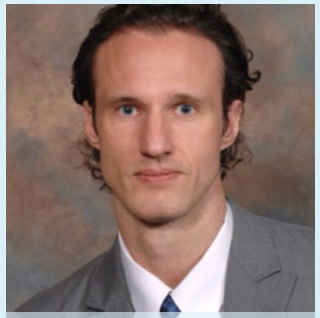
Matt Vorst,

CTO; High Enroll, LLC

HIGH ENROLL

FACILITATING CLINICAL RESEARCH
PATIENT RECRUITMENT

TEAM



Dylan Steen MD MS
CEO/Founder

Premier clinical/research experience and academic/industry connections at all levels and types of research

Ginger Conway CNP
COO/Founder

Decades of research team management, operational oversite, and connections to research professional organizations

Sarma Singam MD
Founder

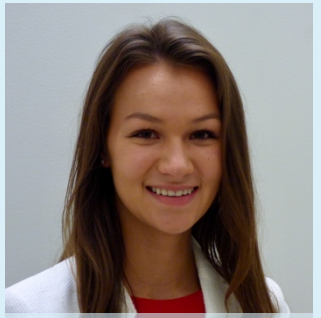
Biomedical engineering background, clinical/research experience, and healthcare innovation training (e.g. AI)

Joal Barbehenn JD
Revenue Officer

Past experiences as Chief Legal Counsel and Director of Business Development in the software industry

Matt Vorst
Chief Technical Officer

Experienced entrepreneur and start-up CTO, with successful exits (e.g. Dotloop)



Rachel Kimura MS
Account Manager

Experienced in finance and now evaluating user and customer experience

Chris Brinkman JD
KMK Law

He and broader firm provide all legal support for High Enroll

Julie Altherr CPA
CSH Business Advisors

He and broader firm provide all legal support for High Enroll

James Elder CPA
Executive Advisor

Experienced in fund-raising and the all financial modelling necessary to support the effort.

Oscar Meyer MBA
Executive Advisor

Past experiences as a Senior Executive in the medical device, durable medical equipment, and healthcare Services markets

OUR MISSION

Clinical Research is the Foundation of Modern Medicine.

High Enroll was founded to eliminate patient recruitment barriers which compromise the quality, volume, and economics of clinical research.

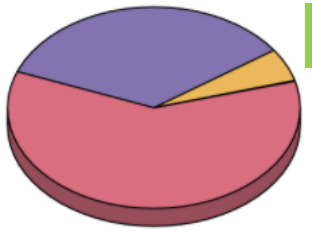
◆

Poor Patient Recruitment is the Largest Operational and Cost Barrier to Clinical Research for:

- Manufacturing industry (e.g. Merck, Amgen, Medtronic)
- Industries that support research conduct (e.g. Medpace)
- Organizations ("sites") that recruit the research patients (e.g. UC, Christ Hospital)
- Scientists that design and take responsibility for the studies (e.g. Dylan Steen)

SIZE OF THE PROBLEM

Current Recruiting Sites



Non-U.S. only (60%)

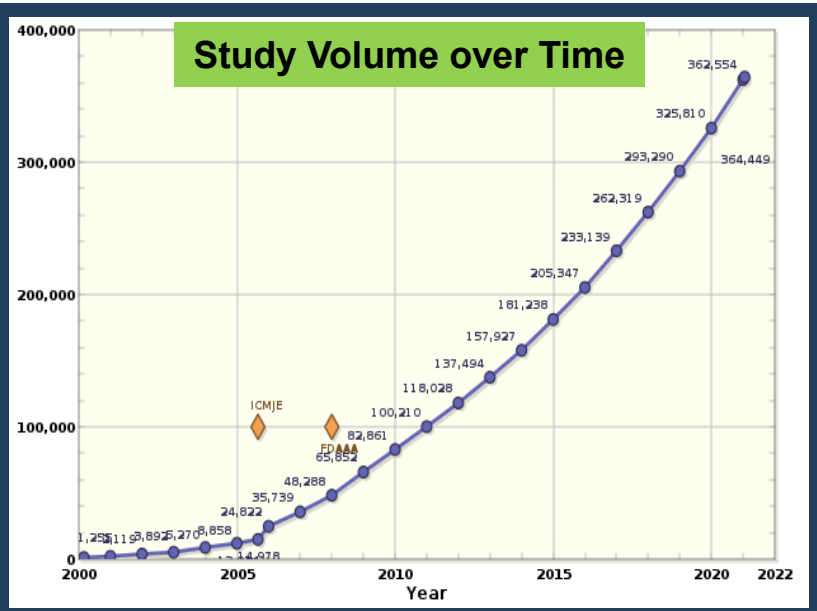
U.S. only (34%)

Both U.S. and non-U.S. (5%)

Location	Number of Recruiting Studies and Percentage of Total (as of January 19, 2021)
Non-U.S. only	33,280 (60%)
U.S. only	19,022 (34%)
Both U.S. and non-U.S.	2,993 (5%)
Not provided	148 (0%)
Total	55,443 (100%)

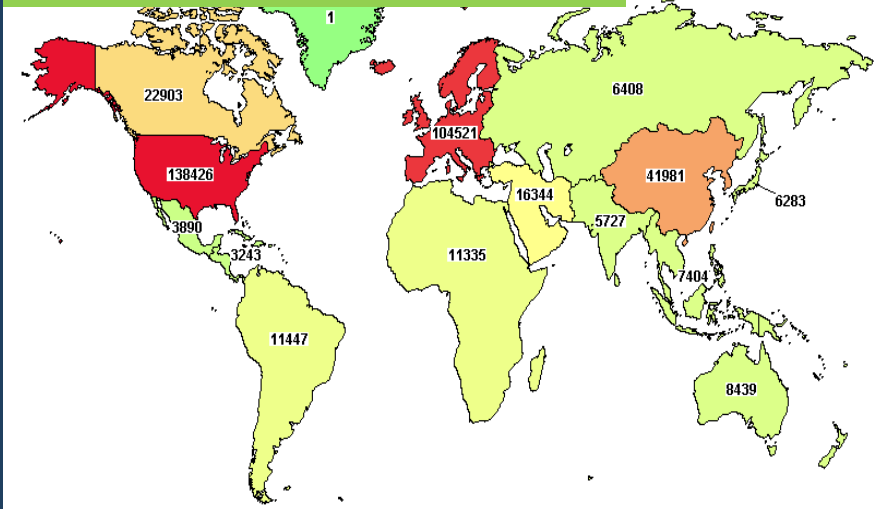
55,443 sites across 219 countries

Study Volume over Time



Study volume accelerating (↑↑↑)

Current Study Volume by Region



U.S. is key; vast international future

*Data reflect registered studies: Sites and studies only account for registered studies (actual revenues will be underestimates)

https://clinicaltrials.gov/ct2/resources/trends

THE CURRENT SITUATION

U.S. Example

FDA increasingly mandates:

1) Greater U.S. participation;
2) Greater expectations for quality;
3) Recruitment of specific patients (e.g. race, health status).

Current Outcomes:

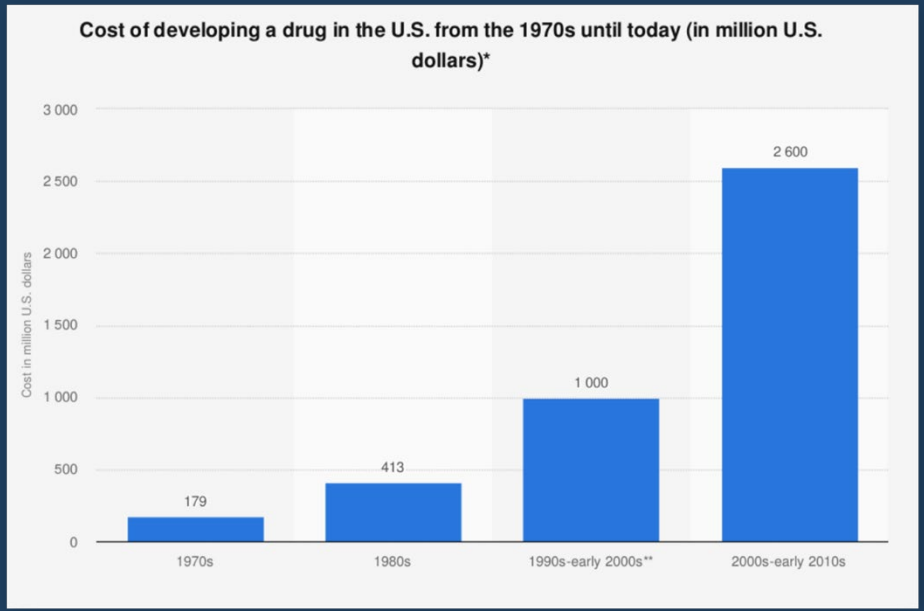
Although >20,000 total U.S sites exist, companies still struggle with a reliable mechanisms to select the right sites or to predict their performance. And sites struggle with being able to accurately predict their performance.

Despite 40% of study budgets being spent on recruitment, 80% of studies do not meet recruitment deadlines, 37% of sites do not meet minimum goals, and more than 10% of sites do not recruit a single patient.

Hundreds of U.S. sites are often needed per study (expensive in time and money).

Industry Impact:

Sky-rocketing drug development costs. Loss of enormous revenue; just for each day of delay to FDA approval, companies on average lose $8 million per day.



Largest driver of development costs are the required clinical studies

PhRMA; Statista 2019

Article

CLINICAL TRIALS

Clinical Trials
1–12
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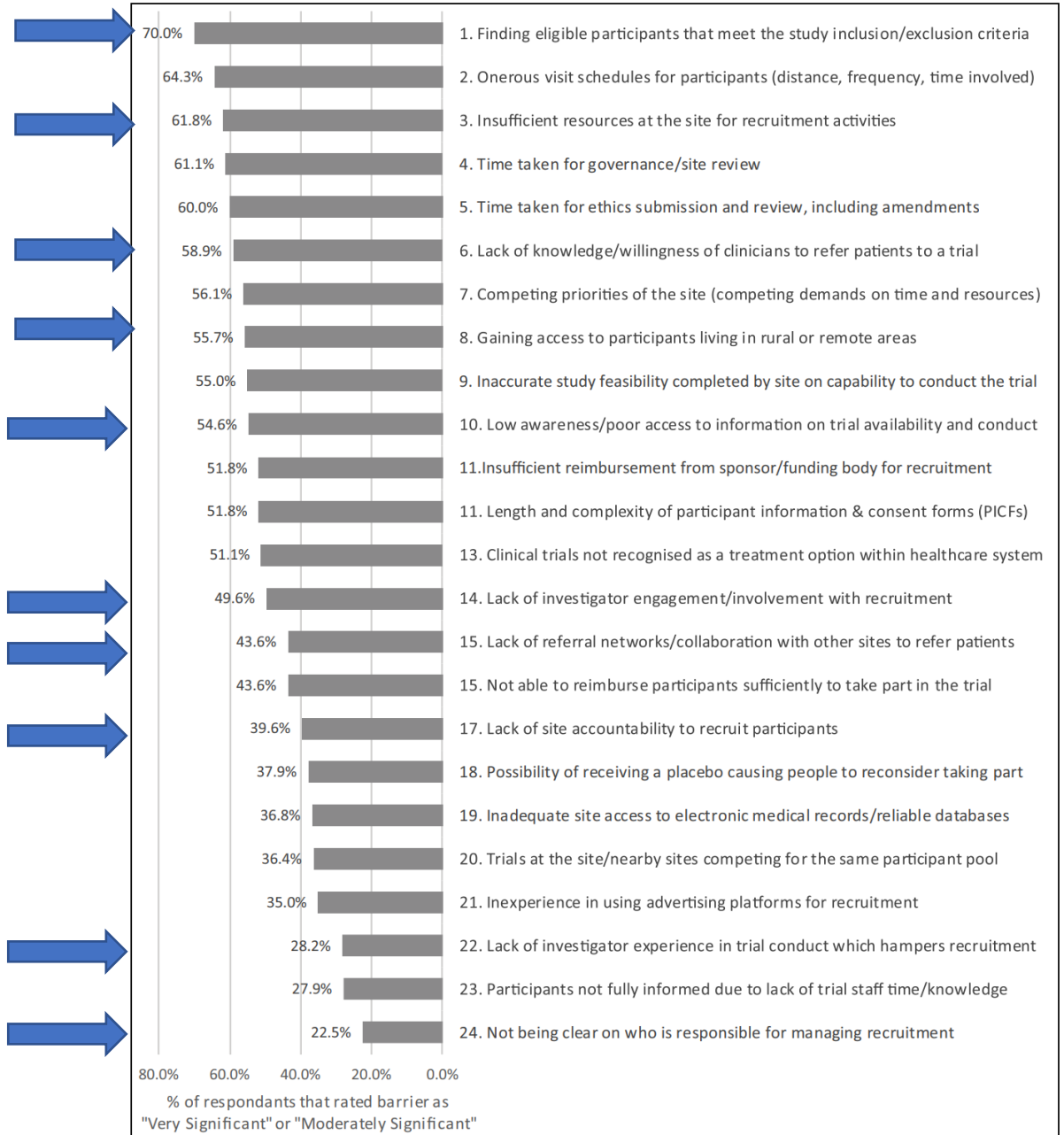
Clinical trials site recruitment optimisation: Guidance from Clinical Trials: Impact and Quality

Christine Zahren[1], Sonia Harvey[2], Leanne Weekes[2], Charlotte Bradshaw[3], Radhika Butala[4], John Andrews[5] and Sally O'Callaghan[6] on behalf of the CT:IQ GREET project team



Survey related to barriers to enrollment. 280 respondents from sites, sponsors and CROs. (2/3 were from sites)

SITE CHALLENGES

Patient Recruitment Requires Healthcare Provider Engagement

Background:

Patients trust their healthcare providers with optimizing their medical care.

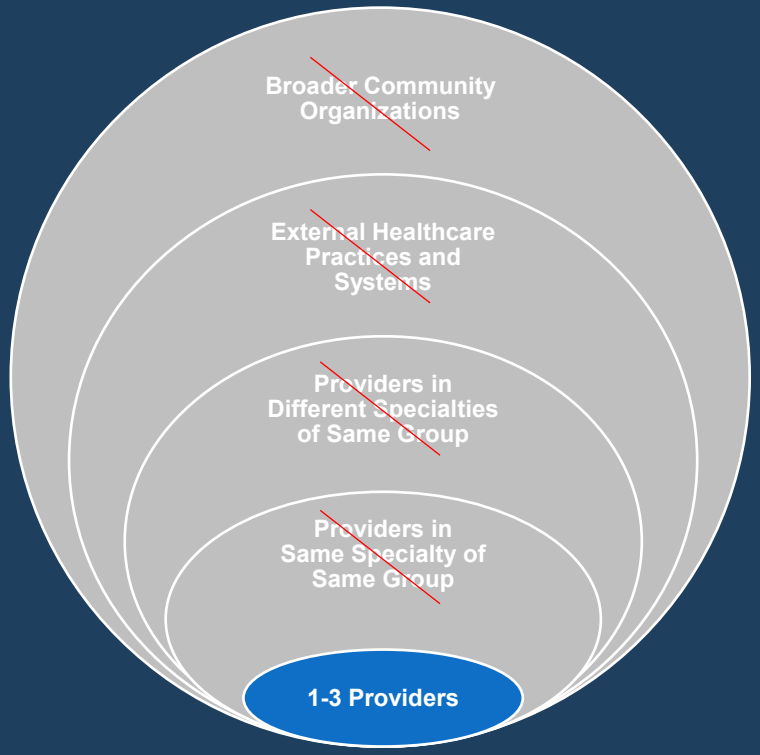
Patients want to participate in research opportunities that have the support of their doctors (e.g. study of a new chemotherapy).

Currently, hospitals and outpatient practices constitute 99% of the world's research sites.

The Site's Big Problem

Only 1-3 healthcare providers per site study have the tools required to speak to their patients and refer them into a study.

The vast majority of healthcare providers, both internal and external to the site, are not currently engaged (FIGURE).



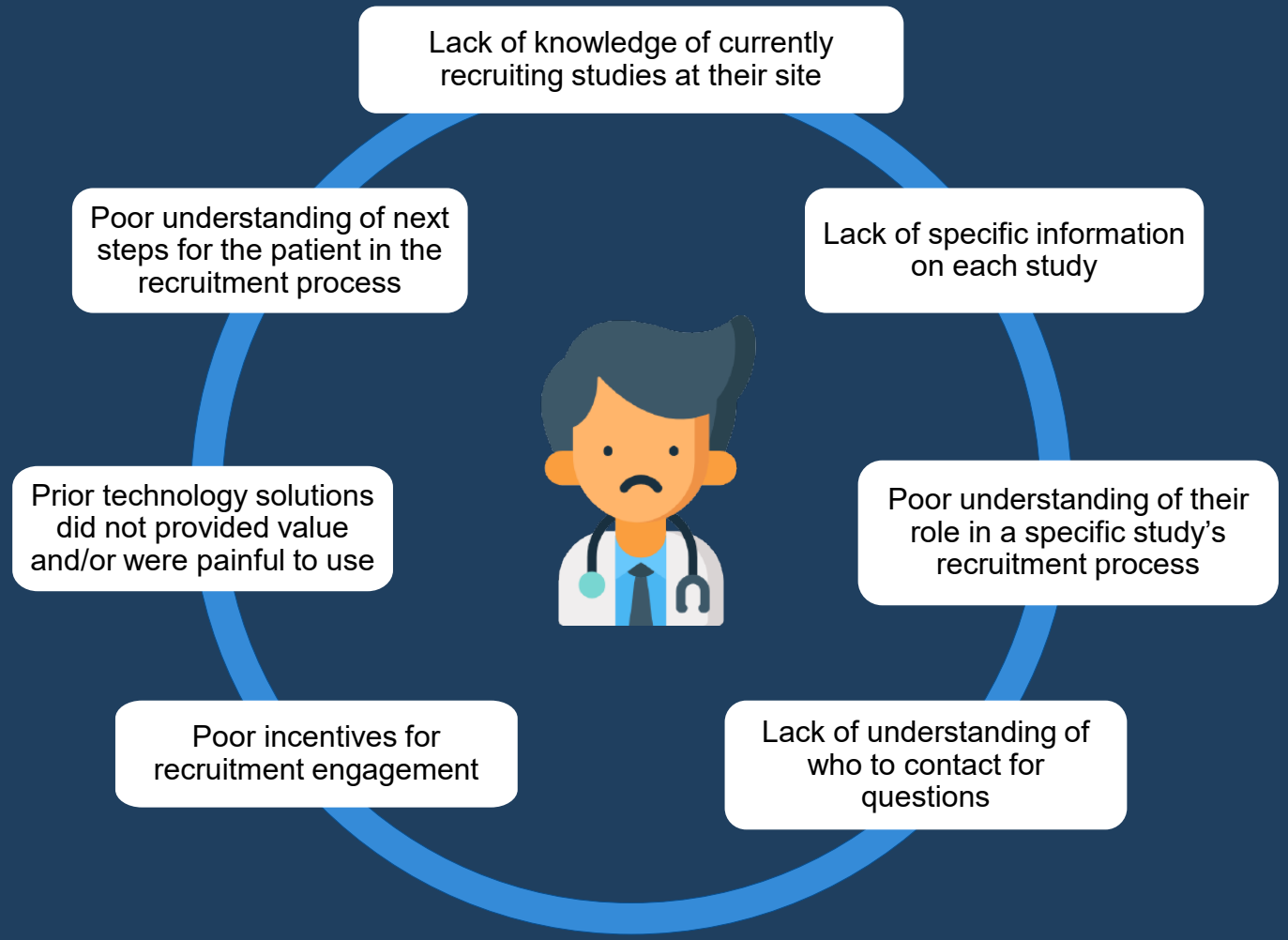
HEALTHCARE PROVIDERS: WHY AREN'T THEY ENGAGED?

Healthcare Providers have Unsolved Challenges in Engagement

DRILLING DOWN

SPECIFIC BARRIERS TO PROVIDER ENGAGEMENT

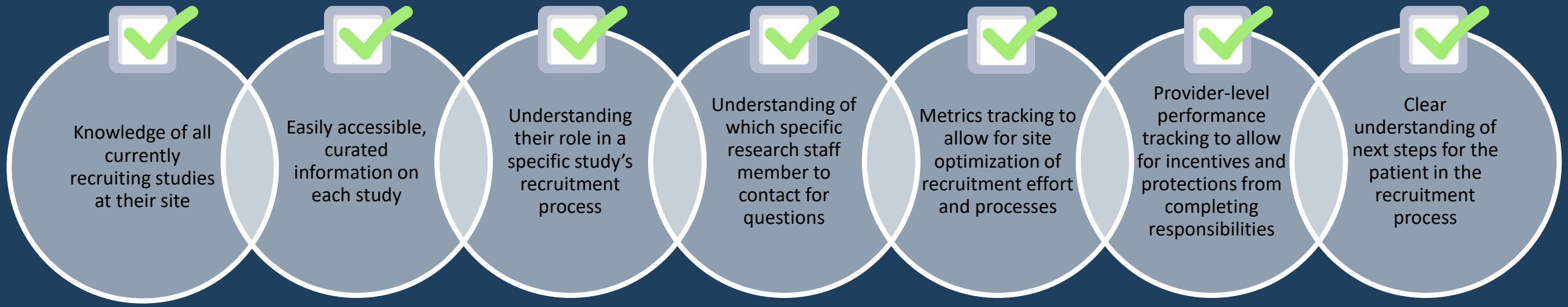
VERIFIED BY
>100 USER INTERVIEWS CONDUCTED
BY HIGH ENROLL



THE IDEAL PRODUCT

Created by Clinician-Researchers for Clinicians and Researchers

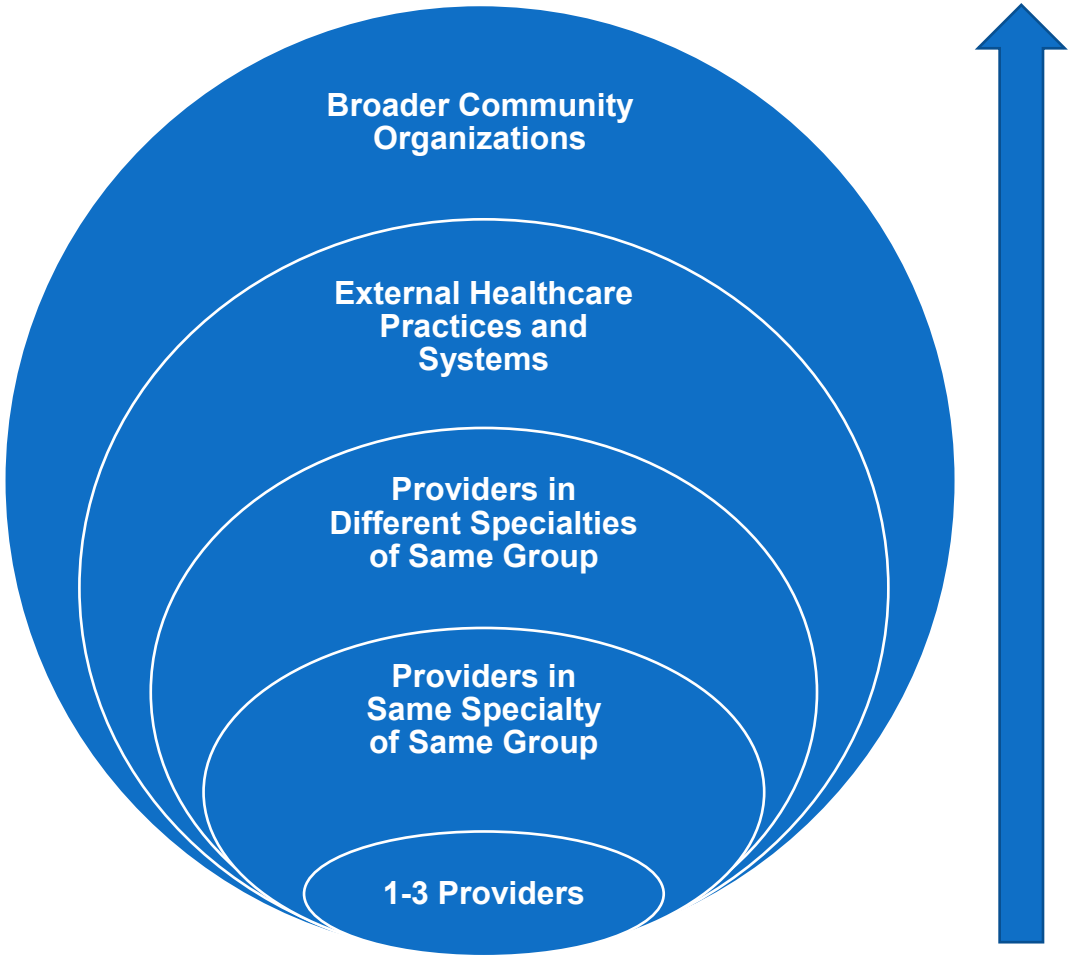
One that comprehensively addresses all the challenges that have previously prevented engagement of their healthcare providers; regardless of the medicine specialty, type of study, or practice location.



End Result: *Decreased Recruitment Time*

SOLVING PAIN FOR SITES

High Enroll Prototype: Capturing the Potential of the Site and Beyond

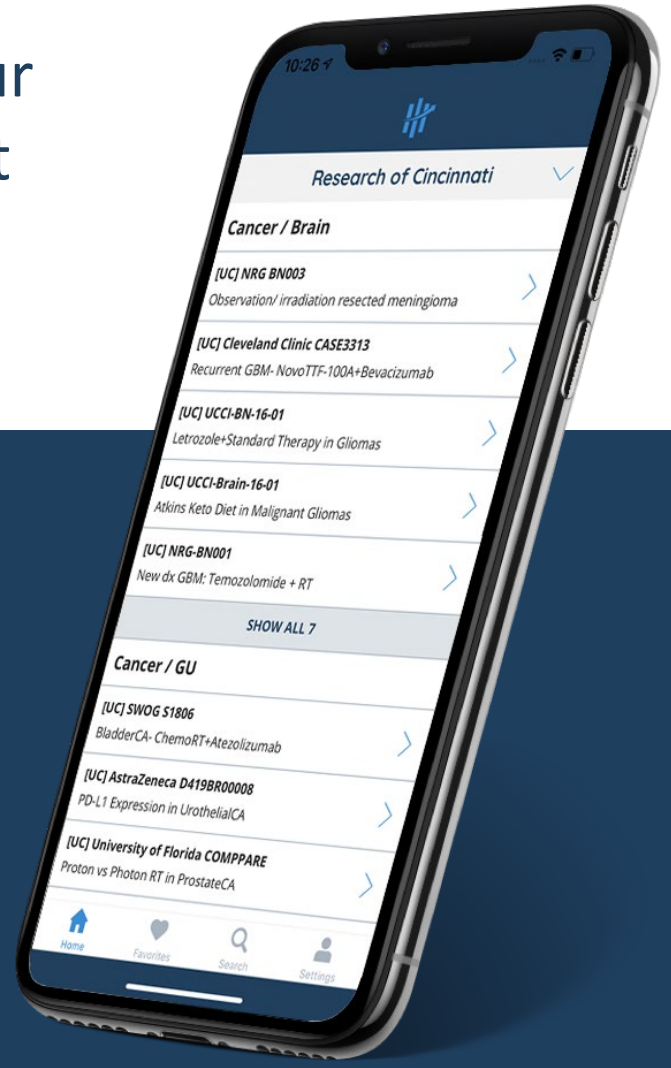


Problem	Before	After
No updated, comprehensive resource for the site's recruiting studies	Yes	Solved
Limited awareness of site's recruiting studies	Only 1-3 providers	Thousands of providers
Inability for providers to remember enough information to talk to and engage their patients	Yes	Solved
Inability for providers to understand who to contact 24/7 on the research team for an immediate referral	Yes	Solved
Limited ability to recruit external patients	Yes	Solved
Minimal data on recruiting providers and performance	Yes	Improved
Difficulty in attracting industry opportunities	Yes	Improved
Difficulty to support staff through research revenue	Yes	Improved
Difficulty to market research to community	Yes	Improved

SOLUTION

Ensure that research is always top of mind

The High Enroll platform gives healthcare providers, at your site and others, quick and easy access to the most relevant studies for their patients.



High Enroll is the single tool providers need to refer patients into your studies

App notifications increase provider engagement by drawing them back to your studies

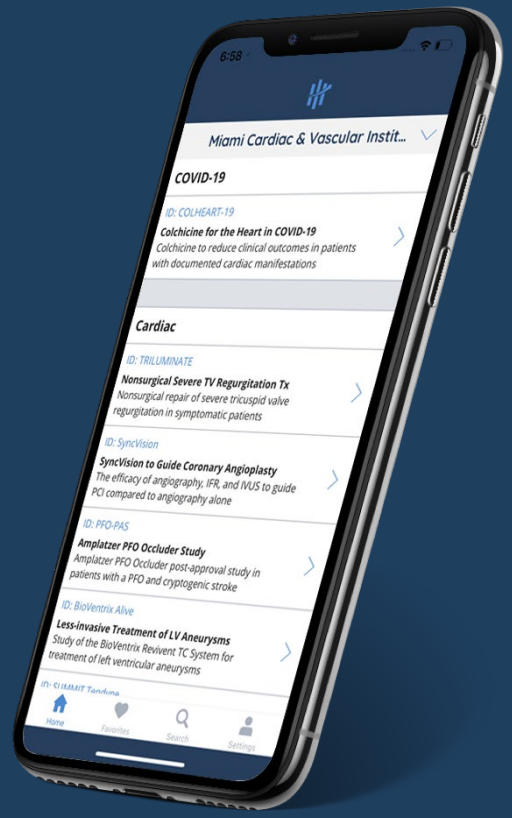
As providers use the app insights are sent to the research team so the study content can be optimized to increase recruitment

THE PLATFORM

Mobile application and administrative portal

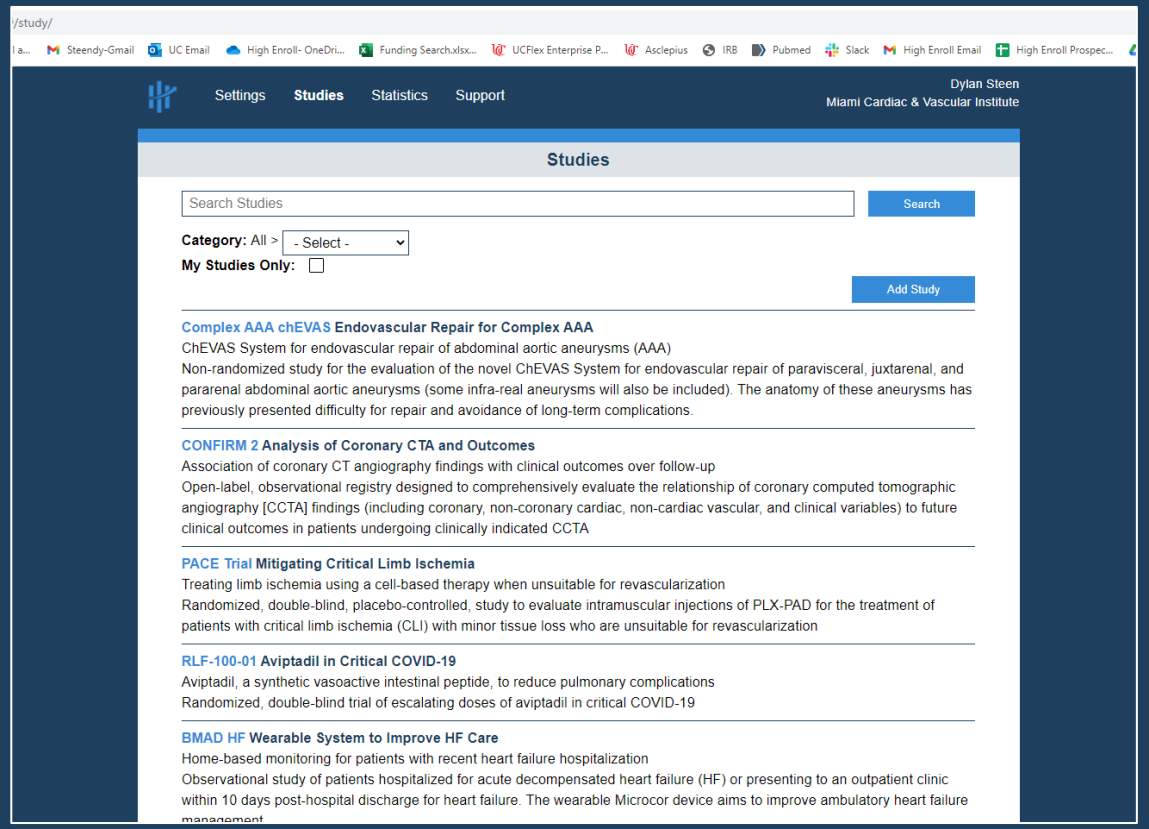
Mobile App

Available to everyone- PIs, staff, internal, and external providers. To promote awareness and referrals.



Web-based Admin Portal

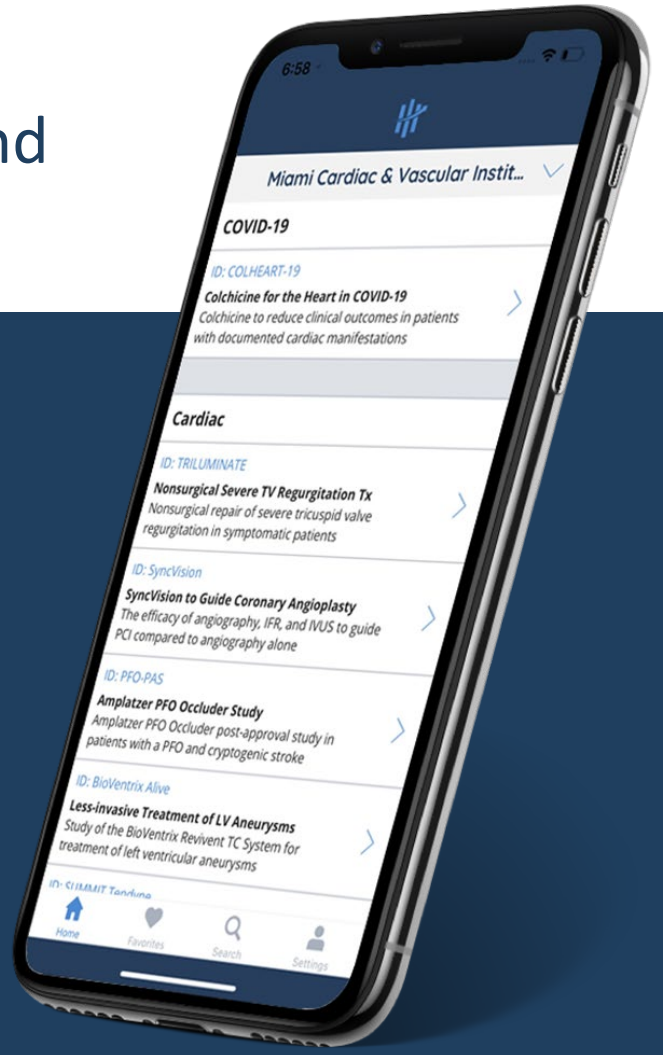
Used by research teams only- PIs and research staff. To manage all app content and analyze electronically collected data.



MOBILE APP DEMO

Painless and Simple

Give doctors, nurses, and other healthcare providers quick and easy access and referral capabilities for recruiting studies.



App features

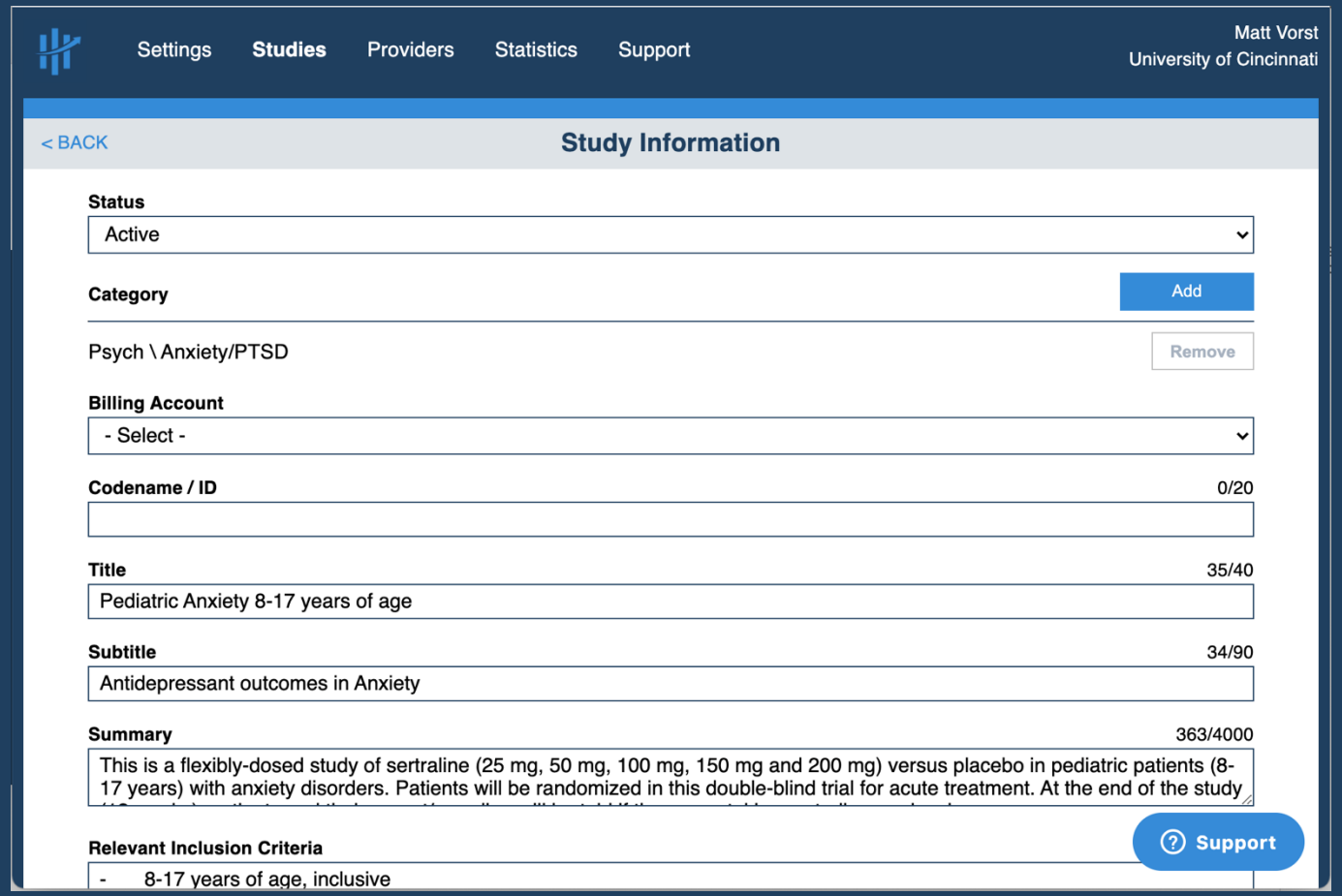
- No login/password to get started
- Unlimited use at site and all its referring and neighboring institutions
- Comprehensive/updated portfolio of all actively, recruiting studies
- Easy searchability for any study in the system
- Curated content for each study (e.g. for provider “pitch”)
- One-touch phone or email communication directly to an available research coordinator
- Availability to collect recruitment data for performance improvement
- Easy-to-share capabilities from one user to another
- One platform for all sites, research teams, and studies
- Personalization of visualized content
- App notifications for new studies, featured studies or study information updates

PLATFORM DEMOS

Site Administrative Portal

You control your content

- Changes to your studies are instant
- Contacts are managed by your team so they're always up-to-date
- Insights to your recruitment efforts can be found in our statistics and the Provider Scorecard



UC BUSINESS MODEL

Research sites pay flat fee per study and pass the expense to the drug or device manufacturer.

Keep the cost low enough so that sponsors see it as a rounding error in the design of most studies. (Retail $1200/study discounted to $960 (80%).

NO BRAINER TERMS

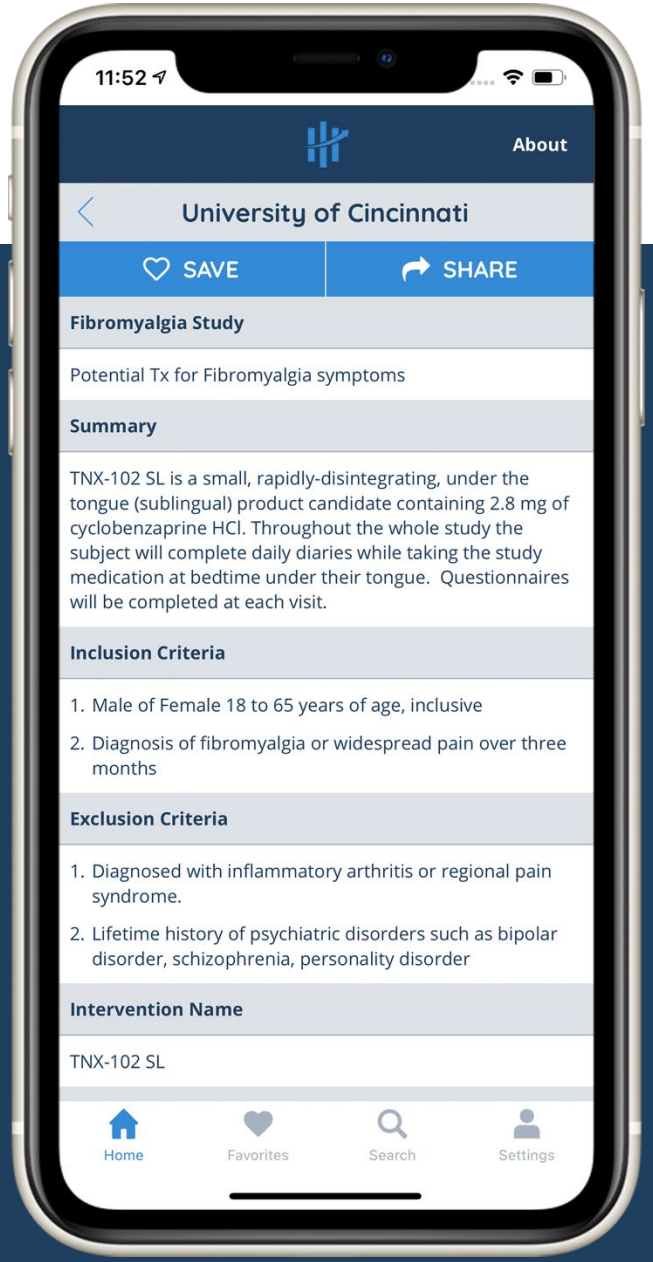
Fast launch – Upon agreement, each user group has 30 days to enter all *currently recruiting* studies into the platform. They will not be billed for any of these studies.

Billing – After 30 days, as additional studies are entered into the platform, the site will be billed. Sites can pass the expense to drug and device manufacturers (i.e. “recruitment budget”).

Payment – The sites are billed quarterly, allowing enough time to receive payment from the manufacturers. Sites are consistently being reimbursed higher than actual cost. Resulting in opportunity to cover costs for underfunded projects.

PLATFORM DEMOS

Mobile Application



Try the app for yourself

https://app.highenroll.org/download/

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