Earth Month Presentations:

High Enroll: Updates, New Features, Demo, Q&A

Friday, April 7th, 2023

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Learning Objectives:

1) Identify gaps in information sharing related to clinical trials between researchers, clinicians, and patients.

2) Identify channels for marketing clinical trials to patients available through the High Enroll platform.

3) Describe the communication flow between researchers, providers, and patients regarding clinical trials via the High Enroll platform.

Today's Presentation does not fit the criteria for Continuing Medical Education (CME) credits.

There will be no CMEs awarded.

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

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April 2023 Study of the month:

Healthy Participant Study
for Children and Teens 3 to 17 Years Old

What
A study to learn more about people's risks to common health conditions through genetic testing and medical and family histories

Who
Healthy children and teens 3 to 17 years old and possibly one or both of their parents may be able to participate

Pay
Up to $100

Contact
If interested, scan the QR code and visit www.emerge.study to complete a survey or contact the study team at e4@cchmc.org or 513-835-3649.

Cincinnati Children's Research Foundation

CCHMC IRB # 2021-0525. V1 BRV152411
Stock photo with models

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Compliance Corner

New OCR SOP: Delegation of Authority

This SOP establishes the method by which the Principal Investigator (PI) delegates study-related duties to applicable personnel. This includes the PI themselves, sub-investigators or co-investigators, study coordinators, and other study staff who perform study-related duties.

Please refer to the following UC Health SOP:

UCH-OCR-OPS-SOP-020-01: Delegation of Authority for Clinical Research

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.

This SOP will also be provided on the UC College of Medicine Template once approved

The New Office of Clinical Research COM Bearcats Landing Webpage:

The older OCR Bearcats Landing website has migrated to a NEW and IMPROVED webpage under the College of Medicine Bearcats Landing website.

As of March 29th, 2023, the New OCR COM Bearcats Landing webpage is Live.

If you attempt to log on to the old OCR website, you will be redirected to the new webpage.

Click here for the new OCR COM Bearcats Landing Webpage

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Thursday, April 20th, 2023, 12:00noon - 1:00pm
Virtual Presentation

The Illustrative Female: Mary Maciel and Other Women in 20th Century Medical Illustration

Though the number of female medical and health professionals rose gradually throughout the early twentieth century, one area of the medical field in which women not only worked, but thrived, was that of medical illustration. Of the 60 charter members of the Association of Medical Illustrators in 1946, forty were women. Though many of these women were trained by the famous Max Brodel at Johns Hopkins, these female artists very soon began to exercise leadership in the field for many years to come. In Cincinnati, this national pattern was personified in Mary Maciel. Like many of her female contemporaries, she was trained by Brodel at Johns Hopkins. It was Maciel however who began the medical illustration department here at the University of Cincinnati College of Medicine and served as its chair for over twenty years. This presentation will share insights primarily into the life and work of Mary Maciel, while at the same time look at the work of several other women whose skill at depicting human anatomy made them invaluable to the medical profession they served.

next lives here

Gino Pasi
Archivist/Curator
Donald C. Harrison Health Sciences Library
University of Cincinnati, College Of Medicine

University of CINCINNATI

UC/UCH Clinical Research Professional

May 18th, 2023

4pm – 7pm

Location: TBA in an announcement to the CRP listserv

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lives
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CINCINNATI

Today's Presentation:

High Enroll: Updates, New Features, Demo, Q&A

Discrimination is a significant social determinant of health and women can be disproportionately impacted. Illegal discrimination can impact women's access to healthcare, health outcomes, and overall well-being.

In contrast, promoting diversity, equity, and inclusion initiatives can promote health equity by addressing social determinants of health, reducing implicit bias, promoting diversity in the healthcare workforce, and improving access to culturally competent healthcare for women.

Ginger Conway, COO

High Enroll, LLC

Matt Vorst CTO

High Enroll, LLC

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HIGH ENROLL

University of Cincinnati
First Friday
04/07/23

Ginger Conway
Matt Vorst

gaconway@highenroll.org
859-992-5339 (C)
mavorst@highenroll.org

AGENDA

- Review of Provider Facing Platform
- Introduction of the Public Facing Platform
- Discussion of Features

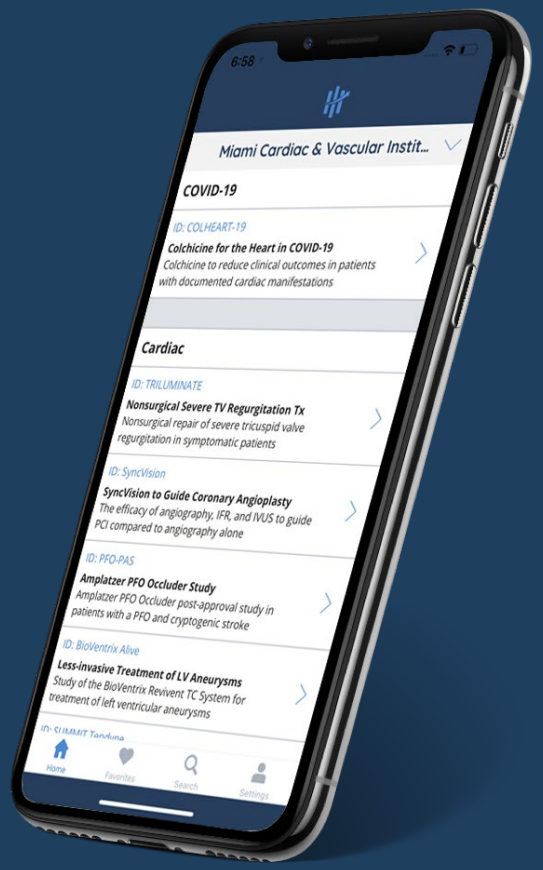
THE PLATFORM

Painless and Simple

Open Access Mobile App

Available to all internal and external healthcare providers-

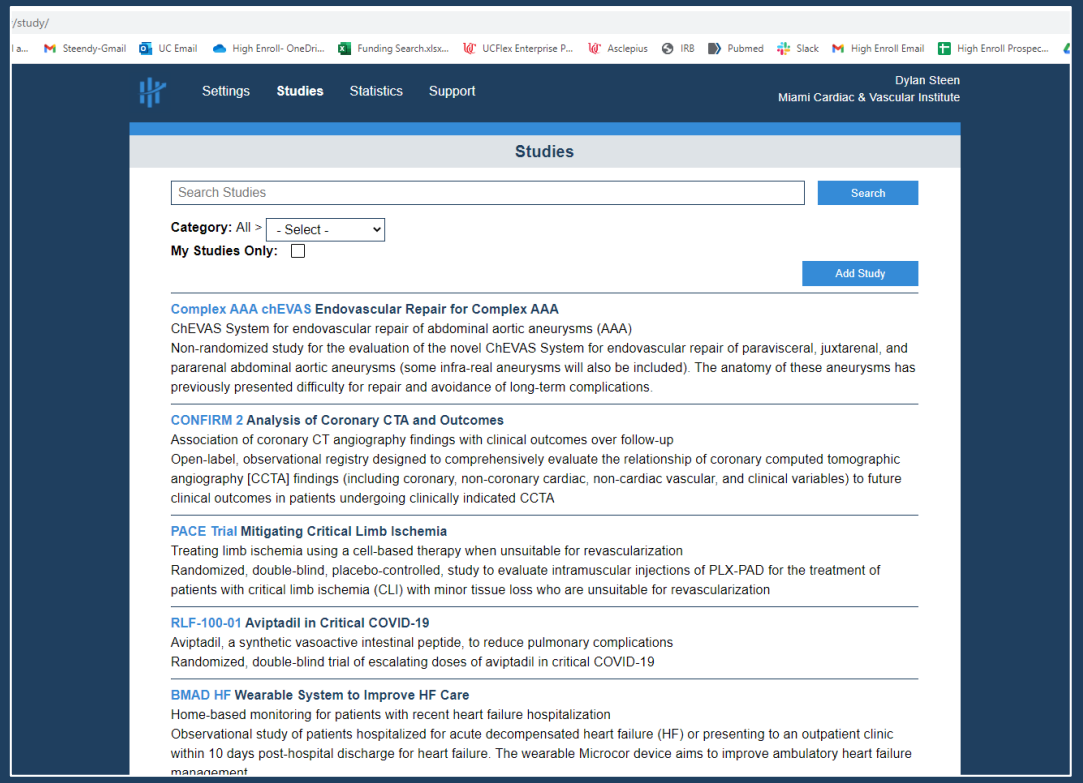
Study awareness, info, communication, and referrals at scale.



Web-based Admin Portal

Used by research managers and coordinators-

Create/update content easily and access data.



OPEN ACCESS MOBILE APP

Engage Doctors, Nurses, and Other Healthcare Providers

Key app features:

- No login/password to get started
- Personalization to each user's research interests
- Easy searchability for any study in the system
- One-touch phone or email communication directly to study contact
- Easy-to-share capabilities from one user to another
- Unlimited use at site and all its referring and neighboring institutions
- Notification of new studies and study reminders
- Performance data for improvement

UC #s

298 active studies on platform

> 640 Users

> 10,000 Study Views

INCREASING AWARENESS OF CLINICAL TRIALS

- Technology has transformed how we get information
- The public uses the internet as a primary source of information
- Social Media can be a powerful tool to increase recruitment and decrease cost
- Collaboration with key stakeholders such as community groups, advocacy groups, churches, and other local institutions are novel approaches to support recruitment of subjects

Brooks et al. (2015) *Increasing Minority Enrollment Onto Clinical Trials: Practical Strategies and Challenges Emerge From the NRG Oncology Accrual Workshop.* Journal of Oncology Practice. DOI: 10.1200/JOP.2015.005934

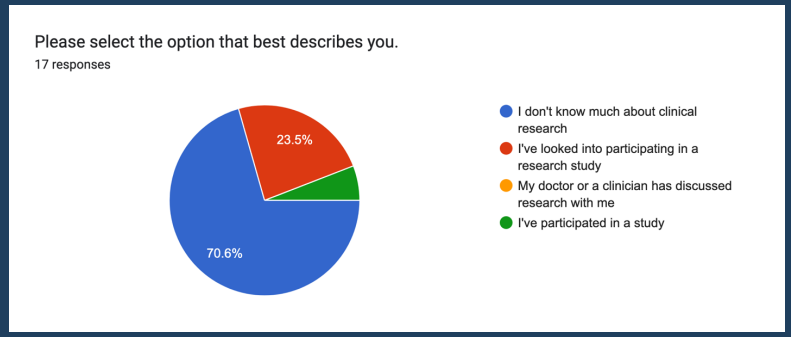
The Role of Social Media in Enhancing Clinical Trial Recruitment: Scoping Review; J Med Internet Res 2020;22(10):e22810

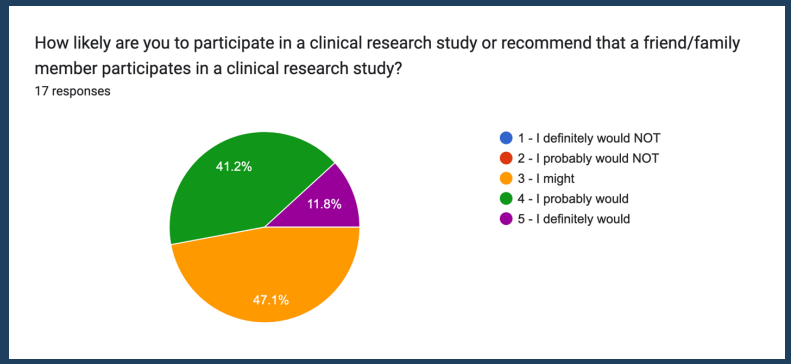
FROM THE PUBLIC'S PERSPECTIVE

- Patients identify lack of knowledge of clinical research as a major barrier

- Patients want to be informed about
  - Purpose
  - Procedures
  - Value
  - Why they should participate

- Key factors to increase knowledge
  - Provide valuable information
  - Accessible and easy to use
  - Multimedia approach
  - Visual aids
  - Give the user a sense of control of the information





Survey of local support group

Brooks et al. (2015) *Increasing Minority Enrollment Onto Clinical Trials: Practical Strategies and Challenges Emerge From the NRG Oncology Accrual Workshop.* Journal of Oncology Practice.
DOI: 10.1200/JOP.2015.005934

HEALTHCARE BASED SOURCES OF INFORMATION

- The most trusted source is their healthcare providers
- Healthcare facilities may utilize
  - Digital media, print materials, My Chart etc.
- Less frequently used sources
  - Google
  - TV/Radio
  - Social Media
  - Patient Advocates
  - Support Groups
- Development of the materials can be challenging and inefficient

PUBLIC FACING APPLICATION (PFA)

Site Administrative Portal

The site administrative portal allows entry of provider and public facing study information for sharing with the public. It has image/content creation tools for customized content, and content management tools for efficient organization of study materials.

Patient Enroll Progressive Web App

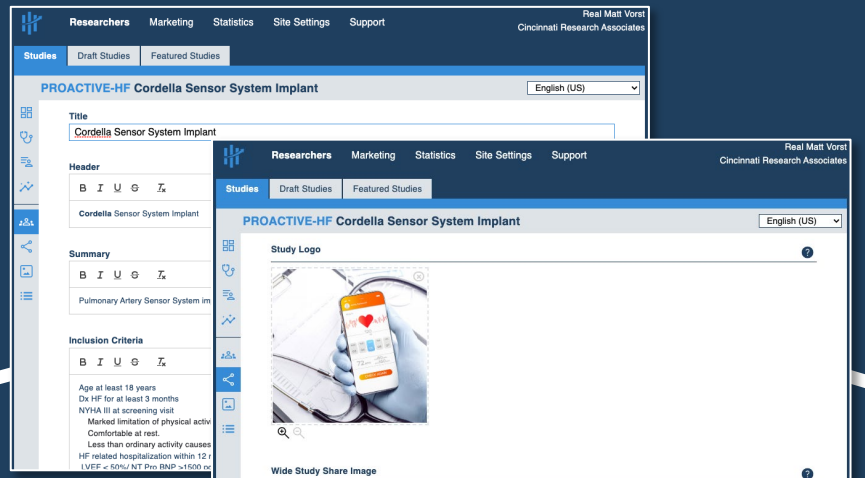
The patient enroll progressive web app, which is accessible on mobile and desktop devices, can be installed like an app for convenient use by the public. It facilitates efficient communication and dissemination of research studies to a broader audience.

Data Feed

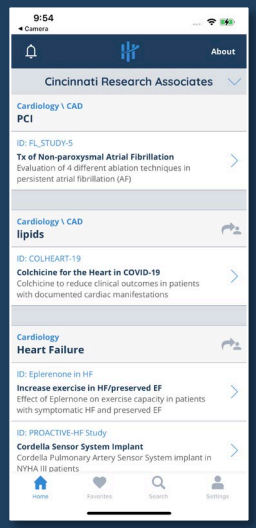
The data feed allows content to be published to websites or other systems.

PLATFORM OVERVIEW

Researchers / Administrators



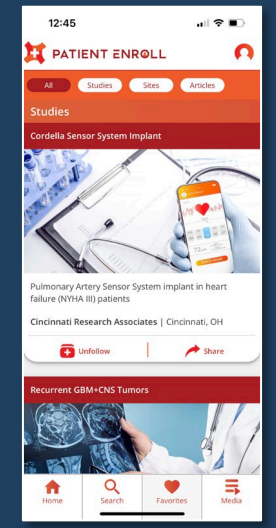
High Enroll App



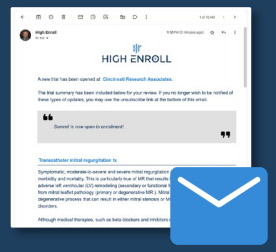
Study Content for Providers

Study Content for Patients

Patient Enroll PWA



Email Distribution



Facilitate discussions between patients and their providers (and vice versa)

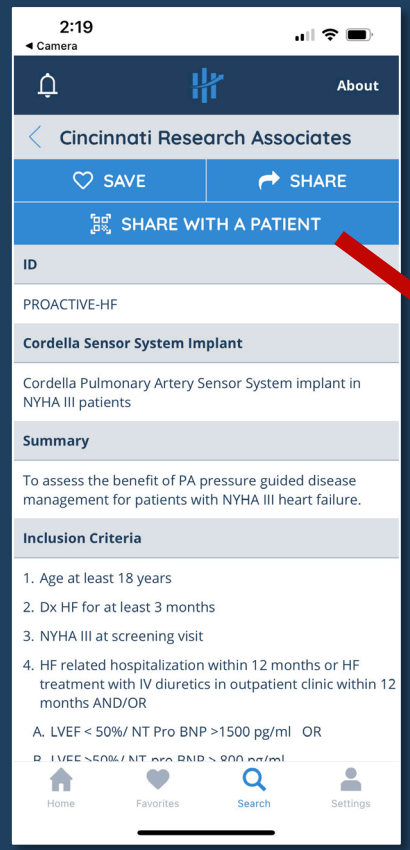
Site Website (API)

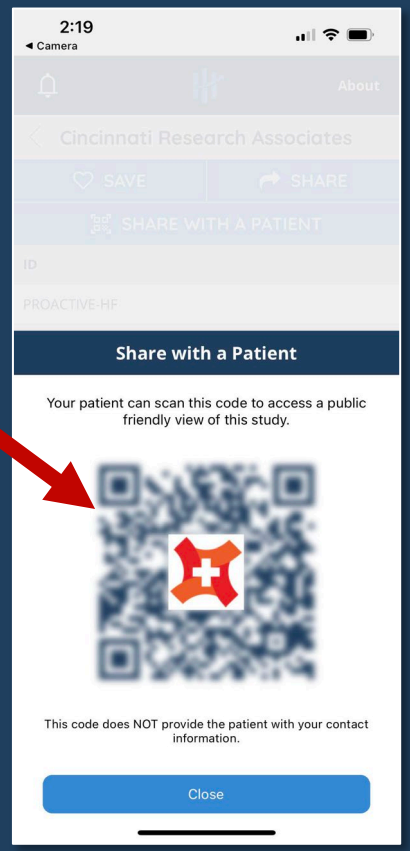
Social Media

SHARING STUDIES

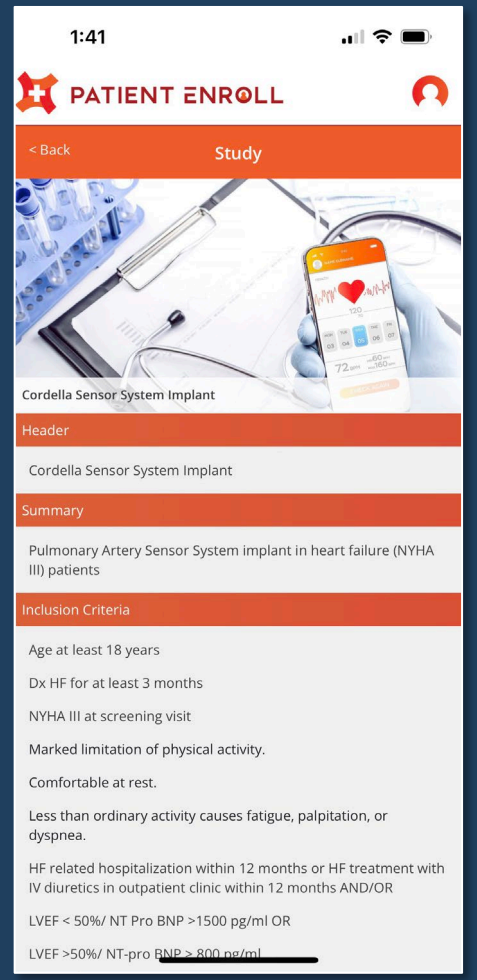
High Enroll gives healthcare providers an easy means to share studies and supplemental materials with prospective study participants.

Care Provider via High Enroll

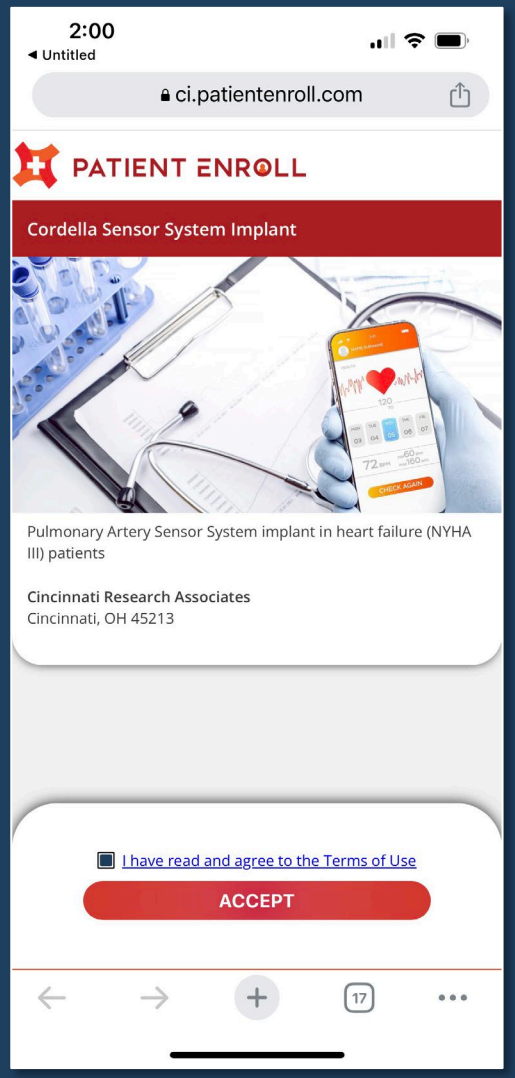




Scanning the QR code opens **Patient Enroll** in the patient's browser



PATIENT INTERACTION



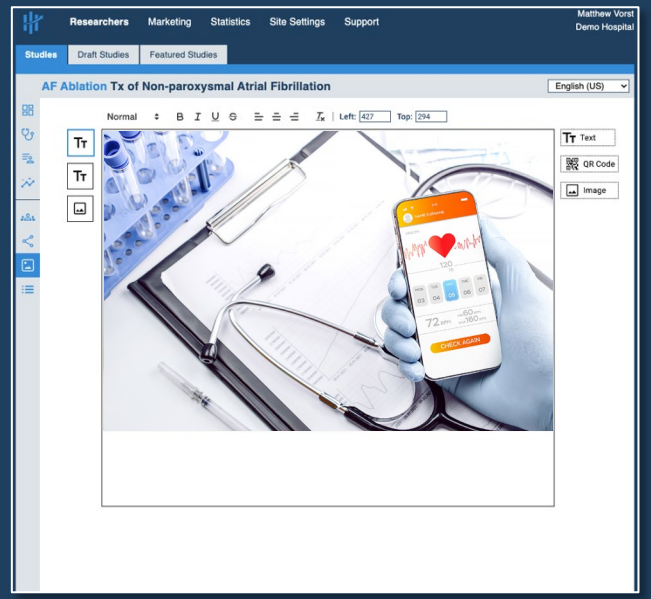
Potential volunteers that scan the QR code are directed to the Patient Enroll website and given an overview of the study.

You can think of this as a digital tear-pad. Potential volunteers can take the study home, review the details with family, then contact a coordinator with questions.

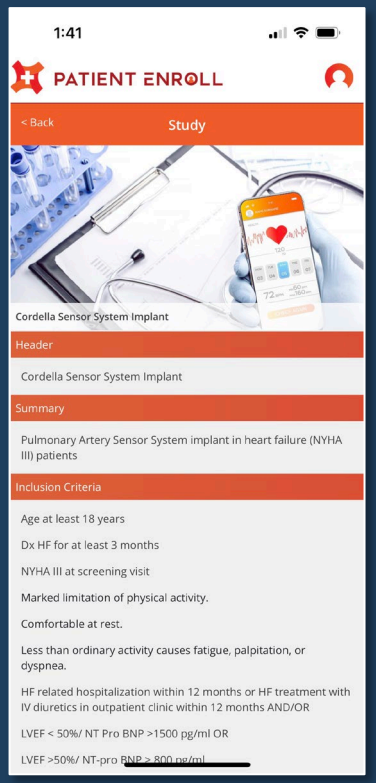
MULTI-CHANNEL MARKETING

High Enroll gives the research and marketing teams tools to easily disseminate approved content.

High Enroll Site Portal



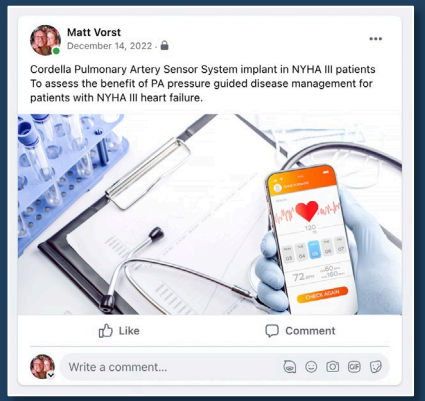
PatientEnroll.com



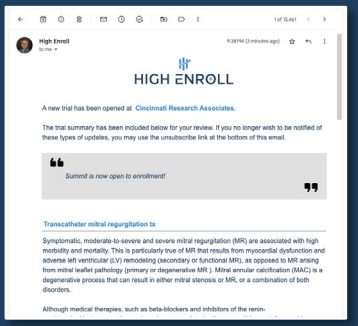
Site Website

Print Media

Facebook / Digital Media



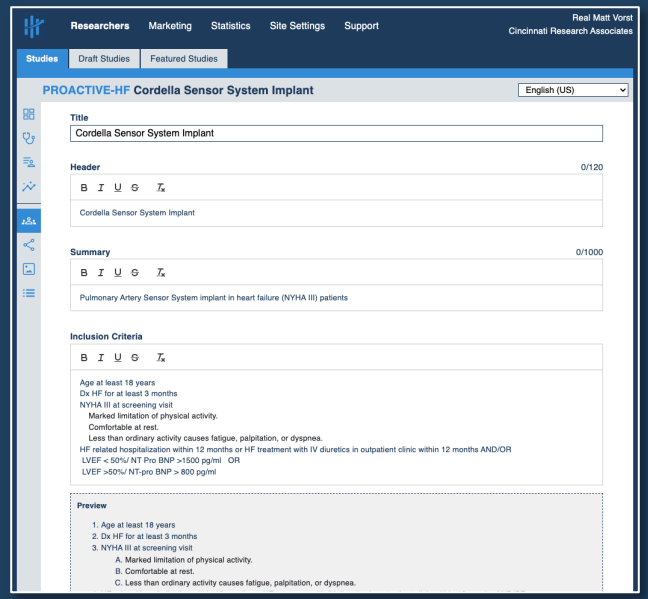
Patient Advocate Notification



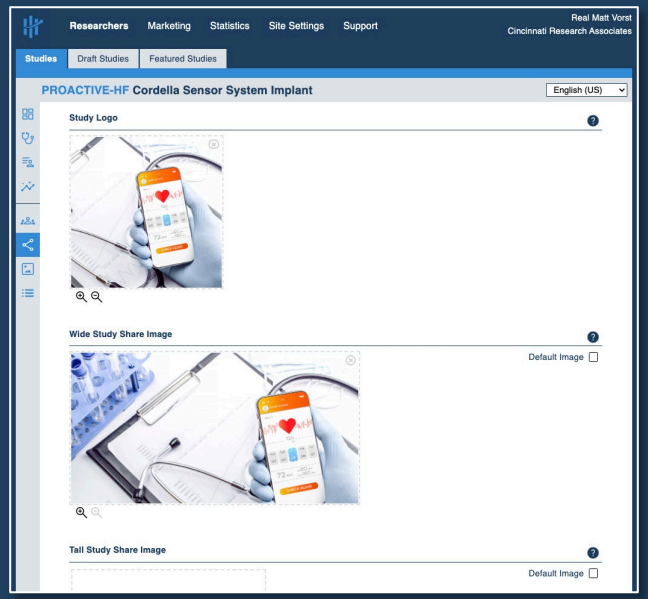
INCLUSION OF THE MARKETING TEAM

All assets that will be shared with healthcare providers and patients can be managed in one place.

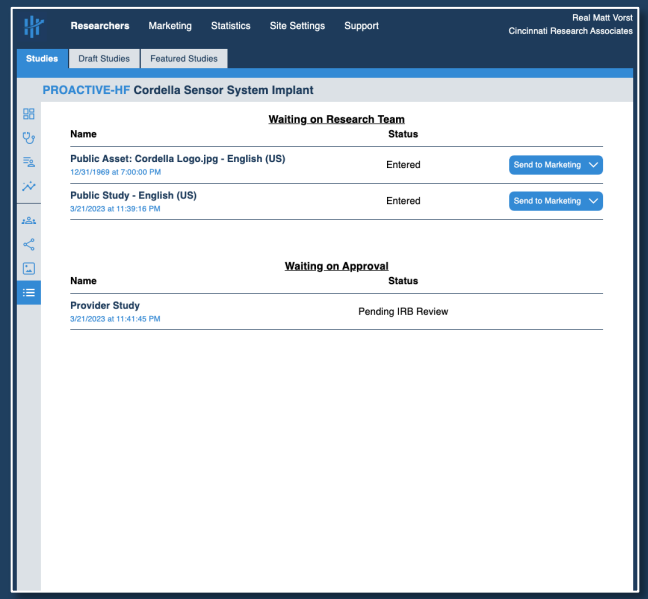
Multi-Lingual Patient Content



Social Media Images



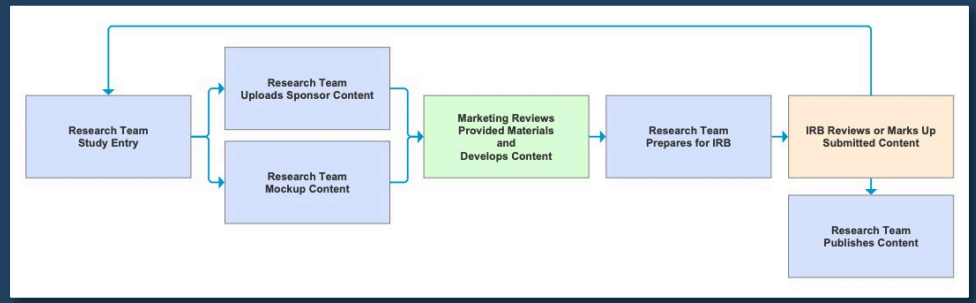
Sponsor Provided & Other Assets



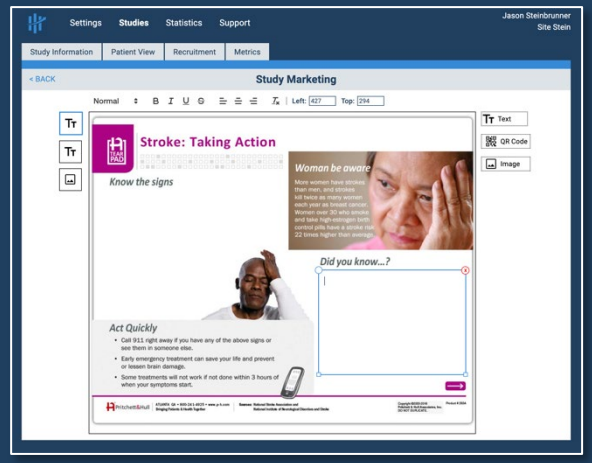
BRAND CONSISTENCY

All of the tools within High Enroll have been designed to help maintain your brand.

Marketing and research teams work together from day one.

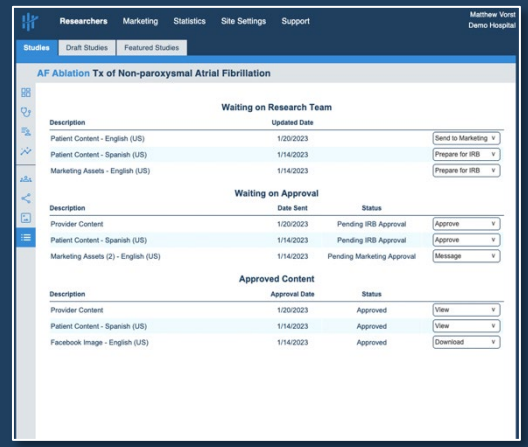


Customized processes ensure content is reviewed before publication.



Marketing can develop templates to streamline the process of publishing content.

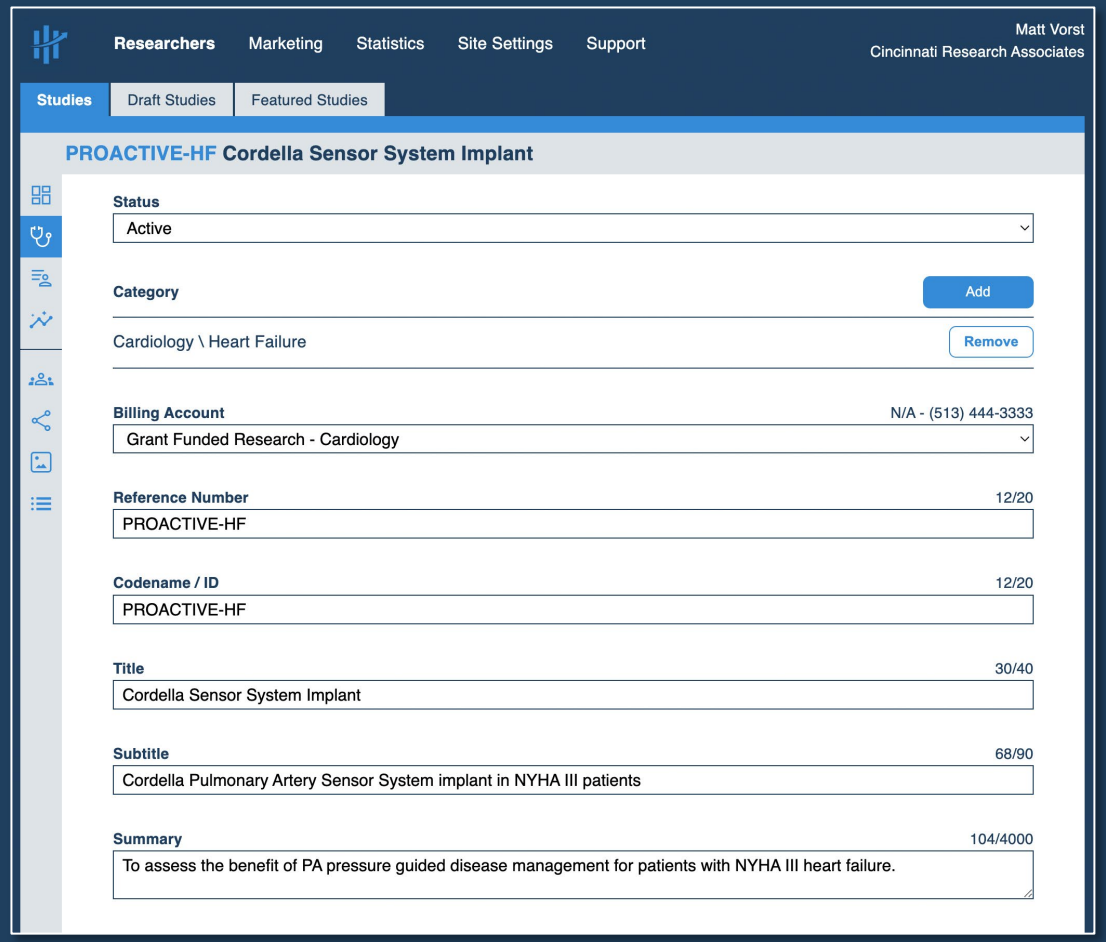
Dashboards make communication between teams quick and painless.



A STANDARD PROCESS

PROCESS: PROVIDER STUDY INFORMATION

Healthcare Provider Study Information

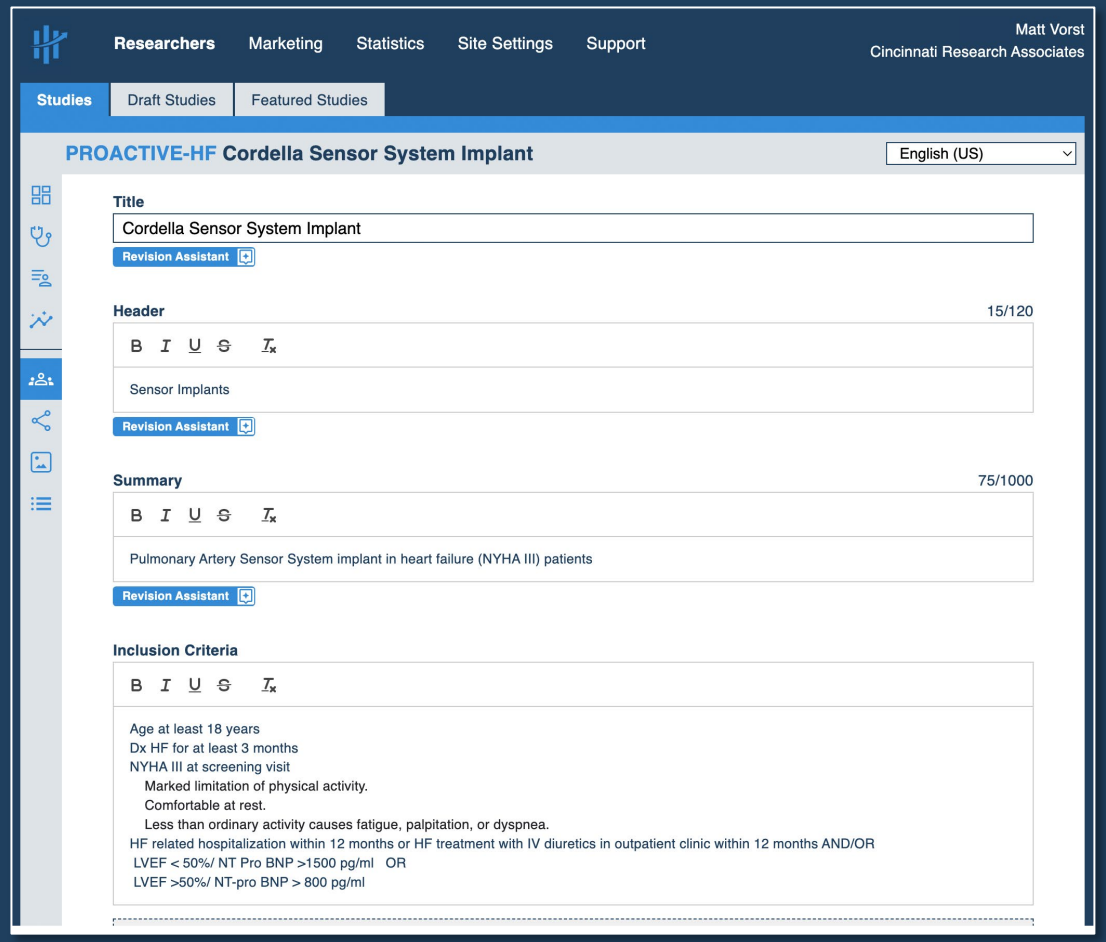


Studies can be entered as inactive once the protocol is available (before you submit to the IRB). When the study is open to enrollment, it can quickly be made active and published to all healthcare providers.

Provider Study Entry | Public Study Entry | Sponsor Asset Upload | Marketing Review / Assistance | Prepare for IRB Review | Publish

PROCESS: PUBLIC STUDY INFORMATION

Public Focused Study Information



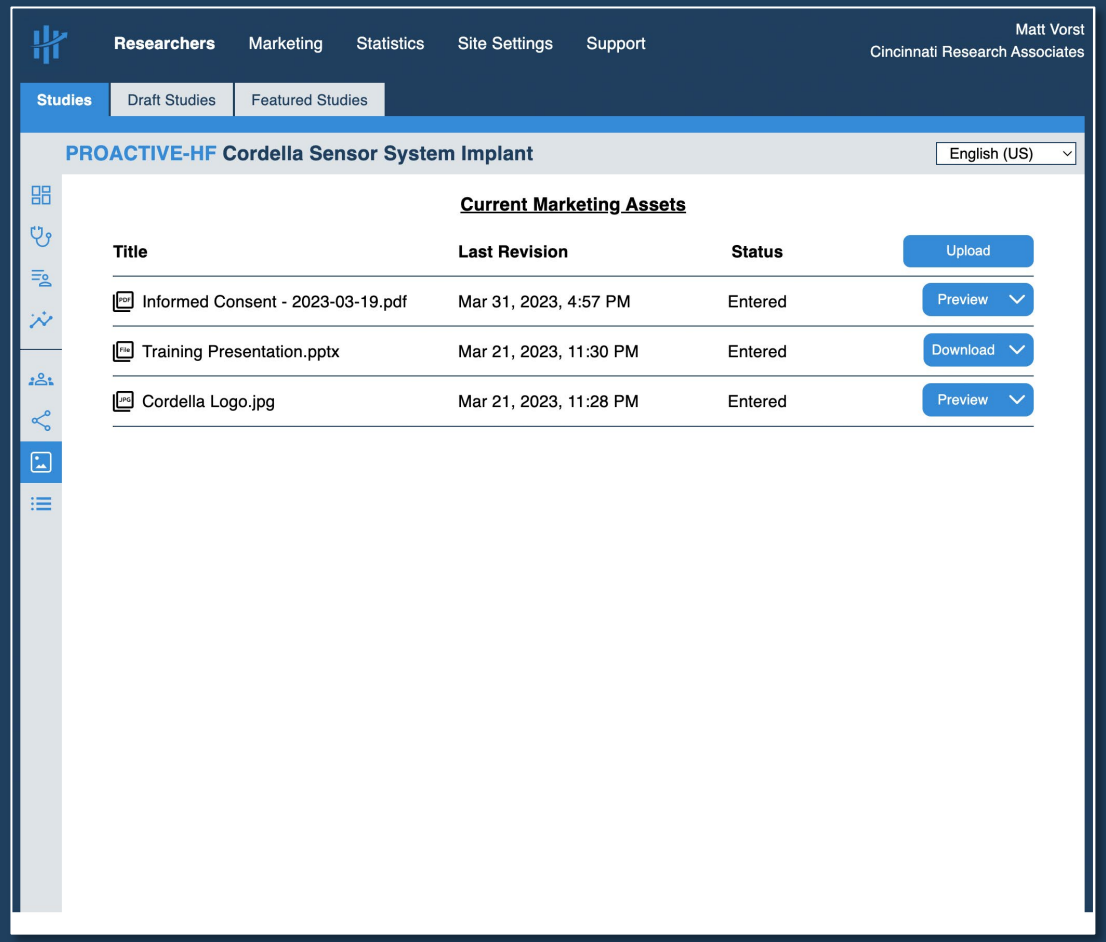
Content is pre-populated from the provider study screen. The revision assistant can then be used to suggest content that is more public friendly.

Features:

- Automated Reading Level Assessment
- AI Powered Revision Assistant
- Content can be entered in multiple languages

PROCESS: MARKETING ASSET LIBRARY

Marketing Asset Library



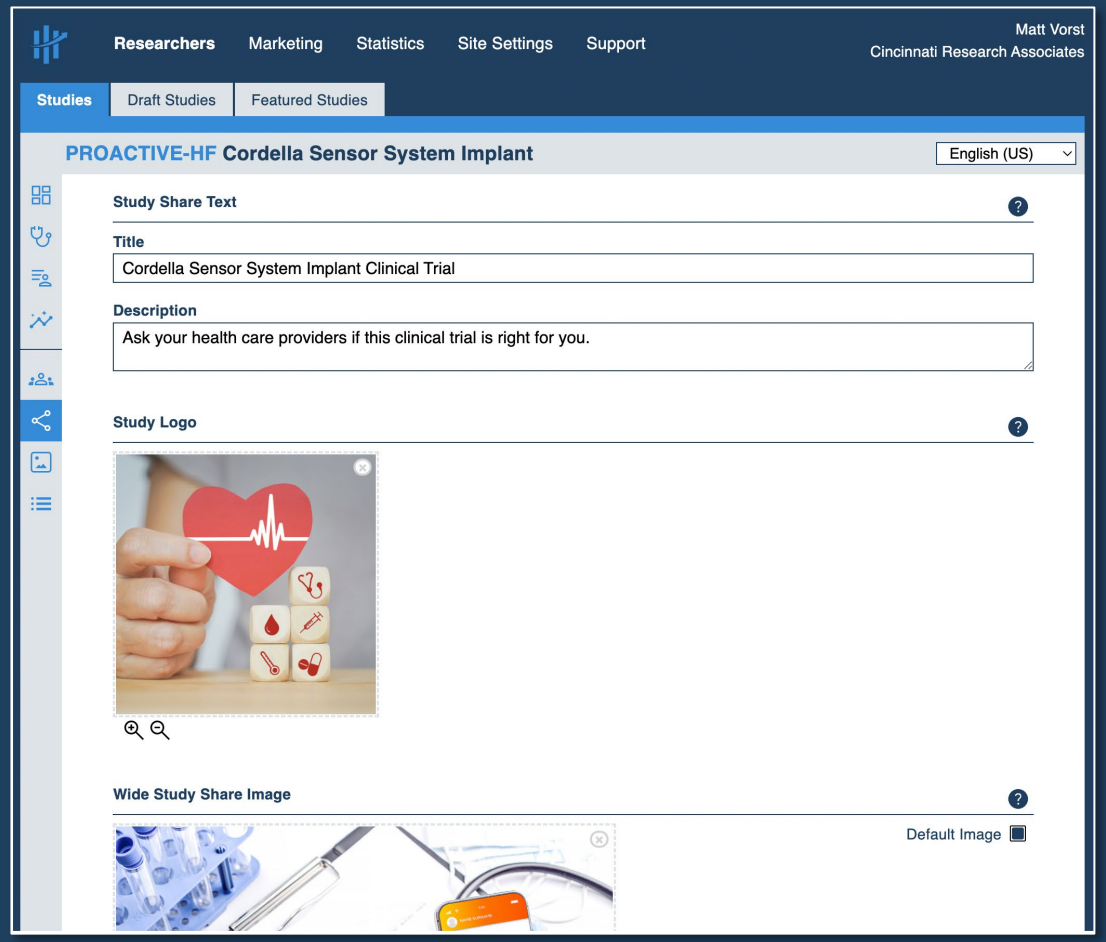
All sponsor provided marketing content can be uploaded to the study asset library so it is accessible by your team as well as marketing.

This may include:

The informed consent form
Tear pads
Flyers
Logos
Social Media Imagery

PROCESS: MARKETING REVIEW / ASSISTANCE

Social Media Content



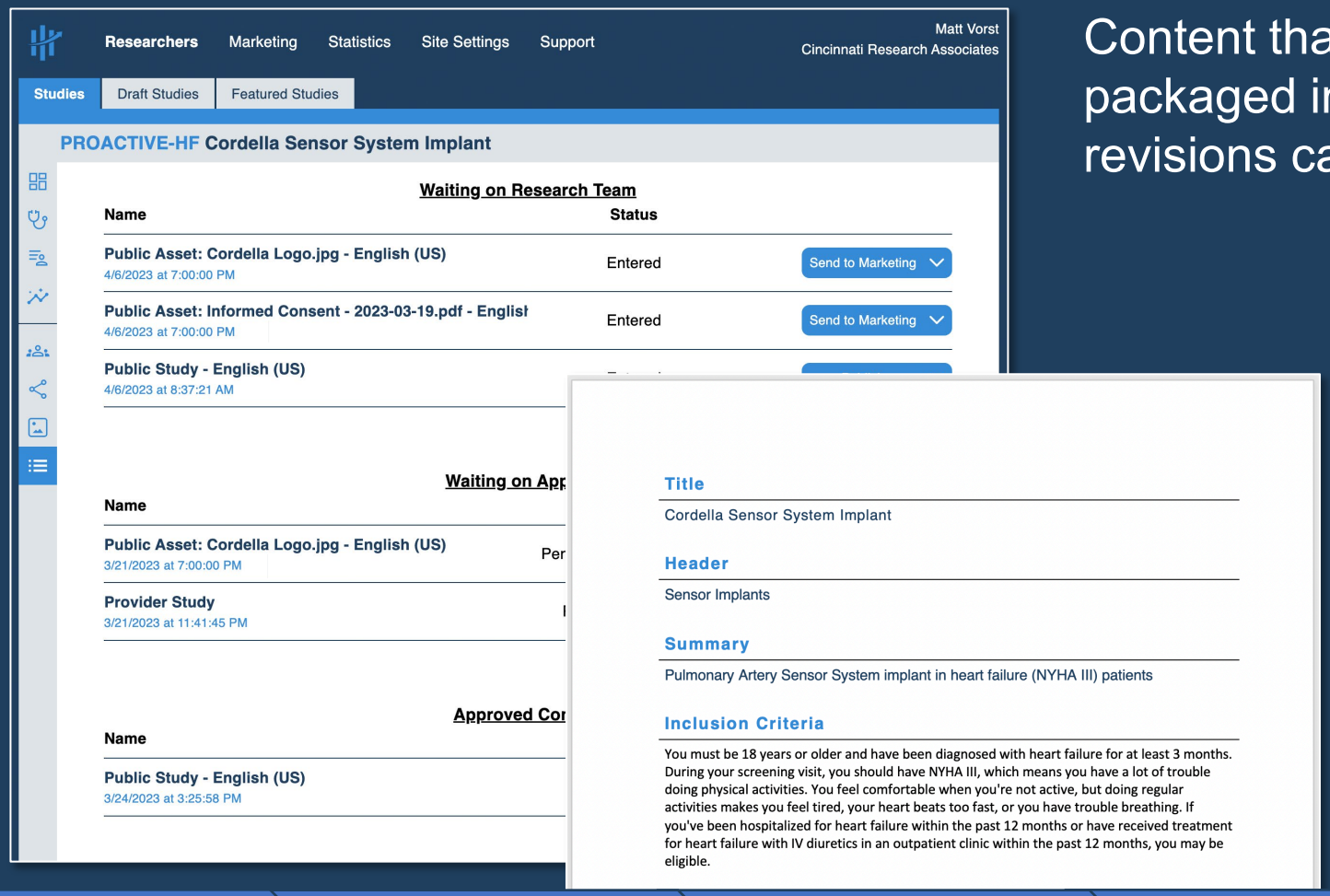
Social media text and images can be added and/or reviewed by marketing. This content is used when a public study is shared via social media.

Features:

- An image editor makes content creation simple
- Images can be uploaded in several sizes
- This content can be pushed to your website

PROCESS: IRB SUBMISSION

Content Approval Management



Content that has been approved by marketing is packaged into a word document where IRB revisions can be tracked.

Included in the Document:

- Public study information
- Images with their intended use
- Public platform overview

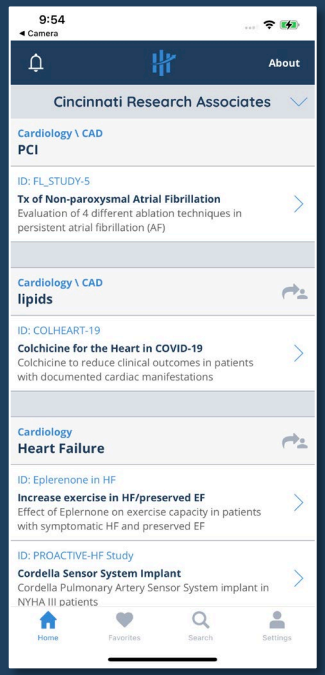
Provider Study Entry | Public Study Entry | Sponsor Asset Upload | Marketing Review / Assistance | **Prepare for IRB Review** | Publish

PROCESS: PUBLICATION

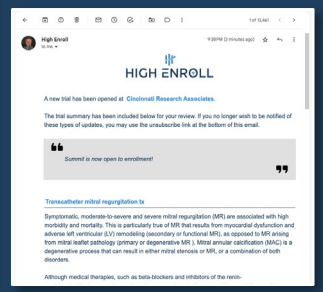
Approved content is managed in one place and published in seconds to all channels.

Provider Content

High Enroll



Provider Email

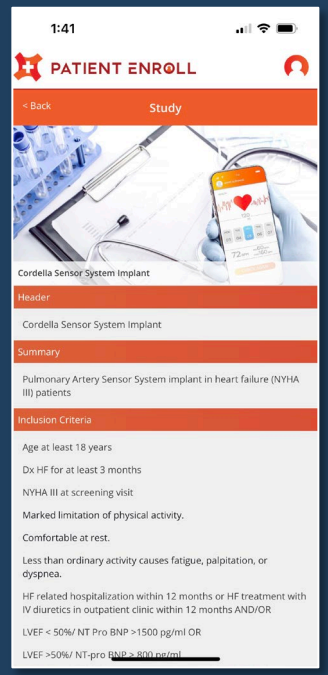


Public Content

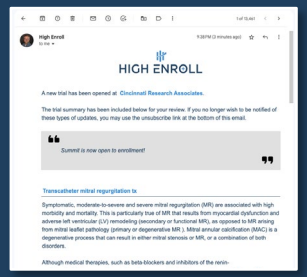
Print Media

Site Website

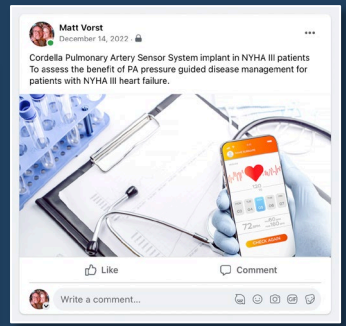
PatientEnroll.com



Patient Advocate Notification



Facebook & Digital Media



Provider Study Entry → Public Study Entry → Sponsor Asset Upload → Marketing Review / Assistance → Prepare for IRB Review → **Publish**

CUSTOM PROCESSES

The process can be configured to meet the needs of each department. Each task in the process is like a building block that can be moved to best fit into your existing workflow.

Existing tasks control the status of content, allow content to be exported, notify the appropriate stakeholders, and publish content to the data feed and Patient Enroll.

More tasks can be built to meet your needs.

EXAMPLE OF IRB SUBMISSION

Header

Immunotherapy for resected **NSCLC**

Summary

A081801 | National Cancer Institute

Inclusion Criteria

[Not entered]

Exclusion Criteria

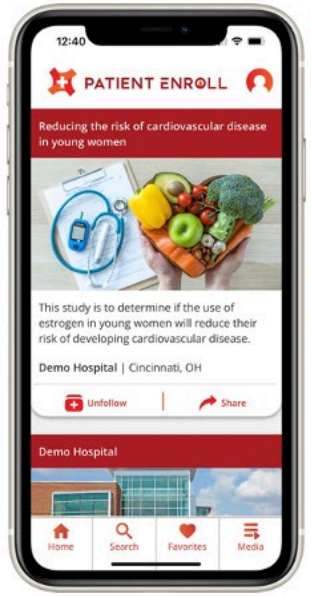
[Not entered]

Detail

This phase III ALCHEMIST trial compares the addition of pembrolizumab to usual chemotherapy versus usual chemotherapy for the treatment of stage IB, II, or IIIA non-small cell lung cancer that has been removed by surgery. Immunotherapy with monoclonal antibodies, such as pembrolizumab, may help the body's immune system attack the cancer, and may interfere with the ability of tumor cells to grow and spread. Drugs used in chemotherapy, such as cisplatin, pemetrexed, carboplatin, gemcitabine hydrochloride, and paclitaxel, work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. The purpose of this trial is to find out if the addition of pembrolizumab to usual chemotherapy is better or worse than usual chemotherapy alone for non-small cell lung cancer.

Exported directly from High Enroll Admin Portal to word for submission

Patient Enroll



What is Patient Enroll?
Patient Enroll is a Progressive Web App that provides information about clinical research and specific research studies. This content is curated by the research team so it is easy for the general public to understand.

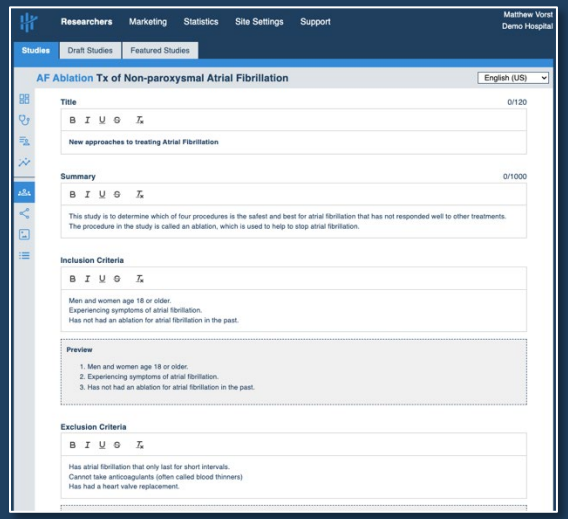
What is a Progressive Web App?
A progressive web app (PWA) is a webpage that has been specifically designed to be used on mobile phones. It looks and feels like an app that has been installed from the app store without having to download and install the app.

Includes a description of Patient Enroll with how and where content might be used

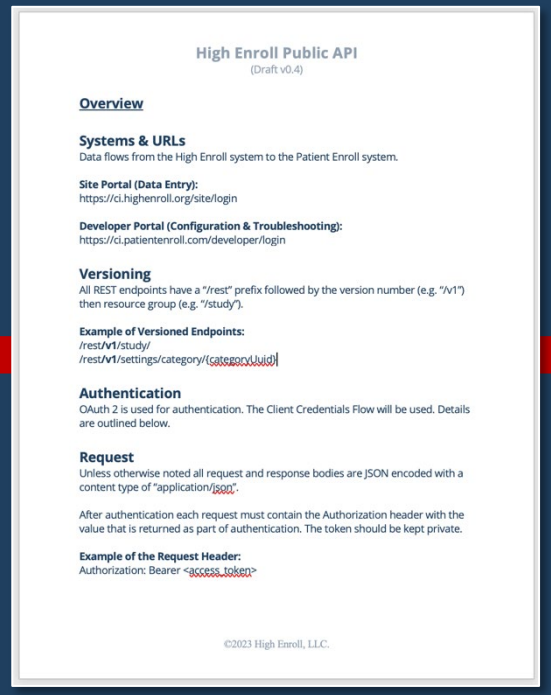
PATIENT ENROLL DATA FEED

Once the initial integration has been completed, the High Enroll data feed can be used to publish patient facing content to your website without ongoing involvement from IT.

Multi-Lingual Patient Content



API Implementation Guide



IT integration needed

Site Website

NEXT STEPS

- Patient Enroll
  - To ensure the right people are at the table and working on the workflow we are working with
    - Researchers
    - Marketing
    - OCR
    - ARS
    - IRB
    - IT
- Feedback!