



**Office of Clinical Research
First Friday**

Earth Month Presentations:

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

Friday, April 7th, 2023

**next
lives
here**



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.

**next
lives
here**

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.



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

BRV152411

next
lives
here



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](#)

**next
lives
here**



Office of Clinical Research Lunch & Learn

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

HAPPY HOUR

May 18th, 2023

4pm – 7pm

Location: TBA in an announcement to the CRP listserv

**next
lives
here**

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

**next
lives
here**

University of
CINCINNATI



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

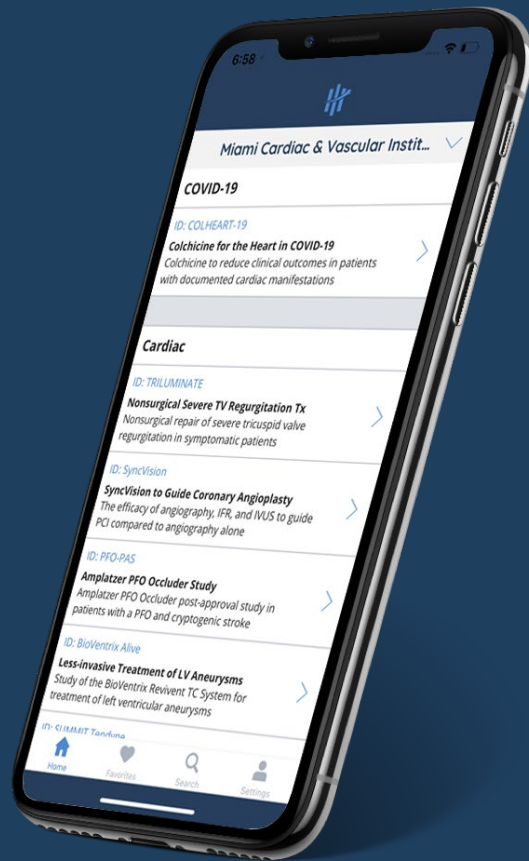
- Review of Provider Facing Platform
- Introduction of the Public Facing Platform
- Discussion of Features

THE PLATFORM

Painless and Simple

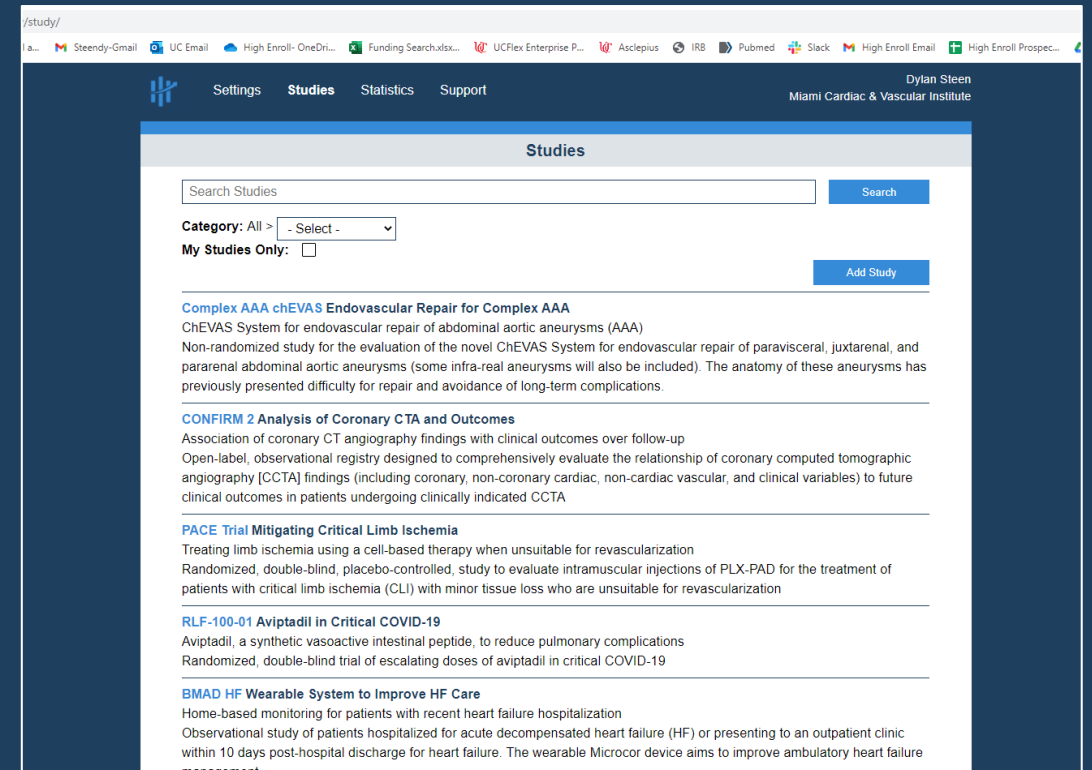
Open Access Mobile App

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

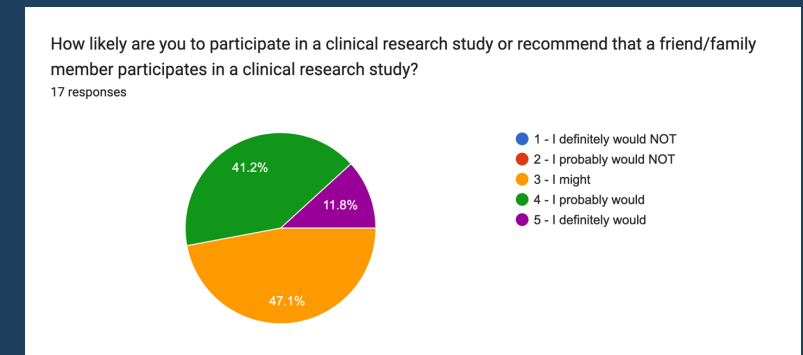
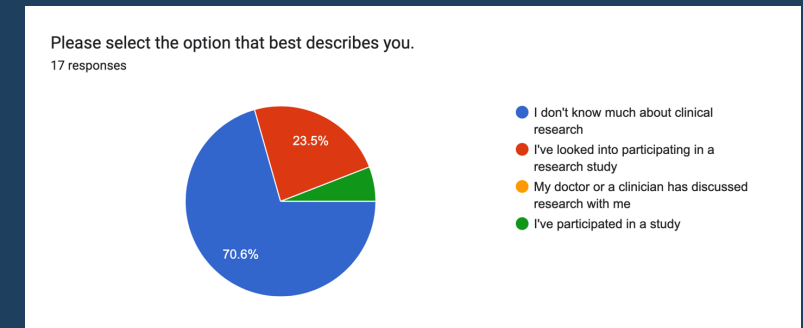


INCREASING AWARENESS OF CLINICAL TRIALS

- 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

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

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

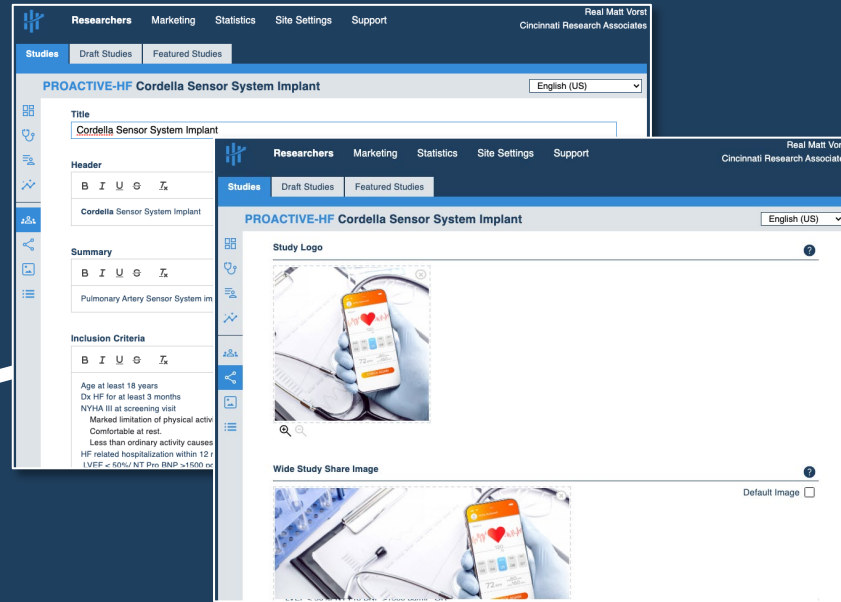
The patient enroll progressive web app, which is accessible on mobile and desktop devices, can be installed like an app for convenient use by the public. It facilitates efficient communication and dissemination of research studies to a broader audience.

Data Feed

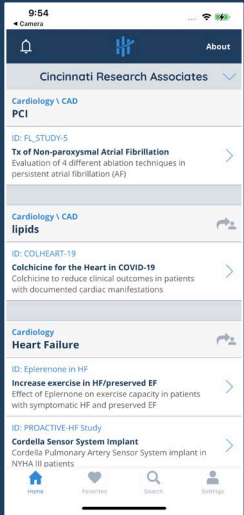
The data feed allows content to be published to websites or other systems.

PLATFORM OVERVIEW

Researchers / Administrators

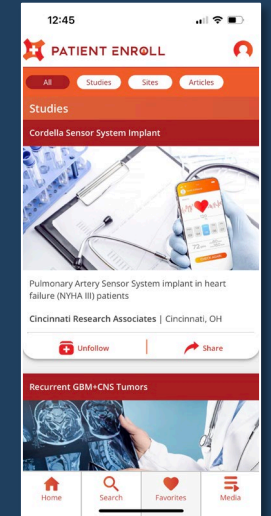


High Enroll App



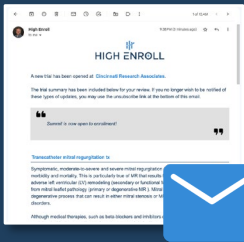
Study Content
for Providers

Patient Enroll PWA



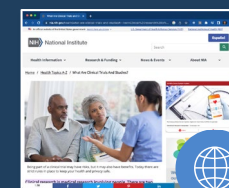
Study Content
for Patients

Email Distribution

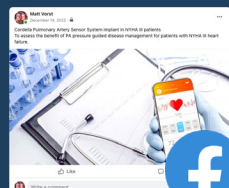


Facilitate discussions between patients and their providers (and vice versa)

Site Website (API)



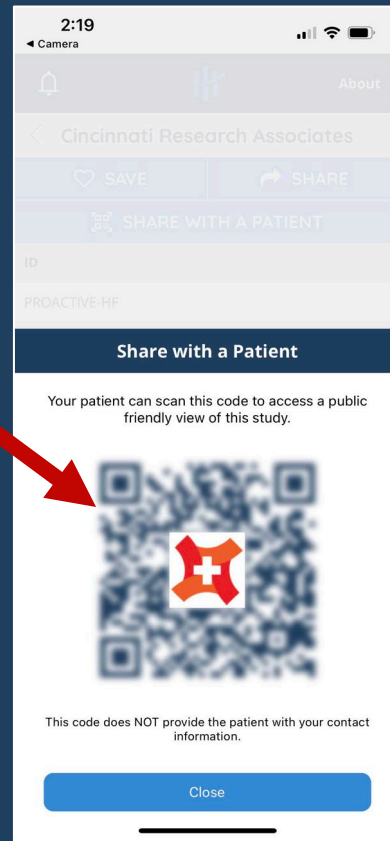
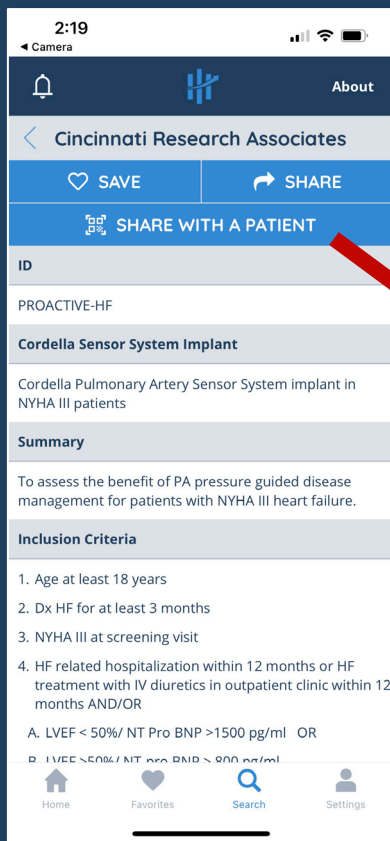
Social Media



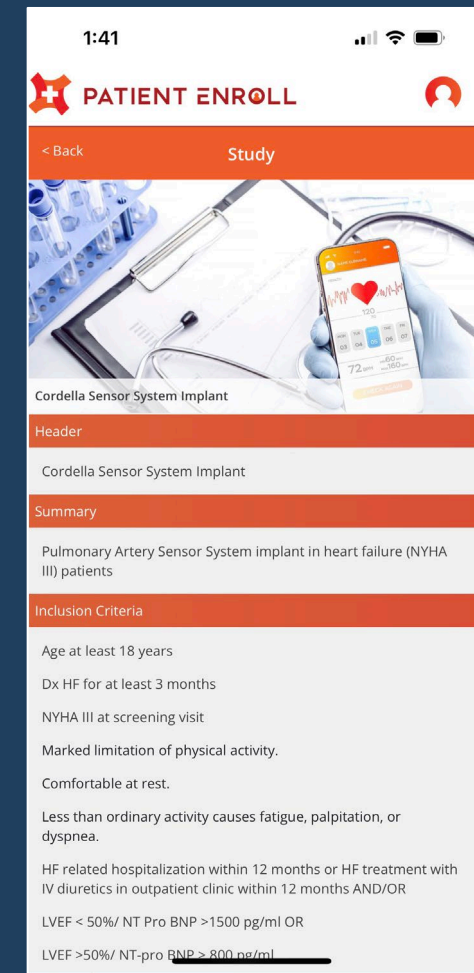
SHARING STUDIES

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

Care Provider via High Enroll



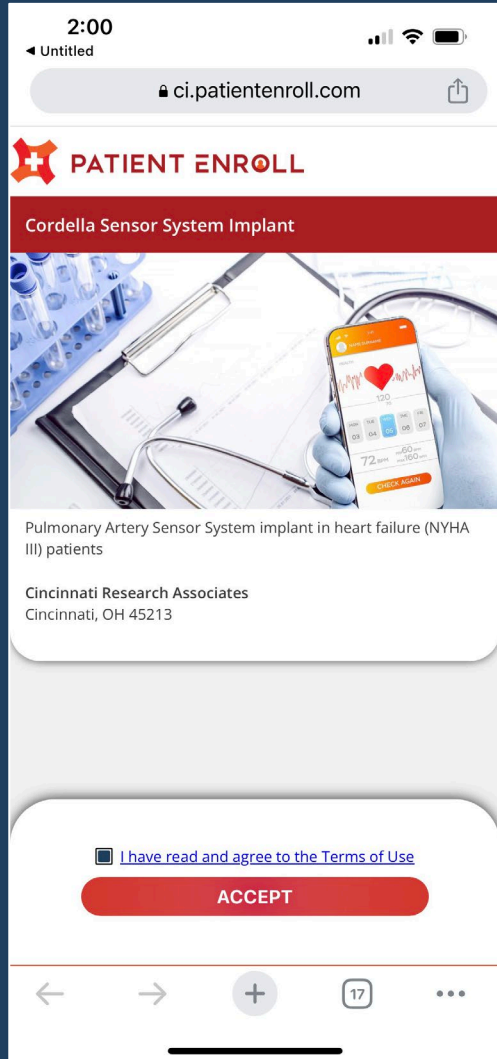
Scanning the QR code opens **Patient Enroll** in the patient's browser



PATIENT INTERACTION

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

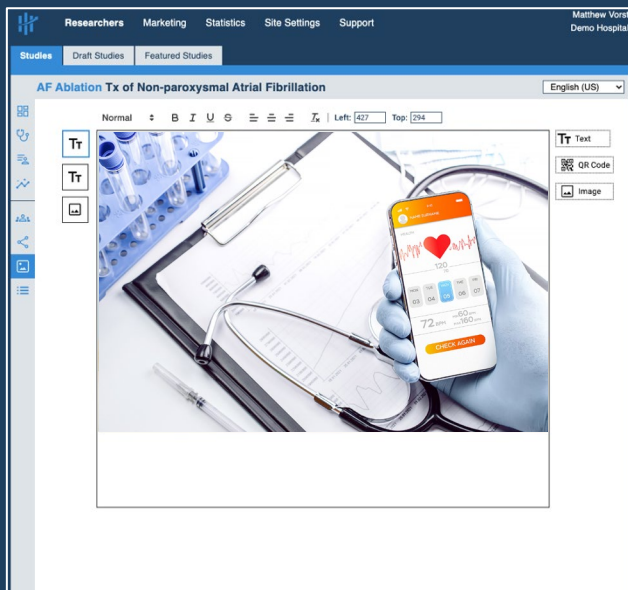
You can think of this as a digital tear-pad. Potential volunteers can take the study home, review the details with family, then contact a coordinator with questions.



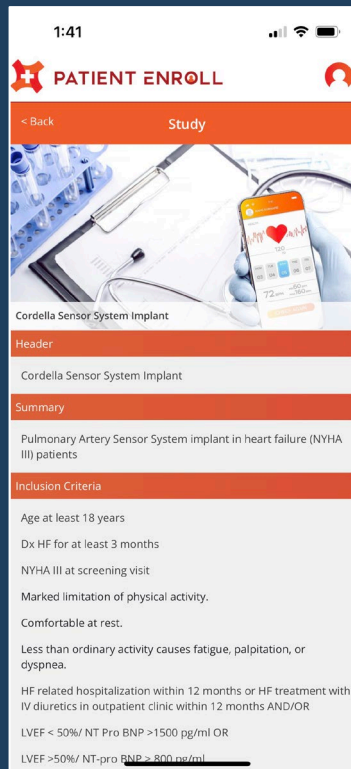
MULTI-CHANNEL MARKETING

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

High Enroll Site Portal



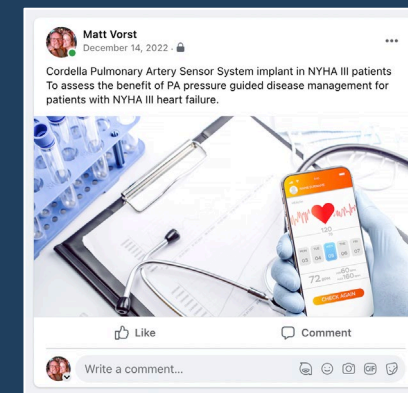
PatientEnroll.com



Site Website



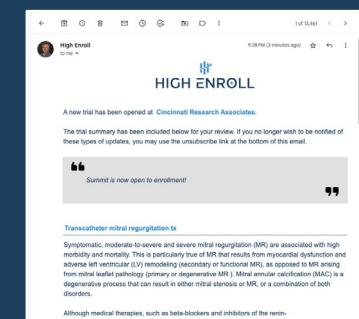
Facebook / Digital Media



Print 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

The screenshot shows the 'Multi-Lingual Patient Content' interface for the 'PROACTIVE-HF Cordella Sensor System Implant' study. The page is in English (US). It features a title field with 'Cordella Sensor System Implant', a header field with 'Cordella Sensor System Implant', and a summary field with 'Pulmonary Artery Sensor System implant in heart failure (NYHA III) patients'. The inclusion criteria section lists: 'Age at least 18 years', 'Dx HF for at least 3 months', 'NYHA III at screening visit', 'Marked limitation of physical activity. Comfortable at rest.', 'Less than ordinary activity causes fatigue, palpitation, or dyspnea.', 'HF related hospitalization within 12 months or HF treatment with IV diuretics in outpatient clinic within 12 months AND/OR LVEF <math>< 50\%</math> NT-pro BNP >=1500 pg/ml OR LVEF >=50% NT-pro BNP > 800 pg/ml'. A preview section lists: '1. Age at least 18 years', '2. Dx HF for at least 3 months', '3. NYHA III at screening visit', 'A. Marked limitation of physical activity.', 'B. Comfortable at rest.', 'C. Less than ordinary activity causes fatigue, palpitation, or dyspnea.'

Social Media Images

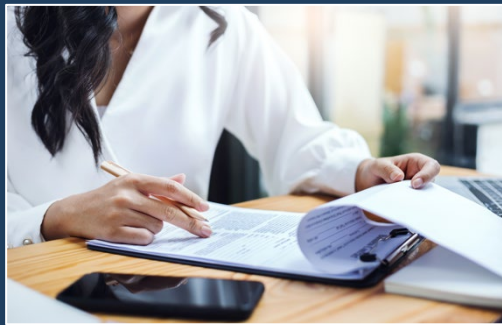
The screenshot shows the 'Social Media Images' interface for the 'PROACTIVE-HF Cordella Sensor System Implant' study. It features a 'Study Logo' field with a placeholder image of a hand holding a smartphone displaying a heart rate monitor. Below it is a 'Wide Study Share Image' field with a placeholder image of a hand holding a smartphone displaying a heart rate monitor, with a 'Default Image' checkbox. At the bottom is a 'Tall Study Share Image' field with a placeholder image and a 'Default Image' checkbox.

Sponsor Provided & Other Assets

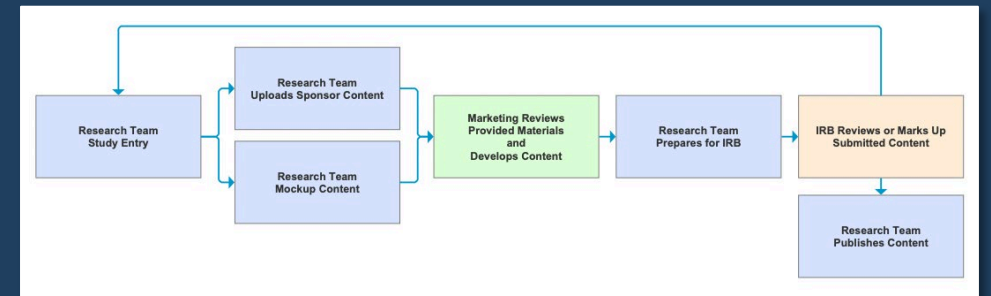
The screenshot shows the 'Sponsor Provided & Other Assets' interface for the 'PROACTIVE-HF Cordella Sensor System Implant' study. It features a table with columns for 'Name' and 'Status'. The table is divided into two sections: 'Waiting on Research Team' and 'Waiting on Approval'. The 'Waiting on Research Team' section includes: 'Public Asset: Cordella Logo.jpg - English (US)' with status 'Entered' and a 'Send to Marketing' button; and 'Public Study - English (US)' with status 'Entered' and a 'Send to Marketing' button. The 'Waiting on Approval' section includes: 'Provider Study' with status 'Pending IRB Review'.

BRAND CONSISTENCY

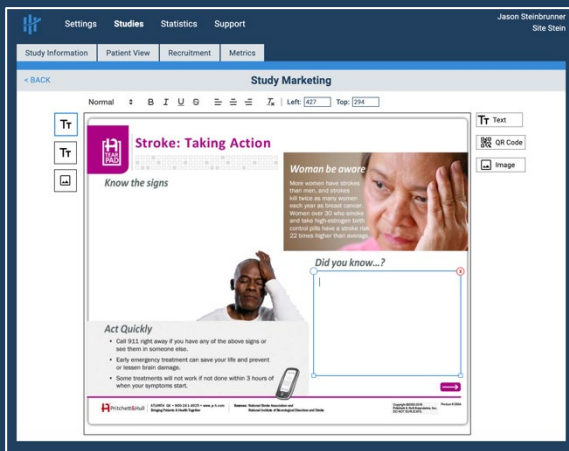
All of the tools within High Enroll have been designed to help maintain your brand.



Marketing and research teams work together from day one.

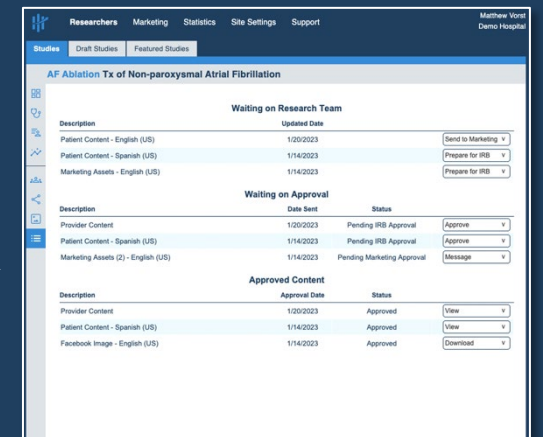


Customized processes ensure content is reviewed before publication.



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

The screenshot shows a web application interface for managing study information. At the top, there are navigation tabs: 'Studies', 'Draft Studies', and 'Featured Studies'. The current study is titled 'PROACTIVE-HF Cordella Sensor System Implant'. The form includes several fields:

- Status:** A dropdown menu set to 'Active'.
- Category:** A text field containing 'Cardiology \ Heart Failure' with an 'Add' button and a 'Remove' button.
- Billing Account:** A dropdown menu set to 'Grant Funded Research - Cardiology' with a 'N/A - (513) 444-3333' label.
- Reference Number:** A text field containing 'PROACTIVE-HF' with a '12/20' character count.
- Codename / ID:** A text field containing 'PROACTIVE-HF' with a '12/20' character count.
- Title:** A text field containing 'Cordella Sensor System Implant' with a '30/40' character count.
- Subtitle:** A text field containing 'Cordella Pulmonary Artery Sensor System implant in NYHA III patients' with a '68/90' character count.
- Summary:** A text area containing 'To assess the benefit of PA pressure guided disease management for patients with NYHA III heart failure.' with a '104/4000' character count.

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

The screenshot shows a web interface for editing study information. At the top, there are navigation tabs for 'Studies', 'Draft Studies', and 'Featured Studies'. The main title is 'PROACTIVE-HF Cordella Sensor System Implant' with a language dropdown set to 'English (US)'. The interface is divided into sections: 'Title' (Cordella Sensor System Implant), 'Header' (Sensor Implants), 'Summary' (Pulmonary Artery Sensor System implant in heart failure (NYHA III) patients), and 'Inclusion Criteria' (Age at least 18 years, Dx HF for at least 3 months, NYHA III at screening visit, Marked limitation of physical activity, Comfortable at rest, Less than ordinary activity causes fatigue, palpitation, or dyspnea, HF related hospitalization within 12 months or HF treatment with IV diuretics in outpatient clinic within 12 months AND/OR LVEF < 50%/ NT Pro BNP >1500 pg/ml OR LVEF >50%/ NT-pro BNP > 800 pg/ml). Each section has a 'Revision Assistant' button.

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

Provider Study
Entry

Public Study Entry

Sponsor Asset
Upload

Marketing Review /
Assistance

Prepare for IRB
Review

Publish

PROCESS: MARKETING ASSET LIBRARY

Marketing Asset Library

The screenshot shows the Marketing Asset Library interface for the study 'PROACTIVE-HF Cordella Sensor System Implant'. The interface includes a navigation menu with options like 'Researchers', 'Marketing', 'Statistics', 'Site Settings', and 'Support'. The user is identified as 'Matt Vorst' from 'Cincinnati Research Associates'. The main content area displays a table of 'Current Marketing Assets' with columns for Title, Last Revision, Status, and an action menu. The assets listed are:

Title	Last Revision	Status	Action
Informed Consent - 2023-03-19.pdf	Mar 31, 2023, 4:57 PM	Entered	Upload, Preview
Training Presentation.pptx	Mar 21, 2023, 11:30 PM	Entered	Download
Cordella Logo.jpg	Mar 21, 2023, 11:28 PM	Entered	Preview

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

Provider Study Entry

Public Study Entry

Sponsor Asset Upload

Marketing Review / Assistance

Prepare for IRB Review

Publish

PROCESS: MARKETING REVIEW / ASSISTANCE

Social Media Content

The screenshot shows a web interface for editing social media content for a study. The study title is "PROACTIVE-HF Cordella Sensor System Implant". The form includes fields for "Study Share Text", "Title" (Cordella Sensor System Implant Clinical Trial), and "Description" (Ask your health care providers if this clinical trial is right for you.). There is a "Study Logo" section with an image of a hand holding a heart with a stethoscope and medical icons. Below that is a "Wide Study Share Image" section with a default image of medical equipment.

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

Provider Study
Entry

Public Study Entry

Sponsor Asset
Upload

Marketing Review /
Assistance

Prepare for IRB
Review

Publish

PROCESS: IRB SUBMISSION

Content Approval Management

The screenshot displays the 'Content Approval Management' interface. At the top, there are navigation tabs for 'Studies', 'Draft Studies', and 'Featured Studies'. The main content area is titled 'PROACTIVE-HF Cordella Sensor System Implant'. It shows a list of entries under the heading 'Waiting on Research Team'. Each entry includes a 'Name' and a 'Status'. The entries are:

Name	Status
Public Asset: Cordella Logo.jpg - English (US) 4/6/2023 at 7:00:00 PM	Entered
Public Asset: Informed Consent - 2023-03-19.pdf - English (US) 4/6/2023 at 7:00:00 PM	Entered
Public Study - English (US) 4/6/2023 at 8:37:21 AM	

Below this list, there are sections for 'Waiting on Approval' and 'Approved Content'. The 'Waiting on Approval' section shows a 'Public Asset: Cordella Logo.jpg - English (US)' and a 'Provider Study'.

The 'Approved Content' section shows a 'Public Study - English (US)'.

On the right side of the interface, there is a user profile for 'Matt Vorst' from 'Cincinnati Research Associates'.

A preview of a document is shown in the foreground, containing the following sections:

- Title:** Cordella Sensor System Implant
- Header:** Sensor Implants
- Summary:** Pulmonary Artery Sensor System implant in heart failure (NYHA III) patients
- Inclusion Criteria:** You must be 18 years or older and have been diagnosed with heart failure for at least 3 months. During your screening visit, you should have NYHA III, which means you have a lot of trouble doing physical activities. You feel comfortable when you're not active, but doing regular activities makes you feel tired, your heart beats too fast, or you have trouble breathing. If you've been hospitalized for heart failure within the past 12 months or have received treatment for heart failure with IV diuretics in an outpatient clinic within the past 12 months, you may be eligible.

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



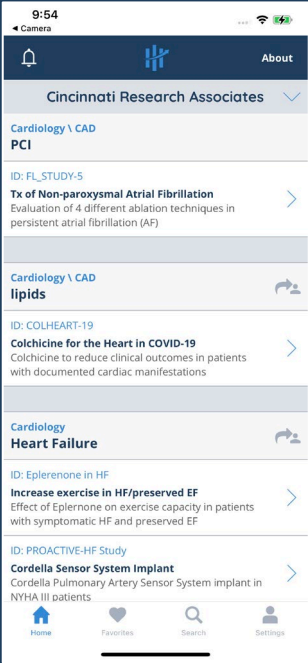
PROCESS: PUBLICATION

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

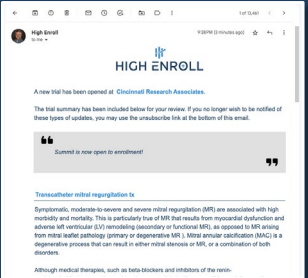
Provider Content

Public Content

High Enroll



Provider Email



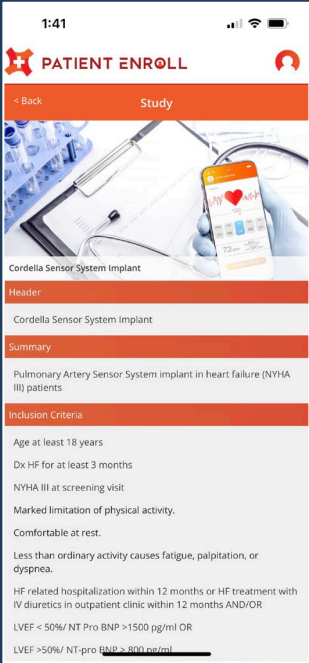
Print Media



Site Website

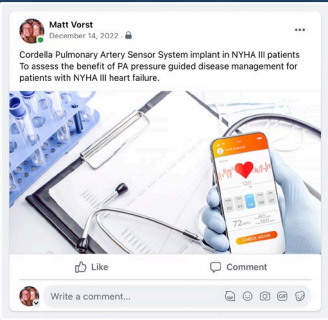
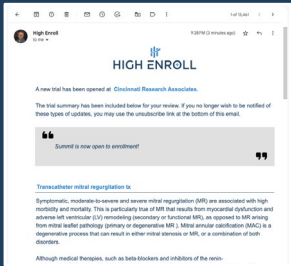


PatientEnroll.com



Facebook & Digital Media

Patient Advocate Notification



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

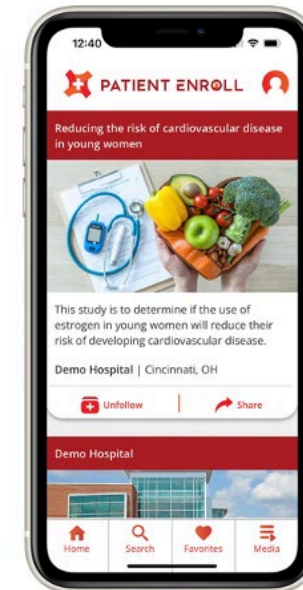
[Not entered]

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.

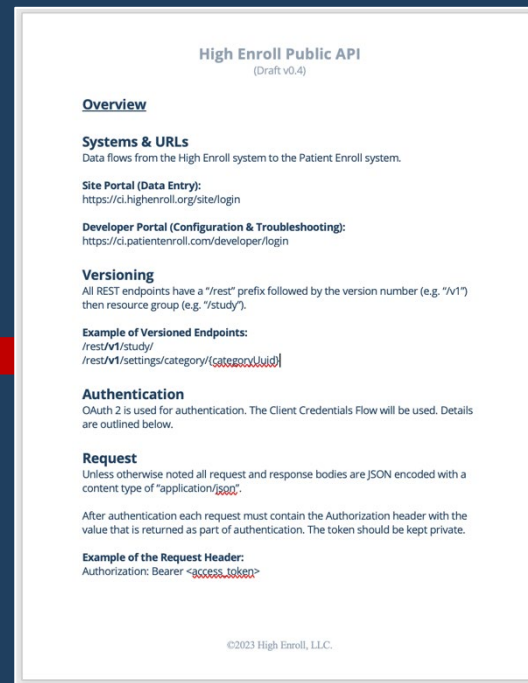
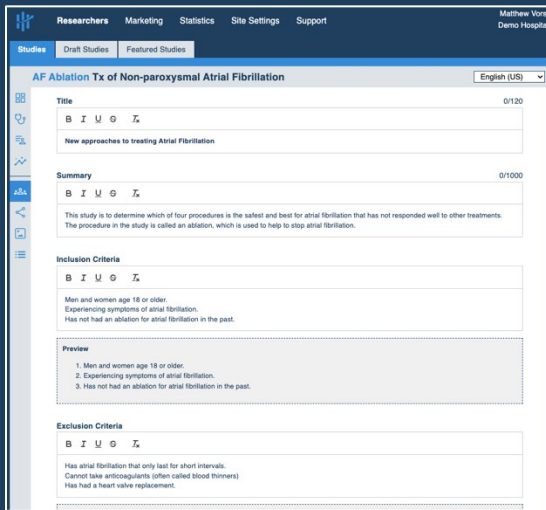
Includes a description of Patient Enroll with how and where content might be used

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.

API Implementation Guide

Multi-Lingual Patient Content



Site Website



IT integration needed

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!