



Colorado Clinical and Translational
Sciences Institute (CCTSI)



Element E: Pragmatic EHR-Embedded Trials (PEET) Program

Neil Aggarwal, MD, MHSC
Bethany Kwan, PhD, MSPH
Element E co-leads

<https://cctsi.cuanschutz.edu/resources/pragmatic-research-resources>

<https://cctsi.cuanschutz.edu/resources/pragmatic-research-resources#ft-pragmatic-ehr-embedded-trials-3>



PEET Leadership Team and Staff



**Neil Aggarwal,
MD, MHSc
Element E Co-
Lead**
Associate
Professor



**Bethany Kwan,
PhD, MSPH
Element E Co-
Lead**
Professor



**Lindsay
Lennox, MA
Program
Manager**
Research
Scientist



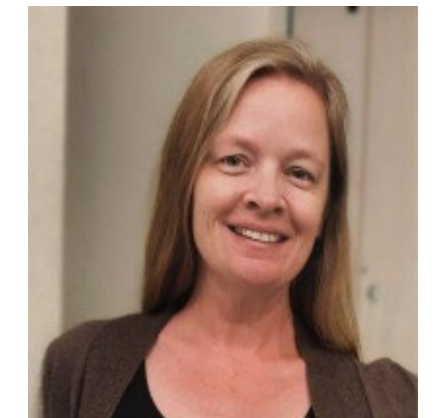
**Sarah Kautz,
PhD, LCSW
Program
Coordinator**
Principal
Research
Services
Professional



**Shelby
West, MPH
Program
Specialist**
Senior
Research
Services
Professional



**Aaron Barbour
Analytics
Support**
Data Analytics
and Business
Intelligence
Developer



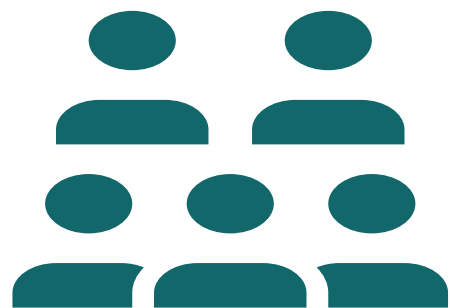
**Izzie Clinton
Analytics
Support**
Senior Business
Intelligence
Developer

**Previous Co-Lead Dr. Adit Ginde is now Sr.
Associate Dean for Clinical Research &
Assistant Vice Chancellor for Clinical Trials
Champion for PEET from above!**

Strategic Goals

- 1. Goal:** Build the PEET Research Program infrastructure and governance needed for prioritization and support throughout the UCHealth system.
- 2. Goal:** Engage community partners in co-design of user guidance materials and protocols to implement PEET infrastructure and “designing for dissemination” across the CTSA consortium.
- 3. Goal:** Conduct a pragmatic EHR-embedded clinical trial and use lessons learned to inform user guidance for a broad range of subsequent EHR-embedded clinical trials (up to 2 ongoing per year) to be funded through this mechanism over the 7 years of the UM1 award.

Year 3 Impact



UCHealth partnership
Steering Committee
Community engagement



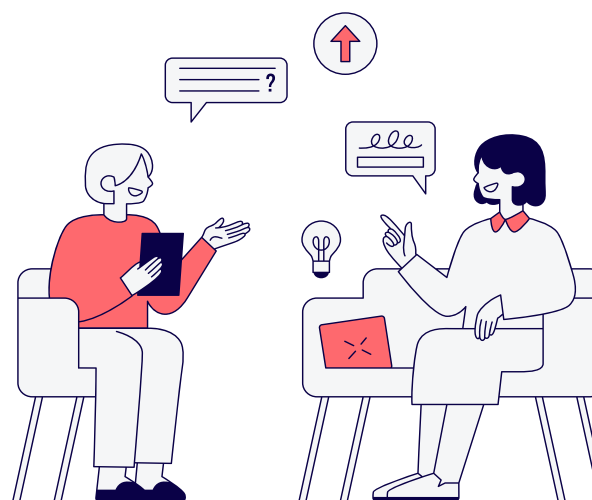
Year 2 for 2nd demonstration project
(OCCULT-O2)
Launched 3rd demonstration project
(ALERT-ED)



Dissemination
activities



Investigator guidance
materials and education
UCHealth Research
Administration resources



PEET request for applications
(RFA) optimization
Customer discovery interviews



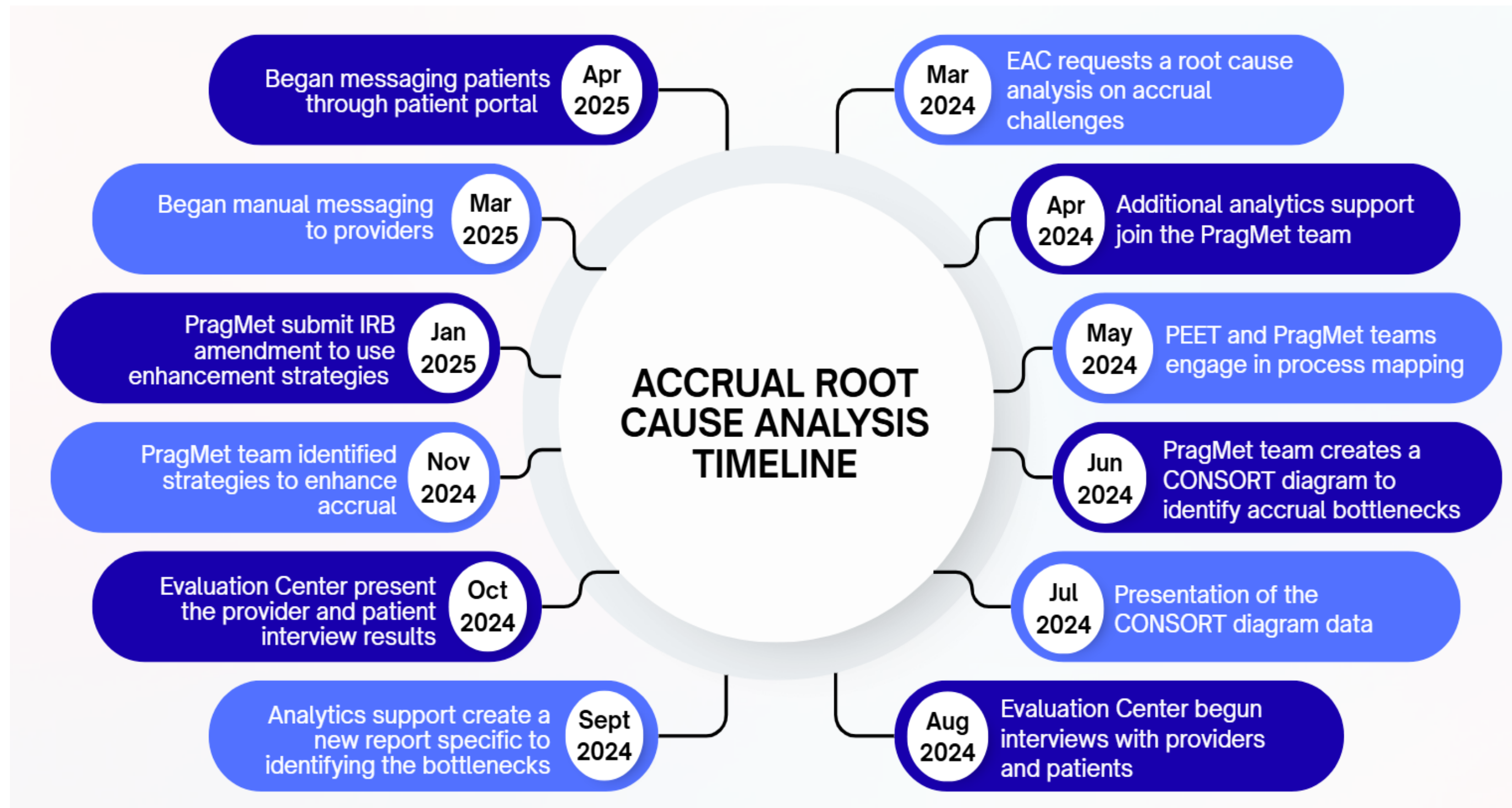
Fourth demonstration project
application solicitation and
review underway



PEET Demonstration Projects

- **Demonstration Project 1 (2023-2025):** “Randomized, Pragmatic, Adaptive trial of Metformin for Glucose Intolerance or Increased Body Mass Index in Prostate Cancer Patients” (the PragMet study), PI: Flaig
- **Demonstration Project 2 (2024-2026):** “Optimizing Care in Critically ill at UCHealth by Liberalizing the Target O2 in mechanically ventilated ICU patients” (OCCULT O2 Project), MPIs: Aggarwal and Sottile
- **Demonstration Project 3 (2025-2027):** “Awareness and Linkage to Resources for At-Risk Emergency Department Patients” (the ALERT-ED Project), MPIs: Goldberg and Portz
- **Demonstration Project 4 (2026-2028):** Review process underway
 - Emphasis on UCHealth organizational alignment and feasibility, scientific rigor and impact, community priorities, and innovations in EHR-embedded trials

Addressing Participant Accrual Barriers in the PragMet Study



KEY TERMS

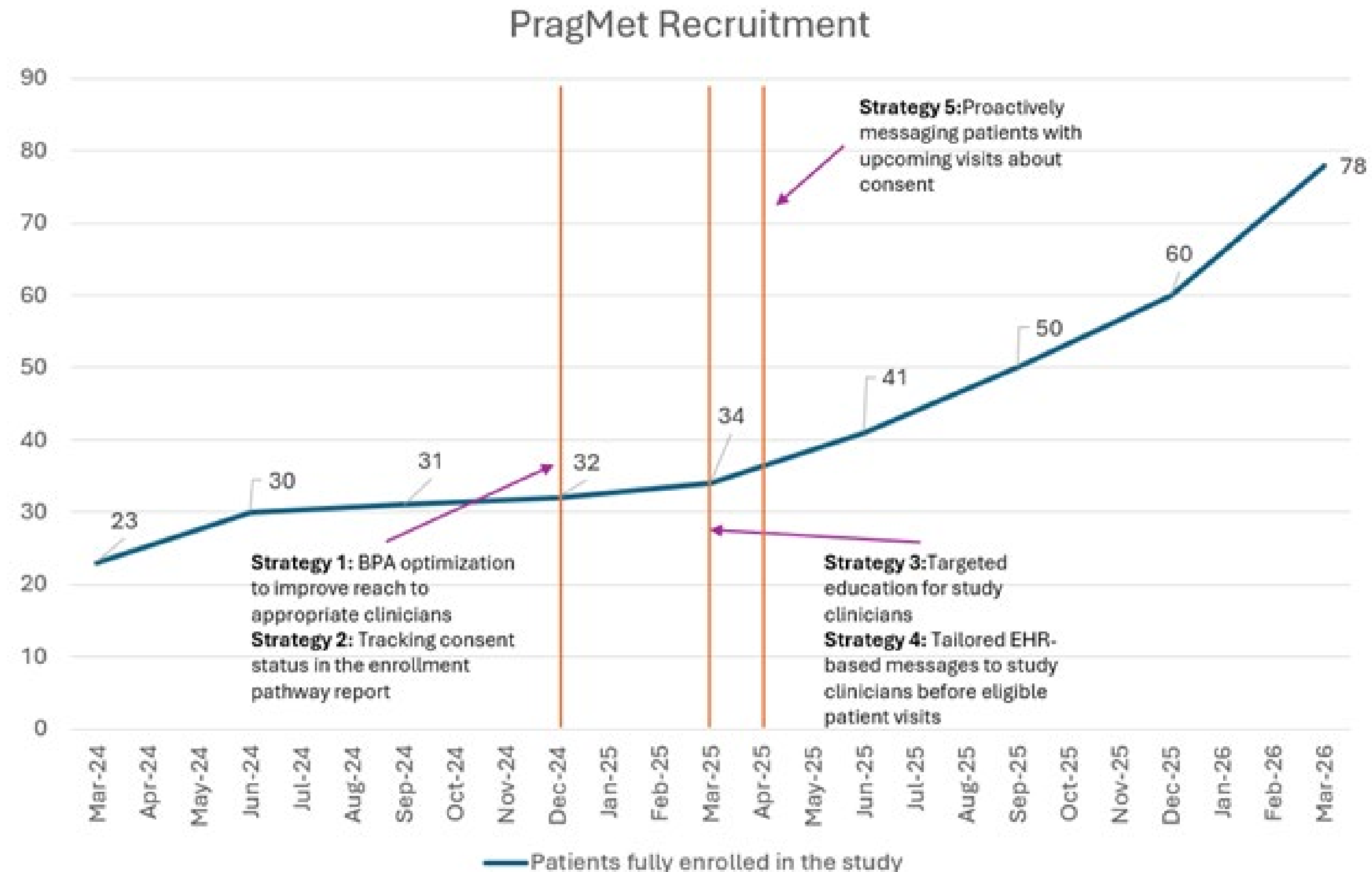
PragMet
Randomized, Pragmatic, Adaptive trial of Metformin for Glucose Intolerance or Increased Body Mass Index in Prostate Cancer Patients

EAC
External Advisory Committee

CONSORT
Consolidated Standards of Reporting Trials

IRB
Institutional Review Board

Addressing Participant Accrual Barriers in the PragMet Study



Major Components of Pragmatic EHR-Embedded Trials

Scientific

Technical
components

Health system
partnerships

Administrative
& Regulatory
components



Investigator Guidance Materials



UCHealth Research Administration Resources

The screenshot displays the UCHealth Research Administration Resources page. At the top, the header includes the UCHealth logo, 'Microsoft 365', a search bar labeled 'Search this site', and user information 'Kwan, Bethany (G...)' with initials 'KB'. Below the header is a navigation menu with items: 'The Source', 'Find Resources', 'Clinicians', 'Cafes', 'Connect', 'Who We Are', 'Help Me With...', and 'My...'. The main content area is titled 'Research Administration' and features a grid of 18 resource cards. A 'Resources' sidebar on the right lists: 'Contact Us' (Email us at UCH-ResearchAdmin@uchealth.org), 'Research Administration Contacts', 'Systemwide Research Collaboration', and 'UCHealth Fact Sheet FY2023'.

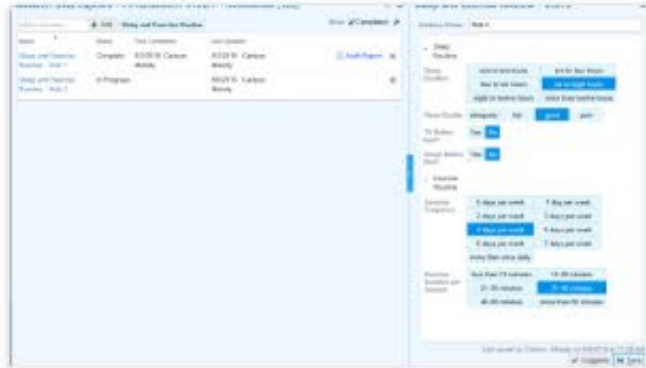
Resource	Resource	Resource
RECRUIT Tools	Decedent and Pre-Research	PI Research Essentials
Medicare Coverage Analysis (MCA)	Research Pricing	UCHealth Clinical Services
Onboarding & Applications	Language Proficiency Certification	Epic Tools
Data Capture in Epic	Letters of Support	EHR Access Requests
Operational Data Requests	Investigational Products	OnCore (CTMS)
Policies and Procedures	Research Related Injury	Help and Contacts

UCHealth Research Administration Resources

Research Coordinator- My Studies Dashboard

External Registries

SmartTools, SmartTexts, and SmartPhrases - Oh My!



Data Capture



EHR-Embedded Research



Adverse Event Documentation

Linking Encounters

How to obtain Epic access

Research Data Requests



Research Expo: Bringing Epic functionality to study teams!

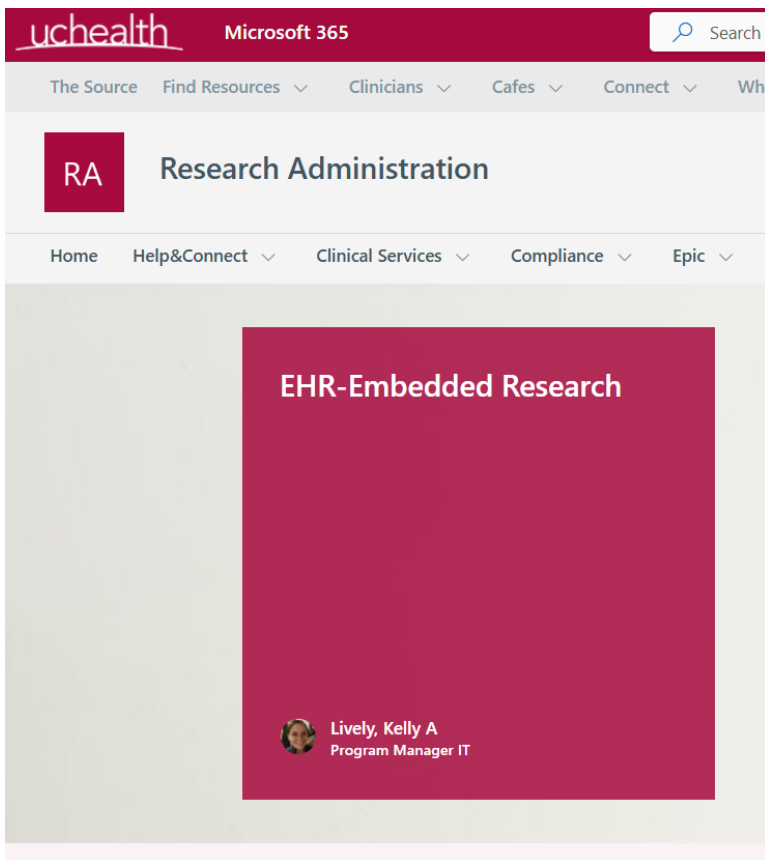
myuch.sharepoint.com

Epic is UCHealth's electronic health record (EHR). For researchers, we have multiple resources and tools in Epic. Please join this webinar series for an in depth exposure to different Epic tools and resources. These tools are designed to enhance study execution and ensure efficient documentation and maintenance of study activities.

Past Research Expo Webinars- Session Recording & Slides

[Research Exp_Updated Epic Functionality &](#)

UCHealth Research Administration Resources



What types of requests should be submitted through this process?

Projects that involve...

- EHR-embedded applications
- Integrations
- Interfaces
- Devices that collect protected health information (PHI)
- Devices that need to connect to the UCHealth network
- Patient or provider-facing tools
- Artificial intelligence
- Customizing native Epic functionality for research use unless excluded below
- Native Epic functionality that exceeds 10 hours of build effort

What types of requests do **not** need to be submitted through this process?

Requests for...

- [E-consents](#)
- [Recruitment lists](#)
- [Research data capture forms](#)
- [Flowsheets](#) (if *only* requesting a flowsheet)
- PEET projects

Elements required before build can begin (many of these can be done simultaneously)

- Human Subjects Research Portal submission
- IRB approval with appropriate consent/waiver and HIPAA authorization/waiver
- Research Administration review/approval
- Research Integrated Team (RIT) review/approval
- Enterprise Architecture (EA) review/approval

Whether you're seeking an LOS for a grant, or you're ready to get started on your project, kick off the process by submitting a request!


[Submit a Request](#)

Resources

-  [Process Diagram \(Visio\)](#)
-  [Research builds in Epic Guiding Principles-FINAL](#)
-  [Vendor Agreement Template](#)

Research Expo: EMR-Embedded Research

Webinar Session Recording & Slides

-  [Research Expo: EMR-Embedded Research Webinar Recording](#)
-  [Research Expo: EMR-Embedded Research Slide Deck](#)

Pragmatic Research Education & Resources



Pragmatic Research Resources

What is Pragmatic Research?

Pragmatic research spans a wide variety of research activities, and research can be more or less pragmatic in different ways. Pragmatic research:

- Includes research activities ranging from pragmatic clinical trials (focusing on testing interventions and procedures at the patient level) to testing interventions and models of care at the practice and system level, with consideration of health system and policy contexts
- Helps support decisions by service and care providers – and policy makers, patients, and other interested parties – on whether and in what context to adopt, deliver or make use of an intervention
- Usually includes biostatistics and study design, technology integration, data and informatics tools, D&I science, qualitative and mixed methods, partnership development, and community and stakeholder engagement

Use the tabs below to learn more about resources, education and consult requests available to CCTSI investigators to support pragmatic research.

We partner with [ACCORDS Education](#) and the [Pragmatic Research and Trials Core](#) for [pragmatic research consultations](#).

Cite Our Grant

Resources Overview

Clinical and Translational Research Centers (CTRC)

Info for Your Grant Applications

Translational Informatics

Biostatistics, Epidemiology, and Research Design (BERD)





Trial Innovation Network (TIN)

Research Ethics

Research Studio Program

Find a Researcher (PROFILES)



 Pragmatic Trials Resource Navigation	 Education	 Consultations	 Pragmatic EHR-Embedded Trials
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PEET Demonstration Project Request for Applications (RFA) Optimization

Project 1 – 1
proposal (in
UM1)

Project 2 – 7
invited project
concepts, 2 full
concept papers

Project 3 – 1st
RFA; 5 letters of
intent, 4 full
proposals

Request for Applications (RFA)

The RFA describes eligibility and application requirements

[View the PEET 2026 RFA Here](#) ↗

[Intent to Apply](#) ↗

Information & Resources

If you have any questions about eligibility or the application please [contact Sarah Kautz](#), PEET Program Coordinator.

[View the 2026 Grant Application Checklist](#) ↗

[View the 2026 Required Budget Template](#) ↗

[View the PRECIS-2 Scores and Figures](#) ↗





Customer Discovery Interviews

School/Unit	Interviewees
CU School of Medicine	14
Colorado School of Public Health	2
CU School of Pharmacy	1
CU College of Nursing	2
Colorado State University	2
TOTAL	21

Approach: use ‘customer discovery’¹ approach to learn about real/perceived barriers to PEET-type research generally, and PEET RFA specifically

Audience: Investigators who engage in PEET and PEET-type studies

- Past RFA applicants, researchers identified using CU Profiles, and snowball sampling
- 21 interviews completed (Aug/Sep 2025), focusing on investigators’ key pains, gains and ‘jobs to be done’ in PEET-type research
- Findings synthesized using the Value Proposition Canvas²



PEET Demonstration Project Request for Applications (RFA) Optimization

- Modified eligibility criteria
 - 2025: Principal Investigators must be Associate Professors or above with at least one R01-equivalent research award. Multiple Principal Investigators (MPIs) may be included; MPIs can be later-stage Assistant Professors (3+ years at rank) or above.
 - 2026: Contact Principal investigators (PI) must be Associate or Full Professors with an established track record of obtaining research funding awards as a PI. There can be up to two multiple PIs (MPI), which includes the contact PI; MPIs must be at least at the Assistant Professor level.
- Updated communication & marketing plan
- Formatting & clarifications regarding what “counts” as a pragmatic EHR-embedded trial
 - The PEET program funds pilot trials that are: (1) pragmatic clinical trials of interventions expected to impact patient health outcomes, with patient health outcomes assessed as either primary or secondary outcome measures; (2) conducted within UCHHealth; (3) involve one or more Epic EHR integration features. EHR integration features of interest include cohort identification, recruitment, e-consent, randomization/group assignment, intervention delivery, accrual tracking, and/or outcomes assessment via the Epic EHR or affiliated databases such as Health Data Compass; and (4) are not currently funded or underway.



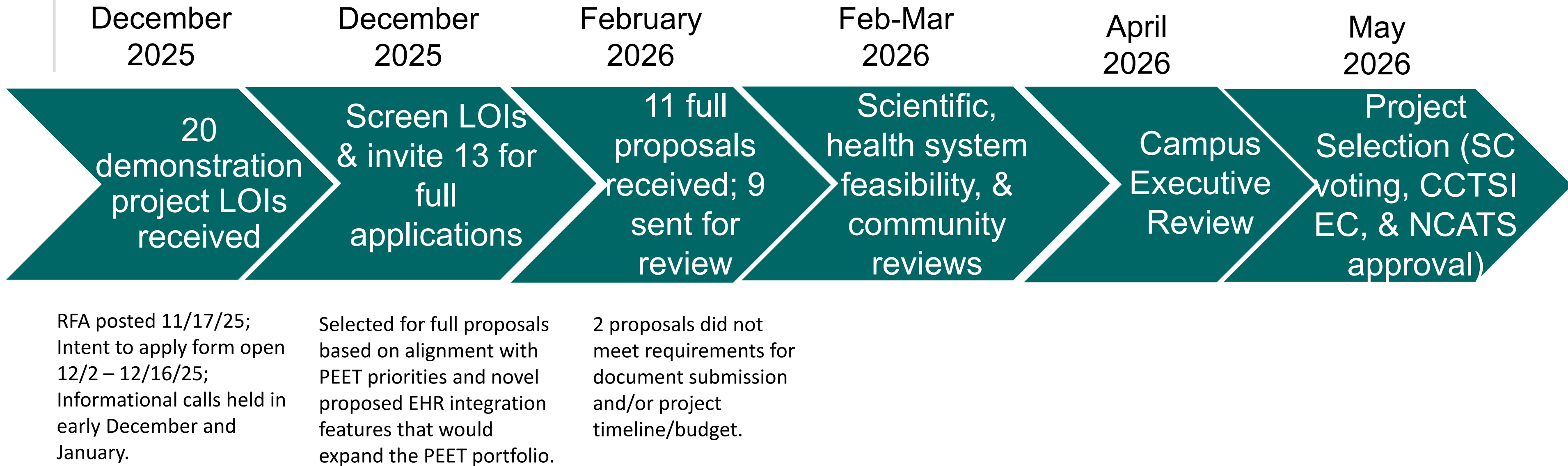


RFA Communication & Marketing Plan

Audience	Key Messages
Experienced UCHHealth-affiliated clinical investigators	<p>PEET demonstration project grants help you implement your intervention and access research quality data .</p> <p>These grants are more than just funding – they include Epic facilitation and dedicated data/informatics support to help your study succeed.</p> <p>PEET demonstration projects benefit from fast-tracked UCHHealth approval processes, and the PEET team helps overcome barriers to Epic feasibility review.</p>
Early-career UCHHealth-affiliated clinical investigators	<p>A PEET demonstration project grant can help you build your research CV as an MPI .</p> <p>The PEET team provides support in building the expertise and relationships you need to conduct pragmatic, EHR-embedded trials at UCHHealth.</p>
CCTSI clinical investigators NOT affiliated with UCHHealth	<p>A PEET demonstration project grant is an opportunity to expand your collaborative network, and conduct research in UCHHealth’s large patient population</p> <p>These grants are more than just funding – they include Epic facilitation and dedicated data/informatics support to help your study succeed.</p>



Demonstration Project 4 Solicitation & Review



Demonstration Project #4: Letter of Intent Topics

Topics addressed in LOIs:

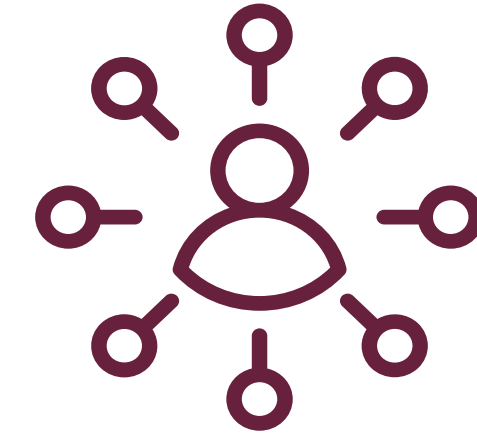
- Mental health
- Infectious disease/antibiotic stewardship
- Chronic disease management
- Medication safety
- Emergency and acute care
- Social determinants of health
- Digital tools for patient engagement



Proposed demonstration project EHR integration features



Cohort identification or tracking: **8**



Consults or referrals (including e-referrals/routing): **6**



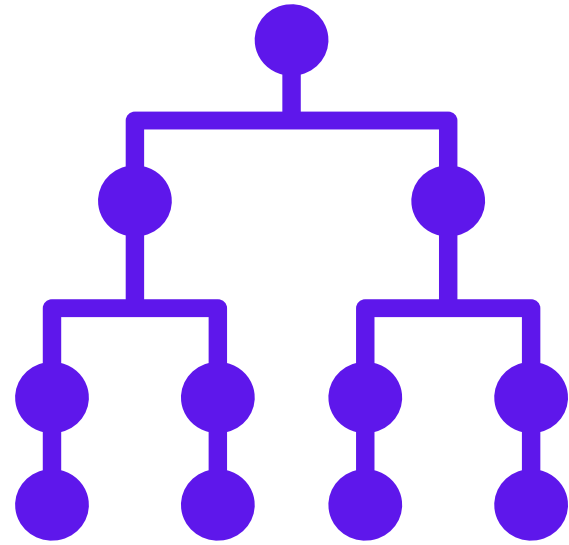
Patient portal or app delivery and messaging (MyChart): **7**



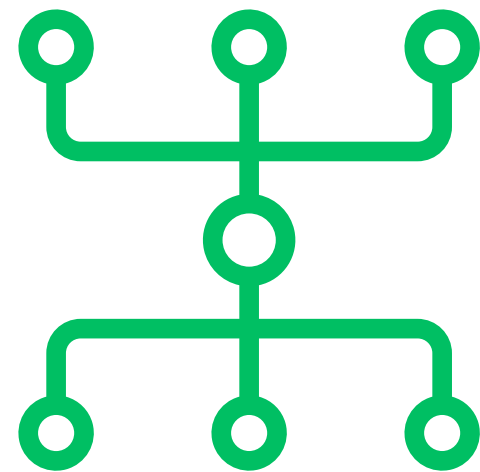
E-consent: **3**



Proposed demonstration project EHR integration features



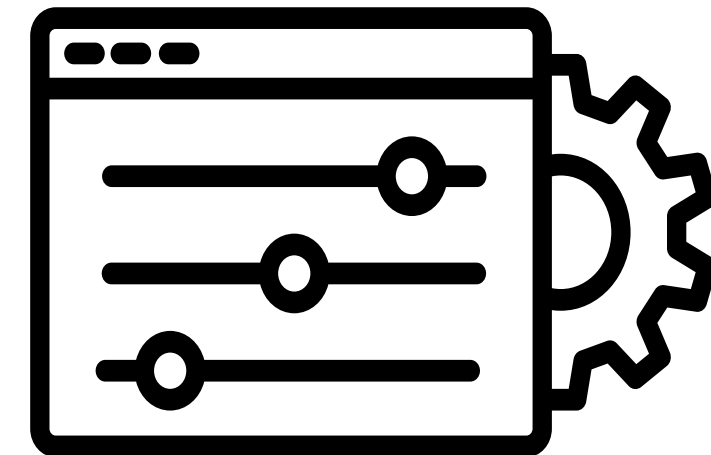
Randomization in the EHR: **5**



FHIR/SMART/APIs: **5**



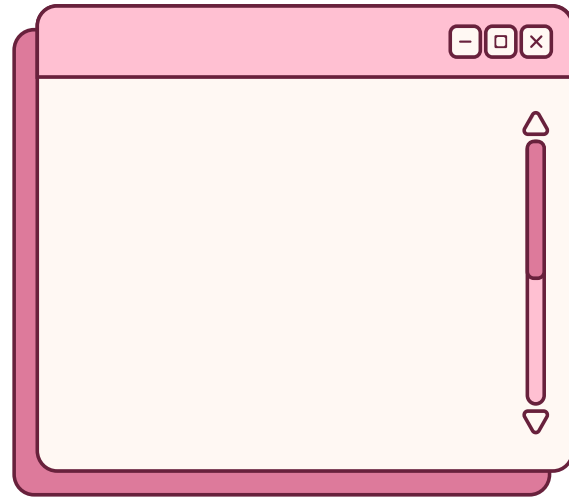
Clinical decision support
(OPAs/alerts/nudges/advisories): **5**



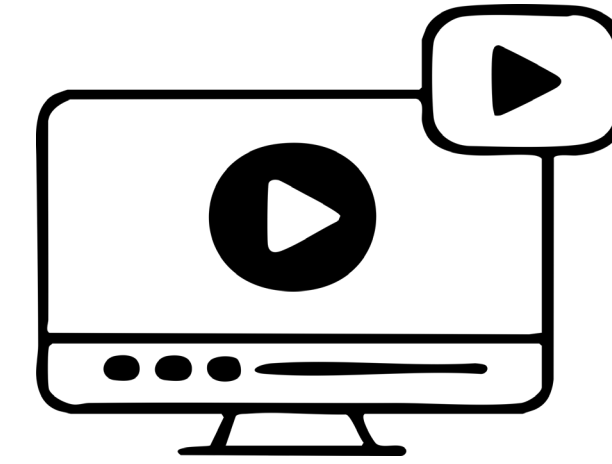
Ordersets/defaults/workflows
(SmartSets, panels, pre-populated): **5**



Proposed demonstration project EHR integration features



Epic UI elements
(lists/flowsheets/pop-ups): **3**



Embedded EHR content
(videos/roadmaps/decision aids): **3**



PROs/PROMIS questionnaires: **3**



Dashboards or analytics: **6**

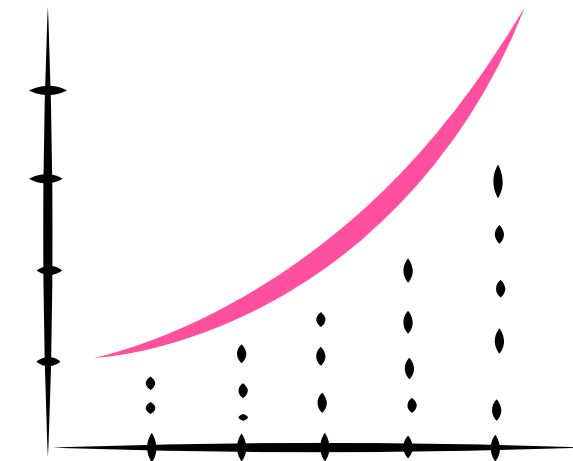
Proposed demonstration project EHR integration features



Embedded risk score/calculator: **2**



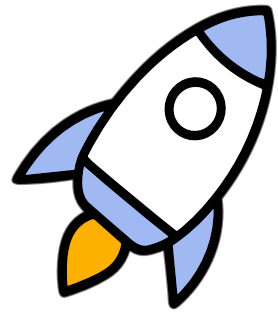
Device data integration
(wearables/CGM): **2**



Outcomes capture from EHR: **5**

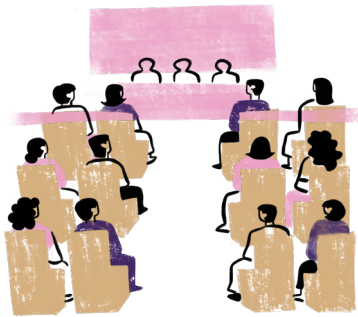
Year 4 Plans

- **Demonstration Projects and Innovations in EHR-Embedded Trials**



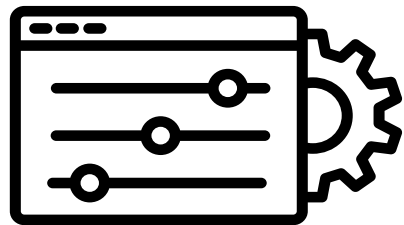
- Launch demonstration project 4
- Innovations in EHR integration features
- Solicit 5th demonstration project

- **Packaging and Dissemination of PEET Infrastructure, Governance, and Processes**



- UCHHealth and PEET panel seminar at Denver Health (September 23rd)
- Pragmatic EHR-Embedded Trials Panel at AMIA (under review)

- **Document, Optimize, and Disseminate EHR-Embedded Trial Processes**



- Finalize guidance materials
- Collaborate with UCHHealth to identify governance and process improvement opportunities

Response to EAC Critiques

- 1. As CCTSI learns more about how PEET works with inpatient studies, the team can consider assessing the value proposition for pragmatic EHR embedded trials. As the team reports, it did not reduce the effort or time for recruiting. It is possible that other types of trials may have greater success, including T4 trials or trials to bypass clinicians and directly recruit patients. Interviews with researchers, informatics team members, clinicians, and patients who have participated in the two prior trials or who may want to use PEET for future trials may help in better understanding the long-term value of the approach:**
 - There are many ways in which PEET-type studies can be implemented
 - PragMet team lessons learned regarding patient recruitment may not be generalizable now that the university has adopted the RECRUIT tool
 - Projects 2 and 3 allowed for automatic cohort identification and included waivers of informed consent
- 2. The CSRN team could benefit from the lessons of the PEET team. Reconnecting given that the Vanguard trial will launch June 2, 2025, might be useful for both teams for improving EHR-based recruitment:**
 - We connected with the local Vanguard trial team to explore opportunities for sharing lessons learned. While we had interesting discussions, it became clear that there was limited alignment between the two initiatives.

