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

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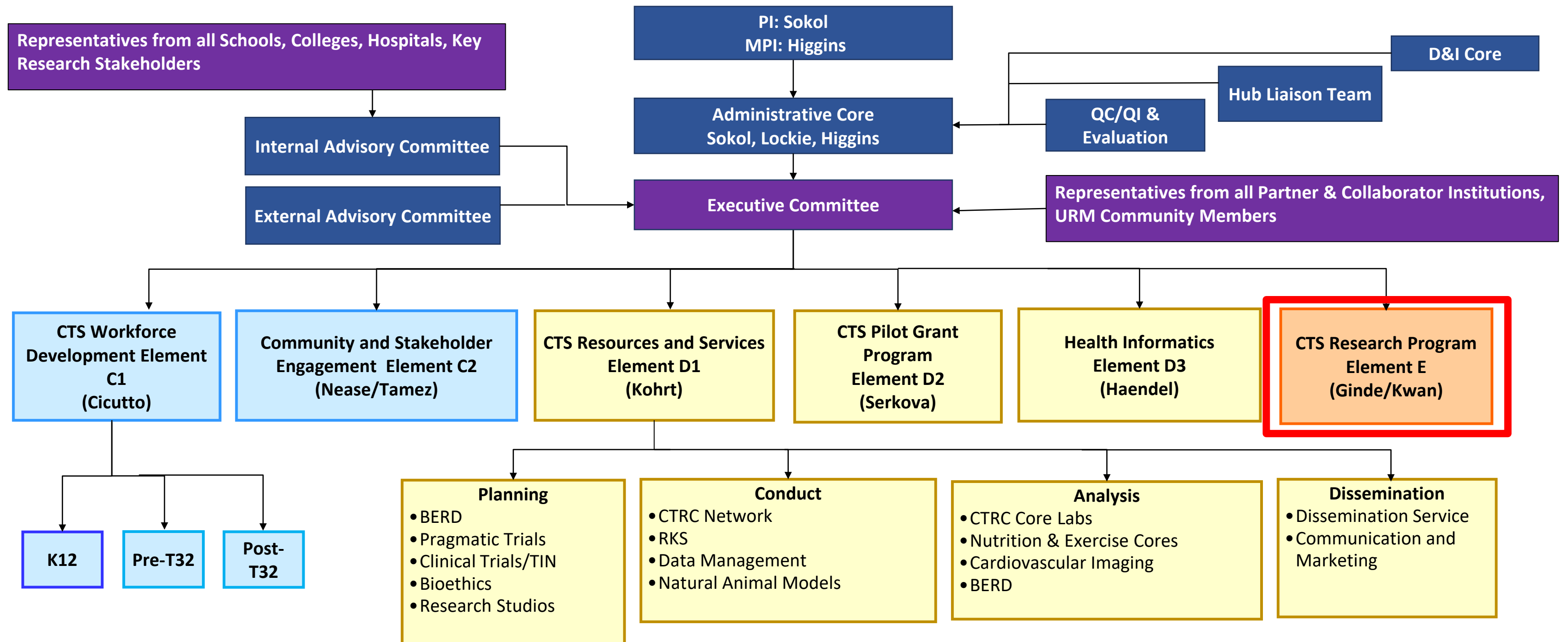
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CCTSI

Colorado Clinical and Translational Sciences Institute (CCTSI)

UNIVERSITY OF COLORADO **DENVER | ANSCHUTZ MEDICAL CAMPUS**

Integration Across CCTSI

Leadership Team & Diversity

Element E Co-Lead
Adit Ginde, MD, MPH
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Bethany Kwan, PhD, MSPH
Director of D&I Research Core, CCTSI

Element E Demonstration Project 1 PI
Thomas Flaig, MD
Vice Chancellor for Research, CU Anschutz

Program Manager
Lindsay Lennox
Program Manager, D&I Research Core & PEET, CCTSI

Research Svcs Professional TBN
Research Services Professional (Senior or Principal), CCTSI

ELEMENT E (PEET Program)
50% Female or nonbinary   33% PhD or other

CTS Roadblocks Addressed

1. **High participant and provider burden, costs and resources** associated with randomized, controlled clinical trials (RCTs)

2. **Lack of community engagement and health system expertise,** limiting access to studies for rural and minority populations and hospitals/clinics outside of urban, academic centers

3. **Challenges harnessing health system IT infrastructure** to review and prioritize requests for EHR-embedded trials

Strategic Goals

1. **Goal**: Build the PEET Research Program infrastructure and governance needed for prioritization and support of proposed Pragmatic EHR-embedded Clinical Trials throughout the UCHealth system.

   - Roadblocks addressed: participant/provider burden/cost/resource needs, health system integration, hospital IT expertise

2. **Goal**: Engage community partners in co-design of user guidance materials and protocols for implementation of PEET infrastructure and "designing for dissemination" across the CTSA consortium.

   - Roadblocks addressed: community engagement and access

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.

   - Roadblocks addressed: participant/provider burden/cost/resource needs, health system integration, hospital IT expertise

Health Equity Goals

1

Accessibility

By reducing the administrative burden of pragmatic trials across the UCHealth system, we will provide increased access to patients receiving care outside University of Colorado Hospital, including rural populations.

2

Diversity

We will engage communities to co-design and implement patient-centered protocols, including recommended e-consent adaptations and alternatives, that will enhance diversity in trial participation.

3

Inclusivity

We will develop automated study dashboards to allow PIs to monitor diversity in trial participation in real time and adapt recruitment strategies as needed to ensure trials are inclusive.
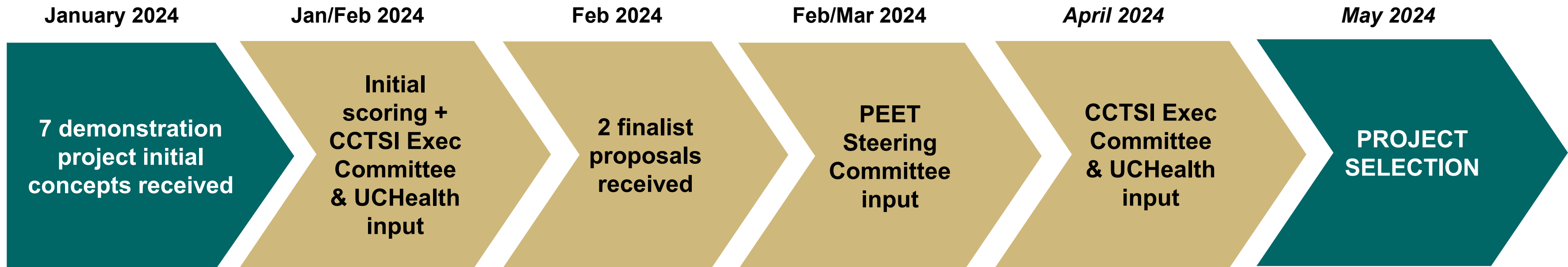
Year 1 Progress & Impact

- ***PEET Demonstration Project 1:** "A Randomized, Pragmatic, Adaptive trial of Metformin for Glucose Intolerance or Increased Body Mass Index in Prostate Cancer Patients" (PI: Flaig)*

- **Engaged transdisciplinary UCHealth-CCTSI team** (leadership, informatics, regulatory, research administration) to define PEET infrastructure scope and resource needs, ensure strategic alignment for demonstration projects

- Invited concepts for **second demonstration project** to support momentum while developing formal review and RFA process – final project selection in May 2024, with input from PEET Steering Committee, UCHealth and CCTSI leadership

- **Confirmed membership and convened PEET Steering Committee** to review demonstration project concepts

- Added a **Program Manager** (0.2FTE), and conducted a search for a full-time **Program Coordinator**

Demonstration Project 2

January 2024	Jan/Feb 2024	Feb 2024	Feb/Mar 2024	April 2024	May 2024
7 demonstration project initial concepts received	Initial scoring + CCTSI Exec Committee & UCHealth input	2 finalist proposals received	PEET Steering Committee input	CCTSI Exec Committee & UCHealth input	PROJECT SELECTION

- OCCULT O2 Project
- Silence Lp(a) prescreen mini-protocol
- ED fall risk mHealth intervention
- Heart failure mHealth intervention
- Naloxone CDS / Epic randomization
- Embedded dementia caregiver intervention
- GLP-1 agonists for gestational diabetes
- Combined proposal: ED fall risk mHealth intervention + embedded dementia caregiver intervention

- OCCULT O2 Project
- Combined proposal: ED fall risk mHeath intervention + embedded dementia caregiver intervention

Demonstration Project 2 Finalists

Optimizing Care in Critically ill at UCHealth by Liberalizing the Target O_2 in mechanically-ventilated ICU patients (OCCULT O_2 Project)

Project Team:
Neil Aggarwal, MD (Associate Professor, Dept of Medicine)
Peter Sottile, MD (Assistant Professor, Dept of Medicine)

Specific Aims:

- **Aim 1:** To determine the effectiveness of a multimodal educational and remote monitoring (via VHC RT) intervention targeting a pre-specified, standardized SpO_2 target range to decrease ventilator length of stay and also impact other patient-centered endpoint among mechanically ventilated (MV) patients.

- **Aim 2:** To determine whether a higher SpO_2 target range (90-96%) using a hospital-level, cluster randomized trial (Phase 1) can reduce the incidence of hypoxia, hyperoxia, and occult hypoxemia (OH) as compared to current standard of care.

- **Aim 3**: To iteratively develop and evaluate OH reduction effectiveness of an EPIC-embedded clinical decision support tool

Embedded Risk Assessment Nudge to Livi Chatbot Linkage for Resources

Project Team:
Hillary Lum, MD, PhD (Associate Professor, Dept of Medicine)
Elizabeth Goldberg, MD, ScM (Associate Professor, Dept of Emergency Medicine)

Specific Aims:

- **Aim 1:** Refine and implement Ask and Connect pathways to link at-risk older adults with caregiving support or falls resources. We will iteratively refine Epic tools among patients, care partners, and clinical staff (n=5 each) to optimize use and acceptability to our target population.

- **Aim 2:** Assess feasibility, usability, and acceptability of each pathway at four weeks in n=30 older adult patients/care partners (n=15 per pilot) at UCHealth Seniors Clinic. To assess feasibility including estimates of reach and representativeness, we will measure delivery of each pathway to patients/care partners and engagement with Livi Chatbot

- **Aim 3:** Test the impact of delivering the Ask and Connect pathways on pragmatic outcomes important to patients/ care partners at four weeks. We will implement use over a 6-month demonstration period with an estimated reach of n=~250 care partners and n=~200 patients with a fall-related ED visit. Patients randomized to control receive online educational resources, instead of a link to Livi.

Demonstration Project 2 Evaluation Rubric (Finalists)

PEET Demonstration Project Evaluation Matrix	OCCULT O2 Project	Embedded Risk Assessment Nudge
Minimum requirements		
Meets definition of a pragmatic-EHR embedded trial?	Yes	Yes
Patient-level treatment / intervention?	Yes	Yes
Phase 2 clinical trial or equivalent?	Yes	Yes
Not currently funded or underway? (No overlap)	Yes	Yes
Adult, UCHealth population?	Yes	Yes
Readiness to launch (within 3 months)	Yes	Yes
Short duration to completion (2 years)	Yes	Yes
Meets minimum requirements?	Yes	Yes
EHR integration		
Cohort identification	Yes	Yes
Recruitment	Yes	Yes
Consent	No	No
Randomization / group assignment	Yes	Yes
Intervention delivery (including connection to external tools/resources)	Yes	Yes
Real-time dashboards	Yes	No
Final data collection	Yes	Yes
Patient/participant-reported outcomes	Yes	Yes
Other (please specify)		
EHR integration score	7	6

Research Innovation, Rigor & Impact	1 (best) to 9 (worst)	1 (best) to 9 (worst)
Innovation (builds upon the existing evidence in an innovative way; enables innovative approaches and/or infrastructure for the PEET program)		
Rigor (study design, methods, measures, data collection, and analysis are likely to lead to valid and generalizable conclusions)		
Impact (important topic, addresses a significant problem, addresses health equity, will directly inform clinical practice, leverages an effective intervention or approach)		
Research Innovation, Rigor & Impact score		
Additional criteria		
Broad reach/potential for impact across UCHealth regions	5	4
CU/UCHealth distinguishing domain alignment*	4	4
UCHealth priority clinical area alignment**	3	4
Feasibility of study implementation in intended setting	4	3
Ease of cohort identification	5	3
Experienced/engaged champion (PI and PM)	3	4
No anticipated regulatory challenges	4	4
Additional criteria score (higher is better)	28	26

*Personalized medicine, targeted therapies, drug rescue, value-based care
**Cancer, transplant, brain health (neurosciences/psychiatry), orthopedics, cardiovascular

Year 2 Plans

- **Launch second PEET demonstration** project starting August 1, 2024; continue to work closely with both the Steering Committee and the UCHealth infrastructure group to support the development of clinical informatics infrastructure and governance

    - Document implementation processes and challenges in real time

- **Develop and launch formal RFA process** for future demonstration projects, in consultation with PEET Steering Committee and using customer discovery, value proposition design and usability testing to promote interest in the PEET RFA among investigators

- **Co-design user guidance materials and protocols** for implementation of PEET infrastructure by engaging with health providers, patients and health system leadership, with a focus on trust and equitable participation, and addressing concerns about electronic consent processes

Response to EAC Critiques

1. *Continue to develop workflows for more intensive projects where clinicians are "engaged in research" and some where it is minimally- or non-intrusive and clinicians are not engaged in research*:

We are continuing to document and develop workflows for both more intensive (Project 1) and minimally intrusive (Project 2) demonstration projects.

2. *Approach as a learning opportunity with the expectation that the design and functions will evolve from projects and lessons learned; share broadly across CTSA hubs nationally*:

The approach for all PEET demonstration projects is iterative learning and dissemination of lessons learned to other health systems and across CTSA hubs nationally.

Questions for EAC

1. How and when should we bring less experienced investigators/teams into the demonstration projects?

We would like to expand PEET capabilities to less experienced investigators/teams, while ensuring the experience goes well/smoothly with the health system partnership.

2. What types of generalizable lessons learned would be most beneficial to document and disseminate across CTSA Hubs nationally?

We would like to focus these activities on areas that would optimally support national dissemination (in addition to informing local processes)