



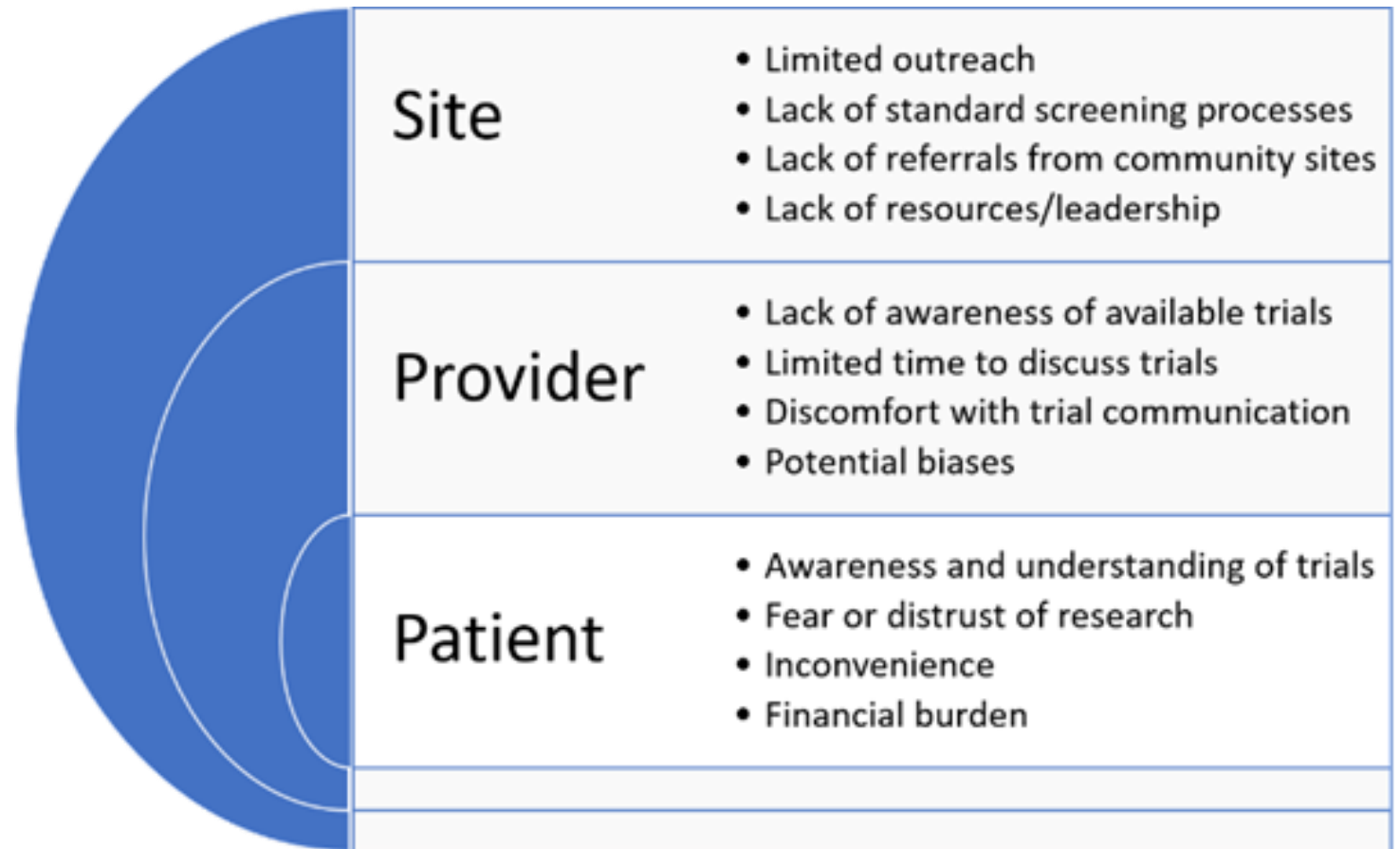
# CUSP2CT: Connecting Underrepresented Populations to Clinical Trials

*Clinical Trials and Translational Research  
Advisory Committee*

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Center for Cancer Health Equity

# Multilevel Barriers to CT Referral of Racial and Ethnic Minorities

- There are multiple barriers at different levels that keep racial and ethnic minority patients from being referred to Clinical Trials (CTs)
- It is necessary to address barriers at all levels to impact referral, and future recruitment into CTs using an integrated team approach



# Strategies to Increase Participation in Clinical Trials



## Prioritize Inclusive Community-Engaged Research

- Involving community as equal partners
- Conducting needs assessments
- Optimizing inclusive consent, recruitment, and retention strategies
- Building trust and maintaining relationships



## Establish Metrics and Evaluate Impact

- Implementing multifaceted approaches for evaluating:
- Scientific outcomes
  - Clinical trials
  - Patient health and behavioral outcomes
  - Community engagement (reach, collaborations, partnerships, education, awareness, etc.)



## Build Academic and Community Partnerships

- Leveraging resources, facilities, and expertise
- Championing community health workers and educators to establish programs, projects and community events
- Assessing collaboration readiness/processes



## Promote Bidirectional Communication and Shared Decision Making

- Culturally tailoring mutually beneficial communication approaches
- Offering multi-channel communication platforms
- Leveraging catchment area data
- Reporting back results in a community-friendly manner

**CUSP2CT Purpose:** To **develop** and/or **adapt, implement, and evaluate** multi-level and culturally tailored outreach and education interventions with the primary goal to increase referral of racial and ethnic minority populations to NCI-supported clinical trials.

CUSP2CT enhances CT participation among racial and ethnic minority populations through integrated partnerships of healthcare professionals and collaborators

# The Definition of Clinical Trial Referral

A communication behavior or an action conducted by an individual (e.g., health care provider, clinical coordinator, lay health worker, patient caregiver (care partner, loved ones, friends and family, paid or unpaid, etc.)) to link a potential participant to a clinical trial.

# CUSP2CT: Enhancing Existing NCI CT Programs

## National Clinical Trial Network (NCTN)

Coordinates and supports cancer clinical trials at more than 2,200 sites

## NCI's Community Oncology Research Program (NCORP)

CT conduction and care delivery:  
7 Research Bases and 46 Comm Sites & 14 minority sites

## Experimental Therapeutics Clinical Trials Network (ETCTN)

Conducting early-stage trials of cancer treatment therapies

## Community Outreach and Engagement (COE)

Embedded within CCs, addresses cancer concerns in respective catchment areas

**CUSP2CT:** Enhances CT participation among racial and ethnic minority populations through a partnership of Community Health Educators (CHEs)/ Lay Health Advisors (LHAs), CT Coordinators (CTCs), and referring providers (PCPs and Oncologists)

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**Recommendation PA2.** *Identify and pilot tactics that have high potential to improve patient recruitment and retention, including for minority and underserved patients*

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The CUSP2CT Program supports the Recommended Implementation Actions for PA2:

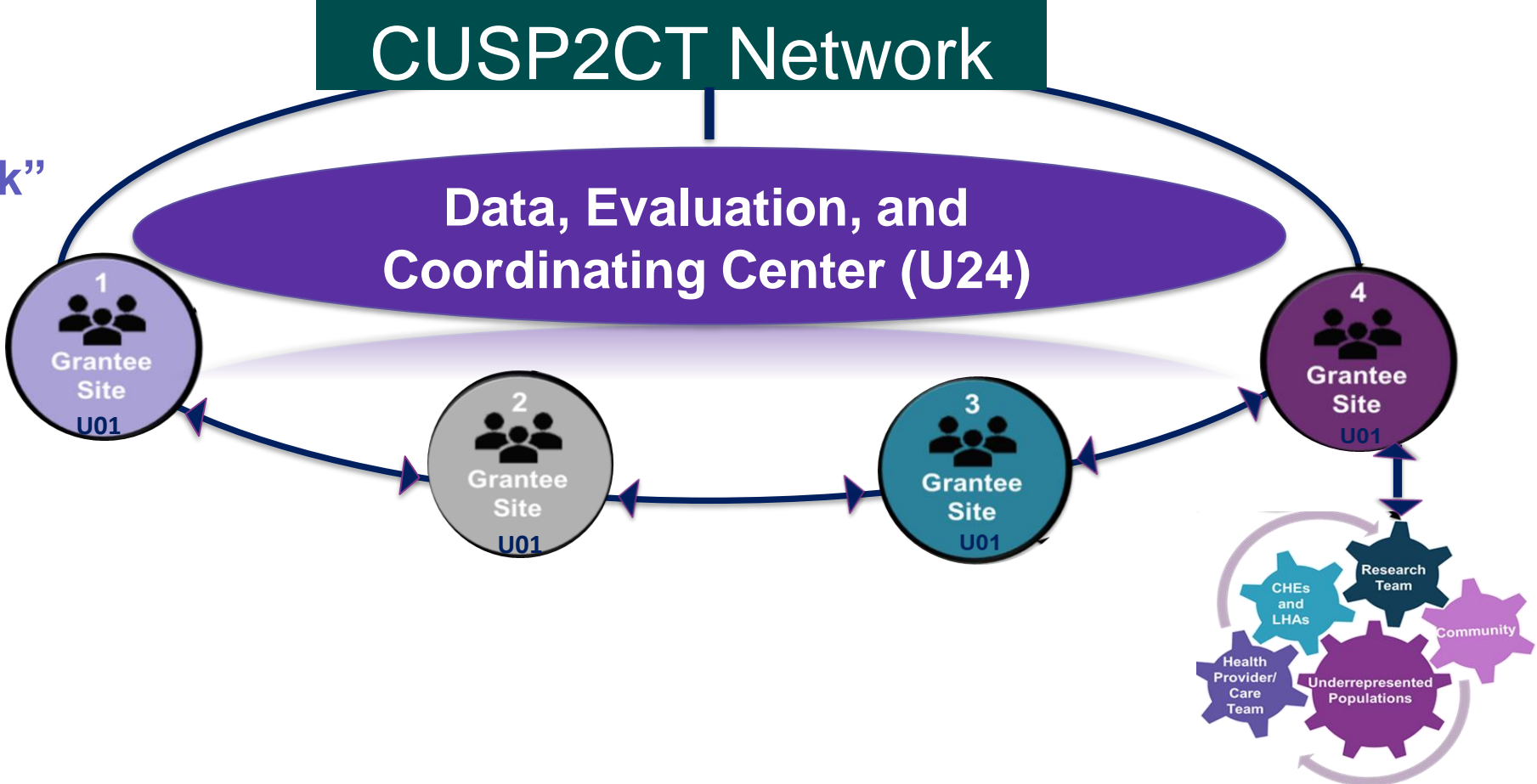
- Determine which multi-level strategies for CT participation are most successful
- Identify successful dissemination strategies
- Assess the potential value of new strategies that are of value to focal communities
  - Equitable communication
  - Outcomes valued by patients and communities
  - Expansion of workforce to ensure investigators and navigators are reflective of focal communities
- Implement strategies with flexibility and cultural humility

*Adapted from the 2020 NCI CTAC Strategic Planning Working Group report (page 19)*

# CUSP2CT Network Structure

## “Integrated Network”

The CUSP2CT Network is composed of a Data, Evaluation, and Coordinating Center (DECC), which connects and coordinates the grantee sites (U01s).



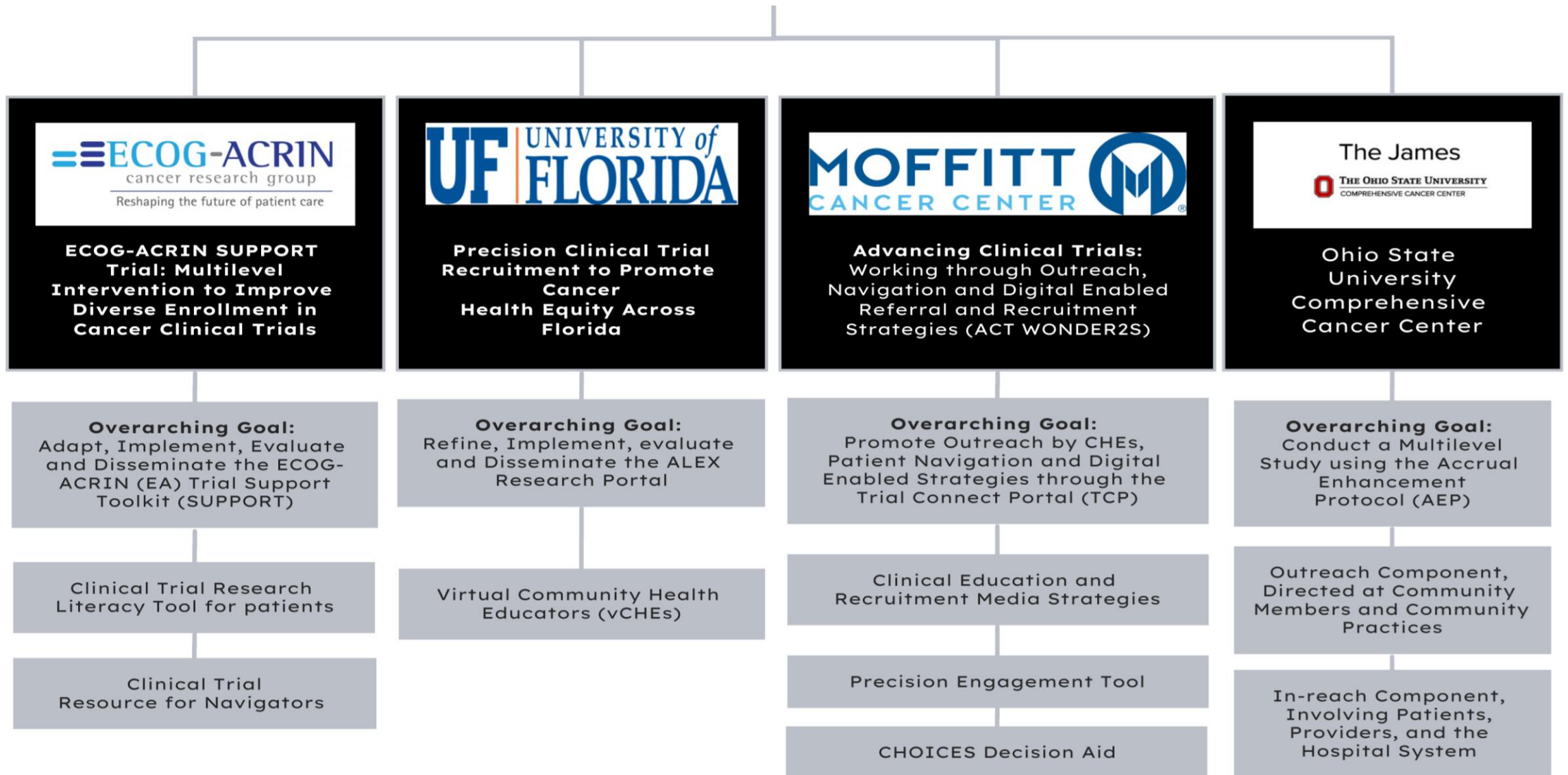


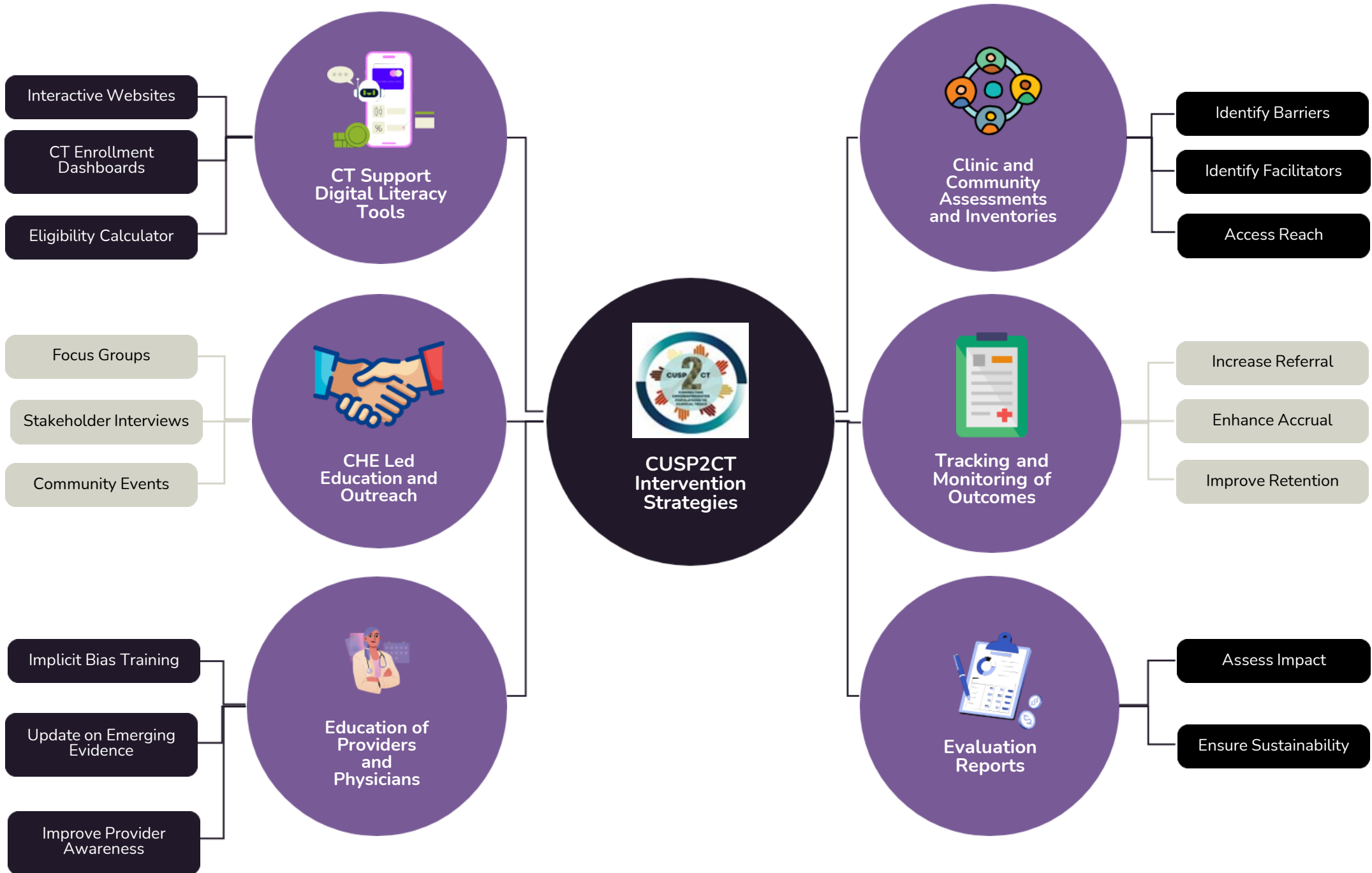
# Program Expectations of each U01 Grantee Site

- Leverage existing partnerships and foster new partnerships with community-based organizations to collaborate in tandem with CHEs/LHAs
- Leverage existing partnerships and foster new partnerships with referring providers to enhance the identification of potential racial and ethnic minority referrals to CTs
- Identify available and appropriate CTs that have a strong potential for positively impacting cancer health disparities
- Establish baseline data regarding community members awareness and knowledge of CTs as well as referring providers' referral of racial and ethnic minority patients to CTs
- Implement, and evaluate novel multilevel interventions to enhance racial and ethnic diversity in NCI-supported (CTs)



# CUSP2CT Program U01 Sites





**CT Support Digital Literacy Tools**

Interactive Websites

CT Enrollment Dashboards

Eligibility Calculator

**CHE Led Education and Outreach**

Focus Groups

Stakeholder Interviews

Community Events

**Education of Providers and Physicians**

Implicit Bias Training

Update on Emerging Evidence

Improve Provider Awareness

**CUSP2CT Intervention Strategies**

**Clinic and Community Assessments and Inventories**

Identify Barriers

Identify Facilitators

Access Reach

**Tracking and Monitoring of Outcomes**

Increase Referral

Enhance Accrual

Improve Retention

**Evaluation Reports**

Assess Impact

Ensure Sustainability

# Intervention Example: Leveraging Artificial Intelligence (AI)

## ALEX: Agent Leveraging Empathy for eXams

- Increase referral of AA/B and H/L populations to CTs in FL
- Virtual Human Technology intervention including virtual CHEs (vCHEs)

## Aims & Intervention

- Assess baseline referrals and adapt scalable resources
- Implement and evaluate ALEX Research Portal with vCHEs, (n=350)
  - **Control:** Portal, CHEs + CT resources (n=175);
  - **Experimental:** Control + vCHEs (n=175)
- Disseminate ALEX portal using OneFlorida



Stefan H, Pratik, S, Bhavna A, Jiannyng H. (2019). Artificial Intelligence for CT Design, Trends in Pharmacological Sciences. 40 (8), 577-591.

# Site-Specific Referral Pathway



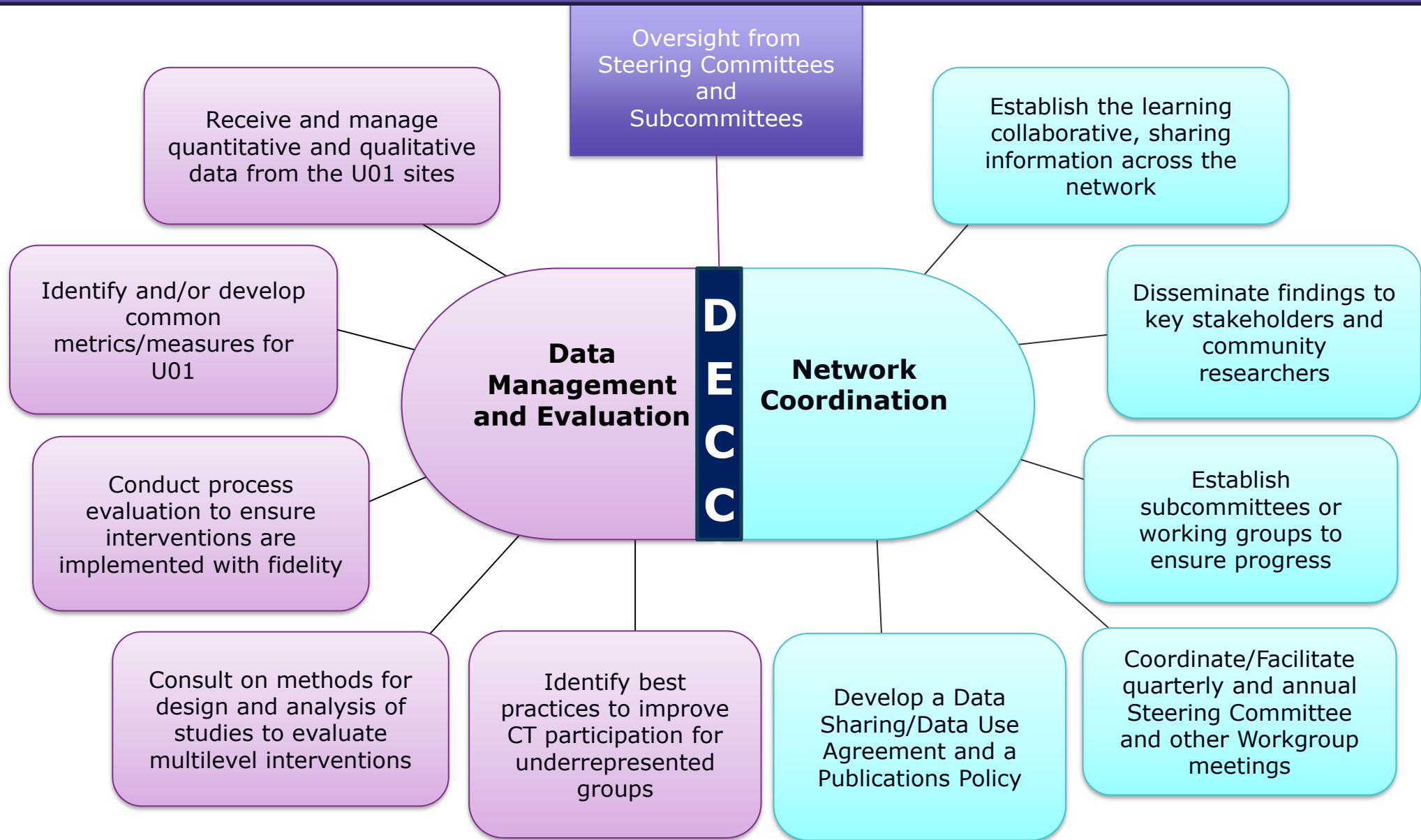
- 125 participants with or without CCT experience
- 350 *rural and ethnic/racial minority patients*
- Clinicians
- CHEs

- Review all active Cancer Clinical Trial (CCT) and **collect baseline data** on the rate and source of patient referrals to CCTs by clinicians, CHEs and patients/community members.
- **Stakeholder interviews** (community members, PIs and coordinators) to finalize intervention.
- **Deliver** educational information and model behaviors to rural and ethnic/racial minority patients through engagement **with the ALEX research portal**.
- **Evaluate** the effectiveness of a vCHE intervention for increasing referral to CCTs; specifically navigating Black and Hispanic adult cancer patients and their family members (from referral to CCT)

- Use of virtual human technology (VHT) to improve communication with and willingness to participate in clinical research.
- Leverage **technology** (ALEX research portal) and vCHE to navigate racial and ethnic minority patients to active CCTs using digital patient-navigation resources (vCHEs).

- Improve **eHealth literacy, behavioral intention to participate in CCT, clinical trial attitude, and personal relevance of CCT**.
- Improve **communication** with rural and ethnic/racial minority patients.
- Increase **willingness to participate** in clinical research
- Increased **clinical trial referrals and enrollments** among targeted racial/ethnic minority populations.

# Program Expectations of the U24 DECC





# THE DECC U24: Working Groups

**The U24 DECC at Mayo Clinic provides project management expertise for CUSP2CT network activities, including data management and analysis. The DECC has formed 3 active Working Groups to support program activities.**

## **Working Group 1:**

**Data Collection, Management, Statistical Analyses, Sharing and Research Dissemination**

- Provide Expertise for the Collection, Harmonization, and Management of Data
- Provide Support for Network-wide Program Evaluation
- Foster Data Sharing and Dissemination of Findings

## **Working Group 2: Program Evaluation**

- Foster Consensus Building Towards Shared Benchmarks, Metrics, and Measures
- Maintains Metrics
- Coordinated Program Evaluation Reports

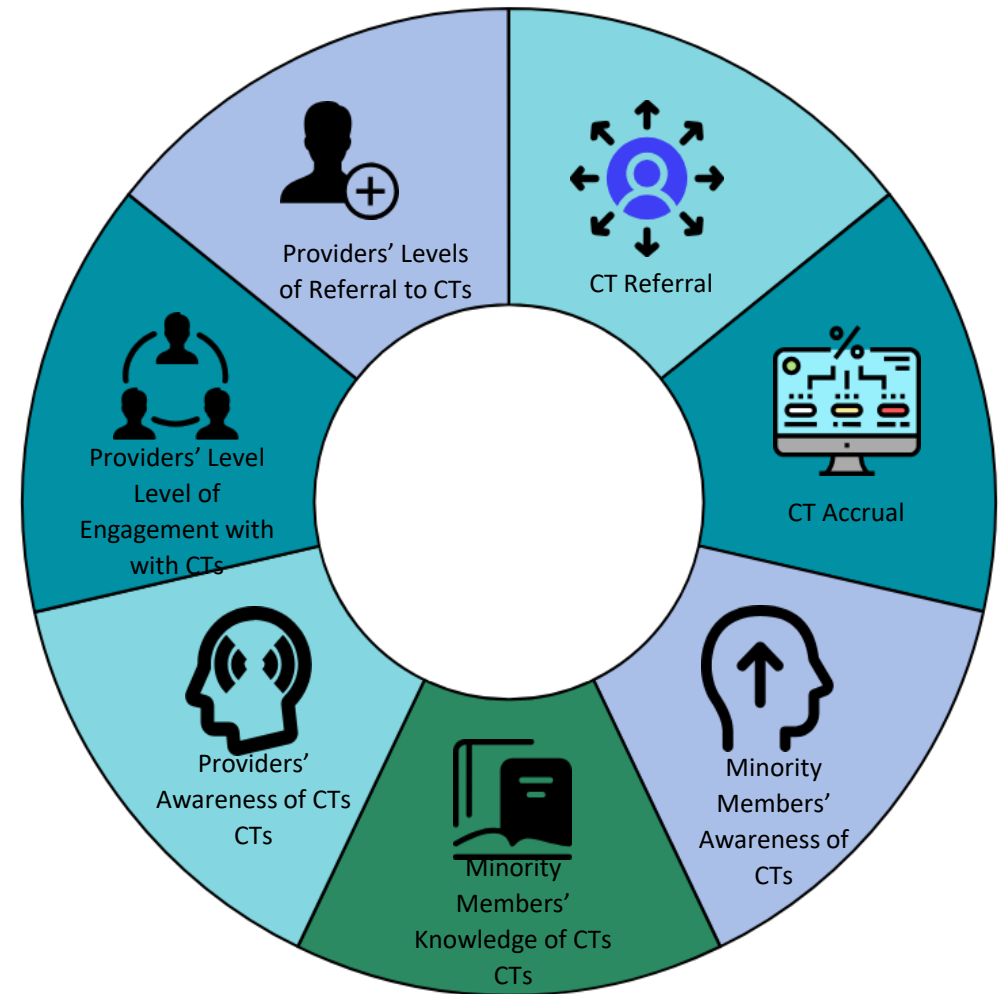
## **Working Group 3: Learning Collaborative**

- Facilitate Communication and Collaboration
- Develop Resources and Training Materials
- Disseminate Information to the Scientific and Public Communities

# Constructs and Common Data Elements

- The DECC is Working with U01 sites to establish Common Data Elements across seven constructs:

- CT Referral
- CT Accrual
- Minority Members' Awareness of CTs
- Minority Members' Knowledge of CTs
- Providers' Awareness of CTs
- Providers' Level of Engagement with CTs
- Providers' Levels of Referral to CTs





# CUSP2CT Communication and Community



## Engagement of Community Advisory Members

Active engagement of community representatives in discussions and decision-making processes for practical integration and implementation



## Developing Tailored Communication with Multichannel Approaches

Developing targeted materials and utilizing various dissemination channels to increase reach and impact across different audiences



## Gathering Qualitative Data

Gathering quantitative data on user preferences, information needs, and satisfaction to make informed decisions about content and functionality improvements



## Implementing Feedback Mechanisms

Establishing continuous feedback loops with audiences to refine and improve dissemination strategies to enhance the effectiveness and relevance of the communication efforts

# Community Participation at 2024 Annual Meeting

- Community-led presentations
- Community roundtable
- Participation in strategy/decisions



# Community Feedback from 2024 Annual Meeting

Category	Strategy	Description
<b>Engagement &amp; Connectedness</b>	1. Build Relationships	Listen & engage with community members
	2. Compensation	Offer fair compensation (e.g., monetary, transportation vouchers)
	3. Public Outreach	Use Public Service Announcements in newspapers, radio, community events
	4. Storytelling	Share testimonials, spotlights, host gatherings or other culturally responsive activities that encourage storytelling
	5. Community Leaders	Train charismatic leaders as health educators and community workers
	6. Community Events	Host health fairs and workshops to educate & recruit champions
	7. Community Reports	Disseminate community reports & health letters
<b>Decision-Making</b>	1. Inclusive Study Design	Involve community representatives in study design, planning, implementation, and evaluation
	2. Bi-Directional Communication	Encourage open dialogue, co-learning, thoughtful feedback
	3. Representative Voices	Ensure diverse community needs are represented

# CUSP2CT Accomplishments and Next Steps

## Accomplishments

- **U01** data collection and analysis being finalized
- **The DECC** formed three active working groups and the Steering Committee
- **Community members** as active participants
- **Consensus process** resulted in seven constructs
- **The definition of clinical trial referral** was operationalized

## Next Steps

- **Common Data Elements** will be finalized
- **Community members** will be continuously integrated into program activities
- **Interventions** implemented
- **Program evaluation** ongoing

# Thank you!

## Collaborators and Contributors

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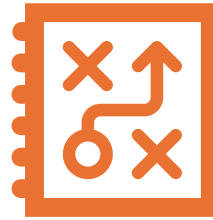
## The CUSP2CT Program Team

Drs. Whitney Barfield Steward, Sarah Szurek, Sandra San Miguel

# Discussion



How can we **better engage with CTAC** and leverage your expertise going forward?



How **responsive** is the CUSP2CT Program to the CTAC Patient Access recommendations?



What steps can we take to ensure **sustainability** of these efforts to preserve impact for years to come?

# Thank you!



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