

NCI Community Oncology Research Program (NCORP): Program Evaluation & Planned Modifications to the Reissuance

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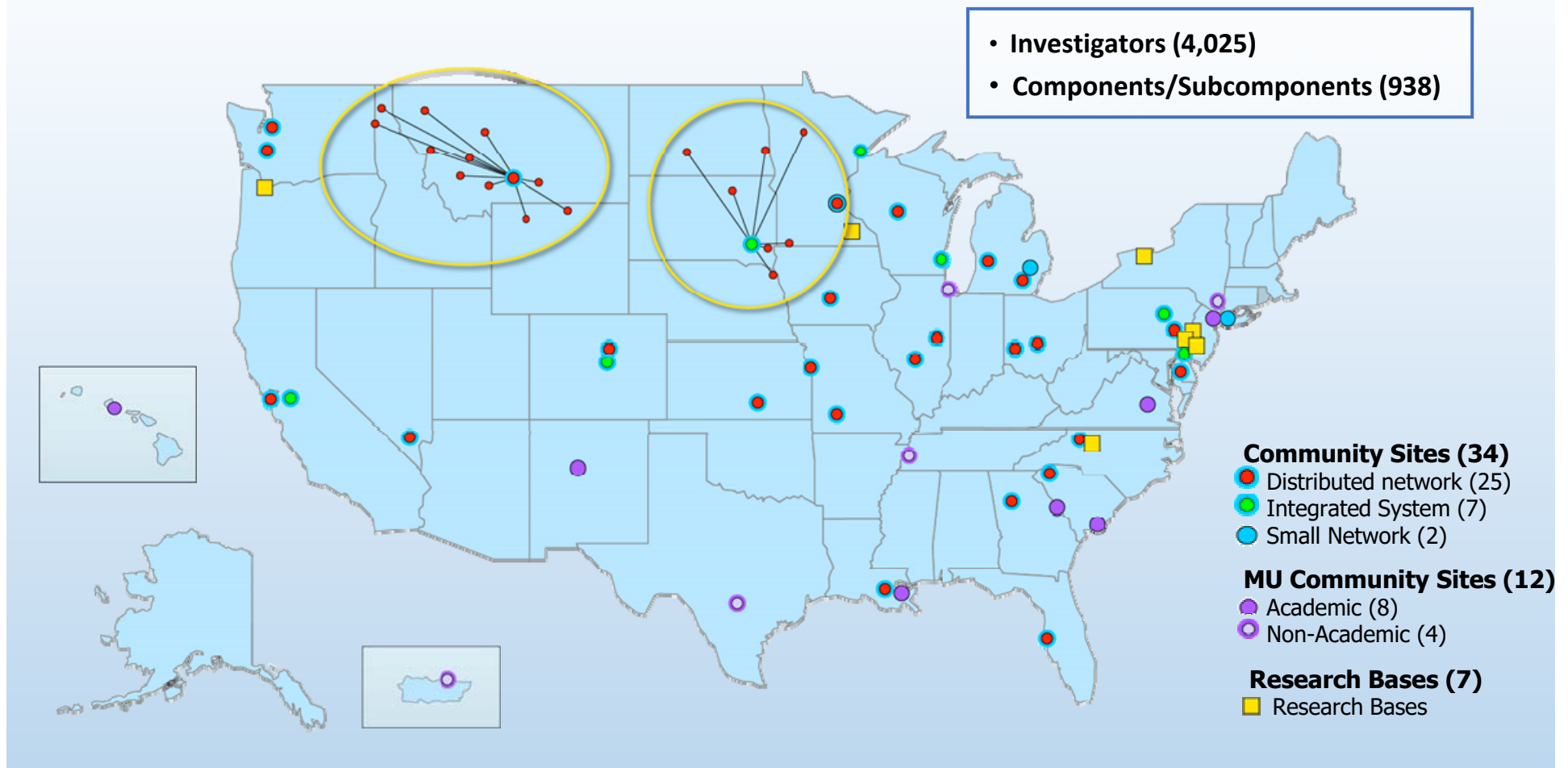
NCORP External Evaluation: Today's Discussion

- **Summary of the Evaluation Report**
- **NCI's Response to the Evaluation Report**
- **Proposed Modifications to the Program**

NCI Community Oncology Research Program

- Launched in 2014
- Community-based research network to bring state of the art trials and studies to individuals in their own communities
 - **Clinical trials** in prevention, symptom science, screening, surveillance, and QOL in treatment trials
 - **Accrual** to National Clinical Trials Network (NCTN) treatment and imaging trials
 - **Cancer care delivery** to develop clinical practices that achieve optimal clinical outcomes
 - **Cancer disparities** research questions integrated into clinical trials and cancer care delivery research

NCORP Community Site, M/U Community Site and Research Bases Geographic and Organizational Diversity



Updated: May 2017

Purpose of NCORP Evaluation

NCI requires an external evaluation as part of the funding opportunity renewal concept review package

- ✓ Assess whether the scientific contributions of NCORP support reissuance of the funding opportunity**
- ✓ Develop recommendations for enhancing the scientific and operational functioning of this community-based research program**

NCORP Evaluation Committee

Robin Zon, MD - Chair

Howard Bailey, MD

Joanna Brell, MD

Arnold Kaluzny, MD

Patrick Loehrer, MD

Nikhil Munshi, MD

Lisa Newman, MD

Gregory Reaman, MD

Mary Jackson Scroggins, Advocate

Memorial Hospital, South Bend, IN

University of Wisconsin Cancer Center

Case Western Reserve University

University of North Carolina

Indiana University Cancer Center

Dana Farber Cancer Institute

Henry Ford Health System

FDA

In My Sister's Care

1. Overall Scientific & Clinical Value and Impact

The Evaluation Committee concluded that NCORP has made important contributions in terms of scientific and clinical value and impact.

- Advancing symptom science and quality-of-life research**
- Stimulating cancer prevention & screening**
- Introducing the science of overdiagnosis**
- Contributing to NCTN trials**
- Stimulating new cancer disparities research initiatives**

1. Overall Scientific & Clinical Value and Impact

Response(s) to Recommendations/Plans for Reissuance

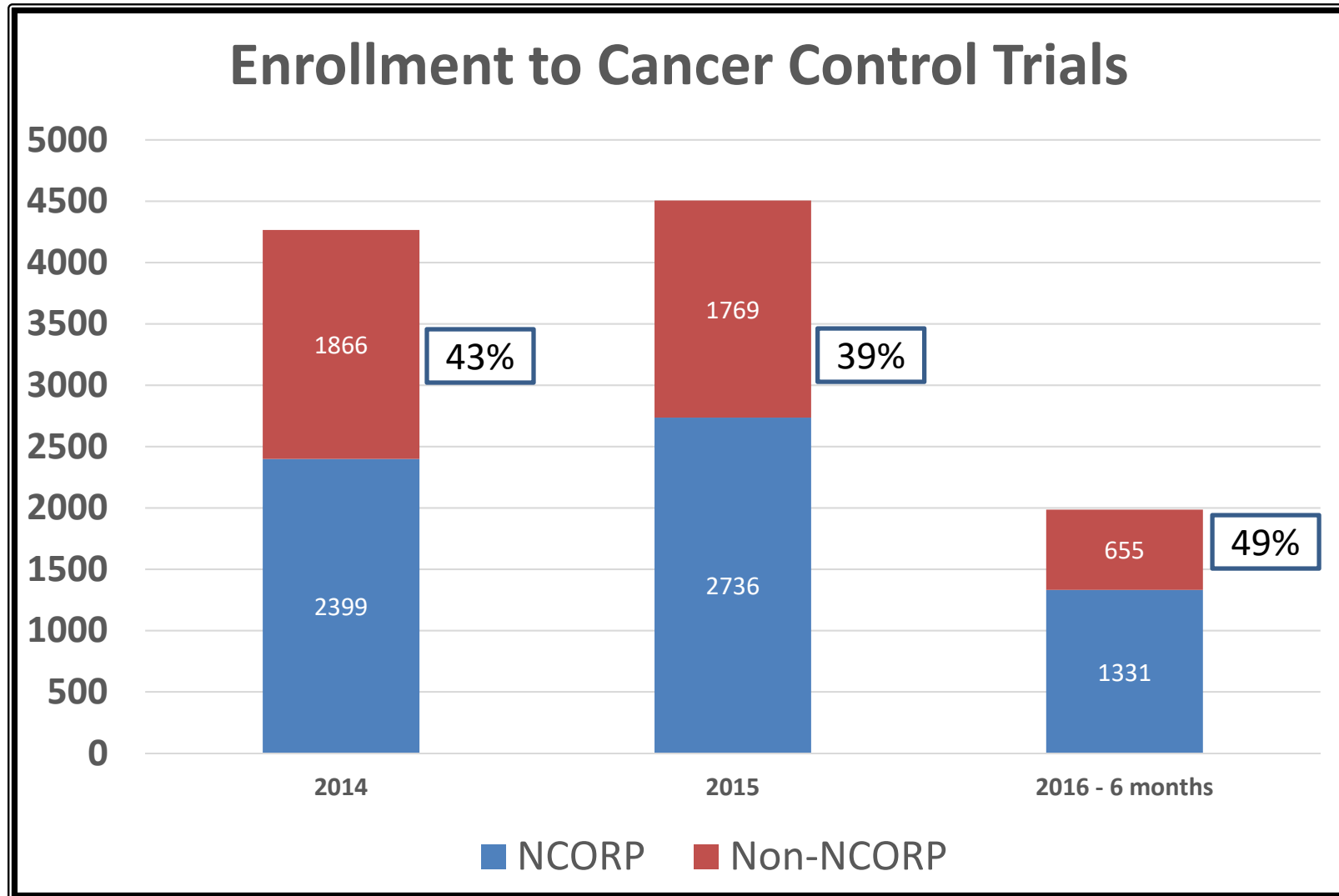
- **To Focus on Symptom Science Steering Committee priorities:
7 Cardiovascular Toxicity; 5 Cognitive Impairment; 1 Fatigue; 2
Cancer Specific Pain; 1 Steering Committee Planning Meeting for
peripheral neuropathy**
- **To evaluate the mechanistic basis of symptoms:
Program will request funding for correlative sciences and biobanks
to support symptom science to better understand the mechanistic
basis of symptoms**

2. Infrastructure Support of Research Portfolio

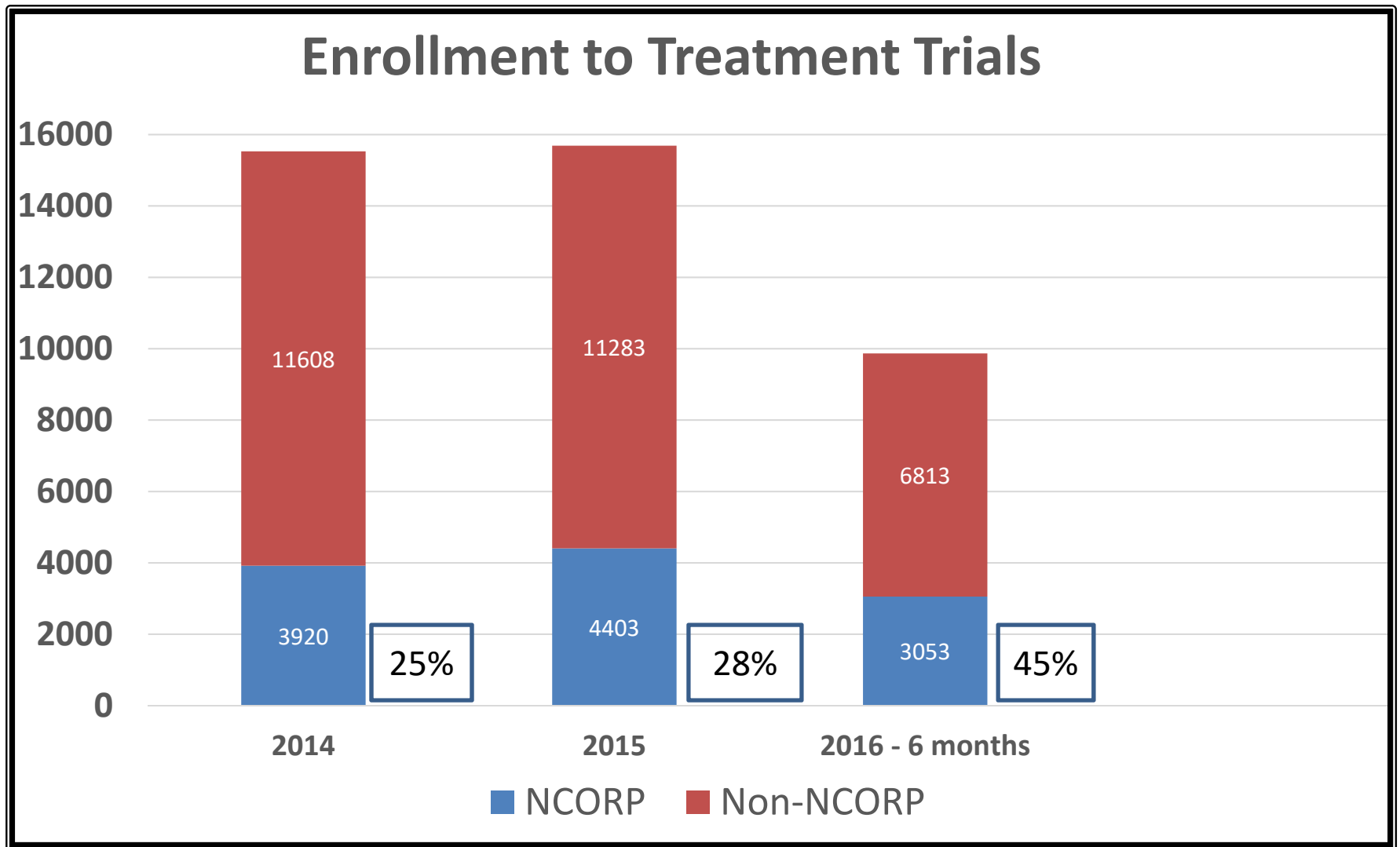
The Evaluation Committee concluded that the infrastructure (Community Sites, Minority Underserved Sites, and Research Bases) and the NCI infrastructure adequately support the research portfolio.

- Network reflects the spectrum of health care environments in the United States**
- Strong accrual to treatment and imaging trials, as well as cancer control and prevention.**
 - Accruals between 2014 and 2016 are a testament to the successful accrual efforts of the network.**
- Other infrastructure changes identified to advance the research agenda include the CIRB, Radiation Oncology Working Group, Early Onset Malignancy Initiative**

NCORP and Non-NCORP



NCORP and Non-NCORP



2. Infrastructure Support of Research Portfolio

Response(s) to Recommendations/Plans for Reissuance

- **Expand cancer care delivery research infrastructure at the Sites:**
 - **Program will request increased funding implementation & site infrastructure CCDR**
- **Optimize advocates/community members across the network:**
 - **NCI will promote this engagement at the Site, Group, and national level**
- **Increase minority/underrepresentation from Community Sites:**
 - **Trans-Group concept development, trials to address research questions for underrepresented populations, and partnerships e.g., Center to Reduce Cancer Health Disparities**
- **Provide Support in the transition from large adjuvant trials to new molecularly targeted and precision trials**
 - **Program is reviewing information about best practices and strategies to sustain them**

3. Efficiency of Study Development and Accrual

The Evaluation Committee identified strengths in study development and accrual.

- 51 concepts were submitted (cancer control/prevention) over 32 months with a 55 percent approval rate**
- 31 studies activated since August 2014 with 23 pending activation**
- An increase (6,319 to 8,768) in accrual credits between 2014-2016**
- NCORP contribution to NCTN trials is 25-30 percent**
- NCORP enrolled 44 percent of MATCH patients registered for screening**

Examples of Trials Activated & Completed During NCORP Cancer Control & Prevention

Protocol Number	Title	Activation date	Accrual Cut Off Date	Planned Accrual	Actual Accrual
A221303	Randomized Study of Early Palliative Care Integrated with Standard Oncology Care Versus Standard Oncology Care Alone in Patients with Incurable Lung or Non-Colorectal Gastrointestinal Malignancies	5/15/2015	4/10/2017	400	405
A221304	A Phase III Placebo-Controlled, Randomized Three-Arm Study of Doxepin and a Topical Rinse in the Treatment of Acute Oral Mucositis Pain in Patients Receiving Radiotherapy With or Without Chemotherapy	11/1/2014	3/29/2017	270	275
E4112	Prospective Study of Magnetic Resonance Imaging (MRI) and Multiparameter Gene Expression Assay in Ductal Carcinoma In Situ (DCIS)	2/17/2015	4/28/2016	350	368
NRG-CC002	Pre-Operative Assessment and Post-Operative Outcomes of Elderly Women with Gynecologic Cancers	2/10/2015	11/2/2015	228	190
URCC-13070	Improving Communication for Cancer Treatment: Addressing Concerns of Older Cancer Patients and Caregivers	10/29/2014	4/30/2017	1056	973

3. Efficiency of Study Development and Accrual

Response(s) to Recommendations/Plans for Reissuance

- **Research Bases and NCI should identify ways to expedite the timeline for trial and study development; collaborate in monitoring timelines for development and activation of studies; tracking actual vs. accrual rates for trials; and assessing barriers**
 - **NCI has formed a Working Group to assess the variations in timelines and review processes, and to establish guidelines & stopping rules for the heterogeneous research portfolio within NCORP**
 - **NCI has a Screening Log to capture number of individuals screened per trial**
 - **Program proposes increased funding for screening and enrollment activities**

4. Collaboration

The Evaluation Committee identified several indicators of collaboration, including across-Research Bases and external collaborations.

The Working Group noted evidence of active Community Site & Minority/Underserved Site participation in Research Base committees, NCORP Working Groups and other NCI initiatives.

4. Collaboration

Response to Recommendations (s)/Plans for Reissuance

- **NCORP plans to continue to promote trans-Research Base research, e.g., AYA, elderly, in the development of screening and surveillance studies**
- **The NCORP Working Groups are designed to work together with experts to serve as champions for NCORP research, partner with respective professional societies, and to prospectively address barriers to enrollment**
- **Several ongoing collaborations exist with other organizations, e.g., PCORI, ASCO, AACR, International Research Groups, and other NIH Institutes**

5. Cancer Care Delivery Research

The Evaluation Committee noted the NCORP offers clear advantages for the conduct of cancer care delivery studies, and the network serves as a microcosm of the larger health care delivery environment.

5. Cancer Care Delivery Research

Response to Recommendations (s)/Plans for Reissuance

- **NCORP should expand the participation of community oncologists, primary care physicians and chief operating officers in Study design:**
 - **CCDR Landscape Assessments, sites have engaged new stakeholders (including COO, CEO) in CCDR work, and the CCDR subcommittees at the Research Bases are continuing the conversations as the studies are developed**
 - **NCORP should explore opportunities for CCDR studies in payer, utilization, and big data.**

Continuum of Care Delivery Research



- Hypothesis-generating
- Existing NCI portfolio
- Less familiar to NCORP Sites



- Patient, clinician & organizational factors
- Expanding NCI portfolio
- Increasingly familiar to NCORP Sites



- Intervene on patients, clinicians & organizations
- Gap in NCI portfolio
- Unique strength of NCORP Sites



- Policies that support delivery of high value care
- Contextual factor in NCI grants
- Challenging methods
- Natural experiments

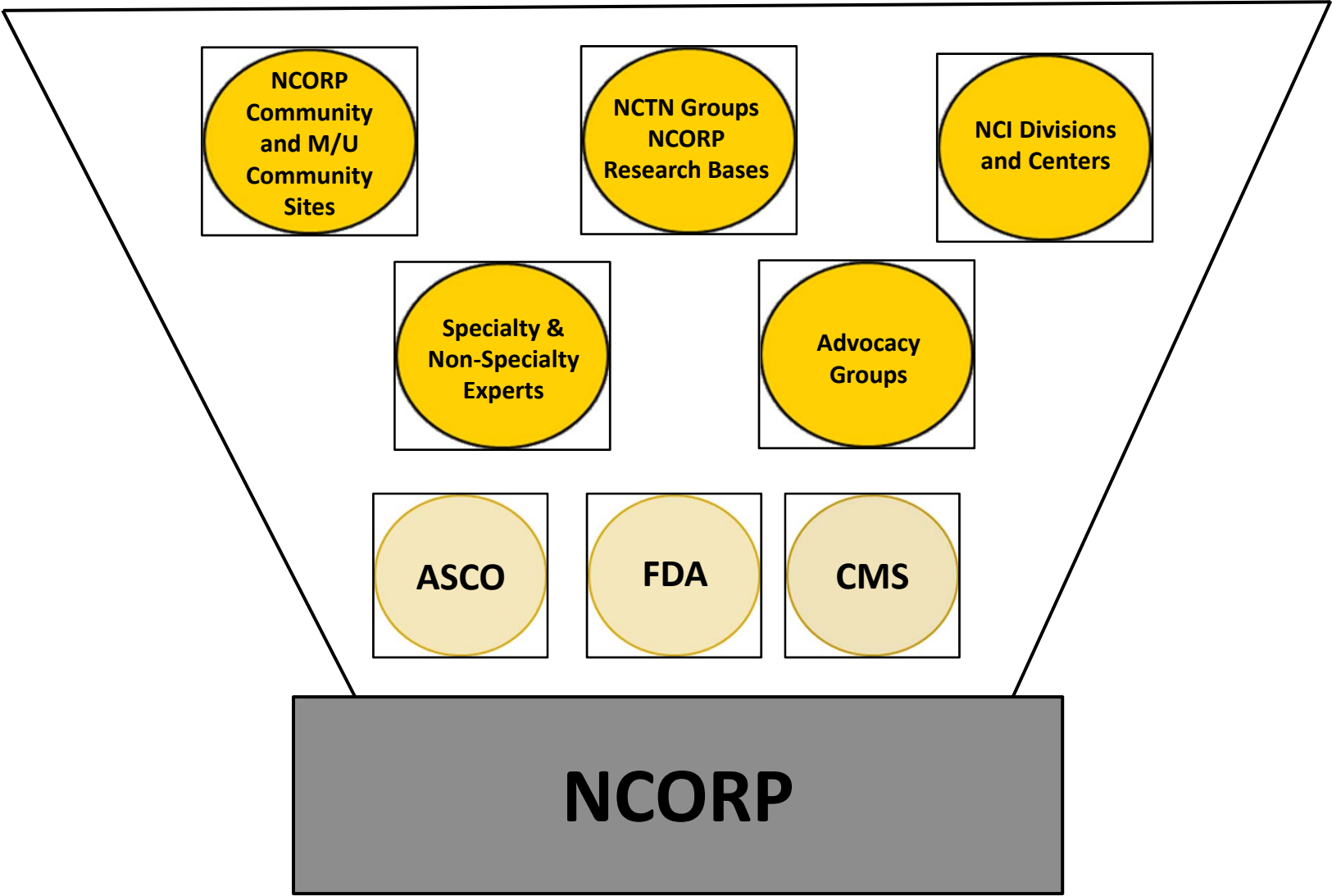
Examples of Qualified Scientists

Name	Affiliation	NCORP CCDR Role
Patricia Ganz, M.D.	Univ. of California Los Angeles	CCDR Steering Committee NRG CCDR Committee
Scott Ramsey, M.D., Ph.D	Fred Hutchinson Cancer Research Center	CCDR Steering Committee Co-chair Coordinating Committee SWOG CCDR Committee Co-chair
Dawn Hershman, M.S., M.D.	Columbia Univ.	CCDR Steering Committee Coordinating Committee member SWOG CCDR Committee Co-chair
Brad Pollock, M.P.H, M.D.	Univ. of California, Davis	CCDR Steering Committee co-chair COG PI
Ethan Basch, M.S., M.D.	Univ. of North Carolina, Chapel Hill	CCDR Steering Committee Alliance CCDR Committee co-chair
Kathryn Weaver, Ph.D	Wake Forest Univ.	CCDR Landscape Assessment Lead CCDR Steering Committee Coordinating Committee Member Wake Forest CCDR Lead
Supriya Mohile, M.S., M.D.	Univ. of Rochester	Coordinating Committee member URCC CCDR lead

Overall Recommendation

**The NCORP External Evaluation Committee
Recommends that NCI Proceed with the
NCORP RFA Reissuance**

Process for Seeking Input for RFA Reissuance



NCORP: Future Directions

- **Ongoing: TMIST and its associated biorepository**
- **Surveillance: colon cancer screening surveillance, pancreatic cyst progression**
- **Cancer Prevention: topical applications, e.g., breast, HPV dose scheduling, and utilization in pediatric cancer survivors**
- **PreCancer Atlas: molecular characterization of preneoplastic lesions**
- **Symptom Science: assess immunotherapy-related toxicities**
- **NCORP Expansion: capture underrepresented geographical areas**

Potential Topics for Cancer Care Delivery Randomized Clinical Trials

Implementation

- Early Palliative care (15% survival improvement at one year)
- Telehealth (<1/3 of CCDR practices report using it for care)
- Any type of DNA sequencing (< ¼ of CCDR practices report routine use)

De-implementation

- Contralateral prophylactic mastectomy (no survival benefit yet use >10%)
- Use of serum tumor markers for breast cancer surveillance (no survival benefit yet use >20%)

Intervene on financial toxicity (bankruptcy associated with 50% decreased survival)

Questions!