

NCI Community Oncology
Research Program

A program of the National Cancer Institute
of the National Institutes of Health

Board of Scientific Advisors
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Request for Application (RFA) – Reissuance

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In collaboration with the Divisions of Cancer Treatment & Diagnosis & the Center to Reduce Cancer Health Disparities

NCI Community Oncology Research Program (NCORP) is an Academic/Community Partnership

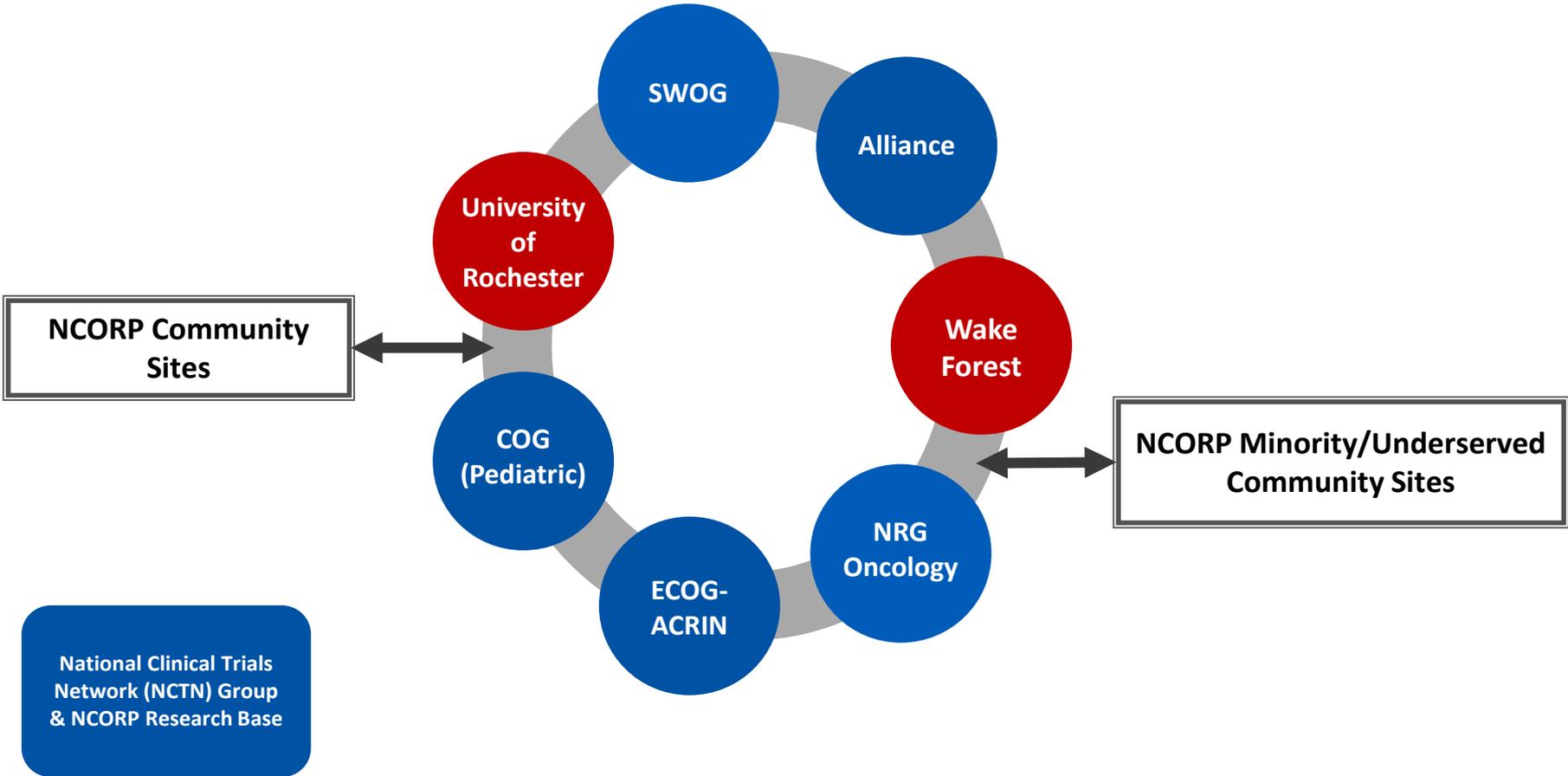
Clinical Trials for cancer control and prevention, comparative effectiveness, and screening

Accrual to National Clinical Trials Network (NCTN) treatment and advanced imaging trials

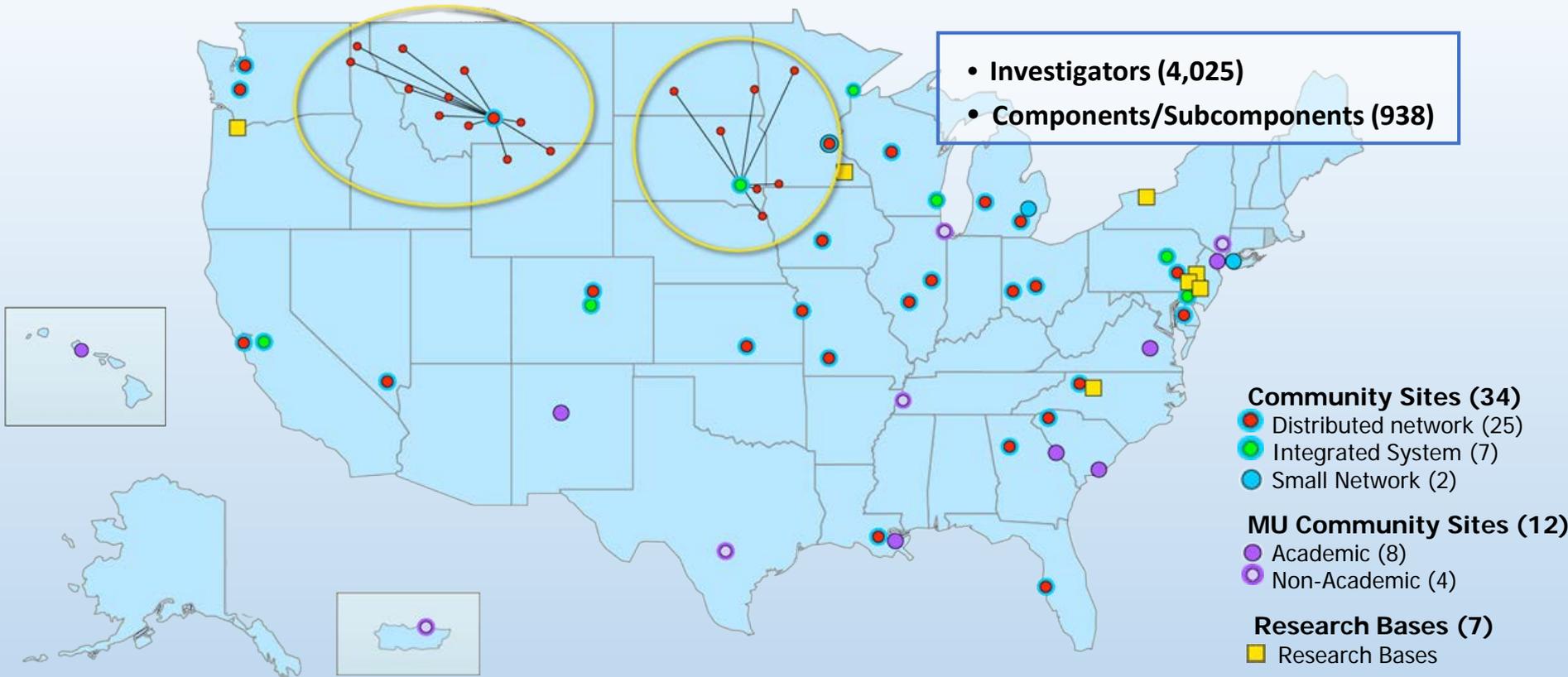
Cancer Care Delivery Research to develop clinical practices that achieve optimal clinical outcomes

Incorporation of Cancer Disparities Research into clinical trials and cancer care delivery research

NCI Community Oncology Research Program: Research Bases & Community Sites

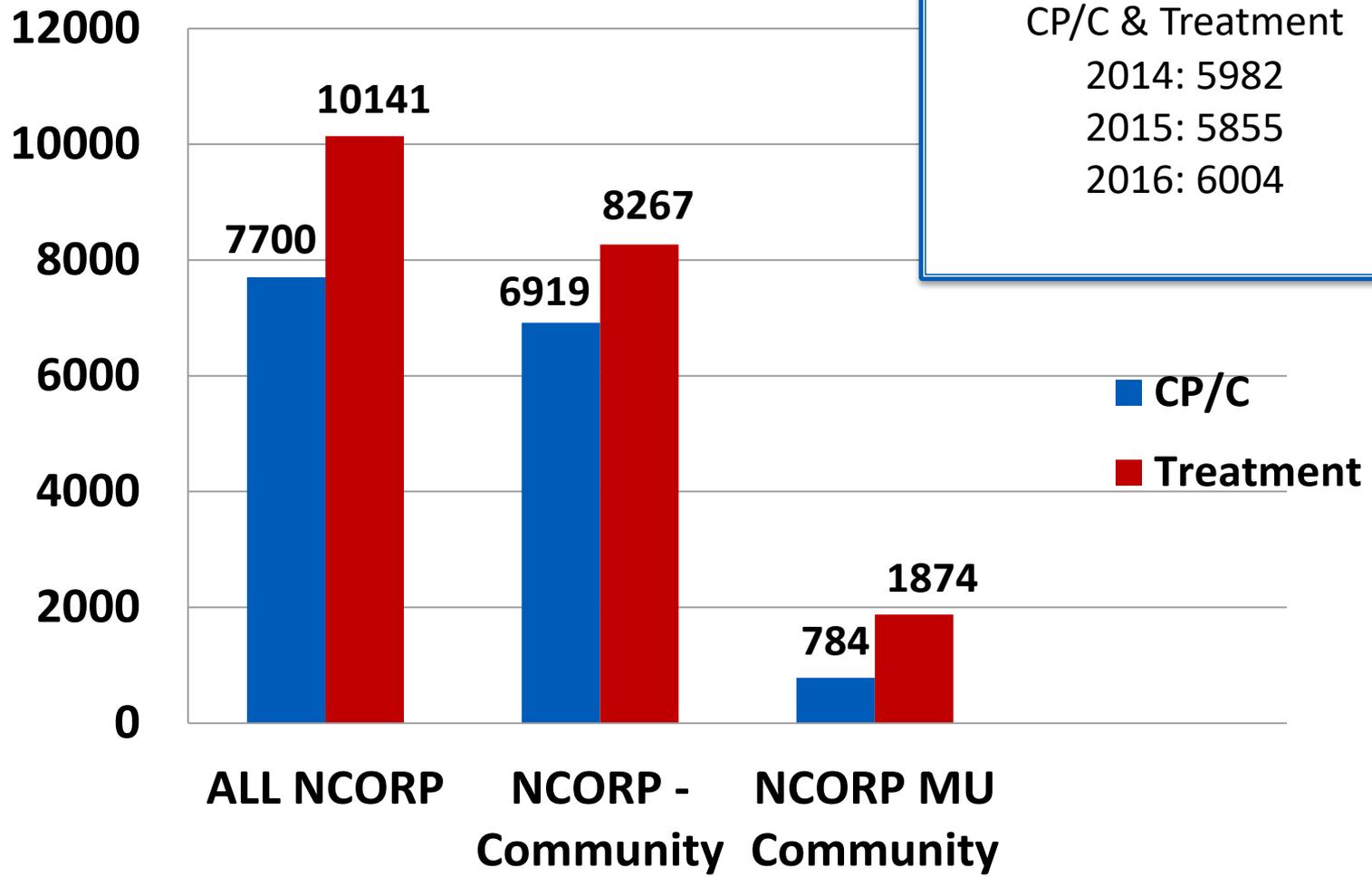


NCORP Community Site, M/U Community Site and Research Bases Geographic and Organizational Diversity



NCORP Accrual*

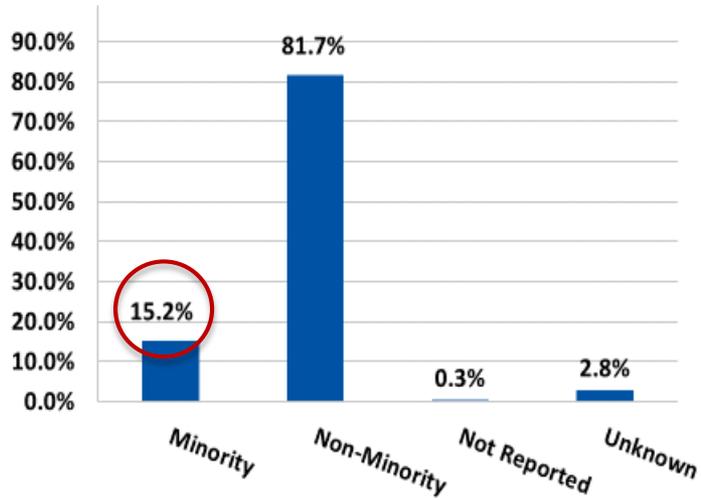
2014 - 2016



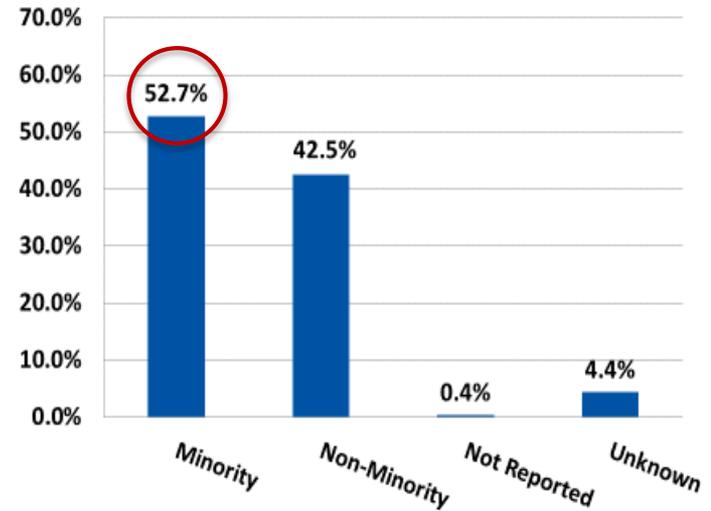
* Does not include accrual to CCDR studies

NCORP Minority Enrollment by Community Type

NCORP Community Sites - 2016



NCORP Minority/Underserved Sites - 2016



Cancer Control & Prevention Trials

- **Currently: 52 Active Trials available from NCORP Research Bases**
- **Trials activated & completed during NCORP thru 8/1/17**

Protocol Number	Title	Activation date	Accrual Cut Off Date	Planned Accrual	Actual Accrual
A221301	Olanzapine for the Prevention of Chemotherapy Induced Nausea and Vomiting (CINV) in Patients Receiving Highly Emetogenic Chemotherapy (HEC): A Randomized, Double-Blind, Placebo-Controlled Trial	8/5/2014	4/5/2015	372	401
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
URCC-13091	Feasibility of Omega-3 Supplementation for Cancer-Related Fatigue	2/26/2015	3/31/2016	75	108
URCC-14079	Effectiveness of Prophylactic Topical Agents for Radiation Dermatitis	10/13/2015	6/30/2016	180	192

NCORP Quality of Life Accrual

Enrollment Accrual	2014	2015	2016
Enrollments to QOL sub-studies to treatment trials	2485	1897	2391
NCORP Community Sites	957	821	1333
Non-NCORP Sites, i.e., LAPS, Main members, affiliates	1528	1076	1058

Symptom Science: Symptom Management & QOL

Steering Committee Priorities

- **Cardiovascular Toxicity: 7 Trials – e.g., ALTE11C2-Health Effects after Anthracycline and Radiation Therapy (HEART): Dexrazoxane and Prevention of Anthracycline–related Cardiomyopathy**
- **Cognitive Impairment: 5 Trials – e.g., NRG C003 Randomized Phase II/III of Prophylactic Cranial Irradiation with/without Hippocampal Avoidance for Small Cell Lung Cancer.**
- **Fatigue: 1 trial -A221101 – A Phase III Randomized, Double Blind Placebo Controlled of Armodafinil to Reduce Cancer-Related Fatigue in Patient in High Grade Glioma**
- **Cancer Specific Pain: 2 trials , e.g., E1Z11 A Cohort Study to Evaluate Genetic Predictors of Aromatase inhibitor Musculoskeletal Symptoms**

Accomplishments of Cancer Care Delivery Research

- **2 Capacity Assessments covering 225 practice units**
- **5 open studies have accrued over 1,300 patients and clinicians**
- **7 protocols in development**
- **Study features**
 - **Topics include use of guidelines, financial toxicity, smoking cessation, and geriatric assessment**
 - **6 with additional funding (3 NIH, 1 AHRQ, 1 PCORI, 1 Leukemia & Lymphoma Society)**
 - **5 cluster-randomized controlled trials**

NCORP's Contributions in NCI's Precision Medicine Initiatives Molecular Analysis for Therapy Choice (MATCH)

“A trial of therapy based on genetic characteristics of the tumor is feasible in the institutions of the NCTN and NCORP”



Collectively, 342 NCORP sites contributed 44 percent (2788/6408) of patients registered for screening in MATCH

New-Onset Diabetes (NOD) Cohort Study

NIDDK, Pancreatic Cancer Consortium & Early Detection Research Network

- **Background: 25-40% of pancreatic ductal adenocarcinoma cancer patients (PDAC) develop diabetes between 6-24 months prior to diagnosis**
- **Goals:**
 - **Identify and follow a large cohort**
 - **Develop a biorepository**
 - **Clinically validate promising biomarkers of PDAC**
 - **Develop an early detection protocol for sporadic PDAC**
- **Planned enrollment from NCORP: 6,000/10,000**
 - **Estimated number of PDAC cases: 85 (over 3 year follow up)**

Early Onset Malignancy Initiative (EOMI): Cancer Disparities: Priority Opportunity Area

- Discover mechanisms for early onset cancer
- Determine if there is genetic variation between/among groups
- Identify rare genetic variants that drive differences
- Identify risk factors that impact outcome
- Use information to better treatment options and prognosis

Cancer Sites	Age Cut Offs
Breast	≤45
Colorectal	≤55
Liver	≤55
Multiple Myeloma	≤50
Prostate	≤55
Renal*	≤50

Populations: African American, Caucasian, Hispanic, Native American
*Renal in Native Americans Only

***External Evaluation
Working Group
Report***

1. Overall Scientific & Clinical Value and Impact

Response(s) to Recommendations/Plans for Reissuance

- **To Focus on Symptom Science Steering Committee priorities:**
 - **Cardiovascular Toxicity; Cognitive Impairment; Fatigue; and Cancer Specific Pain**
 - **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**

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 for implementation & site infrastructure**
- **Increase minority/underrepresentation from Community Sites:**
 - **Trans-Group concept development for trials to address research questions for underrepresented populations**
- **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

Response(s) to Recommendations/Plans for Reissuance

- **Research Bases and NCI should identify ways to expedite the timeline for trial and study development**
 - **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**
 - **NCI has a Screening Log to capture number of individuals screened per trial**
 - **Program proposes increased funding for screening and enrollment activities**

4. Collaboration

Response to Recommendations (s)/Plans for Reissuance

- **NCORP plans to continue to promote trans-Research Base research, e.g., AYA, elderly, including advocates**
- **NCORP Working Groups are designed to work together with experts to serve as champions for NCORP research, address barriers to enrollment**
- **Several ongoing collaborations exist, e.g., PCORI, ASCO, AACR, International Research Groups, and other NIH Institutes**

5. Cancer Care Delivery Research

Response to Recommendations (s)/Plans for Reissuance

- **NCORP should expand participation of community oncologists, primary care physicians and chief operating officers in Study design:**
 - **CCDR Landscape Assessments have provided opportunity to engage these stakeholders**
- **NCORP should explore opportunities for studies involving payers, big data, and policy change:**
 - **Investigators are welcome to explore these possibilities, bearing in mind that the capacity for conducting trials distinguishes NCORP from other components of the NCI portfolio**

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:** assessing immunotherapy related toxicities
- **NCORP Expansion:** capture underrepresented geographical areas

Potential Topics for Cancer Care Delivery Randomized Clinical Trials

- **Implementation**
 - Any type of tumor DNA sequencing (< 1/4 of CCDR practices report routine use)
 - Early palliative care (15% survival improvement at one year)
 - Telehealth (< 1/3 of CCDR practices report using for care)
- **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)

Annual Funding Request

NCI Community Oncology Research Program (NCORP)

<i>NCORP Component</i>	<i>No. of Sites</i>	<i>Clinical Trials \$ Millions</i>	<i>CCDR Funding \$ Millions</i>	<i>Total Annual Funding</i>
<i>NCORP Community Sites</i>	40	\$47	\$9.5	\$56.5
<i>NCORP-M/U Sites</i>	14	\$10	\$4.0	\$14.0
<i>NCORP Research Bases</i>	7	\$43	\$6.5	\$49.5
SUBTOTAL	61	\$100	\$20	\$120
<i>Large Scale Screening/Prevention Trials+</i>		\$25	\$25
Total RFA Request	61	\$125	\$20	\$145*
<i>Biobanking Support</i>		\$2.5	\$2.5
<i>Imaging and Radiation Oncology Core Support</i>		\$1.5	\$1.5
<i>NCI DCTD Contract ++</i>		\$8.5	\$2	\$10.5
SUBTOTAL		\$12.5	\$2	\$14.5
Total NCORP Initiative Funding		\$137.5	\$22	\$159.5

* The 6-Year Total RFA Funding Request for NCORP for FY 2019 to FY 2024 is \$870 Million.

+ Includes Year 3 TMIST (FY2019)

++ DCTD Contract Support: NCI Core Systems, CIRB, CTSU, CT Log

Funding Request with Proposed Increases

NCI Community Oncology Research Program (NCORP)

<i>NCORP Component</i>	<i>No. of Sites 2017 / Increase</i>	<i>Clinical Trials 2017 Base / Increase \$ Millions</i>	<i>CCDR Funding 2017 Base / Increase \$ Millions</i>	<i>Total 2017 Base / Increase</i>
<i>NCORP Community Sites</i>	<i>34 / 6</i>	<i>\$35.4 / \$11.6</i>	<i>\$5 / \$4.5</i>	<i>\$40.4 / \$16.1</i>
<i>NCORP-M/U Sites</i>	<i>12 / 2</i>	<i>\$7.3 / \$2.7</i>	<i>\$2 / \$2.0</i>	<i>\$9.3 / \$4.7</i>
<i>NCORP Research Bases</i>	<i>7 / 0</i>	<i>\$38.3 / \$4.7</i>	<i>\$5 / \$1.5</i>	<i>\$43.3 / \$6.2</i>
<i>SUBTOTAL</i>	<i>53 / 8</i>	<i>\$81 / \$19</i>	<i>\$12 / \$8</i>	<i>\$93 / \$27</i>
<i>Large Scale Screening/Prevention Trials+</i>		<i>\$5 / \$20</i>	<i>.....</i>	<i>\$5 / \$20</i>
<i>RFA Base/Increase Total</i>	<i>53 / 8</i>	<i>\$86 / \$39</i>	<i>\$12 / \$8</i>	<i>\$98 / \$47</i>
<i>Biobanking Support</i>		<i>.... / \$2.5</i>	<i>.....</i>	<i>.... / \$2.5</i>
<i>Imaging and Radiation Oncology Core Support</i>		<i>.... / \$1.5</i>	<i>.....</i>	<i>.... / \$1.5</i>
<i>NCI DCTD Contract ++</i>		<i>\$5 / \$3.5</i>	<i>\$1.2 / \$0.8</i>	<i>\$6.2 / \$4.3</i>
<i>Subtotal</i>		<i>\$5 / \$7.5</i>	<i>\$1.2 / \$0.8</i>	<i>\$6.2 / \$8.3</i>
<i>Total NCORP Initiative Funding (Base/Increases)</i>		<i>\$91 / \$46.5</i>	<i>\$13.2 / \$8.8</i>	<i>\$104.2 / \$55.3</i>

+ Includes Year 3 TMIST (FY2019)

++ DCTD Contract Support: NCI Core Systems, CIRB, CTSU, CT Log

Questions?