Lessons Learned from the
National Cancer Institute’s Community-Based
Clinical Trials

Society of Clinical Trials- May 16, 2022

Worta McCaskill-Stevens, M.D., M.S.
Chief, Community Oncology and Prevention Trials Research Group
Director, NCI Community Oncology Research Program
Division of Cancer Prevention
Setting the Stage

• Over 80% of cancer care takes place in community settings

• Only 3-5% of patients in the US participate in cancer clinical trials

• Clinical trials are designed to advance cancer prevention, screening, treatment, and survivorship by providing scientific evidence

• “Without adequate rates of participation by patients and physicians, it is unlikely that important research questions with the potential to improve patient outcomes will be answered efficiently and effectively”

• Commemoration of the 50th Anniversary of the National Cancer Act

National Cancer Clinical Trials System for the 21st Century, IOM
NCI’s Community-Based Clinical Trials: Today’s Discussion

- History of NCI’s Community-Based Programs
- NCORP Community Oncology Research (NCORP)
- Community-Based Clinical Trials: Informing Public Health Policy with Compelling Evidence
  - Trials
  - Successes
  - Challenges
- Future Directions of Clinical Trials in Community Settings
History of NCI Community-Based Clinical Trials
A Journey Continues!

Community Clinical Oncology Program (CCOP) -1983
Minority-Based CCOP – 1990

NCI Community Cancer Centers Program (NCCCP) - 2007

NCI Community Oncology Research Program (NCORP) 2014
Community & Minority-Based Clinical Oncology Programs (CCOPs & MB-CCOPs)

• 30-40% of treatment accrual to the NCI Cooperative Groups
• Chemoprevention Trials:

<table>
<thead>
<tr>
<th>Study Description</th>
<th>Outcome/Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Breast Cancer Prevention Trial (P-1) n=13,388</td>
<td>FDA Approval of Tamoxifen</td>
</tr>
<tr>
<td>Prostate Cancer Prevention Trial (PCPT), n=18,882</td>
<td>Finasteride reduced the risk of prostate ca. by 30%</td>
</tr>
<tr>
<td>Study of Tamoxifen and Raloxifene (STAR), n=19,747</td>
<td>FDA Approval of Raloxifene</td>
</tr>
<tr>
<td>Selenium and Vitamin E Cancer Prevention Trial (SELECT) n=35,533</td>
<td>No reduction in prostate ca.; increase in ca. In the Vitamin E arm</td>
</tr>
</tbody>
</table>

• Introduced symptom management into the clinical trials network
NCI Community Clinical Oncology Program Network
Accrual 2000 – 2013

Minority accrual:
MB-CCOPs: 62%
CCOPs: 10%

Total accrual 170,685
(40% to NCTN treatment)
SELECT
(Estudio del Señor y la Vitamina E para Prevenir el Cáncer)
Dr. Jaime Claudio - Investigador Asociado 787-791-9026
Multivitamínico y suplementos del estudio, gratuito por 12 años

¿Quieres saber cómo participar en el más grande estudio clínico de prevención del cáncer de próstata jamás realizado?

Un estudio de hombres sanos de 50 años o más, para el estudio de prevención clínica de cáncer de próstata en los hombres de más de 50 años. El estudio se inició en 1983 y sigue en marcha hasta hoy. La principal cuestión es si los hombres tienen una mejoría a largo plazo de cáncer de próstata que no se ha detectado.

Dr. Jaime Claudio
Profesor Ad-Honorem
Medicina de Familia-UPR-Ciencias Médicas
CCOPs & MB-CCOPs Cont’d: Lessons Learned

• Enthusiasm for RCT and contributors to trials, e.g., breast and bowel adjuvant
• Community physicians who participate in trials more rapidly adopt state-of-the-art care
• Partnerships with industry for chemoprevention – enhance recruitment efforts
• Targeted practices needed to enhance racial/ethnic minorities
• Challenges from local IRBs
• Essential role of Community and Participant Advisory Boards
NCI Community Cancer Centers Program (NCCCP)

• Pilot Program of 21 Sites
  ❖ Reduce cancer health disparities
  ❖ Increase participation in clinical trials
  ❖ Improve quality of cancer care
  ❖ Enhance cancer survivorship and palliative care services
  ❖ Promote collection of high-quality biospecimens
NCI Community Oncology Research Program (NCORP)
Revamping NCI Clinical Trials

1. Improve the speed and efficiency of the design, launch, and conduct of trials
2. Incorporate innovative science and trial design into trials
3. Improve the means of prioritization, selection, support, and completion of trials
4. Incentivize the participation of patients and physicians in trials
Organization and Infrastructure for the NCTN

LEGEND:
- **Centralized Functions:**
  - NCI IRB with 4 Boards
  - Cancer Trials Support Unit
  - RT/Imaging Core Center
  - NCI Disease-Specific Steering Committees
  - Common Data Mgt with System Central Hosting

- Lead Academic Participating Sites (LAPS)
- Operations Centers
- Statistics & Data Management
- Tumor Banks

≈ 2,200 enrolling sites across North America plus international sites

NCI Community Oncology Research Program (NCORP)
Site Participation

NCI IRB with 4 Boards
Cancer Trials Support Unit
RT/Imaging Core Center
NCI Disease-Specific Steering Committees
Common Data Mgt with System Central Hosting

Centralized Functions:

- Alliance
- SWOG
- NRG
- COG (pediatric)
- ECOG-ACRIN

≈ 2,200 enrolling sites across North America plus international sites

Canadian Network Group

LEGEND:
NCORP: Community/Academic Partnership

• Clinical Trials/Studies:
• Accrual to symptom management, palliative care, prevention, surveillance, screening, and QOL embedded in treatment trials
• Accrual to National Trials Network (NCTN): treatment, advanced imaging trials, and tissue acquisition studies
• Accrual of patients, clinicians, & organizational factors that influence care delivery through cancer care delivery research (CCDR) trials and studies
• Cancer disparities research incorporated into clinical trials and CCDR
• Biobanks and Imaging Radiation Oncology Core to support the research portfolio
NCORP Organizational Relationships

Members & Affiliates:
- Accrual to cancer control, prevention & screening protocols

National Cancer Institute
- Overall direction
- Program management funding

7 Research Bases
- Develops protocols
- Data management & analysis

32 Community Sites
- 14 Minority/Underserved Sites
  - 30% racial/ethnic or rural
- Accrual to protocols
- Data management
- Community Engagement
NCORP Organizational Relationships

National Cancer Institute
Overall direction
Program management funding

Members & Affiliates:
Accrual to cancer control, prevention & screening protocols

7 Research Bases
Develops protocols
Data management & analysis
Alliance, SWOG, ECOG/ACRIN, COG, NRG, URCC, Wake Forest

32 Community Sites
14 Minority/Underserved Sites
30% racial/ethnic or rural
Accrual to protocols
Data management
Community Engagement
NCI Community Oncology Research Program (NCORP)
Community and Minority/Underserved Sites, 1000+, 4000+ investigators
Design and conduct cancer prevention, control, and screening/post-treatment surveillance clinical trials

Longitudinal biospecimens: Blood and/or tissue samples with two or more time points including: archival, baseline, on treatment, & progression
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<thead>
<tr>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ALL NCORPs</strong></td>
<td><strong>2763 / 3911</strong></td>
<td>3822 / 5058</td>
<td>3603 / 4523</td>
<td>4649 / 3627</td>
<td>6353 / 3712</td>
<td>6603 / 3306</td>
<td>7483 / 4284</td>
<td>4777 / 2715</td>
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<td>6,674</td>
<td>8,880</td>
<td>8,126</td>
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<td>10,065</td>
<td>9,868</td>
<td>11,743</td>
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<tr>
<td><strong>Community NCORPs</strong></td>
<td>2430 / 3261</td>
<td>3384 / 3848</td>
<td>3187 / 3543</td>
<td>3939 / 2916</td>
<td>5015 / 3000</td>
<td>5174 / 2456</td>
<td>5784 / 3209</td>
<td>3729 / 1982</td>
</tr>
<tr>
<td><strong>Minority NCORPs</strong></td>
<td>333 / 650</td>
<td>438 / 1210</td>
<td>416 / 980</td>
<td>710 / 711</td>
<td>1338 / 712</td>
<td>1429 / 850</td>
<td>1699 / 1075</td>
<td>1048 / 733</td>
</tr>
</tbody>
</table>

* 9 Month Data
## NCORP Minority/Underserved Sites (affiliates)

<table>
<thead>
<tr>
<th>Institution</th>
<th>States</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baptist Health (12)</td>
<td>Ark, MS, TN</td>
</tr>
<tr>
<td>Columbia University (2)</td>
<td>NY, FL</td>
</tr>
<tr>
<td>GaCares (10)</td>
<td>GA</td>
</tr>
<tr>
<td>Gulf South (49)</td>
<td>LA, MS</td>
</tr>
<tr>
<td>Hawaii (24)</td>
<td>HI, Guam</td>
</tr>
<tr>
<td>Kansas U (16)</td>
<td>KS, MO</td>
</tr>
<tr>
<td>Medical University of South Carolina (14)</td>
<td>SC</td>
</tr>
<tr>
<td>Montefiore (6)</td>
<td>NY</td>
</tr>
<tr>
<td>National Capital (Georgetown) (2)</td>
<td>DC</td>
</tr>
<tr>
<td>U of New Mexico (16)</td>
<td>NM</td>
</tr>
<tr>
<td>Puerto Rico (18)</td>
<td>PR</td>
</tr>
<tr>
<td>Stroger/Cook County</td>
<td>IL</td>
</tr>
<tr>
<td>Texas Pediatric (2)</td>
<td>TX</td>
</tr>
<tr>
<td>Virginia Commonwealth University (18)</td>
<td>VA</td>
</tr>
</tbody>
</table>
Minority Accrual

MINORITY ACCRUAL BY COMPONENT
2014 - 2019

MINORITY ACCRUAL BY COMPONENT
August 1, 2020 - July 31, 2021

Overall Minority Accrual: 23%
CCDR Minority Accrual

- Total Accrual – 9,360 patients (Aug. 1, 2014 – Mar. 31, 2022)
  - 24% minority accrual
  - MU Sites contribute 61% of total minority accrual

Data Source: DCP Dashboard/OPEN
Lessons from the NCORP Network

• Majority of cancer care is provided in the community; however, there are major practice changes

• Access to diverse “real world” healthcare delivery settings

• Access to an increasingly diverse patient populations across the US

• Tests feasibility of implementing new interventions and processes in the community setting

• Enhances potential that outcomes will be broadly applicable in practice

• Accelerates the uptake of new interventions and processes into routine practice
Precision Medicine Trials

The term precision refers to prospects for enhanced molecular resolution, mechanistic clarity, and therapeutic cogency that may accompany clinical implementation of genomics technologies.

Precision medicine’s more individualized, molecular approach to cancer will enrich and modify but not replace, the successful staples of oncology – prevention, diagnostic, some screening methods and effective treatments – while providing a framework for accelerating the adoption of precision medicine in other spheres.
NCI Community Oncology Research Program
Molecular Analysis for Therapy Choice (MATCH)

43.3% 2770/6391 of Patients Registered for Screening are from NCORP Community and Minority Community Sites

Since 2021: 40% 37/92
NCI Cancer Moonshot™ Initiatives within NCORP

Goal: To Evaluate Sensivity and Drug Resistance to FDA Approved Moleculary Targeted Agents Used in Standard of Care.

- NCI Protocol 10231: To procure and bank formalin-fixed, paraffin-embedded (FFPE) tissue (& snap-frozen as well), blood (for cell-free DNA analysis), and nucleic acids from patients (n = 150) with advanced solid cancers prior to 1st-line standard targeted therapy and at 1st recurrence.

- NCI Biobank Protocol 10323: To support investigations through the procurement & distribution of multiple longitudinal specimens and data. Including a central biorepository; clinical tumor biomarker testing; e-consent; sub-studies on patient engagement and ethical, legal, social implications, and a biobank website for participants and providers to access to biomarker reports, and educational resources.

Biospecimens: Baseline, on treatment, and at disease-progression.
Research Priorities in Cancer & Treatment Related Toxicities

1. Cognitive Impairment
2) Neurotoxicity
3) Cardiovascular Toxicity
4) Fatigue
5) Cancer Specific Pain
Strategies Toward Precision Medicine in Symptom Management

- Longitudinal Studies
- Preclinical Models
- Establishing Biobanks to support
- Establishing industry relationships
- Working with Early Detection Network to study biomarkers of risk prediction and response
• NRG-C003 Randomized Phase II/III Trial of Prophylactic cranial irradiation w/wo Hippocampal avoidance for SCLC
Disparities Research in Symptom Management

• Targeted populations with across Research Base pooled analyses

  ❖ URCC-21038: Disparities in REsults of Immune Checkpoint Inhibitor Treatment (DiRECT): A Prospective Cohort Study of Cancer Survivors Treated with anti-PD-1/anti-PD-L1 Immunotherapy in a Community Oncology Setting

  ❖ Patient Reported Outcomes language translations

  ❖ EAZ171 Prospective validation of taxane therapy and risk of chemo-induced peripheral neuropathy in African American women
Accelerating the translation of knowledge gained from clinical trials into clinical practice
# Few Older Adults Included in Registration Studies

## Breast Cancer as an Example

<table>
<thead>
<tr>
<th>Agent Name</th>
<th>Approval</th>
<th>N</th>
<th>Age ≥ 65</th>
<th>N</th>
<th>Age ≥ 75</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abemaciclib</td>
<td>09/2017</td>
<td>154</td>
<td>35%</td>
<td>39</td>
<td>9%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>42</td>
<td>32%</td>
<td>10</td>
<td>8%</td>
</tr>
<tr>
<td>Neratinib</td>
<td>07/2017</td>
<td>172</td>
<td>14%</td>
<td>25</td>
<td>2%</td>
</tr>
<tr>
<td>Ribociclib</td>
<td>03/2017</td>
<td>150</td>
<td>45%</td>
<td>35</td>
<td>11%</td>
</tr>
<tr>
<td>Palbociclib</td>
<td>2/2015</td>
<td>181</td>
<td>41%</td>
<td>48</td>
<td>11%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>86</td>
<td>25%</td>
<td>27</td>
<td>8%</td>
</tr>
<tr>
<td>Ado-Trastuzumab Emtansine</td>
<td>2/2013</td>
<td>65</td>
<td>13%</td>
<td>11</td>
<td>2%</td>
</tr>
<tr>
<td>Everolimus</td>
<td>7/2012</td>
<td>290</td>
<td>40%</td>
<td>109</td>
<td>15%</td>
</tr>
<tr>
<td>Pertuzumab</td>
<td>6/2012</td>
<td>60</td>
<td>15%</td>
<td>5</td>
<td>1%</td>
</tr>
<tr>
<td>Eribulin Mesylate</td>
<td>11/2010</td>
<td>121</td>
<td>15%</td>
<td>17</td>
<td>2%</td>
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<tr>
<td>Lapatinib</td>
<td>1/2010</td>
<td>34</td>
<td>17%</td>
<td>2</td>
<td>1%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>282</td>
<td>44%</td>
<td>77</td>
<td>12%</td>
</tr>
<tr>
<td>Ixabepilone</td>
<td>10/2007</td>
<td>45</td>
<td>10%</td>
<td>3</td>
<td>&lt;1%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>32</td>
<td>13%</td>
<td>6</td>
<td>2.5%</td>
</tr>
</tbody>
</table>

*Package Insert, “Geriatric Usage” section*
✓ Facilitating the participation of minorities and other underserved populations across all study types and settings

- A171601: A Phase II Trial Assessing the Tolerability of Palbociclib in Combination with Letrozole or Fulvestrant in Patients Aged 70 and Older with Estrogen Receptor-Positive, HER2-Negative Metastatic Breast Cancer

  • Primary Objective: To estimate the safety and tolerability (adverse event rate) of the combination of palbociclib and letrozole or fulvestrant in adults age 70 or older with estrogen receptor-positive, HER2-negative metastatic breast cancer.

  • Primary Endpoint: Primary Endpoints: The primary endpoint is the adverse event rate at 6 months, defined as the proportion of patients with documentation of grade 3 - 5 toxicity
Precision Medicine in Cancer Prevention & Screening
NRG-CC005 – FORTE (Five- or Ten-Year Colonoscopy for 1-2 Non-Advanced Adenomatous Polyps)

Primary Objective

1. To examine colorectal cancer incidence in participants with 1 to 2 non-advanced adenomas randomized to surveillance colonoscopy at 10 years compared to participants randomized to surveillance colonoscopy at 5 and 10 years.

Secondary Objectives

1. To examine advanced adenoma incidence in participants with 1 to 2 non-advanced adenomas randomized to surveillance colonoscopy at 10 years compared to participants randomized to surveillance colonoscopy at 5 and 10 years.
2. To examine colorectal cancer mortality in participants with 1 to 2 non-advanced adenomas randomized to surveillance colonoscopy at 10 years compared to participants randomized to surveillance colonoscopy at 5 and 10 years.

Exploratory Objective

1. Collection of blood, stool, and tissue samples for purposes of the NRG-CC005 study and for future unspecified research.

Trial Design: The sample size of 9,500 participants randomized 1:1 will achieve 90% power to detect a non-inferiority margin difference of 0.387% at alpha 5% one-sided.

Accrual Goal – 9,500
Primary Objective

1. To determine whether the cumulative rate of advanced breast cancer in women undergoing screening with tomosynthesis + digital mammography (TM) is reduced compared to digital mammography (DM) alone

Secondary Objectives

1. To compare the diagnostic performance of TM and DM
2. To compare the recall rates and biopsy rates for TM versus DM
3. To compare the rate of interval cancers for TM and DM
4. To examine the correlation between BIRADS imaging features and histologic and genetic features
5. To estimate and compare breast-cancer-specific mortality between the two study arms
6. To estimate and compare the prevalence of breast cancer subtypes and classify histologically malignant, pre-malignant and benign lesions using PAM 50.

Trial Design: Occurrence of advanced cancer at any time up to 7 years from randomization (time-to-event endpoint, comparison via log rank test) and powered at 85% for a 20% relative reduction in advanced cancer at 4.5 years from randomization

Biorepository: Biopsy tissue, blood, and buccal cell biospecimens

Accrual Goal: 69,297/128,905

Current Enrollment: 20.4 AA; 5.9 Hispanic; 1.8, Asian, 0.3, AI/AN; NH/PI 0.2
Non-treatment/IND Investigators

- Current registration process places unnecessary burden on researchers that wish to exclusively participate on non-treatment and/or non-IND studies.

<table>
<thead>
<tr>
<th>Documentation Required</th>
<th>IVR</th>
<th>NPIVR</th>
<th>NONIVR</th>
<th>AP</th>
<th>A</th>
<th>AB</th>
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<tr>
<td>FDA Form 1572 / International Investigator Statement (IIS)</td>
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<td>✔</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Financial Disclosure Form</td>
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<td>✔</td>
<td></td>
<td>✔</td>
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<tr>
<td>NCI Biosketch (education, training, employment, license, and certification; includes GCP training)</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agent Shipment Form (if applicable)</td>
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</tr>
<tr>
<td>CV (optional)</td>
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<td>✔</td>
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</tr>
</tbody>
</table>

IVR = Investigator; NPIVR = Non-physician Investigators; NONIVR = Non-treatment/Non-IND Investigator; AP = Associate Plus; A = Associate; AB = Associate Basic
NCI Community Oncology Research Program (NCORP) Challenges
COVID-19: Past, Current & Future Impact

MEMORANDUM

DATE: March 13, 2020

TO: Principal Investigators and Operations/Statistics Offices of NCI CTEP Supported Clinical Trials Network & Consortia and DCF-Supported NCI Community Oncology Research Programs (NCORP), Research Bases

FROM: Meg Moore, MD, Associate Director; CTEP, DCTD, NCI

SUBJECT: Interventions Guidance for Patients on Clinical Trials Supported by the NCI Cancer Therapy Evaluation Program and the NCI Community Oncology Research Program (NCORP)

Due to concerns regarding the spread of the novel coronavirus and the impact it is having on hospitals, clinics, physician offices, and patients' ability to travel, the NCI Cancer Therapy Evaluation Program (CTEP) and the NCI Community Oncology Research Program (NCORP) are providing clarification on measures to address some of the current challenges in providing care to patients enrolled in clinical trials supported by CTEP and the NCORP in order to mitigate immediate burdens to the patients.

General Guidance for All Trials (Both IND and Non-IND Trials)

Transfer of Patient’s Care to a Different Participating Study Site: If it becomes necessary to transfer a patient's care to a different study site, this can be accomplished online using standard operating procedures available on the Cancer Trials Support Unit (CTSU) OPEN website. Active study sites can be found on the CTSU members site at [https://www.ctsu.org/public/default_login.aspx](https://www.ctsu.org/public/default_login.aspx).

- For NCTCN and NCORP studies: Use the CTSU OPEN Website ([https://open.ctsu.org](https://open.ctsu.org)) to access the Transfer and Update Module (TACM). Please review the TACM User Guide located under Training and Demonstration Materials before logging into OPEN.

Alternatively, investigators can use the Patient Transfer Form located on the CTSU website ([https://www.ctsu.org](https://www.ctsu.org)) under the Resource tab → CTSU Operations Information → CTSU Forms (login required). This form can be completed online or by hand and uploaded to the Regulatory Submissions Portal.

- For ECOG and Other Consortia: Complete the Patient Transfer Form online or by hand and upload it to the Regulatory Submissions Portal.

Sites can contact the CTSU Help Desk with any questions or concerns regarding patient transfers and identifying active study sites at CTSUContact@nctrihc.org or 1-800-823-0523.

- Are there specific trials more affected than others?
- Are there specific populations more affected others?
- Are there specific institutions more affected than others?
Patients at the Nashville General Hospital
Meharry Minority CCOP/Vanderbilt

Co-morbidities per Patient

<table>
<thead>
<tr>
<th>Co-morbidities per Patient</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>15</td>
</tr>
<tr>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>10</td>
</tr>
<tr>
<td>4</td>
<td>20</td>
</tr>
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<td>7</td>
<td>5</td>
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<tr>
<td>9</td>
<td>5</td>
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<tr>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>11</td>
<td>5</td>
</tr>
</tbody>
</table>

Legend:
- NGH
- VU
Patients at the Nashville General Hospital
Among the most important factors are **social determinants of health**, which are defined by the NCI as the conditions in which people are born, grow, live, work, and age, including the health system.

Division of Cancer Control & Population Sciences, National Cancer Institute, NIH. https://cancercontrol.cancer.gov/
Expanded Data Collection to Characterize Trial Participants
Use of a Clinical Trial Screening Tool to Address Cancer Health Disparities in (NCORP)

Of the 19,373 individuals invited to participate in an NCORP/CTEP trial within NCORP

16,095 (83%) provided informed consent

11,902 (74%) enrolled onto a clinical trial

Not-enrolled: 50% were ineligible; 47% were eligible but declined

“Without adequate rates of participation by patients and physicians, it is unlikely that important research questions with the potential to improve patient outcomes will be answered efficiently and effectively”
NCORP 2020: Cancer Prevention & Primary Care

• Changes in NCORP Institutions:
  ❖ Community Sites: 10 integrated health systems, 6 non-integrated health systems, and 16 hospital practices,
  ❖ Minority/Underserved Community Sites: 1 safety net hospital, 1 health system, 3 academic/safety net, and 9 academic
• 9 Veterans Administration Hospitals
• Increased complexity of trials
• Increased co-existing comorbidities, different restricted referral patterns, closed systems
THE GREAT MIGRATION

THE GREAT RESIGNATION!!!
NCORP Trial Enrollments by NPIVRs (APPs)*

*NCI DCP/DCCPS Guideline permitting APPs to enroll participants to NCORP trials/studies released 10/14/20

1,007 NPIVR’s listed in NCORP-SYS as members of NCORP’s (as of 4/1/22)
• 948 are fully active
• 55 are awaiting rostering to a NCORP Research Base
• 4 pending approval

<table>
<thead>
<tr>
<th></th>
<th>8/1/19 – 7/31/20</th>
<th>8/1/20 – 7/31/21</th>
<th>8/1/21 – 2/28/22**</th>
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<tbody>
<tr>
<td>NCORP Clinical Trials</td>
<td>0</td>
<td>458</td>
<td>342 (annualized = 586)</td>
</tr>
<tr>
<td>NCORP CCDR Studies</td>
<td>0</td>
<td>24</td>
<td>88 (annualized = 151)</td>
</tr>
<tr>
<td>Total</td>
<td>0</td>
<td>482</td>
<td>430 (annualized = 737)</td>
</tr>
</tbody>
</table>

** Reflects 7-months
Overall Challenges

• Co-morbidities
  • ASCO- NCI, Kim, et al., Clin Cancer Res 2021 May 1;27(9):2394-2399.

• Culture of some populations and clinical disciplines

• Cost to the patients and practices

• Staffing
  ❖ New NCI Advanced Practice Providers Policy
NCORP: Cancer Disparities Strategies

Provide Access for Participation in Clinical Research

Develop Concepts to Reduce Disparities among Underserved & Underrepresented Populations in the Network

Evaluate cancer care in the context of its diverse delivery
Early Onset Malignancy Initiative: Eligibility - Newly Diagnosed Patients

<table>
<thead>
<tr>
<th>Cancer Sites</th>
<th>Age Cut Offs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast</td>
<td>≤45</td>
</tr>
<tr>
<td>Colon</td>
<td>≤55</td>
</tr>
<tr>
<td>Liver</td>
<td>≤55</td>
</tr>
<tr>
<td>Multiple Myeloma</td>
<td>≤50</td>
</tr>
<tr>
<td>Prostate</td>
<td>≤55</td>
</tr>
<tr>
<td>Renal*</td>
<td>≤50</td>
</tr>
</tbody>
</table>

Tumor and nI tissue sample: early dx pts Molecular characterizations Host immune status w immunophenotype

A collaboration between the Division of Cancer Prevention (DCP), Center for Cancer Genomics (CCG), and Center for Research Strategy (CRS)

Populations:
African-American, Caucasian, Hispanic, Native American

*Renal in Native Americans Only
Focus on Health Disparities: Which Pandemic?

…the COVID-19 pandemic has shone a bright and deeply distressing light on just how much health inequity persists in our society. We need to look at this unflinchingly, and embrace that challenge, enlisting the vision of the talent all around us.”  Francis Collins, NIH, June 2020

“During these unprecedented times, I do take comfort in knowing that our mission includes and benefits everyone, regardless of race, socio-economic status, education, geographic location or access to care. The events taking place today only strengthen our resolve to help eliminate these injustices.”  Ned Sharpless, NCI, June 2020
Health equity is the aspirational goal of optimal health for all.
NCORP Disparities-Focused Portfolio

- S1417CD is the first national prospective cohort study to measure the financial impact of cancer diagnosis and treatment on patients (and caregivers)
- To estimate the cumulative incidence of self-reported major financial hardship (MFH) at 12 months in patients age ≥ 18 within 120 days of mCRC diagnosis on systemic chemo or biologic tx.
- One of more of the following:
  — New debt accumulation
  — Selling/refinancing home
  — ≥ 20% income decline
  — Borrowing money/Loans to pay for cancer treatment
NCORP Disparities-Focused Portfolio

S1417CD

N=368 eligible patients (73% alive at end of 12 mo)
Median age: 60.2 (21.2, 89.3); Gender: Male (62%)
Race: White (78%); Black (13%); Asian (4%)
Marital status: Married (59%)
Insurance: Private (46%); Medicare (39%); Medicaid (12%); Uninsured (2%)
Annual household income: ≤ $50K (58%)
Education: ≤ high school graduate (40%)
Employment (pre-diagnosis): Employed (62%); Retired (26%); Disability (7%)
NCORP Disparities-Focused Portfolio

• S1417CD Conclusions:
  • Patients are willing to participate in research that aims to address their financial concerns.
  
  • MFH accumulates over time. Nearly 75% of pts experienced MFH at 12 mo despite access to health insurance. Lower income and assets increased risk for MFH.

  • Clinical and policy interventions are needed to protect cancer patients from financial devastation during and after treatment
Disparities Research Approaches to Move toward Equity:

• **Clinical Trials: Integration/Partnerships**
  - Pooling and sub-analyses of data from completed studies or DCP-001
  - Enrich data to analyze sub-groups in new studies
  - Add disparities research questions to existing concepts
  - Initiatives to engage primary care physicians
  - Convene Research Base statisticians to explore trial designs
Considerations?

• Implementation of Medicaid Coverage

New Law Requires Medicaid Coverage of Clinical Trial Participation. Effective Jan. 1, 2022, Clinical Treatment Act expands clinical trial access to more than 41.6 million Medicaid beneficiaries
Re-assess strategic vision for clinical trials system for 2030 and beyond

Review and address necessary clinical trials infrastructure

Developed 15 recommendations & 3 operational initiatives

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**Themes:**

**Trial Complexity and Cost**

<table>
<thead>
<tr>
<th>Decentralized Trial Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local/Remote Conduct of Study Procedures</td>
</tr>
<tr>
<td>Telehealth Use in Clinical Trials</td>
</tr>
</tbody>
</table>

**Promoting Accrual and Access**

| Broaden Eligibility Criteria |
| Conduct Trials to Support Minority & Underserved Pt Needs |

**New Data Collection Approaches**

| Limit Data Elements Collected |
| Using EHRs to Support Clinical Trials |

**PRO Data for Clinical Trials**

**Operational Burden**

**Statistical Issues**

**Workforce Outreach and Training**
In Conclusion:

- Community-Based NCI Clinical Trials Network supports unique research studies that complement treatment
- Community-Based NCI Trials Network supports trials that are moving toward precision medicine
- Experiences from community investigators and practices inform all components of trial design and the conduct of those trials ----necessary before influencing policy
- Cancer care is primarily in the communities in which individuals live, community networks are at the helm as contributors of identifying and reducing cancer health disparities
Questions/Comments?