Initial Considerations in Developing CCDR Study Ideas Proposed for NCORP: Suggestions from NCI

The following questions and suggestions are intended to assist investigators and NCORP Research Bases and Sites in the early stages of developing a CCDR study. The goal is to identify questions and potential challenges that it would be helpful to address prior to moving forward. Please use this as a resource for discussions on conference calls and in-person meetings, as well as any other venue where it might be helpful to talk through an idea in a structured fashion.

To *assess an idea for fit with CCDR*, please consider:

Is there a well-articulated primary focus and related scientific question for the proposed study?

Per the definition of CCDR in RFA-CA-18-015, would the study have the potential to improve clinical outcomes and patient well-being by addressing a challenge experienced in community-based oncology practice?

Per the CCDR study type priorities described in RFA-CA-18-015, is the proposed work an observational or interventional study? For observational studies, what potential intervention targets will be identified? For interventional studies, is the study intended to generate evidence showing benefit or to disseminate an intervention that has been shown to be beneficial?

Is there an opportunity to include an aim addressing the unique needs and circumstances of minority or underserved populations?

To *assess feasibility and resource needs*, please consider:

Will the study be conducted within community-based oncology practice settings currently funded by NCORP or will disciplines outside the network need to be engaged? If the latter, what experience do the investigators and Research Base have in conducting research in those practice settings?

Can the Research Base NCORP infrastructure and funding support intervention development and delivery (if any); data auditing and management; statistical analysis; and all other study activities? If not, what other resources are potentially available?

Do the recruitment and data collection expectations seem generally reasonable within NCORP Community and Minority/Underserved Site infrastructure and funding?

To *prepare for a discussion with NCI staff*, in addition to the questions above please consider:

What are the plans for obtaining scientific and feasibility input from the Research Base's CCDR Committee? If the idea has been discussed formally or informally, what potential strengths and limitations were identified?

What are the plans for obtaining scientific and feasibility input from Community and Minority/Underserved Site investigators and staff? If the idea has been discussed formally or informally, what potential strengths and limitations were identified?

Do the investigators have a basic understanding of the distinction between a concept that gets peer-reviewed by the CCDR Steering Committee and a grant application that gets peer-reviewed by a NIH study section? If not, please provide an orientation prior to the discussion with NCI that includes the requirement to select one or the other types of peer review and, if a grant application is planned, to notify NCI of the submission in advance.

Developing Cancer Care Delivery Research Concepts

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NRG Oncology CCDR Committee
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#1: Assess Fit with Cancer Care Delivery Research

- Well-articulated primary focus and related scientific question?
  - Addresses challenge in community oncology practice?
  - Potential to improve clinical outcomes and patient well-being?
  - Interventional or observational study?
    - If observational, what intervention targets will be identified?
    - If interventional, generate evidence of benefit or dissemination of beneficial intervention?
- Opportunity to include aim addressing the unique needs and circumstances of minority or underserved populations?

#2: Assess Feasibility and Resource Needs

- Conducted within community-based oncology practice settings funded directly by NCORP or are other disciplines needed?
  - If latter, experience conducting research in those practice settings?
- Research Base infrastructure and funding adequate to support all activities?
  - If not, other source(s) of support?
- Recruitment and data collection expectations reasonable for NCORP Sites?

#3: Prior to Discussion with NCI

- Plans for obtaining scientific and feasibility input from
  - Research Base CCDR Committee?
  - Community and Minority/Underserved Sites?
- Investigators understand distinction between concept and grant?
  - Key: federal peer review by Steering Committee versus study section
  - Also important: process differences

Discussion with NCI*

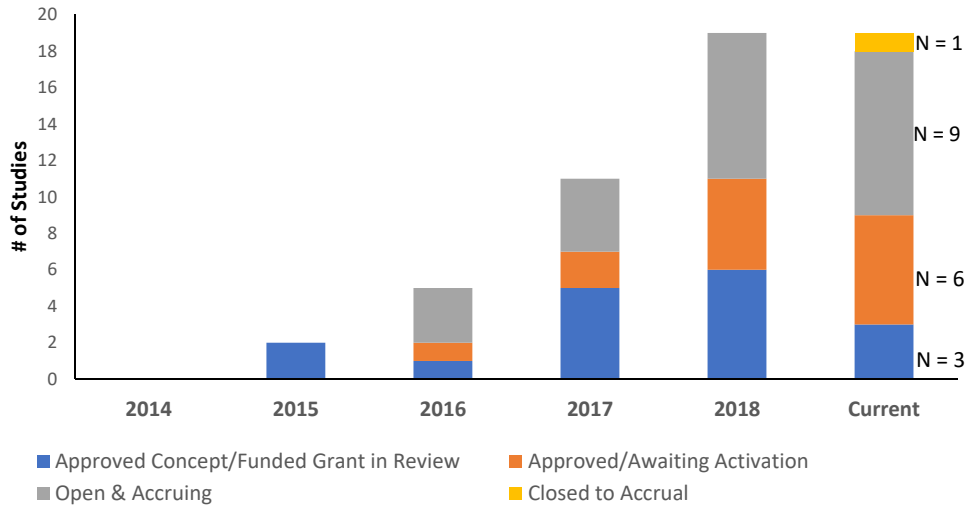
- Participants
  - Study PI (and others as desired)
  - Research Base CCDR Leads
  - NCI staff
- Goals
  - Identify potential pitfalls
    - Poor fit with CCDR
    - Potentially infeasible or excessive resource needs
    - Duplication of activities underway elsewhere
  - Identify additional resources
    - Contacts with relevant scientific and/or feasibility expertise
    - Option of applying for federal grant funding
  - Discuss timeframe

*Encouraged but not required

Reminder: Suggestions for Concept Preparation

- Develop empirically testable question with potential for immediate impact on clinical practice
  - What will sites do differently in response to results?
- Articulate essential methods
  - Population, timeframe, measures, and analysis (focus on primary endpoint)
- Document feasibility
  - Interest and capacity across NCORP affiliates & sub-affiliates
  - Landscape assessment
- Consult Steering Committee representatives

CCDR Portfolio Growth (as of 2/4/19)



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Accrual to CCDR Protocols (as of 2/4/19)

Protocol ID: Title	Current/Planned Enrollment
S1417CD: Implementation of a Prospective Financial Impact Assessment Tool in Patients with Metastatic Colorectal Cancer	Patients: 380/374 **CLOSED to Accrual**
S1415CD: A Pragmatic Trial to Evaluate a Guideline-Based Colony Stimulating Factor Standing Order Intervention (TRACER)	Patients: 2,615/3,960
ACCL15N1CD: Improving the use of Evidence-Based Supportive Care Clinical Practice Guidelines in Pediatric Oncology	Patients: 447/450 Clinicians: 35/82
A191402CD: Testing Decision Aids to Improve Prostate Cancer Decisions for Minority Men	Patients: 139 /172
ACCL16N1CD: Documentation and Delivery of Guideline-Consistent Treatment in Adolescent and Young Adult (AYA) ALL	Patients: 141/270 Clinicians: 10/48
WF20817CD: Implementation of Smoking Cessation Services in NCORP Organized Lung Cancer Screening Programs (OaSiS)	Patients: 363/1,114 Clinicians: 60/78
EAQ162CD: Longitudinal Assessment of Financial Burden in Patients with Colon or Rectal Cancer Treated with Curative Intent	Patients: 217/563
WF30917CD: A Stepped Telehealth Approach to Treat Distress in Rural Cancer Survivors	Patients: 6/90
WF-1803CD: Supportive Care Service Availability in Cancer Caregivers in Community Oncology Practices	Practices: 0/138 Providers: 0/690
EAQ161CD: Biomarker Testing in Common Solid Cancers: An Assessment of Current Practices in Precision Oncology in the Community Setting	Pathology Labs: 0/201
TOTAL	**Patients: 4,308** **Clinicians: 135**


EHR
CANCER CARE CLINIC
RESEARCH INTO PRACTICE
CANCER RESEARCH
PROVIDE BEST CARE
CANCER CARE DELIVERY RESEARCH
TIME
COST
HEALTH CARE
NATIONAL HEALTH POLICY ENVIRONMENT
STATE HEALTH POLICY ENVIRONMENT
LOCAL COMMUNITY ENVIRONMENT
ORGANIZATION
PROVIDER/TEAM
FAMILY & SOCIAL SUPPORTS
INDIVIDUAL PATIENT
900 SETTINGS
~4000 CLINICIANS
COMMUNITY
ORGANIZATION &/OR PRACTICE SETTING
PROVIDER TEAM
FAMILY & SOCIAL SUPPORT
PATIENT
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