
**NATIONAL CANCER INSTITUTE
COMMUNITY ONCOLOGY RESEARCH PROGRAM (NCORP)
EXTERNAL EVALUATION WORKING GROUP**

WORKING GROUP FINAL REPORT, SEPTEMBER 22, 2017

EXECUTIVE SUMMARY

The National Cancer Institute Community Oncology Research Program (NCORP) External Evaluation Working Group was tasked with assessing the value and impact of NCORP in order to determine whether NCI should proceed with the NCORP funding opportunity reissuance. After considering the clinical and scientific value of NCORP, the Working Group recommends that the program be continued. This report contains the evidence for that recommendation as well as recommendations for NCORP improvement going forward.

INTRODUCTION

NCORP is a network of Research Bases, Community Sites, and Minority/Underserved (M/U) Community Sites that (1) designs and conducts cancer prevention and control (CP/C) clinical trials, (2) designs and conducts cancer care delivery research (CCDR) studies, and (3) provides enhanced patient and provider access to treatment and imaging trials conducted through the National Clinical Trials Network (NCTN). NCORP was created in 2014 as the successor to two existing NCI community-focused programs, the NCI Community Clinical Oncology Program (CCOP) and the NCI Community Cancer Centers Program (NCCCP). The overall goal of the program is to bring cancer clinical trials, as well as CCDR studies, to individuals in their own communities, generating evidence that is broadly generalizable and contributes to improved patient outcomes as well as a reduction in cancer disparities.

To fulfill NCI's requirement for an external evaluation in association with funding opportunity renewals, the NCORP External Evaluation Working Group was convened to address two key questions:

1. Is NCORP of sufficient value to recommend that NCI proceed with consideration of re-competing the program?
2. Are there any major recommendations that NCI should consider to improve the conduct and impact of research within NCORP?

In addressing these questions, the Working Group was asked to consider five areas of evaluation:

1. Overall scientific and clinical practice impact of NCORP activities
2. Extent to which the NCORP infrastructure supports its research portfolio
3. Efficiency of NCORP clinical trial development and conduct
4. Collaborations across NCORP and with other federal and non-federal organizations
5. NCORP's support and conduct of CCDR

Assessment of individual program components, specific clinical trials, specific funding levels, and content and language for the NCORP Requests for Applications (RFAs) was outside the Working Group's charge.

The NCORP External Evaluation Working Group members (listed in Appendix 1) were chosen for their knowledge of oncology research in the community setting and were determined to be free from conflicts of interest related to NCORP. In preparation for the evaluation, members reviewed the source materials listed in Appendix 2. At a face-to-face meeting on July 10, 2017, NCI provided its perspective on NCORP, and Working Group members assigned to the five areas of evaluation presented the strengths and weaknesses of NCORP drawing on the evaluation source materials. Based on this information, the Working Group recommended the continuance of NCORP. The Working Group then summarized the evidence in support of this recommendation and identified opportunities for NCORP improvement.

OVERALL RECOMMENDATION

The NCORP External Evaluation Working Group recommends that NCI proceed with NCORP RFA reissuance.

EVIDENCE IN SUPPORT OF NCORP CONTINUATION

Working Group members identified the following strengths of NCORP, organized by the five areas of evaluation, as the most important evidence in support of NCORP RFA reissuance.

OVERALL SCIENTIFIC AND CLINICAL VALUE AND IMPACT

The Working Group concluded that NCORP has made important contributions in terms of scientific and clinical value and impact. The members noted that NCORP acts as a critical engine to support cancer research in the community setting and designs and manages CP/C trials and CCDR studies focused on important issues that have the potential to improve patient care. The Working Group concluded that the program has (1) made progress in advancing symptom science, (2) conducted important quality of life (QOL) studies in association with therapeutic trials, (3) reinvigorated the cancer prevention and screening research portfolios including a new emphasis on the important topic of overdiagnosis, (4) introduced new initiatives to enhance cancer disparities research, and (5) made substantial contributions to accrual for NCTN treatment and imaging trials.

INFRASTRUCTURE SUPPORT OF RESEARCH PORTFOLIO

The NCORP network is designed to (1) reflect the unique challenges of caring for patients in diverse community settings, (2) support accrual from Community Sites and M/U Community Sites to CP/C trials, NCTN treatment and imaging trials, and CCDR studies, and (3) promote effective development and management of CP/C trials and CCDR studies at Research Bases. The Working Group concluded that the infrastructure across NCORP Community Sites, M/U Community Sites, and Research Bases, as well as the infrastructure housed at NCI, adequately support the majority of these requirements.

In support of this conclusion, the Working Group cited the fact that the 34 NCORP Community Sites and 12 M/U Community Sites and their 930 components have a wide geographic distribution and reflect the spectrum of healthcare environments providing cancer care across the U.S. (including integrated health systems, consolidated oncology practices, safety net hospitals, small oncology practices, and academic institutions with substantial minority patient populations). These sites treat a diverse population, resulting in 21% minority accrual overall and 54% at M/U Community Sites. The Working Group identified the diversity of NCORP community settings and patient populations as one of the program's greatest strengths.

The Working Group noted that NCORP Community Sites and M/U Community Sites continue to accrue well to NCTN treatment and imaging trials, as well as to CP/C trials. Working Group members acknowledged that there are accrual challenges due to the changing nature of clinical trials and a decrease in the number of trials available nationally, but considered the increase in NCORP accruals to screening, biomarker, and QOL studies between 2014 and 2016 a testament to the successful accrual efforts of the NCORP network.

The Working Group also concluded that the infrastructure of the NCORP Research Bases supports the development of trials consistent with NCORP's research priorities. The development of CCDR infrastructure at Research Bases was identified as a specific accomplishment that advanced NCORP's ability to achieve its scientific objectives.

In addition to infrastructure associated with NCORP Community Sites, M/U Community Sites, and Research Bases, the Working Group also discussed NCI activities in support of NCORP. Examples of NCI infrastructure changes that were judged to have advanced the NCORP scientific agenda include the creation of the NCI Division of Cancer Prevention (DCP) Central Institutional Review Board (CIRB) and new initiatives in health disparities research (e.g., identification of tumor genomic variations and gathering data on patients screened for participation in clinical trials in order to identify accrual barriers). The NCI has also convened working groups to improve trials for adolescents/young adults and underserved populations, accrual to prevention trials, and the conduct of radiation oncology trials.

EFFICIENCY OF STUDY DEVELOPMENT AND ACCRUAL

NCORP's success depends on the efficiency of both study development (from concept submission through enrollment of the first patient) and accrual. Working Group members identified several NCORP strengths in these two areas as evidence in support of NCORP RFA reissuance.

The Working Group noted that 51 study concepts have been submitted to NCORP over a period of 32 months; 55% of these concepts have been approved, an approval rate comparable to that observed for NCTN concepts.¹ A total of 31 NCORP studies have been activated since August 2014, and an additional 23 studies have been approved but are pending activation.² Working Group members noted that the top-accruing trials are high impact clinical trials and important cancer control studies.

¹ Data cited in this paragraph include both CP/C and CCDR studies.

² Many of the approved and activated studies were already in the concept approval or study development process when NCORP was formed.

The Working Group also noted the increase in overall NCORP accrual to treatment and cancer control trials from 2014 to 2016 (from 6,319 accrual credits to 8,768³ accrual credits). NCORP Sites contributed 25-30% of accrual to NCTN treatment trials between 2014 and 2016, including 44% of MATCH accrual.⁴ Minority accrual across NCORP is robust at 21%, including 15% at Community Sites and 54% at MU Community Sites. Between 2014 and 2016, 75-90% of NCORP enrollments were primary study enrollments rather than ancillary study enrollments. However, substantial enrollment by NCORP sites to QOL sub-studies of NCTN treatment trials was also identified by the Working Group as a strength of the program.

COLLABORATION

The Working Group identified several indicators of the extent of collaboration across NCORP. Among the Top Achievements reported by Research Bases, 12% involved cross-Research-Base collaboration, 38% involved collaboration with one or more NCORP sites, and 28% involved collaboration with institutions external to NCORP (e.g., pharmaceutical companies, international organizations, or other NCI/NIH programs). Some NCORP studies also have funding from other NIH entities, scientific societies, advocacy groups or industry (e.g., 30% of symptom management/QOL studies receive outside support). Furthermore, many NCORP studies require that Sites collaborate with other departments at their institutions. Finally, the Working Group noted there was evidence of active Community Site participation in Research Base committees and working groups.

CANCER CARE DELIVERY RESEARCH

The Working Group noted that NCORP offers clear advantages for the conduct of CCDR studies. Because 85% of cancer care is delivered in the community setting and the NCORP network encompasses a variety of such settings, NCORP can serve as a microcosm of the larger healthcare delivery environment, providing a realistic setting for the conduct of CCDR studies and the opportunity to assess how organizational structures affect care. The Working Group commented that incorporation of CCDR into NCORP provides Community Sites and M/U Community Sites with the opportunity to leverage NCI funding to participate in other CCDR initiatives, such as those of the Patient-Centered Outcomes Research Institute (PCORI).

The Working Group noted further that the number of CCDR study concepts reviewed, the concept approval rate, and the number of studies opened per year are all similar to comparable metrics for NCTN and symptom management trials. This was viewed as an important measure of progress in launching this new area of NCORP research.

RECOMMENDATIONS FOR NCORP IMPROVEMENT

In addition to assessing the evidence in support of NCORP RFA reissuance, the NCORP External Evaluation Working Group made recommendations for future improvement relevant to each area of evaluation.

³ The 8,768 figure is an annualized estimate based on six months of 2016 NCORP accrual. It includes screening accruals to precision medicine trials.

⁴ All acronyms are defined in Appendix 3.

RECOMMENDATION RELATED TO OVERALL SCIENTIFIC AND CLINICAL VALUE AND IMPACT

- 1. NCORP should focus on (1) studies addressing priorities established for symptom science, (2) incorporating correlative science into study designs in order to understand the mechanistic basis of symptoms, (3) studies addressing real-life community practice issues, (4) studies to validate current practice guidelines, and (5) developing clinical evidence to address gaps in existing guidelines.**

The Working Group acknowledged NCORP's contributions to date in symptom science, cancer prevention, cancer disparities and CCDR, but expressed the opinion that, going forward, the program should focus on the five critical areas listed in the recommendation. The first recommended focus is to emphasize symptom management/QOL trials that align with the priorities established by NCORP and the Symptom Management/QOL Scientific Steering Committee. In addition, because of the importance of understanding the mechanistic basis of symptoms, whenever feasible, it is recommended that symptom management/QOL trials should incorporate correlative science sub-studies. The Working Group also noted that NCORP should place additional emphasis on studies which could have important real-life, community practice implications, particularly studies that could validate current practice guidelines or develop clinical evidence addressing gaps in existing guidelines.

RECOMMENDATIONS RELATED TO INFRASTRUCTURE SUPPORT OF RESEARCH PORTFOLIO

- 1. NCORP should consider expanding CCDR infrastructure at Community Sites and M/U Community Sites.**

Working Group members noted that although CCDR is a priority research area for NCORP, evidence of dedicated CCDR infrastructure at the Site level is limited. Because expanded CCDR infrastructure at Community Sites and M/U Community Sites might enhance the program's ability to conduct CCDR, the Working Group suggested that NCORP examine whether CCDR infrastructure at Community Sites and M/U Community Sites is adequate and consider expanding it if the determination is made that insufficient infrastructure is limiting CCDR progress.

- 2. NCORP should optimize the involvement of advocates and other community members in the activities of Research Bases, Community Sites, and M/U Community Sites.**

Working Group members acknowledged the existence of advocacy committees at NCORP Research Bases, as well as the presence of advocates within other NCORP committees and the involvement of advocates in the activities of many NCORP Sites. However, to more effectively engage with this important group of stakeholders, the Working Group recommended that NCORP continue to seek additional opportunities for productive involvement of advocates and other community members in activities throughout the NCORP network. The group noted that the importance and utility of engaging advocates and community members is especially high at the Site level.

3. NCORP should investigate additional approaches for increasing the representation of underrepresented populations in clinical trials and advancing cancer health disparities research.

Working Group members noted that the NCORP research agenda would benefit from additional accrual from underrepresented populations. For example, while 54% of accrual from M/U Community Sites is minority accrual, other Community Sites accrue only 15% from minority populations. Some Working Group members felt that the program should seek to improve this latter figure. Members acknowledged the value of the NCORP Clinical Trial Screening Tool to inform efforts to improve accrual from underrepresented populations, including racial/ethnic groups, adolescents and young adults, and the elderly. However, the Working Group recommended that NCORP investigate two additional approaches to improve accrual from underrepresented populations. The first approach was to conduct focus groups aimed at identifying the barriers to and potential solutions for increasing accrual from underrepresented populations as well as for identifying important areas for future cancer health disparities research. The second was to review the demographic profiles (e.g., gender, age, race, ethnicity) of NCORP oncologists and other research team members to determine if provider characteristics correlate with accrual patterns in terms of underrepresented populations.

4. NCORP should provide support for Community Sites and M/U Community Sites in transitioning from large adjuvant studies to new molecularly targeted and precision medicine trials.

Working Group members acknowledged the challenge faced by some Community and M/U Community Sites in achieving their accrual goals due to the replacement of large, easy-to-accrue adjuvant trials in high volume diseases such as breast and colon cancer with smaller trials targeted at specialized patient populations. This trend is also at odds with the desire of community oncologists to be able to offer trial opportunities to a large number of their patients. Therefore, the Working Group recommended that NCI work closely with the Sites to understand these challenges and identify approaches for facilitating the transition. Such efforts could include education, re-evaluating the credit system to make credits more in line with the effort required for various activities and other incentives for participation in targeted and precision medicine trials.

RECOMMENDATIONS RELATED TO EFFICIENCY OF TRIAL DEVELOPMENT AND ACCRUAL

1. Research Bases and NCI should identify ways to expedite the timeline for trial and study development.

For study concepts submitted to NCORP, the average time between concept submission and concept approval is 148 days. The period between concept approval and protocol approval averages 449 days, including 130 days for finalization of the initially submitted protocol between DCP and Research Base staff. However, because of the time required to proceed from protocol approval to patient enrollment, the average time between concept approval and enrollment of the first patient is 581 days. Timelines are similar for CP/C trials and CCDR studies. The Working Group considered these timelines to be unacceptably long and made the following recommendations for reducing the timelines.

- Research Bases should examine their internal processes and identify ways to expedite the development of initial protocols based on approved concepts and also shorten the time required to enroll the first patient following final protocol approval.
- Research Bases and NCI should examine the iterative process required to finalize a protocol following submission of the initial draft protocol by a Research Base and identify ways to reduce both the number of iterations (“comment/revise/resubmit”) and the time required for each iteration.
- NCI should identify ways to expedite CIRB approval and final DCP approval of protocols.

2. NCI and the Research Bases should collaborate in monitoring timelines for development and activation of NCORP studies and identifying opportunities for improvement.

The Working Group acknowledged that the NCORP Research Bases and NCI DCP share responsibility for the lengthy timelines associated with study development and suggested that they work together to develop a formalized process for monitoring these timelines, identifying opportunities to expedite them and intervening when necessary.

3. NCORP Research Bases should be provided increased funding to support study chairs in protocol development.

The Working Group noted that NCORP CP/C clinical trial and CCDR study protocols are developed by physicians or scientists acting as study chairs. This role is in addition to their numerous other competing duties and is generally undertaken as a volunteer activity. This was viewed by the Working Group as a contributing factor to the lengthy time required for both initial protocol development and the iterative process with NCI for finalizing the protocol. Furthermore, members expressed concern that this effort may be overly burdensome for physicians and scientists and could contribute to burn-out and turnover among study chairs. The success of the NCORP research enterprise depends on engaged and committed study chairs, and, without additional study chair assistance, NCORP may be challenged in achieving its potential. The Group concluded that NCI should provide increased funding to the NCORP Research Bases to support study chairs in protocol development. Such funds could be used by the Research Bases to offer partial salary support for study chairs to develop protocols, to fund non-physician staff, such as scientific writers, to assist the chairs in protocol development or for any other purpose considered valuable in supporting protocol development by study chairs. Such funding would be expected to both

improve trial development efficiency and incentivize physicians to remain engaged with NCORP as study chairs.

4. NCI should track actual versus projected accrual rates for all NCORP trials.

The Working Group was unable to comment on accrual efficiency for NCORP trials because data were not available on the actual accrual rate for each study compared to the projected accrual rate when the study was activated. The group therefore recommended that NCI develop a process for comparing on a periodic basis (e.g., quarterly) the projected accrual rate for each active NCORP study with the study's actual accrual rate as a tool for identifying in real-time studies that are experiencing accrual problems.

5. Research Bases, Community Sites, and M/U Community Sites should identify accrual barriers and corrective actions for trials achieving less than 50% of their projected accrual rates.

The Working Group recommended that, using data from the accrual monitoring system recommended above, all NCORP components - Research Bases, Community Sites and M/U Community Sites - should implement a proactive process for identifying accrual barriers and possible corrective actions for any trial accruing at less than 50% of the projected accrual rate for that trial.

6. NCI should consider providing Community Sites and M/U Community Sites with funding targeted to recruitment and enrollment activities.

The Working Group noted that current NCORP funding for Community Sites and M/U Community Sites does not provide any dollars targeted specifically for recruitment and enrollment activities. Because such dedicated funding might address some of the difficulties in achieving projected accrual rates, the members recommended that NCI consider whether such targeted funding could be incorporated into the NCORP Site awards.

RECOMMENDATIONS RELATED TO COLLABORATION

1. An integrated, cross-Research Base approach for study development should be emphasized.

The Working Group acknowledged that 12% of the Top Achievements reported by NCORP Research Bases involved cross-Research-Base collaborations but indicated that NCORP would be strengthened by encouraging additional collaborations among Research Bases in study design and development.

2. NCORP Research Bases should coordinate with community physicians to develop study designs that are more implementable.

Working Group members emphasized that one of NCORP's greatest strengths is its role in facilitating cancer research within community oncology practices where the majority of cancer care is delivered. The group noted, however, that practical challenges in implementing NCORP study protocols at NCORP Community Sites and M/U Community Sites can impede progress. The Working Group therefore recommended additional coordination between Research Bases and Sites to create study designs that can be more easily implemented. Measures that might improve the feasibility of implementation include

less restrictive eligibility requirements, simpler procedures, and use of existing electronic health record data fields, among others. In addition, there should be proactive communication concerning the strategic benefits to the host organization from participating in the trial.

3. Proactive efforts should be developed to disseminate NCORP research results to the larger world of community oncology practices.

The Working Group acknowledged the contributions of NCORP-supported research to the CP/C and CCDR knowledge bases, recognized that the NCORP model is well-suited to encourage integration of research results into practice at NCORP Community Sites and M/U Community Sites, and noted the contributions that NCORP CCDR makes to the study of implementation. The group also indicated that while it is not NCORP's role to *ensure* implementation of research results, NCORP should be more proactive in disseminating research results to *facilitate* translation to practice within the larger oncology community.

4. NCORP should expand the Non-Oncology Working Group to include providers outside of the Research Base sphere.

Working Group members expressed concern that the NCORP Non-Oncology Working Group is composed mainly of health care providers associated with Research Bases rather than with community practices. The Working Group recommended the inclusion of other provider groups that are not associated with Research Bases but are engaged in prospective research in the community setting, such as providers associated with Clinical and Translational Science Award (CTSA) institutions.

5. NCORP Community Sites and M/U Community Sites should engage community members and advocates to enhance accrual and dissemination of results by educating, informing, and updating them on the value of NCORP clinical research.

The Working Group emphasized that NCORP Sites could improve outreach efforts to better engage patient advocates and other community members at the local level. Such efforts should be geared toward increasing understanding of the function, value, and outputs of NCORP with the goal of enlisting the support of advocates and other members of the community in promoting accrual to NCORP studies and disseminating NCORP study results. The Sites were also encouraged to engage relevant community members on a trial-specific basis to facilitate accrual and dissemination. Finally, Sites were encouraged to share best practices for successful outreach efforts.

6. NCORP should develop collaborations with additional non-NCORP entities.

Working Group members viewed additional collaborations between NCORP and non-NCORP entities such as the Centers for Disease Control and Prevention-sponsored state cancer consortia, state Departments of Health, the American Society of Clinical Oncology (ASCO), and the Commission on Cancer, among others, as critical partnerships to grow and advance the NCORP research agenda.

RECOMMENDATIONS RELATED TO CANCER CARE DELIVERY RESEARCH

1. NCORP should explore opportunities for CCDR studies addressing payer, utilization management, and big data/rapid learning system influences on care processes.

The Working Group indicated that there were some notable gaps in NCORP's CCDR portfolio and identified these gaps as opportunities for NCORP to engage in additional research related to major drivers of care delivery. Areas in need of additional research include payer practices, such as the Merit Based Incentive Program System (MIPS) and Alternative Payment Models (APMs); implementation of utilization management tools such as pathways; and big data/rapid learning systems. The Working Group clarified that the intent of this recommendation is not to deemphasize the current CCDR portfolio but rather to seek opportunities to explore additional research topics.

2. NCORP should better match compensation for the conduct of CCDR studies at Community Sites and M/U Community Sites

While the Working Group acknowledged that the NCORP network is an ideal platform for CCDR studies, members expressed concern that the current funding levels do not adequately compensate Community Sites and M/U Community Sites. CCDR work is an often uncompensated effort which is challenging in the current environment of shrinking budgets and reduced discretionary income. The Working Group therefore recommended studying real costs involved for CCDR to be implemented and providing appropriate compensation the conduct of such studies.

3. NCORP should expand the participation of community oncologists, primary care physicians, and practice managers/chief operating officers in CCDR study design and review.

Working Group members expressed the view that greater involvement of health services researchers and community oncologists in NCORP CCDR study design and review would be valuable and recommended additional engagement of these stakeholders. Moreover, because of their critical role in determining how care is delivered in the community setting, practice managers were also identified as particularly valuable stakeholders with whom to engage concerning study design. Practice managers control the resources and operationalization within the organization and their commitment to NCORP participation is critical to its success. It is also important to communicate to all these stakeholders the strategic benefits of participating in NCORP CCDR studies.

4. The Centers for Medicare and Medicaid Services (CMS) and commercial payers should be engaged to facilitate the conduct of CCDR studies.

As part of efforts to secure funding for CCDR studies, Working Group members recommended that NCORP engage CMS (particularly the Center for Medicare and Medicaid Innovation) as well as commercial payers to learn how they might facilitate the conduct of CCDR studies (e.g., through pre-authorization for reimbursement).

5. NCORP should develop collaborative relationships with organizations such as CMS, AHRQ, ASCO, and PCORI awardees for development of CCDR studies.

Working Group members identified additional individuals and institutions that might serve as useful collaborative partners during the development of CCDR studies, including CMS, the Agency for Healthcare Research and Quality (AHRQ), ASCO, PCORI awardees, the National Comprehensive Cancer Network (NCCN), and Komen scholars.

6. Research Bases, Community Sites, and M/U Community Sites should be encouraged to capitalize on delivery system changes that can serve as “natural experiments” for CCDR studies.

The Working Group identified ongoing changes in care delivery systems as opportunities for natural experiments that may provide valuable data and enhance understanding of cancer care delivery. Although the group acknowledged the difficulties associated with capitalizing on natural experiments in practice, they emphasized that opportunities should be identified and exploited insofar as is feasible.

7. Enrollment in CCDR studies should be expanded to NCTN sites.

Working Group members shared their perception that many NCTN sites have the required capability and would be eager to participate in NCORP CCDR studies.

APPENDIX 1 – WORKING GROUP MEMBERS

Chair

Robin Zon, MD, FACP

MHO Chair – Finance and Quality Committees
Government Relations Chair, ASCO
Clinical Practice Committee Past-Chair, ASCO
Past NICRC Principal Investigator for CCOP
Past Medical Director of Oncology Research
Memorial Hospital

Members

Howard Bailey, MD

Director, UW Carbone Cancer Center
Professor of Medicine
Associate Dean for Oncology
University of Wisconsin School of Medicine
and Public Health

Joanna M. Brell, MD

Associate Professor of Medicine
Case Western Reserve University
Associate Cancer Center Director
Clinical Research – MetroHealth Medical
Center

Arnold D. Kaluzny, PhD

Professor Emeritus of Health Policy &
Management
UNC Gillis Schools of Global Public Health
Senior Fellow
Sheps Center for Health Services Research
University of North Carolina at Chapel Hill

Patrick Loehrer, MD

Medical Oncologist and Chair for NCTN
Director, Indiana University Melvin and
Bren Simon Cancer Center
Associate Dean for Cancer Research
Indiana University School of Medicine

Nikhil C. Munshi, MD

Professor of Medicine
Harvard Medical School
Associate Professor, Medical Oncology
Dana-Farber Cancer Institute

Lisa Newman, MD, MPH, FACS

Director of the Breast Oncology Program
Henry Ford Health System

Gregory H. Reaman, MD

Associate Director, Oncology Sciences
Office of Hematology and Oncology
Products
Center for Drug Evaluation and Research
Associate Director for Pediatric Oncology
U.S. Food and Drug Administration

Mary Jackson Scroggins

Advocate
Pinkie Hugs, LLC
In My Sister's Care

APPENDIX 2 – SOURCE MATERIALS USED IN THE EVALUATION

1. NCORP program description (background, organizational structure, research priorities, portfolio descriptions)
2. Description of the Cancer Prevention and Control CIRB
3. NCORP Working Groups (mission, members, accomplishments, future directions)
 - a. Disparities
 - b. Non-Oncology Specialist
 - c. Radiation Therapy
 - d. Adolescent/Young Adult
4. NCORP accrual tables
 - a. Top eleven accruing NCORP trials
 - b. NCORP accrual to precision medicine NCTN trials
 - c. Accrual since August 2014 to all open CP/C trials by trial type and NCORP/non-NCORP, including minority accrual
 - d. NCORP enrollment credits
5. Timelines from concept approval to first patient enrolled for NCORP trials
6. NCORP trials activated or approved since August 2014
7. NCORP involvement in NCI Initiatives
8. NCORP clinical trial screening log
9. Major accomplishments and publications provided by each NCORP Research Base
10. McCaskill-Stevens, W., D. Pearson, B. S. Kramer, L. Ford, and S. M. Lippman. 2016. "Identifying and Creating the Next Generation of Community-Based Cancer Prevention Studies: Summary of a National Cancer Institute Think Tank." *Cancer Prevention Research*. doi: 10.1158/1940-6207.capr-16-0230.
11. Executive Summary: National Cancer Institute Symptom Management and Health-related Quality of Life Steering Committee Clinical Trial Planning Meeting
12. CCDR Overview
 - a. Introduction to CCDR
 - b. NCORP CCDR objectives and progress to date
 - c. Kent, E. E., S. A. Mitchell, K. M. Castro, D. A. DeWalt, A. D. Kaluzny, J. A. Hautala, O. Grad, R. M. Ballard, W. J. McCaskill-Stevens, B. S. Kramer, and S. B. Clauser. 2015. "Cancer Care Delivery Research: Building the Evidence Base to Support Practice Change in Community Oncology." *Journal of Clinical Oncology* 33 (24):2705-2711. doi: 10.1200/jco.2014.60.6210.
 - d. CCDR protocols
 - e. CCDR Landscape Capacity Assessment
 - f. CCDR Landscape abstracts
 - g. NCORP CCDR Coordinating Committee and Working Groups
 - h. CCDR concept to protocol timelines
 - i. NCORP Research Base CCDR evaluation summary
 - j. NCORP Community and MU Site CCDR evaluation summary

APPENDIX 3 – ABBREVIATIONS

AHRQ	Agency for Healthcare Research and Quality
APM	alternative payment model
ASCO	American Society of Clinical Oncology
CCDR	cancer care and delivery research
CIRB	Central Institutional Review Board
CMS	Centers for Medicare and Medicaid Services
CP/C	cancer prevention and control
CTSA	Clinical and Translational Science Awards Program
DCP	NCI Division of Cancer Prevention
MATCH	NCI Molecular Analysis for Therapy Choice
MIPS	Merit-based Incentive Payment System
MU	minority/underserved
NCCN	National Comprehensive Cancer Network
NCI	National Cancer Institute
NCORP	NCI Community Oncology Research Program
NCTN	NCI National Clinical Trials Network
NIH	National Institutes of Health
PCORI	Patient-Centered Outcomes Research Institute
QOL	quality of life
RFA	Request for Application