AD HOC WORKING GROUP ON STRATEGIC APPROACHES AND OPPORTUNITIES IN POPULATION SCIENCE, EPIDEMIOLOGY, AND DISPARITIES

REPORT ON NATIONAL CANCER INSTITUTE (NCI) EXTRAMURAL CANCER EPIDEMIOLOGY COHORT STUDIES

13th Joint Meeting of the BOARD OF SCIENTIFIC ADVISORS & NATIONAL CANCER ADVISORY BOARD
June 10, 2019
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To develop recommendations regarding how the extramurally supported cancer epidemiology cohort program (etiology and cancer survivor cohorts) can be enhanced.
Timeline of Working Group Activities

Invitations to Working Grp.
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- **Invitations to Working Grp.**
- **Sharpless - Charge to Working Grp.**
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May | June | July | Aug | Sept | Oct | Nov | Dec | Jan | Feb | Mar | Apr | May | June
---|---|---|---|---|---|---|---|---|---|---|---|---|---
2018 | | | | | | | | | | | | | 2019
Timeline of Working Group Activities

- **Invitations to Working Grp.**
- **Sharpless - Charge to Working Grp.**
- **All of US COHORT**
- **DCEG CONNECT COHORT**
- **SEER**
- **VIRTUAL POOLED REGISTRY**
- **NCI COHORT EVAL. PROJECT**

**Timeline:**

- May 2018
- June 2018
- July 2018
- Aug 2018
- Sept 2018
- Oct 2018
- Nov 2018
- Dec 2018
- Jan 2019
- Feb 2019
- Mar 2019
- Apr 2019
- May 2019
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- Working Grp. Report

May       June       July       Aug       Sept       Oct       Nov       Dec       Jan       Feb       Mar       Apr       May       June
2018

2019
NCI Current Portfolio
Cumulative Number of Funded Cohorts

Year Cohort Initially Funded by NCI

1976 Nurses’ Health Study


Survivor
Etiology

2001 Southern Community Cohort
NCI Current Portfolio
Cumulative Number of Funded Cohorts

Year Cohort Initially Funded by NCI

- 1976
- 1985
- 1993 Childhood Cancer Survivor Study
- 1995
- 2005
- 2015
- 2019 BMT Survivor Study

- Survivor
- Etiology
Process of Defining the Issues

Question Format
Question 1. The role of cohort studies in etiologic and survivorship research in human populations

How can NCI ensure that its cancer epidemiology cohort portfolio has the potential to address future questions related to cancer risk, cancer recurrence, cancer survival, and cancer-related long-term health outcomes?
Question 2. Utility of cohorts for addressing cancer health disparities

What is the best way to ensure that the portfolio includes cohorts with large numbers of one or more populations that have been understudied and underserved?
Question 3. Study design considerations for extramural cancer epidemiology risk and survivor cohorts

What are the optimal study designs to address cancer risk, recurrence, survival, and long-term health-related outcomes following cancer in human populations?
Question 4. Data sharing and collaboration

How can NCI ensure that the extramural scientists responsible for designing, organizing, and maintaining the cancer epidemiology cohorts remain motivated to continue these time-consuming efforts in this era of rapid sharing of data?
Defining the Issues – Question Format

Question 5. Funding models for cohorts

Is the funding mechanism to support cancer epidemiology cohorts optimal? If not, what other models might be better?
Executive Summary
Overview of Observational Cohorts in the NCI Extramural Portfolio

Q1 - The role of cohort studies in etiologic and survivorship research in human populations
Q2 - Utility of cohorts for addressing cancer health disparities
Q3 - Study design considerations for extramural cancer epidemiology risk and survivor cohorts
Q4 - Data sharing and collaboration
Q5 - Funding models for cohorts

Background
Working Group Assessment
Recommendations and Opportunities for Enhancement
Working Group Report

Executive Summary
Overview of Observational Cohorts in the NCI Extramural Portfolio

11. Q1 - The role of cohort studies in etiologic and survivorship research in human populations

6. Q2 - Utility of cohorts for addressing cancer health disparities

9. Q3 - Study design considerations for extramural cancer epidemiology risk and survivor cohorts

6. Q4 - Data sharing and collaboration

6. Q5 - Funding models for cohorts

Background
Working Group Assessment
Recommendations and Opportunities for Enhancement
Q1. The role of cohort studies in etiologic and survivorship research in human populations

.... there are circumstances where a cohort design reflects the most scientifically rigorous approach..... to investigate important existing and emerging topics relating to cancer risk and outcomes.

Thus, NCI should invest in providing sufficient infrastructure support for cohorts to.... address critical scientific gaps, anticipate the scientific questions of the future, and considers societal issues that are deemed to be of high importance with high impact.
Selected Recommendations and Opportunities for Enhancement

Q1. The role of cohort studies in etiologic and survivorship research in human populations

.... continue to support new and existing focused cohort studies to address specific cancer etiology and survivorship questions...

.... promote and facilitate the use of existing and planned intramural cohorts in order to leverage access of these resources for the broader extramural community....

.... support establishment/expansion of national infrastructure for ascertainment and follow-up of cancer cases....
Selected Recommendations and Opportunities for Enhancement

Q1. The role of cohort studies in etiologic and survivorship research in human populations

.... use of prevention and cancer therapy trials to address etiological research.... new survivor cohorts, opportunities to leverage the patient populations available through the NCI-supported cooperative clinical trials groups and the NCORP...

.. support the conduct of pilot studies to determine the feasibility and design for establishing an adult survivor cohort to investigate treatment-related adverse outcomes....

.... opportunities to draw upon the strengths/attributes of cohorts to conduct intervention research....
Q2. Utility of cohorts for addressing cancer health disparities

Additional cohorts are required to fill existing and future gaps in the NCI cohort portfolio on underrepresented populations. Insufficient numbers across the portfolio allow meaningful within-group comparisons.

Support additional biospecimen collection in existing cohorts that have an appreciable number of participants from a single underrepresented group to address scientifically important questions.
Selected Recommendations and Opportunities for Enhancement

Q3. Study design considerations for cancer epidemiology risk survivor cohorts

.... identify possible opportunities for embedding cohorts in interventions trials for primary prevention, screening and treatment ....

.... when scientifically justified, incorporation of serial data and biospecimen collection over time to capture time-dependent events...

.... support and facilitate methodological research to identify efficient and effective approaches for longitudinal specimen and data collection.
Q4. Data sharing and collaboration

.... Guidelines and/or mandates for data sharing of cohort-based data must take into consideration the investment of time and academic implications for investigators establishing and maintaining the cohort....

.... The investigator and staff time/effort associated with data sharing/collaborative efforts... ongoing funding for data sharing will be needed... supplements have not been an appropriate funding approach because of the limited timeline for activities.
Q4. Data sharing and collaboration

.... for existing cohorts... informed consents may not allow some types of data sharing... may not always be feasible to re-consent participants...

.... new cohorts should consent for broad data sharing as part of the initial enrollment procedure.
Q5. Funding models for cohorts

... NCI should continue to use a Cohort Infrastructure Program Announcement for funding of infrastructure... Investigator-initiated hypothesis-driven research based on cohorts should be funded through R grants, P01s and related mechanisms.

... It may be most effective for NCI to accept applications for new cohorts only in response to a call for applications, which would occur periodically as needed... applications for new cohorts should be considered in a special study section, separate from reviews of continuations of cohort.
Selected Recommendations and Opportunities for Enhancement

Q5. Funding models for cohorts

... Decisions about when to stop funding active follow-up of a given cohort should be based upon peer-review and the likely future productivity and importance of future findings...
Questions and Comments