Request for Information (RFI) NOT-CA-21-036: Leveraging NCTN/NCORP clinical trial populations for observational cancer survivorship research

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NCI staff involved in effort

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NCI Request for Information (RFI)

NCAB

- 2019 working group recommendation to leverage NCTN/NCORP clinical trial populations for cancer survivorship cohort studies

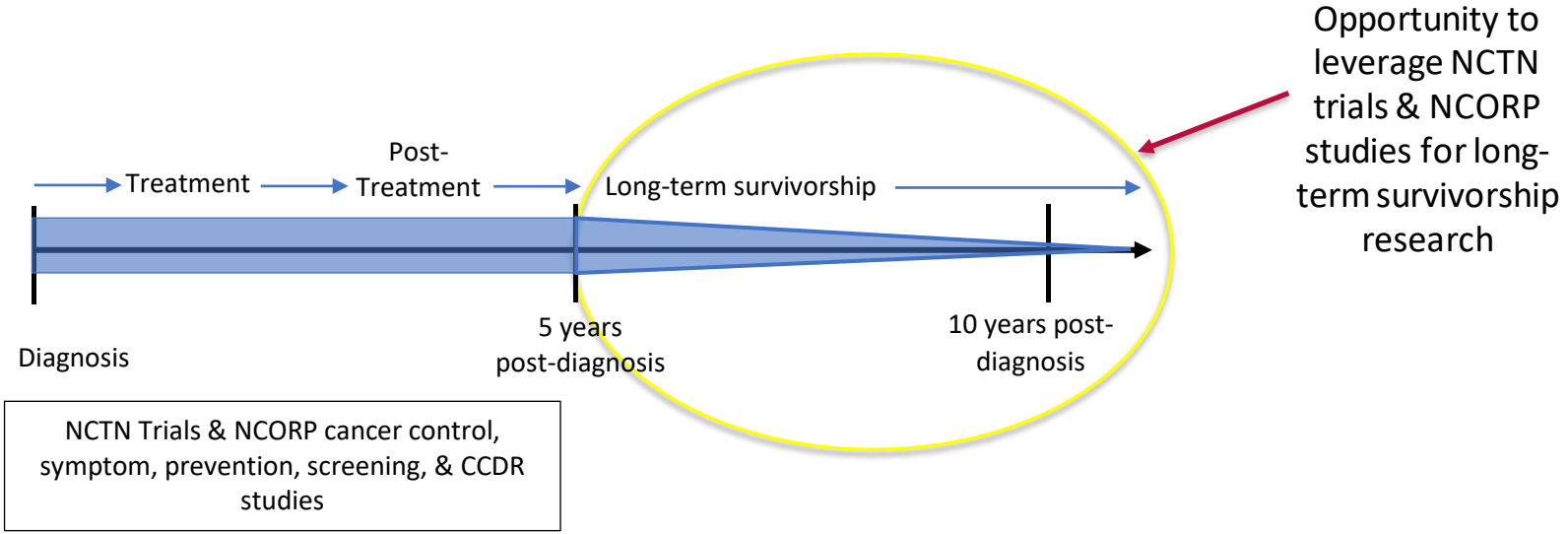
RFI

- NOT-CA-21-036: Leveraging NCTN/NCORP clinical trial populations for observational cancer survivorship studies
- Open February – May 2021

Results

- N=15
- Majority affiliated with NCTN/NCORP
- One response submitted from ECOG-ACRIN NCORP Research Base – with collated responses from investigators

RFI: Leveraging NCTN/NCORP populations for survivorship research



NCI Request for Information (RFI)

- Solicited information on:
  - Specific research questions or evidence gaps in cancer survivorship that can be addressed using existing NCTN and NCORP study populations
  - General methodologies to conduct observational research studies utilizing clinical trial populations
  - Strategies for using existing NCTN or NCORP infrastructure to support long-term cancer survivorship studies
  - Infrastructure needed to facilitate long-term cancer survivorship studies

RFI responses – Research questions

- Long-term survivorship outcomes associated with new or combination anti-cancer therapy (including immunotherapies and targeted therapies)
  - Survivorship outcomes of interest: aging outcomes, cardiotoxicity, cognitive function, sexual function, physical functioning; symptom and adverse outcome trajectories; financial toxicity
- Long-term survivorship outcomes among individuals diagnosed with rarer cancers
- The role of social determinants of health/health disparities on long-term survivorship outcomes
- Technology-based strategies for remote-based management of longer-term physical and psychosocial sequalae of cancer treatment

RFI responses – General methodologies

- Establish a clinical trial survivorship registry that includes all patients enrolled in NCTN treatment trials and NCORP studies for potential long-term cancer survivorship follow-up studies
- Conduct survey studies (of patient, caregiver, and provider) for longer-term follow-up data
- Link clinical trials data to Medicare, Medicaid and other claims data
- Leverage current methods for data collection: EASEE-PRO
- Establish a network of primary care practices – necessary to include and engage primary care practices via NCORP to facilitate large-scale studies of survivorship care

RFI responses – Barriers

- Clinical trial patients are not consented for ancillary or follow-up studies; not consented through a central mechanism; need to be re-consented
  - Can be difficult to re-locate trial participants for re-consent and/or follow-up, as patients may have died or contact information may have changed
- Ability to get sites to “open” ancillary studies
- Data linkages: may be insufficient information (without re-contact) to enable strong linkages
- “Expensive” to collect epidemiologic data in clinical trials

RFI responses – Strategies to utilize existing infrastructure

- Routine collection of patient consent for survivorship studies at time of clinical trial enrollment
- Require inclusion of ‘contact for future research’ section on the consent form; document this information centrally with patient contact information, clinical trial information, and small number of patient demographic characteristics

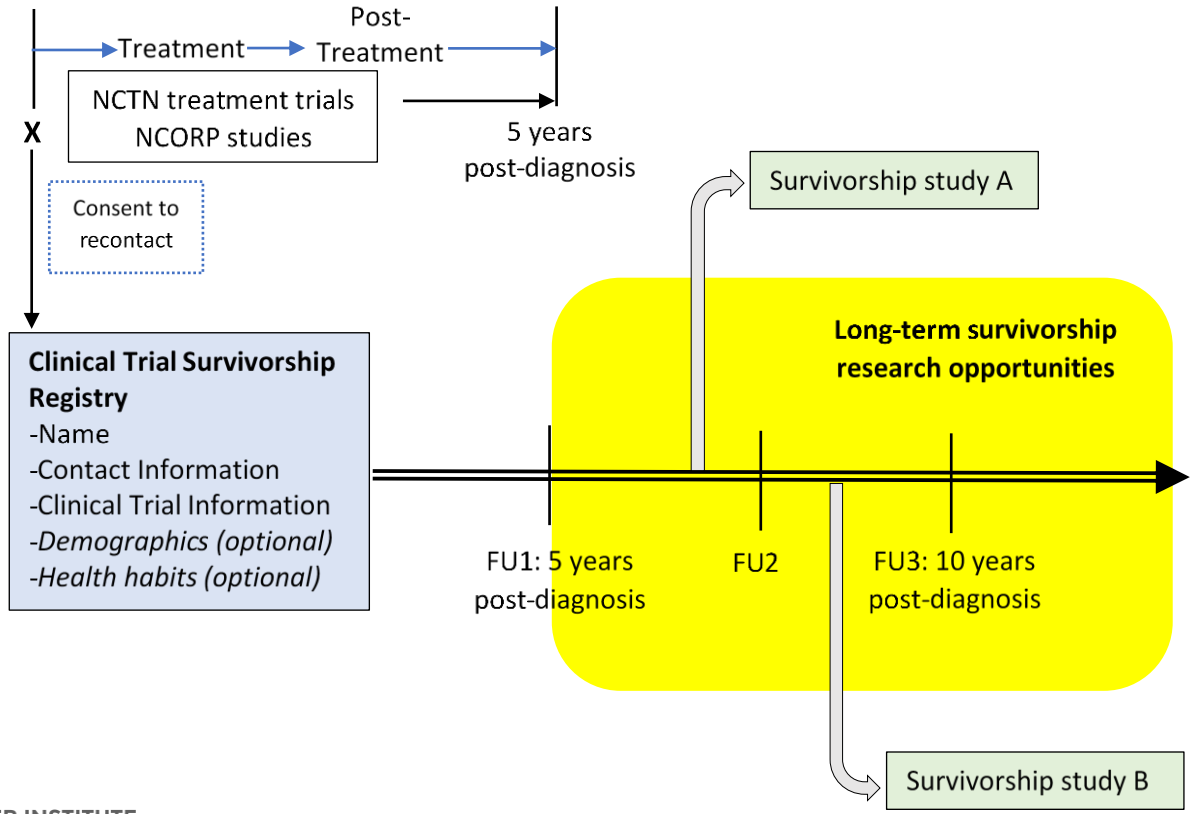
Common theme: Clinical trial survivorship registry

- Not a new idea (mentioned in Ganz et al., *JCS* 2009, 3:137-147)

What is needed is the establishment of "a clinical trials survivorship registry that encompasses participants across NCTN and NCORP trials. This could be accomplished through routine collection of patient consent, indicating patient's agreement to be contacted for future research and patient contact information to allow investigators to feasibly collect data from long-term cohorts. Implementing a mechanism that will allow investigators direct access to survivor cohorts through contacting potential participants directly, assuming approval of the parent NCTN or NCORP, NCI, and CIRB, will greatly maximize feasibility for survivorship cohort research."

-RFI respondent

Conceptual model of clinical trial survivorship registry



Research Base discussions: Clinical trial survivorship registry

- High level of enthusiasm by survivorship investigators in all meetings; appreciative that NCI is following up on NCAB working group recommendation
- Idea in some form has been discussed previously by all Research Bases (e.g., SWOG has discussed this as a "clinical trial survivorship cohort")
- Most investigators recognized that there would be a need to prioritize clinical trial (or other) populations for inclusion into the registry (e.g., those with the potential to live longer)
- There is existing infrastructure that could be utilized at some, but not all, Research Bases (e.g., ECOG-ACRIN: EASEE-PRO; Alliance: Patient Engagement Portal)
- Patients would be "absolutely willing" to consent; patient engagement and involvement of patient advocates is key
- Key considerations: protection of PHI, preventing selection bias resulting from self-selection into registry
- The primary barrier of developing a registry is funds to build and support re-contact of patients once in the registry

Summary

- RFI responses identified gaps in research pertaining to cancer survivorship that can be filled by leveraging NCTN clinical trial/NCORP study populations
  - Long-term (>5 years) survivorship outcomes associated with new treatments & treatment regimens
  - Long-term survivorship outcomes among individuals with rarer cancers
- Building a clinical trial survivorship registry would allow investigators to efficiently leverage NCTN clinical trial/NCORP study populations for cancer survivorship research
  - High level of enthusiasm from those who would utilize a registry
  - Existing infrastructure at NCORP Research Bases could be leveraged

Gaps in knowledge regarding feasibility of registry

- Number and types of NCTN/NCORP clinical trial patient populations eligible for registry
- Patient willingness to participate in registry (both overall and extent)
- NCORP community site willingness/capacity to consent & collect data given current workload
- Research Base ability to conduct follow-up, and for how long
- Data beyond patient contact and clinical trial information to be collected and at what intervals
- Projected effort/costs for building & managing registry, conducting follow-up

Questions for CTAC

- Are there additional gaps in cancer survivorship knowledge not mentioned in this presentation that you think NCTN and NCORP study populations can be leveraged to address?
- What do you think of the NCTN/NCORP clinical trial survivorship registry conceptual model?
- In your opinion, what are the pros and cons of developing a clinical trial survivorship registry for observational cancer survivorship research?