How to Succeed at Uniform Trial Classification

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Background

The New Studies Review Committee (NSR) established in late 2019 at Siteman Cancer Center (SCC) provides a systematic mechanism for reviewing the classifications of all oncology studies submitted via SCC's Clinical Trial Management System, OnCore. The NSR's review process addresses the need of ensuring uniformity in trial classification for categories reported in the Cancer Center Support Grant data tables with annual progress reports as well as the overall grant renewal. NSR membership consists of the SCC clinical research specialist for Clinical Trials Reporting Program (CTRP) / ClinicalTrials.gov registrations, the SCC associate director of clinical research, the SCC protocol development supervisor, the PRMC clinical program manager, and the PRMC senior protocol coordinator. These individuals have both broad and deep experience with oncology clinical research, National Cancer Institute (NCI) requirements and definitions, SCC's Protocol Review and Monitoring System's (PRMS) policies and procedures, and the wide-ranging context how specific trial classification fields affect reported data.

Goals

- Facilitate a collaborative approach for ensuring consistent and thorough reporting to the NCI
- Establish targeted definitions and decision guides for determinations made by the NSR
- Serve as an educational resource for oncologic research teams regarding trial classifications

Solutions and Methods

The NSR receives weekly reports generated from OnCore listing all studies submitted to SCC's PRMS in the preceding week. Using the definitions and decision guides developed by the committee from NIH guidance materials and revised over time, each member completes an electronic review survey for each study no later than a week prior to the monthly NSR meeting. The PRMC program manager then collates all survey responses and produces a Concordance Report highlighting areas for further discussion ("concordance" is defined for each field as at least three reviews in agreement). The Concordance Report is then sent to all members for pre-review in advance of the meeting to prepare for discussions of discordant fields in order to come to a consensus. Following each monthly meeting, the PRMC program manager ensures that the fields for all studies reviewed are listed in accordance with NSR determination within OnCore.

Outcomes, Lessons, Future Directions

Since its inception, the NSR has successfully determined the appropriate classifications for 400-500 new studies annually in the areas of protocol type and purpose, study phase, sponsorship, individual versus summary accrual tracking, program areas, survivorship, and other categories of interest. Prior to NSR, SCC experienced issues with study teams throughout the medical center consistently classifying new protocol submissions incorrectly, resulting in flawed internal reporting as well as external reporting to the NCI. NSR Committee assessment has thereby ensured consistency across studies, provided an avenue for the resolution of complex cases through monthly discussion, and created an opportunity to educate study teams regarding guidelines for trial classifications.

The NSR has proven to be an invaluable asset through use of a team-based model for the trial classification process at SCC. The definitions and decision guides will continue to be enhanced and further developed in conjunction with updated CTRP and NCI guidance.

New Study Review

Please complete the NSR worksheet below.

Thank you!

1) Date of NSR report _____

2) Submission number _____

3) PI last name _____

4) DT4 report type
- ○ ancillary or correlative
- ○ interventional
- ○ not applicable
- ○ observational

5) Protocol type (aka primary purpose)
- ○ basic science
- ○ device feasibility
- ○ diagnostic
- ○ health services research
- ○ other
- ○ prevention
- ○ screening
- ○ single patient
- ○ supportive care
- ○ treatment

6) Phase
- ○ early phase I
- ○ I
- ○ I/II
- ○ II
- ○ II/III
- ○ III
- ○ III/IV
- ○ IV
- ○ N/A

7) Pilot
- ○ Yes
- ○ No

8) Primary program code (aka program area)
- ○ Breast Cancer Research Program (BCRP)
- ○ Hematopoietic Development and Malignancy Program (HDMP)
- ○ Oncologic Imaging Program (OIP)
- ○ Prevention and Control Program (PCP)
- ○ Solid Tumor Therapeutic Program (STTP)
- ○ Tumor Immunology Program (TIP)

9) Secondary program code(s)
- ☐ Breast Cancer Research Program (BCRP)
- ☐ Hematopoietic Development and Malignancy Progra (HDMP)
- ☐ Oncologic Imaging Program (OIP)
- ☐ Prevention and Control Program (PCP)
- ☐ Solid Tumor Therapeutic Program (STTP)
- ☐ Tumor Immunology Program (TIP)

(select all that apply (do not re-select primary program code))

10) Summary accrual info only
- ○ Yes
- ○ No

11) Principal sponsor _____

12) Principal sponsor - roles
- ☐ agent source
- ☐ data analysis
- ☐ design
- ☐ funding source

(select all that apply)

13) Other sponsors _____

(after each sponsor, indicate applicable role(s))

14) Survivorship
- ○ Yes
- ○ No

15) IIT
- ○ Yes
- ○ No

16) Age(s)
- ○ adults only (A)
- ○ children only (C)
- ○ both adults and children (B)

17) Pragmatic study
- ○ Yes
- ○ No

18) Comments _____

19) Reviewer
- ○
- ○
- ○
- ○
- ○
- ○
- ○

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