FAQs related to the CCSG Data Tables (DT)

DT 1:

1. **Should a Shared Resource that was peer-reviewed and funded during the last CCSG grant cycle but is no longer receiving CCSG support because of budget constraints be listed in DT 1D?**

   Yes, this Shared Resource should be listed, if it received CCSG funding at any time during the previous cycle. If it was proposed for funding in the last competitive application but was not funded due to budget realignment, it should not be listed.

   Do not list Shared Resources that were not peer-reviewed during the last CCSG grant cycle.

DT 2A:

1. **How does a Center determine the percentage of a grant's funding that is cancer-relevant and what percentage of it fits into the Center's Research Programs?**

   These are decisions that each Center makes and should be able to justify to a review team.

2. **Centers are required to define a reporting date for DT 2A. Does the FOA mandate a particular date Centers should use?**

   No, the FOA does not specify a particular date for reporting DT 2 data. It is up to the Center to pick its reporting date.

3. **Do the project and program costs refer to those of the year of the reporting period?**

   Yes, these columns refer to the annual funding of the year of the center-defined reporting date, not the funding of the total project period.

   In the event that a multiyear grant is fully funded at the start of the project period, report the average per annum direct and total costs.

4. **Should Centers include cost-sharing contributions in DT 2?**

   No, include only direct and total costs in DT 2.

5. **Can a Center include the grants from another institution's faculty if they are members of the Center?**

   Only grants and contracts that flow to the institution of which the Center is a part can be included, even if the grantee is a member of the Center but whose grants flow to another institution. If the other institution in question is a formal CCSG peer-reviewed consortium partner, or a primary clinical arm, of the Center, then the member's grants may be included.

6. **Does DT 2 include non-cancer center member funding?**

   No, only center members' funding is listed on DT 2.

7. **Does the total funding for a Research Program include training grant dollars?**

   No, the total funding for a Research Program only includes research project dollars; training grants may be listed with each program but they should not be included in aggregate data.

8. **Can the cancer-relevant portion of the Clinical and Translational Science Award be included in Data Table 2?**

   Yes. As for any grant or contract, the Center must estimate and be able to justify the portion of the CTSA that they report as cancer relevant.

9. **How should awards without specific grant numbers be listed?**

   Include "N/A" in the "Complete Project Number" column

10. **How should a Center account for the portion of a grant that is subcontracted to another institution?**

    The Center should claim all annual, cancer-relevant dollars in the "project costs" columns of DT 2. However, only the portion of the funding that remains with the Center is listed under Program Costs. The difference in these amounts is understood to be the subcontracted portion.

11. **Should Centers include grants on a no-cost extension (NCE)?**

    Yes. List the end-date of the NCE and report the dollars remaining at the time of the Center's reporting date for the Costs.

12. **How should cores supported by SPOREs and other similar grant mechanisms be coded on DT 2A?**

All core facilities awarded to your Center, regardless of their funding source, should be coded as ZY (since they are not, in themselves, research projects, even though they support programmatic science and may have resulted from programmatic efforts).

DT 2B:

1. **Does DT 2B include the total cost of all grants?**

   No, as for DT 2A, DT 2B only includes the cancer-relevant portion of the grant portfolio.

2. **How are subcontracts awarded to your Center counted in DT 2B?**

   Each subcontract is counted as one project and the dollars are included in the total.

3. **How are the number of projects calculated for DT 2B?**

   Each research grant or contract, including subcontracts and grants in NCE, are counted as one project. For multi-project awards such as SPOREs or P01s, count each subproject individually. A SPORE with 5 subprojects equals 5 projects for DT 2B.

DT 3:

1. **Are patients in behavioral trials considered to be enrolled in "Interventional Treatment Trials" and included in DT 3?**

   Yes, if the behavioral trial is an intervention focused on treating the disease.

2. **Are primary and secondary prevention trials (*e.g.*, chemoprevention, diet, imaging) and supportive care trials considered to be "Interventional Treatment Trials"?**

   No, patients enrolled in these types of trials should not be included in DT 3, as they are not aimed at directly treating the disease.

3. **Is it possible for a patient to be "newly enrolled" in a trial but not be a "newly registered" patient?**

   Yes – if the patient was enrolled in a trial during the 12-month reporting period but was first seen by the Center before the reporting period.

4. **If a patient has 2 primary tumors that map to the same disease site (*e.g.*, breast), how should this be counted?**

   This patient would be counted twice in "Newly Registered Patients", assuming that both malignancies were diagnosed during the reporting period.

5. **If a patient was first seen for a tumor several years ago and then returned to the Center this year with a new primary tumor in the same disease site, how should this be counted?**

   This patient would count once in this year's "Newly Registered Patients" column. All primaries registered within the specified time frame are considered as new sites and should be counted.

6. **How should the Center report a patient who presents with a metastatic tumor when first seen at the Center?**

   The anatomic site would be the primary, not the metastatic, site.

7. **Should patients seen by private-practice doctors that are located in Center space (either the primary clinical component or affiliated clinics) but are not part of the Center's health plan and cannot participate in trials be reported?**

   These patients should not be counted as "newly registered patients."

8. **How should patients seen at consortium partners be reported in DT 3?**

   If the CCSG peer-reviewed and approved consortium partner reports new patients through the Center's cancer registry, they should be included in one DT 3. If the peer-reviewed consortium partner has a separate registry, a separate DT 3 should be included for each partner. Patients seen at clinical affiliates that are not peer-reviewed consortium partners and do not report patients through the Center's registry, should not be reported.

9. **How do the anatomic site diagnostic codes map to the cancer sites listed in DT 3?**

   The cancer sites reported on DT3 are mapped to the ICD codes listed here: http://cancercenters.cancer.gov/documents/ICD9-508.pdf

10. **Is there a benchmark relationship between the number of "newly registered patients" and number of "newly enrolled patients"?**

    Reviewers use these two sets of data to evaluate whether a Center is conducting clinical research studies on cancers of anatomic sites commonly seen at that Center. NCI does not set a particular benchmark that Centers should meet, and reviewers are reminded that there is not an exact correlation between the two sets of data (since "newly registered patients" usually undergo standard of care before being enrolled in trials).

DT 4:

1. **What studies should be included in DT 4?**

Cancer-relevant, hypothesis-driven studies that meet the definition of a clinical research study should be included in DT 4. This does not include tumor banks. It does not include chart reviews or other types of studies if they do not consent patients.

Clinical Research Categories

2. How should behavioral studies of nutrition, smoking cessation, or dietary supplements, etc., be classified?

Behavioral studies fit the clinical research definition of interventional (INT) studies. If they are intended to treat a disease, their Primary Purpose would be classified as a treatment (TRE) trial, and patients enrolled in such studies would be also be included in DT 3. If the behavior studied is intended to prevent disease (primarily or secondarily), then it should be classified as interventional with a primary purpose of prevention. In that case patients would be included in DT 4 but not DT 3.

3. How are radiologic studies classified?

Radiologic clinical research studies could be Ancillary or Correlative (imaging studies, for example), or radiologic treatments could be interventional.

Study Source

4. How are investigator-initiated trials classified with regard to Study Source?

Investigator-initiated trials are those in which the primary intellectual contribution (conception, design, implementation, *etc*.) originated with a cancer center member. For study source, they may be classified as Institutional, Externally Peer Reviewed, or even Industrial, if the center member was the intellectual source of the trial. Investigator-initiated trials can also include multi-institutional trials in which the center member had a significant intellectual contribution, even if the trial originated with another institution.

5. What trials are classified as "National"?

In addition to the National Clinical Trials Network (NCTN)-sponsored trials, any national trial network funded by NIH should be classified as National. National trial networks sponsored by other organizations should be classified as Externally Peer-Reviewed (if they are funded by the list of organizations found on the OCC website) or Institutional.

Specific Funding Source

6. **How should a Center account for an Institutional trial that receives industry support in the form of the drug?**

   Assuming that the primary intellectual contribution for the trial came from the Center member, the Study Source would be "Institutional" and the Specific Funding Sources would be the Center and the pharmaceutical company supplying the drug.

Anatomic Site

7. **If a Clinical Research Study covers more than one Anatomic Site, what should be included in the Site column?**

   This trial should be coded "multiple."

Protocol ID

8. **For National Clinical Research Studies (*i.e.*, NCTN), what number should be listed as the Protocol ID?**

   Only list the national protocol number; do not include your Center's internal protocol number.

Principal Investigator

9. **Are the clinical research study and the study PI always associated with the same Research Program?**

   Usually, but not always – it is possible that a trial resides with one program but the PI is a member of another program.

10. **Can there be more than one PI on a Clinical Research Study?**

    For the purposes of DT 4, only one PI may be reported.

Start and End Dates

11. **What should be included in the "End Date" column for studies that are open and still actively accruing?**

    Leave the "End Date" column empty; do not enter a space.

Phase

12. What Phase designation should be used for epidemiologic, cancer control/ behavioral, observational, ancillary, correlative, or other biological studies?

"N/A" should be used for these types of studies.

Primary Purpose

13. How many "Primary Purpose[s]" can a clinical research study have?

Each clinical research study has one Primary Purpose; these are Basic Science, Diagnostic, Health Services Research, Prevention, Screening, Supportive Care, Treatment or Other.

Official Title

14. How many characters can a Clinical Research Study's "Official Title" be?

An Official Title can be up to 32,000 characters. The text should be identical to the Official Title for the trial entered it in www.clinicaltrials.gov .

Accrual and Multi-site Studies

15. Does DT4 include accruals of healthy volunteers/ control groups that are part of the clinical research studies?

Yes.

16. Would a clinical research study open at the Center and a local affiliated site be considered a multi-site trial?

No. Multi-site trials recruit patients from two or more geographically distinct enrollment sites not closely affiliated with your Center, such as another NCI-designated Center. These sites are usually distinct in other characteristics (*e.g.*, demographic, socioeconomic, or clinical).

17. If the Center is the lead institution of a multi-site trial, such as an NCTN trial, what is entered into the "Total Targeted Accrual - Entire Study" column?

If the Center is leading the multi-site trial (including National trials), it would fill in the Total Targeted Accrual in the Entire Study column. If the Center is participating in but not leading the trial, this column should be left blank.

18. Should clinical research studies open at the Center's affiliates, and not open at the Center itself, be included in DT 4?

Yes, if the study is the intellectual property of a Center member. The patients accrued would be reported in the "Other Accruals" column.

19. Where should Centers list patients recruited by other institutions who are participating in a Phase 1, Phase 2, or NCTN-supported clinical research studies led by investigators at their Center?

These patients are reported in the "Other Accrual Sites" columns (unless the sites are formal consortium partners of the lead Center, which should be listed in the "Primary Accrual Site" columns).

20. Are hospital systems affiliated with a university-based cancer center considered part of the Primary Accrual Site?

If a hospital is the primary clinical arm of the Center, or a CCSG-reviewed and approved consortium partner, it is a primary accrual site. If the hospital is a community affiliate that reports through a separate cancer registry, it is an "Other"accrual site.

21. Should the number of newly enrolled patients reported in DT 3 and the accruals reported in DT 4 match?

No, these numbers are not expected to match.

Questions about specific types of clinical research studies:

22. How is a study embedded in another clinical research study reported?

Studies embedded in a primary study should be listed separately in DT 4 as Ancillary or Correlative studies.

23. Can a blood draw for the purpose of biomarker analysis for a study be considered a correlative study?

As a general rule, the blood draw and biomarker analysis are considered part of the screen needed to determine eligibility for treatment protocol and thus are an integral part of the study.

24. Is a banking protocol considered clinical research when it is was not designed to answer a specific research question?

No, this type of banking protocol does not fit the NIH definition of clinical research. However, studies utilizing tissue banks should be included in DT 4.

25. Are prospective, hypothesis-driven chart review studies, for which patients are consented, considered Clinical Research?

Yes, these types of studies are considered Clinical Research and should be included in DT 4. Retrospective chart reviews are not considered clinical research and should not be included.

26. Should Clinical Prevention Intervention Studies be included in DT4?

Yes, Clinical Prevention Intervention Studies should be included in DT4. They should not be included in DT3.