P30 Cancer Center Support Grant (CCSG)
Data Guide v3.1.3

Office of Cancer Centers
National Cancer Institute
National Institutes of Health/HHS

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http://cancercenters.cancer.gov/

INTRODUCTION

Purpose of the Data Tables

In competing applications (Types 1 and 2), the Data Tables (DT) facilitate consistency and thoroughness in review by providing peer reviewers with standardized information on center organization and leadership, active cancer-related research, and several aspects of clinical function.

In non-competitive applications (Types 3 and 5), electronic DT1-4 (eData), submitted to the Office of Cancer Centers (OCC), are used to assess center progress, generate reports, and produce benchmark data on the centers program.

Submission Types

Please use the following table to determine appropriate DT submission:

Application Type	ASSIST	RPPR	eDATA (to OCC)
1	DT1-5	None	None (DT1-4 due if CCSG is awarded)
2	DT1-5	None	DT1-4 (60 days prior to start date)*
3	NA	DT1	DT1-4 (60 days prior to start date)
5	NA	DT1	DT1-4 (60 days prior to start date)

Table 1 – Submission Types

***Note:** Per NIH policy, T2 applications serve as the progress report for the fiscal year in which the application is newly funded. Although no separate Research Performance Progress Report (RPPR) needs be submitted 60 days prior to the start date of the newly funded award, DT1-4 must still be submitted at that time.

See eData Guide (eData508.pdf) for instructions on format. General Instructions for DTs:

- Insert the full grant number (e.g., 1P30CA000000-01) in the upper right corner of each page
- Label Data Tables consistently (e.g., 1A, 1B, 1C)
- Provide only the information requested
- It is permissible to have different reporting dates for the different DTs
- Follow the example formats provided

DT1

DT1A-C provide general information about the senior leadership, research programs, cancer center membership, and shared resources.

For Type 2 (T2) applications, "New" in DT1 refers to new since the last T2 application. For Type 3 (T3) and Type 5 (T5), "New" refers to new since the last T3 or T5 progress report.

DT1A – Senior Leadership. For a center-defined reporting date, follow the format below to report the senior leadership:

2P30CA120212-09
[Name of] Cancer Center
Reporting Date: MM/DD/YYYY
Data Table 1A – Senior Leaders

Name of Senior Leader	Title of Leader	Degree(s)	New Leader
Sutton, Baylor	Director and Principal Investigator	MD, PhD	
Marucco, Gina	Deputy Director	PhD	
Galley, Mark	Assoc. Director for Basic Science	MD	Y
Barrie, Thomas	Assoc. Director for Clinical Research	MD, PhD	
Wong, Lee	Assoc. Director for Population	PhD	

DT1B – Research Programs. For a center-defined reporting date, define a center-selected alphanumeric code to denote each research program, and follow the format below to report the research programs:

2P30CA120212-09

[Name of] Cancer Center
Reporting Date: MM/DD/YYYY
Data Table 1B – Research Programs

Program Code	Program Name	Program Leader(s)	Degree(s)	New Leader	New Program	Members
01	Molecular and Cellular Biology	Harrington, Marc Cox, Michael	MD PhD			25
02	Cancer Control and Prevention	Pham, Phuong	PhD	Y	Y	14
03	Epidemiology	Kauman, John Jordon, Mark	MD PhD	 Y		19
04	Prostate	Yeh, Grace	MD	Y		26
WC	Women's Cancers	Miller, Barbara	PhD			22
CCGC	Cell Cycle and Growth Control	Neuhauser, Beverly	MD			12
ZY	Non-aligned members					9
Total Members						127

Note: Include program leaders in number of members. Members in more than one program should be counted once.

DT1C – Shared Resources. For a center-defined reporting date, follow the format below to report the shared resources:

P30CA120212-09

[Name of] Cancer Center
Reporting Date: MM/DD/YYYY
Data Table 1C – Shared Resources

Name of Shared Resource	Resource Director(s)	Degree(s)	New Leader	New Resource	Developing Resource	Category
Biostatistics	Francini, Benjamin	PhD	Y			6.01
DNA Microarray	Poole, Bruce	MD			Y	1.35
DNA Sequencing	Kelley, Mark	MD, PhD				1.22
Genomics and Proteomics	Goldstein, Phillip	MD		Y		1.36
Bioinformatics	Mayrend, Jody	PhD				7.02
Vaccine Core	Mark, Joseph	PhD				1.37
Organic Synthesis	Singer, Richard	PhD	Y			1.12
Transgenic Animals	Peters, Douglas Rogers, Kate	PhD MD				1.03,1.06,1.09
Translational Chemistry	Hahn, Otto	PhD	Y			4.08

Notes:

- Report only CCSG-funded shared resources
- Developing shared resources are those that have not previously been peer-reviewed
- Select up to three category codes from the following table:

Category 1: Laboratory Science	
1.01 Biochemical Analysis	1.19 Cyclotron or Radiolabeling
1.02 General Animal Facility	1.20 Molecular Biology
1.03 Transgenic Facility	1.21 Nucleotide Sequencing
1.04 Special Breeding	1.22 Protein & Peptide Sequencing
1.05 Animal Health (Pathology/Histology)	1.23 Monoclonal Antibodies
1.06 Animal Health (QC)	1.24 NMR
1.08 Specific Pathogen Free (Barrier Animal Facility)	1.26 MRI
1.09 Nude Mouse	1.27 Spectrometry, Other (Specify)
1.10 Specialized Animal Svcs (Irradiation)	1.28 Radiobiology
1.11 Biohazard Control	1.29 Oligonucleotide Synthesis
1.12 Organic & Synthetic Chemistry	1.30 Protein/Peptide Synthesis
1.13 Chromatography	1.31 Toxicology/Mutagenesis Testing
1.14 Cytology-Analytic & Immunologic	1.33 Confocal Microscopy
1.15 Cytogenetics	1.34 Xray Diffraction
1.16 Genetics	1.35 DNA Array
1.17 Electron Microscopy	1.36 Proteomics
1.18 Flow Cytometry	1.37 Other (Define)
Category 2: Laboratory Support	
2.01 General or Equipment Repair	2.07 Tissue Culture
2.02 Machine Shop	2.08 Media Preparation
2.03 Glassware Washing	2.10 Other (Define)
Category 3: Epidemiology, Cancer Control	
3.01 Cancer Control	3.05 Nutrition
3.03 Epidemiology	3.06 Other (Define)
3.04 Survey	
Category 4: Clinical Research	
4.03 Clinical – Other	4.06 Human Tissue Acquisition & Pathology/Histology
4.04 Pharmacology (Animal)	4.07 Gene Therapy/Vector
4.05 Pharmacology (Lab Tests)	4.08 Other (Define)
Category 6: Biostatistics	
6.01 Biostatistics	
Category 7: Informatics	
7.01 Clinical Research Informatics	7.03 Public Health/Epidemiology Informatics
7.02 Bioinformatics	7.04 Other (Define)
Category 8: Miscellaneous	
8.01 Other (Define)	

Table 2 – Shared Resources Category

DT2A and DT2B

DT2A and DT2B report all active cancer-related research grants and contracts held by center members and awarded by external sources to the fiscally responsible institution of which the cancer center is a part. Grants and contracts to center members awarded to other institutions that are not formal consortium partners of the center should not be included.

DT2A

1. Define a reporting date and include cancer-related grants and contracts that are active as of that date, including those in no-cost extension.
2. Organize DT2A into two separate tables: peer-reviewed research projects and non-peer-reviewed research projects.
3. Training grants should be listed as an attachment, in DT2A format, in the Cancer Research Career Enhancement and Other Activities component, but not in the overall DT2A. Label each table.
4. Only grant and contracts from NCI, NIH, or organizations listed in the following URL are considered peer-reviewed: Peer Review Funding Orgs. All others funding sources should be listed as non-peer reviewed. The OCC will perform an administrative review of DT2 in Type 1 and 2 applications to ensure compliance with this rule.
5. Provide a separate DT2A for each consortium partner.
6. Grants and contracts that fund infrastructure, cores, instrumentation, such as the CCSG and its supplements, cores associated with such projects as SPOREs or P01s (i.e, not research projects), should be listed as ZY and should not be assigned to a particular program (i.e., should not be listed in the Research Program DT2A).
7. Report projects in alphabetical order within each table by the principal investigator's (PI) last name or overall PI's name for multi-component projects.
8. Report only grants and contracts that are awarded by external sources to the fiscally responsible institution of which the center is a part and whose PI is a cancer center member. Thus, grants and contracts that flow to other institutions, even if the PI is a member of the center, are not reported unless the other institution is a consortium partner of the center as established by previous CCSG peer review.
9. Report only direct costs.
10. Report the entire direct cost of the project, and then provide the amount of the grant that is considered cancer-relevant. For grants that are 100% cancer-relevant (such as all grants from NCI), these figures will be identical. The center should develop a reasonable method of determining cancer relevance; estimates of cancer-relevance should be defensible in peer-review.
11. For projects that are on a no-cost extension, list only the unobligated balance in the Annual Project and Annual Program Costs and add (NCE) at the end of the project

number.

12. For projects in which a portion of the award is subcontracted to other institutions, report only the amount of the award retained by the center in Annual Project Direct Costs and in Annual Program Direct Costs. Provide subtotals of the Direct Costs at the bottom of each of the 2 tables.
13. Consortium Centers: Submit one DT2A for each consortium partner; combine all consortium partners in DT2B.

Provide the following information:

PI: The last name and first initial of the PI from your center responsible for this project (e.g., Alfred L).

Specific Funding Source: The specific name of the financial sponsor for the project (e.g., NCI, ACS).

Project Number: Use the application or grant number. This unique identification number for NIH grants, for example, is composed of the type code, activity code, Institute code, serial number, support year, and/or suffix code (e.g., 1R01CA059736-01). For projects in a no-cost extension, add (NCE) at the end of the project number.

Project Start Date: Official date a grant award begins; same as the first day of the first budget period.

Project End Date: Official date a grant award ends; same as the last day of the final budget period.

Project Title: The official title of the research project being carried out (e.g., Regulation of mitochondrial inheritance in yeast); please be as complete as possible.

Annual Project Direct Costs: Annual funding awarded for a particular project. For all mechanism types, if a portion is subcontracted to other institutions, report only the Annual Project and Program Direct Costs that are retained by the center.

Cancer-Relevant Annual Project Direct Cost: Estimate, using a method of the centers devising, the cancer relevant portion of a project and report the funding. Be prepared to defend this estimate in peer-review. For grants that are 100% cancer-relevant (such as all NCI grants), this will be identical with the Annual Project Direct Costs.

Program Code: Provide the code of the program, as defined by the center in DT1B, with which this grant is associated. A single grant or contract may be associated with multiple programs. Any grant or contract that is infrastructure-related (such as the CCSG and its supplements, cores associated with such projects as SPOREs or P01s) should be coded ZY.

Percent: The portion of the funding associated with a program.

Annual Program Direct Costs: The portion of direct cost funding associated with the indicated program.

The following examples are illustrated in the table:

Note: Do not number the rows – that is for illustration purposes in this example table.

1. One PI, one program. This grant is 100% associated with program 4 and is 100% cancer-relevant.
2. One PI, one program, partial cancer-relevance. List the entire direct costs under Annual Project Costs and the cancer-relevant portion under Cancer-Relevant Annual Project DC.
3. One PI, two programs. If the PI has dual membership in multiple programs, or if for other reasons the grant/contract should be associated with more than one program, divide the Annual Project Costs between the programs in proportion to the percent. For the second program, you may leave all fields blank except the Program Code, Percent, and Annual Program Costs.
4. Multi-PI. List all PI names only if the project fits the NIH definition of a multiple-PI project: "Multiple PIs have equal authority for the grant or contract and are jointly responsible for the scientific and technical direction of the project." This should be applied to projects from any funding source. (http://grants.nih.gov/grants/multi_pi).
5. Multi-PI, two programs, partial cancer relevance.
6. Multi-PI with one PI being at another institution. List the other institution after PI name. List only the portion of the project direct costs that either remains with the center or flows to the center from the other institution.
7. Subcontract from another institution. List subcontracting institution after Specific Funding Source. List only the funds flowing to your center under Annual Project Costs and Annual Program Costs.
8. Grant with portion subcontracted to another institution. List only funding retained by center.
9. National trial authored by a center member; list only the funding that remains with the center in both Project and Program Costs.
10. Multiple project/component grant (such as SPORE or P01). List overall PI with the Annual Project Direct Costs, leaving and Cancer-Relevant and Program Costs blank. List subprojects separately with overall PI name and subproject PI name. Do not list projects that are subcontracted to other institutions. Note: as for all projects, use code ZY for any funding that is not a research project (e.g., cores, instrumentation grants, CCSG and its supplements), and/or does not fit into a research program (grants to nonaligned members).
11. For accrual-based trials, list the funding awarded for actual or estimated number of patients enrolled in the reporting year.

The following table illustrates how to report DT2A:

Ex.	PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Cancer-Relevant Annual Project DC	Program	Program Percent	Annual Program Direct Costs
1	Alfred L	NCI	1R01CA059736-01	6/1/2016	5/30/2021	Triterpenoids as cancer chemopreventive agents	$200,000	$200,000	4	100	$200,000
2	Mackall, K	NIGMS	1R01GM065789-01	7/1/2016	6/30/2021	The Molecular Basis of Regulation of Obesity by Nocturnin	$300,000	$75,000	2	100	$75,000
3	Dubois Y	NCI	5R01CA067893-02	9/1/2017	8/30/2022	Star trial (Tamoxifen vs. Raloxifene)	$100,000	$100,000	1	60	$60,000
3									5	40	$40,000
4	Birmann B Glick D	NINDS	1R01NS046045-03	3/1/2013	2/28/2018	Targeting the anti-apoptotic protein 9urviving in glioma	$300,000	$300,000	CB	100	$300,000
5	Bhorjee J Vembu D	NHLBI	1R01HL056899-01	5/1/2015	4/30/2020	Natural ligands of the aryl hydrocarbon receptor	$400,000	$300,000	MCB	50	$150,000
5									ET	50	$150,000
6	Michaels H Herman B (UCSF)	NCI	2R01CA876-098-02	12/1/2013	11/30/2018	Combination therapy with anti-CTLA-4 and anti-PD-1	$300,000	$300,000	Epi	100	$300,000
7	Donegan A	NHLBI Dartmouth	3R01HL08685-03S2	8/1/2014	7/30/2019	Calpain and p120 catenin regulation of cadherin function	$50,000	$50,000	3	100	$50,000
8	Wang T	NCI	3R01CA07196-03	8/1/2016	7/30/2021	Southern Community Cohort Study	$775,000	$775,000	3	100	775,000
9	Persky D	NCI	S1001	7/18/2017	6/30/2019	A Phase II Trial of R-CHOP followed by Yttrium-90 Ibritumomab tiuxetan for Early Stage Diffuse Large B- cell Lymphoma	$215,000	$215,000	5	100	$215,000
10	Lee R	NCI	5P50CA119997-04	3/1/2015	2/28/2020	SPORE in Lung Cancer	$1,250,000				
10	Lee R	NCI	5P50CA119997-04	3/1/2015	2/28/2020	SPORE in Lung Cancer Project 1: Anti-tumor Mechanisms of SRC Inhibitors in Lung Cancer		$250,000	2	100	$250,000
10	Lee R Grant U	NCI	5P50CA119997-04	3/1/2015	2/28/2020	SPORE in Lung Cancer Core C: Administration and Patient Advocacy		$40,000	ZY	100	
10	Lee R Jackson A	NCI	5P50CA119997-04	3/1/2015	2/28/2020	SPORE in Lung Cancer: Core A: Tissue Procurement, Pathology, and Bioinformatics		$300,000	ZY	100	
10	Lee R Sherman W, Smith E	NCI	5P50CA119997-04	3/1/2015	2/28/2020	SPORE in Lung Cancer Project. 2: E2F's Impact on Therapeutic Efficacy		$200,000	1	100	$200,000

10	Lee R Stuart, J	NCI	5P50CA119997-04	3/1/2012	2/28/2017	SPORE in Lung Cancer: Project. 3: RRM1 in the Management of Lung Cancer		$210,000	1	100	$210,000
11	Pope B	Vical	N/A	7/1/2014	12/21/2017	Phase II Trial of Allovectin-7 for Metastatic Melanoma	$250,000	$250,000	4	100	$250,000
Total Cancer Relevant Annual Project DC							**$3,565,000**				

Table 3 – DT2A Reporting Example

DT2B

- DT2B describes the total number of cancer-related research projects (excluding the CCSG itself and associated supplements) and their aggregate total annual direct cost.For a center-defined reporting date, list the total number of cancer-related research projects and the sum of annual direct cancer-relevant funding for each major funding agency category as follows: NCI Peer-Reviewed, Other NIH Peer-Reviewed, Other Peer-Reviewed; and Industry Non-Peer-Reviewed and Other Non-Peer Reviewed Projects. Do not include training projects, as they are reported in the Cancer Research Career Enhancement and Other Activities component. Do not include the CCSG itself or associated supplements in DT2B, but include other projects coded ZY.
- Provide subtotals and a grand total where indicated.
- For multiple project grants or contracts, count each subproject as one project (Do not count overall as one – a SPORE with 5 subprojects (example 10 above) would count as 5 projects.

The following example illustrate how to report DT2B:

2P30CA120212-09

[Name of] Cancer Center
Reporting Date: MM/DD/YYYY
Data Table 2B – Active Funded Projects

Specific Funding Source	Project Direct Cost	Total Number of Projects
NCI Peer-Reviewed Projects	$5,180,000	13
Other NIH Peer-Reviewed Projects	$1,916,000	9
Other Peer-Reviewed Projects	$2,377,000	5
Subtotal Of Peer Reviewed Projects	**$9,473,000**	**27**
Industry Non-Peer-Reviewed Projects	$325,000	2
Other Non-Peer-Reviewed Projects	$1,313,000	4
Subtotal Of Non-Peer Reviewed Projects	**$1,638,000**	**6**
Grand Total (All Projects)	**$11,111,000**	**33**

DT3

DT3 is intended to provide reviewers with an overview, organized by primary anatomic cancer site, of the number of cancer cases seen at the cancer center.

For a center-defined 12-month reporting period, DT3 therefore reports the number of newly registered patients at the cancer center (registry analytic and non-analytic cases, as defined below).

Use the following definitions to complete the DT3 table:

- **Name of Reporting Source:** For consortium centers or those with affiliated institutions, indicate the specific name of the reporting institution.
- **Reporting Period:** The 12-month period as defined by the cancer center.
- **Reportable Cancers:** Malignancies with an International Classification of Diseases for Oncology (ICD) behavior code of 2 or 3 should be reported in accordance with the established requirements of registry standard setting organizations. Refer to ICD10 for the list of International Classification of Diseases for Oncology codes.
- **Newly Registered Patients:** Newly registered patients are those patients seen face-to-face and recorded in the Cancer Center's Cancer Registry for the first time for that diagnosis during the reporting period. They include inpatients and outpatients who:

  1) are newly diagnosed and/or receiving first course of treatment at the cancer center, *i.e.*, equivalent to American College of Surgeons-defined analytic case codes 00 – 22 FORDS-2016;

  2) have recurrent or persistent disease and are referred to the cancer center for evaluation and treatment, *i.e.*, equivalent to American College of Surgeons-defined non-analytic code 32 (do not include other non-analytic codes).

  Do not include:

  - Any patient more than once unless they have two malignancies in the same year.
  - Consults (*e.g.,* second opinions), new patient appointments, diagnoses at autopsy, admission of former patients for rehabilitation purposes or treatment of some other condition, or patient follow-up after treatment.
  - Patients whose only contact with the center is due to enrollment on protocol studies organized among community practitioners by cancer center staff.

A cancer center without access to a local or institutional registry should use alternate means to capture data as close as possible to the above definition.

Follow this table to determine method of reporting newly registered patients:

Source of Patients	DT3 "Newly Registered Patients"
Cancer center primary clinical arm(s), e.g., adult and pediatric hospitals and outpatient clinics that report through the center's cancer registry	**Include**
Center primary clinical arm(s) that report through a separate cancer registry	**Include as separate DT3**
CCSG peer-reviewed and NCI-approved consortium partner hospital or clinic that reports through the center's registry	**Include in same DT3**
CCSG peer-reviewed and approved consortium partner's hospital or clinic that reports patients through another registry	**Include as separate DT3**
Cancer center affiliates that do not report through the center's registry	**Exclude**

Table 4 - DT3 Reporting Method

Example Format 2P30CA120212-09

[Name of] Cancer Center
Reporting Period MM/DD/YYYY – MM/DD/YYYY
Data Table 3 – Newly Registered Patients

Name of Reporting Source **Primary Site**	**Newly Registered Patients**
Lip, Oral Cavity and Pharynx	85
Esophagus	62
Stomach	181
Small Intestine	0
Colon	728
Rectum	50
Anus	9
Liver	121
Pancreas	52
Other Digestive Organ	174
Larynx	50
Lung	1257
Other Respiratory and Intrathoracic Organs	105
Bones and Joints	25
Soft Tissue	35
Melanoma, skin	81
Kaposi's sarcoma	21
Mycosis Fungoides	23
Other Skin	6
Breast	1203
Cervix	60
Corpus Uteri	602
Ovary	49
Other Female Genital	33
Prostate	382
Other Male Genital	22
Urinary Bladder	188
Kidney	183
Other Urinary	10
Eye and Orbit	6
Brain & Nervous System	932
Thyroid	188
Other Endocrine System	21
Non-Hodgkin Lymphoma	190
Hodgkin Lymphoma	10
Multiple Myeloma	307
Lymphoid Leukemia	37
Myeloid and Monocytic Leukemia	154
Leukemia, other	1
Other Hematopoietic	83
Unknown Sites	118
Ill-Defined Sites	3
TOTAL:	**7945**

DT4

DT4 serves as a report of the cancer-related hypothesis-driven clinical research studies open at the cancer center during a recent 12-month period. DT4 interventional treatment trials must be generated using the Clinical Trials Reporting Program (CTRP) database. Individual non-consenting (pragmatic) trials, ancillary, correlative and observational studies may be submitted using CTRP or independently of CTRP. Consortium centers submit only one DT4. Title the pdf attachment as "DT4.pdf". New (Type 1) applications are not required to use CTRP in preparation of DT4.

Please use the following table to determine appropriate DT4 submission:

Clinical Research Category	New (T1)	Competing (T2)	Non-Competing (T5)
INT	**CCSG Format**	**CTRP-Generated**	**CTRP-Generated**
OBS	**CCSG Format**	**CCSG Format**	**CTRP-Generated**
ANC/COR	**CCSG Format**	**CCSG Format**	**CCSG Format**

Table 5 – DT4 Submission

Use the following definitions to complete DT4:

Clinical Research includes:

- Patient-oriented research: This type of research is conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual, tissue banking, and studies that do not require patient consent (*e.g.,* retrospective chart reviews). Patient-oriented research includes:
    - Studies of mechanisms of human disease
    - Studies of therapies or interventions for disease
    - Clinical trials, and
    - Studies to develop new technology related to disease
- Epidemiological and behavioral studies: Studies among cancer patients and healthy populations that involve no intervention or alteration in the status of the participants, *e.g.* surveillance, risk assessment, outcome, environmental, and behavioral studies.

- Health services research: Protocol designed to evaluate the delivery, processes, management, organization, or financing of health care.

Accrual: The total number of participants accrued/enrolled who have completed or are actively in the process of completing the study. See Enrollment definition in ClinicalTrials.gov.

Multi-Institutional Clinical Research Study: Clinical research studies that recruit participants from two or more geographically distinct enrollment institutions not affiliated with your cancer center (e.g., other NCI-Designated Cancer Centers or other research institutions). The institutions are usually distinct in other characteristics (e.g., demographic, socioeconomic, or clinical).

Clinical Research Categories

Interventional: Individuals are assigned prospectively by an investigator based on a protocol to receive specific interventions. The participants may receive diagnostic, treatment, behavioral, or other types of interventions. The assignment of the intervention may or may not be random. The participants are followed, and biomedical and/or health outcomes are assessed.

Observational: Studies that focus on cancer patients and healthy populations and involve no prospective intervention or alteration in the status of the participants. Biomedical and/or health outcome(s) are assessed in pre-defined groups of participants. The participants in the study may receive diagnostic, therapeutic, or other interventions, but the investigator of the observational study is not responsible for assigning specific interventions to the participants of the study.

Ancillary or Correlative:

- **Ancillary:** Studies that are stimulated by, but are not a required part of, a main clinical trial/study, and that utilize patient or other resources of the main trial/study to generate information relevant to it. Ancillary studies must be linked to an active clinical research study and should include only patients accrued to that clinical research study. Only studies that can be linked to individual patient or participant data should be reported.

- **Correlative:** Laboratory-based studies using specimens to assess cancer risk, clinical outcomes, response to therapies, etc. Only studies that can be linked to individual patient or participant data should be reported.

Study Source

National: NCI National Clinical Trials Network (NCTN) and other NIH-supported National Trial Networks

Externally Peer-Reviewed: R01s, SPORES, U01s, U10s, P01s, CTEP, or any other clinical research study mechanism supported by the NIH or organizations on this list: Peer Review Funding Orgs.

Institutional: In-house clinical research studies authored or co-authored by cancer center investigators and undergoing scientific peer review solely by the Protocol Review and Monitoring System of the cancer center. The cancer center investigator has primary responsibility for conceptualizing, designing, and implementing the clinical research study and reporting results.

- It is acceptable for industry and other entities to provide support (*e.g.,* drug, device, other funding), but the trial should clearly be the intellectual product of the center investigator

- This category may also include:
  - Institutional studies authored and implemented by investigators at another center in which your center is participating

  - Multi-institutional studies authored and implemented by investigators at your center (Note: National and externally peer-reviewed studies should be listed with those categories, not as institutional studies)

Industrial: A pharmaceutical company controls the design and implementation of these clinical research studies.

Format

Sort the data by Clinical Research Category and Study Source:

INTERVENTIONAL National;
INTERVENTIONAL Externally Peer-Reviewed;
INTERVENTIONAL Institutional;
INTERVENTIONAL Industrial;
OBSERVATIONAL Externally Peer-Reviewed, *etc.,*
ANCILLARY/CORRELATIVE Externally Peer-Reviewed, *etc.*

Report the table alphabetically by PI.

The column headings are defined below:

Specific Funding Source: The specific name of the financial sponsor for the clinical research study. For institutionally sponsored trials or studies, list the name of the applicable funding agencies.

Primary Site: The primary anatomic cancer site(s) (i.e. breast, ovary) the clinical research study focuses on. If the clinical research study is broadly applicable to a

number of potential primary sites, enter the term “multiple” in this column. Refer to ICD10 for a list of primary disease sites.

NCT ID: The unique ID assigned to the trial by the National Clinical Trial program (ClinicalTrials.gov) for trials that have been submitted to ClinicalTrials.gov Protocol Registration System (PRS) previously. This ClinicalTrials.gov ID appears as "NCT" followed by 8 numeric characters (such as NCT12345678 or NCT00009876); If it is not applicable, use the ProtocolID.

NCI ID: The unique ID assigned to the trial by the NCI’s Clinical Trials Reporting Program (CTRP).

Protocol ID/IRB Number (Proto ID): The unique identifier for the study. List the common protocol number that the trial is known under nationally, if one exists. For other trials that do not have an NCT number or a common protocol number that the trial is known under nationally, use an internal protocol identification or IRB number.

Other Protocol ID (Other Proto ID): Additional IDs assigned to the trial, including the following: NCI, Cancer Therapy Evaluation Program (CTEP) or Division of Cancer Prevention (DCP), unique IDs from other registries, protocol numbers assigned by the review board, other IDs.

Local Trial ID: The unique ID assigned at the cancer center level and used at the sites level to identify a trial.

PI: The last name and first initial of the PI from the center who is responsible for this clinical research study.

Program (Prog) Code: Use the research program code defined by the center in DT1B. For clinical research studies that span more than one research program, include both Program Codes in this column.

Date Opened (activation): The official start date of a trial determined by 1) the date of activation noted in an official clinical trial activation announcement or 2) date of first patient accrual if the trial in question did not have a formal activation announcement.

Date Closed: The date the clinical research study closed to accrual. This does not include patient follow-up. If the study is still open, leave this field blank.

Phase:

> **Early Phase I**: Exploratory trials involving very limited human exposure with no therapeutic or diagnostic intent (e.g., screening studies, microdose studies). See FDA guidance on exploratory Investigational New Drug (IND) studies for more information.

I: Includes initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients.

I/II: Trials that are a combination of phases I and II.

II: Includes controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in participants with the disease or condition under study and to determine the common short-term side effects and risks.

II/III: Trials that are a combination of phases II and III.

III: Includes trials conducted after preliminary evidence suggesting effectiveness of the drug has been obtained and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug.

IV: Studies of FDA-approved drugs to delineate additional information including the drug's risks, benefits, and optimal use.

N/A: Trials without phases (for example, studies of devices or behavioral interventions).

Pilot: Pilot attribute can be assigned to any phase. Indicate whether the study is a pilot phase by entering “Y” for yes, “N” or (leave blank) for no.

Primary Purpose:

Basic Science (BAS): Protocol designed to examine the basic mechanisms of action (*e.g.*, physiology, biomechanics) of an intervention.

Device Feasibility (DEV): An intervention of a device product is being evaluated in a small clinical trial (generally fewer than 10 participants) to determine the feasibility of the product; or a clinical trial to test a prototype device for feasibility and not health outcomes. Such studies are conducted to confirm the design and operating specifications of a device before beginning a full clinical trial.

Diagnostic (DIA): Protocol designed to evaluate one of more interventions aimed at identifying a disease or health condition.

Health Services Research (HSR): Protocol designed to evaluate the delivery, processes, management, organization, or financing of health care.

Prevention (PRE): Protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition.

Screening (SCR): Protocol designed to assess or examine methods of identifying a condition (or risk factor for a condition) in people who are not yet known to have the condition (or risk factor).

Supportive Care (SUP): Protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects, or mitigate against a decline in the participant's health or function. In general, supportive care interventions are not intended to cure a disease.

Treatment (TRE): Protocol designed to evaluate one or more interventions for treating a disease, syndrome, or condition. **Note**: This equates to therapeutic trials in previous versions of the guidelines.

Other (OTH): Not in other categories

Note: Assign the appropriate Primary Purpose to Interventional or Non-Interventional (Observational or Ancillary/Correlative) Clinical Research Categories.

Pragmatic Clinical Triall: A clinical trial that is designed to study a health intervention in a real-world setting that is similar or identical to the one in which the intervention will be implemented.

Trials with the following characteristics can be classified as pragmatic:

- Unit of randomization may be other than an individual participant (e.g., the clinic, the healthcare system, or a neighborhood if a community setting)
- Intervention may be multi-level involving changes to:
    - Participant behavior (e.g., completing a symptom report measures online), and
    - Provider behavior (e.g., receiving the participant's symptom report and having to act on it)
- Data are often obtained directly from medical records and are likely collected on a large number of participants
    - Data may be collected during a pre-intervention period and again during a post-intervention period in each clinic that is randomized
    - Participants for whom data are collected in the pre-intervention period may not be the same ones for whom data are collected in the post-intervention period.

Indicate whether the trial is pragmatic by entering "Y" for yes and "N" or (leave blank) for no in the "Prag" column.

Official Title: Official name of the protocol provided by the study PI or sponsor (Limit: 8000 characters or fewer).

Multi-Institutional Clinical Research Study: Indicate if the trial is multi-institutional by entering “Y” for yes and “N” or (leave blank) for no in the “Multi-Inst” column (see definition above).

Total Targeted Accrual: For both single-institution and multi-institutional trials initiated at your center, indicate the total number of participants needed for the entire study. For multi-institutional trials that your center participates in but did not initiate, leave “Entire study”column empty. Do not submit a targeted range, such as “10 – 100.”

Targeted Accrual for your Center: For single-institution and multi-institutional trials initiated at your center, indicate the total number of participants your center is expected to accrue for the study. For single-institution trials the “Total Accrual for your Center” and the “Total Targeted Accrual” numbers will be the same. Do not submit a targeted range, such as “10 – 100.”

Accrual Institutions:

- Cancer Center: List the number of participants enrolled in the clinical research study at your cancer center, including formal consortium partners.

- Other Institutions: List the number of participants enrolled in the clinical research study at all hospitals, treatment facilities, and/or research facilities that are a formal part of the cancer center (*e.g.*, nearby community hospitals).

Accrual Timeframes:

- 12 Months: Provide the number of participants accrued to this clinical research study during the center-defined 12-month reporting period.

- To Date: Provide the number of participants accrued to this clinical research study since the trial was opened.

Notes:

1. For trials initiated and accruing patients only at your center, the number of patients in the “Entire Study” and “Your Center” columns of the Total Targeted Accrual column should match. Enter the actual number of accruals in the “Cancer Center:” columns. Leave the “Other Accrual Institutions” columns blank.

2. For trials initiated and accruing patients at both your center and additional institutions, all columns under the “Total Targeted Accrual”, “Cancer Center: Primary Accrual Institution”, and “Other Accrual Institutions” should be filled in.

3. For trials your center accrues to but did not initiate, leave “Entire Study” blank. Enter the Total Targeted Accrual for your part of the study. Enter the actual number of accruals under “Cancer Center:” Leave “Other Accrual Institutions” blank.

4. If the data are not available or applicable, leave the column empty.

Entire Study Accrual to Date:

- If the Lead Organization column is populated with a summary of accrual for all participating sites on the trial through the last day of the reporting period (directly and not directly connected to the Lead Organization CTRP Family).
- If a Participating Site, column is blank.

The following examples illustrate how to report DT4 data:

Interventional:

	INSTITUTIONAL											Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institution(s)	
Ex.	Specific Funding Source	Primary Site	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date
1	NYU	Multiple	NCT002135	Hook S	10	8/15/2013		II	SUP	Etanercept in Patients With Idiopathic Pneumonia Syndrome After Undergoing a Donor SCT	N	105	105	10	30		
2	COH, NCI	Multiple	NCT204326	Mack F	ET	4/21/2012		III	TRE	Induction & Consolidation Chemo + Midostaurin v Placebo in Newly Diagnosed FLT3 Mutated AML	Y	400	60	22	46	70	240
3	NCI	Myeloid leukemia	NCT 0046572	Lehr D	4	5/1/2012		I	TRE	Tamibarotene and Arsenic Trioxide for Relapsed Acute Promyelocytic Leukemia	Y		6	0	4		

Examples:

1. A clinical research study that is initiated by your center and carried out solely at the center and its consortium partners

2. A study that is initiated at your center and is carried out at your center and other institutions.

3. A study that is initiated by another institution and in which your center participates.

[Name of] Cancer Center
Reporting Period: MM/DD/YYYY – MM/DD/YYYY
Report Prepared: MM/DD/YYYY
Data Table 4 – Clinical Research Protocols

Interventional:

NATIONAL											Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institution(s)	
Specific Funding Source	Primary Site	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date
NRG	Bladder	NCT778523	Armstrong C	2	8/15/2013		III	TRE	Randomized chemo/rt/surg for bladder cancer	Y		220	82	120		
Alliance	Myeloid leukemia	NCT 452761	Kane S	8	4/21/2012		III	TRE	Induction & Consolidation Chemo + Midostaurin v Placebo in Newly Diagnosed FLT3 Mutated AML	Y		70	28	49		
COG	Myeloid leukemia	NCT665883	Lehr D	4	5/1/2012		I	TRE	Tamibarotene and Arsenic Trioxide for Relapsed Acute Promyelocytic Leukemia	Y		6	0	4		

EXTERNALLY PEER-REVIEWED											Total Targeted Accrual		Cancer Center: Primary Accrual Institution		Other Accrual Institution(s)	
Specific Funding Source	Primary Site	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date
NYU, NCI	Multiple	NCT 989551 NCI - 1109	Mack F	3	8/1/2012		III	SUP	Preparatory Aid to Improve Decision Making about Cancer Clinical Trials (PRE-ACT)	Y	400	60	22	46	70	240
NCI	Colon, Rectum	NCT4977 29	Shephear d,A	2	12/5/2014		II	PRE	Polyethylene Glycol For ACF Reduction and Biomarker Modulation in Individuals with CRC Risk	N	140	140	34	68		

INSTITUTIONAL											Total Targeted Accrual		Cancer Center: Primary Accrual Institution		Other Accrual Institution(s)	
Specific Funding Source	Primary Site	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date
NYU	Breast	NCT99 00210N YU-1054	Allen T	2	2/14/2013		I/II	SUP	Dose Finding and Tolerability ALA in Paclitaxel Induced Neuropathy Pts.	N	30	30	4	10		
NYU	Lymphoma	NCT99 03451	Bates S	4	5/1/2012		I	TRE	Ofatumumab for indolent B-cell lymphomas	Y	10	6	0	4	2	4
NYU	Multiple	NCT99 01201 NYU-1133	Dunn R	1	7/4/2015		II	PRE	Restasis Vs Placebo in Primary Prevention of Ocular GVHD	Y	14	6	2	5	2	8
NYU	Multiple	NCT575 757	Hook S	10	1/17/2013		II	SUP	Etanercept in Patients With Idiopathic Pneumonia Syndrome After Undergoing a Donor SCT	N	105	105	10	30		

INDUSTRIAL											Total Targeted Accrual		Cancer Center: Primary Accrual Institution		Other Accrual Institution(s)	
Specific Funding Source	Primary Site	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date
GSK	Leukemia	NCT9903541	Day P	10	3/1/2013		I	SUP	Phase 1 Trial of Palifermin for Oral Mucositis	Y	15	15	6	8		
BMS	Lymphoid leukemia	DRUG 5013	Head R	8	5/1/2014		III	TRE	Lenalidomide as Maintenance Therapy forPatients with B-cell CLL	Y		113	47	79		

Observational:

EXTERNALLY PEER-REVIEWED											Total Targeted Accrual		Cancer Center: Primary Accrual Institution		Other Accrual Institution(s)	
Specific Funding Source	Primary Site	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date
NCI	Brain and Nervous System	NCT552881	Falls R	8	7/2/2012		N/A	OTH	Neurocognitiveoutcomes in pediatric brain tumor survivors following proton beam XRT vs conventional XRT	N	100	100	13	30		
American Cancer Society	Prostate	NCT889111	Rogers S	6	9/5/2014		N/A	OTH	Focus group evaluation of prostate cancer symptom management education materials	Y	30	14	6	8	7	14
NCI	Ovarian	NCT7785236	Lemon J	3	6/1/2013		N/A	OTH	Exogenous hormone use and risk of ovarian cancer	N		50	12	49		

INSTITUTIONAL											Total Targeted Accrual		Cancer Center: Primary Accrual Institution		Other Accrual Institution(s)	
Specific Funding Source	Primary Site	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date
NYU	Multiple	NCT998112	Berry J	8	5/1/2015		N/A	OTH	Risk factors for childhood cancer and hematological disorders by case-control studies	Y	4000	1500	125	499	86	600
NYU, NIH	Multiple Myeloma	NCT889111	Smith S	6	1/1/2010	4/7/2011	N/A	OTH	Treatment Decision Making in Older Adults Newly Diagnosed with MM	N		20	6	18		

Ancillary or Correlative:

INSTITUTIONAL											Total Targeted Accrual		Cancer Center: Primary Accrual Institution		Other Accrual Institution(s)	
Specific Funding Source	Primary Site	Proto ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date
NYU	Brain	NCT998112 4	Okra S	8	2/23/2016		N/A	BAS	Phase I & 2 drug metabolism polymorphisms & outcome in children with medulloblastoma	N	54	54	10	36		
NYU	Leukemia	NCT990991	Granger I	8	6/15/2010		N/A	BAS	Prospective observational trial of telomere length and telomerase mutations in pediatric AML	Y	50	30	12	25	8	18
NYU	Leukemia	NCT872222	Down R	8	2/30/2014		III	OTH	Comparison of Acute and Long-term Toxicities in BM Donors w/wout G- CSF Treatment Prior to Harvest	N		206	48	89		
NYU	Other hemapoietic	NCT778851	Gosden R	8	2/4/2015		N/A	BAS	Biology Study of Transient Myeloproliferative Disorder (TMD) in Children with Down Syndrome (DS)	N		17	1	3		

DT5

DT5 reports the cancer center's current budget (Type 2) and its requested budget (Types 1 and 2).

- Provide the direct cost CCSG budget of the last full year of funding (for Type 2), and the requested budget for the first year of the new competitive project period (Types 1 and 2) for each major budget category listed below. List non-salary funds for research programs separately and list the shared resources as a single combined figure that includes salaries and operating costs/activities. List only the total for developmental funds. Sum all the direct costs at the bottom of the chart.

- The current budget, if applicable, should reflect the last full year of the current competitive project period as submitted in the type 5 application and/or as detailed in the notice of award for that period, exclusive of carryover funds and supplements. The direct cost figures should include any third-party indirect costs, since these are charged as direct costs to the CCSG.

The following example illustrate how to report DT5:

2P30CA120212-09

[Name of] Cancer Center

Reporting Date: MM/DD/YYYY

Data Table 5 –Comparison of Current and Requested CCSG Budgets

CCSG Budget Category	Current Budget (direct costs)* MM/DD/YY – MM/DD/YY (Last full year of the current project period)	Requested Budget (direct costs) MM/DD/YY – MM/DD/YY (First full year of the new project period)
Program Leaders (salary)		
Research Programs (non-salary)		
Program 1		
Program 2, etc.		
Administration		
Leadership, Planning & Evaluation		
Senior Leadership (salary)		
Activities		
Developmental Funds (exclude "Developing New Shared Resources" category)		
Shared Resources		
Salary		
Operating costs/ Activities		
Developing New Shared Resources		
Clinical Protocol and Data Management (CPDM)		
Protocol Review and Monitoring System (PRMS)		

Community Outreach and Engagement (COE)		
Cancer Research Training and Education Coordination		
Plan to Enhance Diversity (PED)		
Total Direct Costs		

*** Note:** DT5 includes third party indirect costs. It does not include CCSG carryover funds or CCSG supplement dollars.

Summary of Changes to the Data Guide:

Updated Date	DT	Change
12/05/2023	DT2A	DT2A, Example 10 Updated from “Multiple project/component grant (such as SPORE or P01). List overall PI with the Annual Project Direct Costs and Cancer-Relevant Annual Project DC (not including subcontracts), leaving Program Costs blank. List subprojects separately with overall PI name and subproject PI name. Do not list projects that are subcontracted to other institutions. Note: as for all projects, use code ZY for any funding that is not a research project (e.g., cores, instrumentation grants, CCSG and its supplements), and/or does not fit into a research program (grants to nonaligned members).“ To “Multiple project/component grant (such as SPORE or P01). List overall PI with the Annual Project Direct Costs, leaving and Cancer-Relevant and Program Costs blank. List subprojects separately with overall PI name and subproject PI name. Do not list projects that are subcontracted to other institutions. Note: as for all projects, use code ZY for any funding that is not a research project (e.g., cores, instrumentation grants, CCSG and its supplements), and/or does not fit into a research program (grants to nonaligned members).”
09/26/2023	DT2A	Updates for DT2A Example 10: ▪ To prevent double counting, $1,250,000 was removed from the "Cancer-Relevant Annual Project DC" column, ▪ To accurately account for the total cancer-relevant Direct Cost (DC), $250,000, $200,00, and $210,00 were added to both “Cancer-Relevant Annual Project DC” and “Annual Program Direct Costs” columns. ▪ Added Total Cancer-Relevant Annual Project DC column.
09/12/2023	DT4	▪ Updated CCSG Data Guide version from v3.1.2 to **v3.1.3** ▪ Updated the definition ▪ Added Table 4 – DT4 Submission
05/01/2023	DT5	▪ Added Plan to Enhance Diversity (PED), ▪ Modified "...and list the shared resources individually." to "... and list the shared resources as a single combined figure that includes salaries and operating costs/activities."
04/01/2023	DT4	▪ Added a new column “Prag”, ▪ Modified the “Pilot” and “Multi-Inst” entry “Y” for yes and “N” for no or leave it blank.
08/24/2022	Introduction DT3 DT4	▪ Fixed broken links: o to the eData Guide in the Introduction, o to FORDS-2016 in DT3, and o to PR Funding Orgs in DT4.

Updated Date	DT	Change
		▪ Updated the definition of Primary Purpose “Device Feasibility” to harmonize with clinicaltrials.org and CTRP.
06/15/2021	Cover Page, Footnote	Modified v3.1 to v3.1.1
	DT4	▪ Due to the consensus at 2020 CCAF IT Conference to maintain consistent Primary Site lists for both DT3 and DT4, modified column name from Anatomic Site to Primary Site, ▪ Modified the definition for Accrual to harmonize with CTRP’s.
	DT2A, DT4	Added Reviewed date to the Organizations with Peer Review Funding document.
08/17/2020	DT5	▪ Modified Table Structure on following categories: o Developmental Funds to: Developmental Funds (exclude "Developing New Shared Resources" category) o Shared Resources to: Shared Resources ▪ Salary ▪ Operating costs / Activities ▪ Developing New Shared Resources o Cancer Research Career Enhancement and Other Activities to Cancer Research Training and Education Coordination
08/29/2018	DT4	Per request from the cancer centers, two new fields were added: Entire Study Accrual to Date and PS Open Date.
02/14/2018	DT3	Modified the definition of the Accrual.
	DT4	To further harmonize fields and definitions with the ClinincalTrials.gov and CTRP: ▪ Renamed NCT Number to NCT ID and modified the definition, modified Phase, ▪ modified the definition of the Protocol ID, and Other Institutions, ▪ added “Dev” option to the Primary Purpose, ▪ added Pilot, Other Protocol ID, NCI ID, and Local Trial ID fields, ▪ removed the Mapping of Previous Study Type and New Primary Purpose Designations and Mapping of Previous and Newly Defined Clinical Research Categories tables.
01/24/2017	DT3	Combined “Female Breast” and “Male Breast” into “Breast”
12/22/2016	DT1	Eliminated 1C – Program Members; added total members to bottom of 1B; 1D is now labeled 1C

Updated Date	DT	Change
	DT2	Eliminated total costs
	DT2	Added total project funding for each grant and cancer-relevant funding
	DT2A and B	Moved all training projects to Cancer Research Career Enhancement and Related Activities
	DT3	Eliminated “Patients newly accrued to treatment trials”
	DT4	No changes – CTRP will generate DT4 in the future (2018 or later)
	DT5	Minor format changes. Although not specifically called for in the FOA (at NIH’s insistence), we recommend centers continue to report both previous and proposed CCSG funding, and new centers (Type 1) report proposed CCSG funding