

P30 Cancer Center Support Grant Data Table Guide 2.0

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

**9609 Medical Center Drive
Rockville, MD 20850**
<http://cancercenters.cancer.gov/>

INTRODUCTION

Purpose of the Data Tables

In competing applications (Types 1 and 2), Data Tables (DT) 1-5 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 DT 1-4 (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	DT 1-5	None	None (DT 1-4 due if CCSG is awarded)
2	DT 1-5	None	DT 1-4 (60 days prior to start date)*
3	None	DT 1	DT 1-4 (60 days prior to start date)
5	None	DT 1	DT 1-4 (60 days prior to start date)

***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 RPPR need be submitted 60 days prior to the start date of the newly funded award, DT 1-4 must still be submitted at that time.

eData Guide (<http://cancercenters.cancer.gov/documents/eData-508.pdf>) for instructions on format.

An FAQ document for further guidance is at available at http://cancercenters.cancer.gov/grants_funding/index.html.

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

DT 1

DT 1A-D provide general information about the Senior Leadership, Research Programs, Cancer Center Membership, and Shared Resources.

For T2 applications, “New” in DT 1 refers to new since the last T2 application. For T3 and T5, “New” refers to new since the last T3 or T5 progress report.

DT 1A – 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	Yes
Barrie, Thomas	Assoc. Director for Clinical Research	MD, PhD	
Wong, Lee	Assoc. Director for Population Research	PhD	

DT 1B – 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	Yes	Yes	14
03	Epidemiology	Kauman, John Jordon, Mark	MD PhD	Yes		19
04	Prostate	Yeh, Grace	MD	Yes		26
WC	Women’s Cancers	Miller, Barbara	PhD			22
CCGC	Cell Cycle and Growth Control	Neuhauser, Beverly	MD			12
ZY	Non-aligned members					9

Note: Include Program Leaders in number of members.

DT 1C – Cancer Center Membership. For a center-defined reporting date, follow the format below to report the Center’s membership:

2P30CA120212-09

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

Type of Member	Total Number
Programmatically Aligned Members (Individuals)	118
Non-Programmatically Aligned Members (Individuals)	9
Grand Total - Total Number of Cancer Center Members (Individuals)	127

Note: Members in more than one program should be counted once.

DT 1D – 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 1D – Shared Resources

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

DT 2A and 2B

DT 2A and 2B report all active cancer-related research grants and contracts awarded by external sources to the fiscally responsible institution of which the Cancer Center is a part.

DT 2A

- Define a reporting date and include cancer-related grants and contracts that are active as of that date, including those in no-cost extension.
- Organize Data Table 2A into four separate tables: peer-reviewed research projects, peer-reviewed training projects, non-peer-reviewed research projects, and non-peer-reviewed training projects. Label each table. Peer-reviewed projects are defined as those awarded by NCI, NIH, or organizations listed here:
<http://cancercenters.cancer.gov/documents/PeerReviewFundingOrganizations508C.pdf>
- 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.
- 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.
- Report only the cancer-related funding for all projects. For projects that are not entirely cancer related, report only the cancer-related portion of the funding, as estimated by the Center. These estimates should be defensible in peer-review.
- For projects that are on a no-cost extension, list the unobligated balance in the Annual Project and Annual Program Costs.
- For projects in which a portion of the award is subcontracted to other institutions, report the full amount of the award in Project Costs, but only the portion of funding retained at the Center in Program Costs.
- Provide subtotals of the Direct and Total Costs at the bottom of each of the 4 tables.
- Consortium Centers: Submit one DT 2A and 2B for the entire consortium.

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).

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

Annual Project Total Costs: The total annual direct and indirect (facilities and administrative) costs awarded to the Center to carry out a project

Program Code: Provide the code of the Program, as defined by the Center in DT 1B, with which this grant is associated. A single grant or contract may be associated with multiple programs

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

Annual Program Total Costs: The portion of the total costs 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.
2. 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.
3. Multi-PI, one program. List all PI names. If there are more than three, you may use “*et al.*” The NIH definition of multiple PIs may be used for grants/contracts from all funding sources:

“Multiple PIs have equal authority for the grant or contract and are jointly responsible for the scientific and technical direction of the project”

(http://grants.nih.gov/grants/multi_pi/faq.htm#a1).

4. Multi-PI, two programs. List the PI names twice (or more, depending on how many programs the grant is associated with), leaving the other fields blank except Program Code, Percent, and Annual Program Costs associated with each Program.
5. Multi-PI with one PI being at another institution. List the other institution after PI name. If the grant flows to the Center and a portion goes to the other institution as a subcontract, report the total funding in Annual Project Costs and list the portion that remains with the Center in Annual Program Costs.
6. 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.
7. Grant with portion subcontracted to another institution. List total funding to Center in Annual Costs; list only the retained portion in Program Costs.
8. National trial authored by a Center member; list only the funding that remains with the Center in both Project and Program Costs.
9. Multiple project/component grant (such as SPORE or P01). List overall PI with the Annual Costs, leaving Program Costs blank. List subprojects separately with overall PI name and subproject PI name. Note: as for all grants, use code ZY for any funding that is not a research project (e.g., cores, instrumentation grants, CCSG), and/or does not fit into a research program (grants to non-aligned members).
10. For accrual-based trials, list the funding awarded for actual or estimated number of patients enrolled in the reporting year.

<i>Ex.</i>	PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Costs	Annual Project Total Costs	Prog Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
1	Alfred L	NCI	1R01CA059736-01	6/1/2014	5/30/2019	Triterpenoids as chemopreventive agents	\$200,000	\$300,000	4	100	\$200,000	\$300,000
2	Dubois Y	NCI	5R01CA067893-02	9/1/2012	8/30/2017	Star trial (Tamoxifen vs. Raloxifene)	\$100,000	\$150,000	1	60	\$60,000	\$90,000
2									5	40	\$40,000	\$60,000
3	Birmann B Glick D	NINDS	1R01NS046045-03	3/1/2013	2/28/2018	Targeting the anti-apoptotic protein survivin in glioma	\$140,000	\$210,000	CB	100	\$140,000	\$210,000
4	Bhorjee J Vembu D	NHLBI	1R01HL056899-01	5/1/2015	4/30/2020	Natural ligands of the aryl hydrocarbon receptor	\$200,000	\$300,000	MCB	100	\$110,000	\$165,000
4	Bhorjee J Vembu D								ET	100	\$90,000	\$135,000
5	Michaels H Herman B (UCSF)	NCI	2R01CA876-098-02	12/1/2013	11/30/2018	Southern Community Cohort	\$300,000	\$450,000	Epi	100	\$250,000	\$325,000
6	Donegan A	NHLBI Dartmouth	3R01HL08685-03S2	8/1/2012	7/30/2017	Calpain and p120 catenin regulation of cadherin function	\$50,000	\$75,000	3	100	\$50,000	\$75,000
7	Wang T	NCI	3R01CA07196-03	8/1/2012	7/30/2017	Southern Community Cohort Study	\$275,000	\$412,500	3	100	\$220,000	\$330,000
8	Persky D	NCI	S1001	7/18/2011	6/30/2014	A Phase II Trial of R-CHOP followed by Yttrium-90 Ibritumomab tiuxetan for Early Stage Diffuse Large B- cell Lymphoma	\$215,000	\$279,500	5	100	\$215,000	\$279,500
9	Lee R	NCI	5P50CA119997-04	3/1/2012	2/28/2017	SPORE in Lung Cancer	\$1,000,000	\$1,300,000				
9	Lee R	NCI	5P50CA119997-04	3/1/2012	2/28/2017	SPORE in Lung Cancer Project 1: Anti-tumor Mechanisms of SRC Inhibitors in Lung Cancer			2	100	\$250,000	\$375,000
9	Lee R Grant U	NCI	5P50CA119997-04	3/1/2012	2/28/2017	SPORE in Lung Cancer Core C: Administration and Patient Advocacy			ZY	100	\$40,000	\$60,000

9	Lee R Jackson A	NCI	5P40CA119997-04	3/1/2012	2/28/2017	SPORE in Lung Cancer: Core A: Tissue Procurement, Pathology, and Bioinformatics			ZY	100	\$250,000	\$375,000
9	Lee R Sherman W, Smith E	NCI	5P50CA119997-04	3/1/2012	2/28/2017	SPORE in Lung Cancer Project. 2: E2F's Impact on Therapeutic Efficacy			1	100	\$220,000	\$330,000
9	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			1	100	\$240,000	\$360,000
10	Pope B	Vical	N/A	7/1/2014	12/21/2016	Phase II Trial of Allovectin-7 for Metastatic Melanoma	\$250,000	\$325,000	4	100	\$250,000	\$325,000

An example of a complete DT 2A follows:

2P30CA120212-09

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

PEER-REVIEWED RESEARCH PROJECTS

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Cost	Annual Project Total Costs	Prog Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Alfred L	NCI	1R01CA059736-01	6/1/2010	5/30/2015	Regulation of mitochondrial inheritance in yeast	\$200,000	\$300,000	4	100	\$200,000	\$300,000
Alison S	Leukemia & Lymphoma Society	LLS 7080-06/7004-11	10/1/2005	9/30/2015	Experimental Therapeutics in CLL	\$1,000,000	\$1,300,000	4	100	\$1,000,000	\$1,300,000
Bariick A Glick D	NINDS	3R01NS046045-03	3/1/2012	2/28/2017	Targeting the anti-apoptotic protein bcl-2 in glioma	\$140,000	\$182,000	3	20	\$140,000	\$182,000
Christy W	ACS	RPG-96-045-04-1	1/1/2005	12/31/2010	The role of an HNF-3 protein in c elegans foregut development	\$104,000	\$135,000	2	100	\$104,000	\$135,200
Donegan A	NHLBI Dartmouth	3R01HL086850-03S2	8/1/2012	7/30/2013	Calpain and p120 catenin regulation of cadherin function	\$50,000	\$65,000	3	20	\$50,000	\$65,000
Dubois Y	NCI	5R01CA067893-02	9/1/2012	8/30/2017	Star trial (Tamoxifen vs. Raloxifene)	\$100,000	\$130,000	1	60	\$60,000	\$78,000
								5	40	\$40,000	\$52,000

Farber J	NHLBI Case Western	2P01HL070149-10	6/1/2013	5/31/2018	MECHANISMS OF GVHD Proj 1: Human Minor Histocompatibility Antigens	\$80,000	\$104,000	3	100	\$80,000	\$104,000	
Gordon E	NCI	TAS 75 0849	1/1/2012	12/31/2018	Surveillance, Epidemiology, and End Results Program	\$400,000	\$520,000	ZY	100	\$400,000	\$520,000	
Jacob M French A	NIAID	1R01AI051273-01	10/1/2013	9/30/2016	Novel Approaches to Detect Virus- Cancer Associations	\$480,000	\$624,000	2	100	\$480,000	\$624,000	
John E Sir P	NSF	1205439	5/1/2012	4/30/2015	mHealth - Computing Infrastructure for Mobile Health and Wellness Monitoring	\$600,000	\$780,000	ZY	100	\$600,000	\$780,000	
Jones J	NHLBI Case Western	2P01HL070149-10	6/1/2013	5/31/2018	Mechanisms OF GVHD Core B: Biostatistics Core	\$40,000	\$52,000	ZY	20	\$40,000	\$52,000	
Lee R	NCI	5P50CA119997-04	3/1/2012	2/28/2017	SPORE in Lung Cancer	\$1,000,000	\$1,300,000					
Lee R	NCI	5P50CA119997-04	3/1/2012	2/28/2017	SPORE in Lung Cancer Proj. 1: Anti-tumor Mechanisms of SRC Inhibitors in Lung Cancer				2	100	\$250,000	\$375,000
Lee R Grant U	NCI	5P50CA119997-04	3/1/2012	2/28/2017	SPORE in Lung Cancer Core C: Administration and Patient Advocacy				ZY	100	\$40,000	\$60,000
Lee R Jackson A	NCI	5P40CA119997-04	3/1/2012	2/28/2017	SPORE in Lung Cancer Core A: Tissue Procurement, Pathology, and Bioinformatics				ZY	100	\$185,000	\$277,500
Lee R Sherman W Smith W	NCI	5P50CA119997-04	3/1/2012	2/28/2017	SPORE in Lung Cancer Proj 2: E2F's Impact on Therapeutic Efficacy				1	100	\$110,000	\$165,000
Lee R Stuart J	NCI	5P50CA119997-04	3/1/2012	2/28/2017	SPORE in Lung Cancer Proj 3: RRM1 in the Management of Lung Cancer				1	100	\$225,000	\$292,500
Mellon C	NIDDK	5R01DK053265-03	2/1/2013	1/31/2018	In vivo Selection for Stem Cell Gene Therapy	\$600,000	\$780,000	4	20	\$520,000	\$582,000	
Murphy J	NCI	3P30CA022354- 30S	5/1/2013	4/30/2014	Cancer Center Support Grant: Community Health Educator	\$140,000	\$182,000	ZY	100	\$140,000	\$182,000	
Offens M News H	NIAID	1R01AI051273-01	10/1/2013	9/30/2016	Novel Approaches to Detect Virus- Cancer Associations	\$320,000	\$416,000	3	100	\$320,000	\$416,000	
Partridge F	NCI UNC	2R01CA055747-06	9/1/2012	8/30/2015	Epidemiologic and Genetic Studies of Breast Cancer	\$480,000	\$624,000	4	100	\$480,000	\$624,000	
Persky D	NCI	S1001	7/18/2011	6/30/2014	A Phase II Trial of R-CHOP followed by Yttrium-90 Ibritumomab tiuxetan for Early Stage Diffuse Large B-cell Lymphoma	\$215,000	\$280,000	5	100	\$215,000	\$280,000	
Sir P John E	NSF	1205439	5/1/2012	4/30/2015	mHealth - Computing Infrastructure for Mobile Health and Wellness Monitoring	\$628,000	\$817,000	1	10	\$62,800	\$81,640	
Smith K	NCI	5P30CA010518-42	4/1/2011	3/31/2016	Consolidated Basic Cancer Research Program	\$2,000,000	\$3,000,000	ZY	100	\$2,000,000	\$3,000,000	
Smith K	NCI	5P30CA010518- 42S1	4/1/2011	3/31/2016	Consolidated Basic Cancer Research Program: CURE Supplement	\$120,000	\$180,000	ZY	100	\$120,000	\$180,000	
			Peer-Reviewed Research Subtotals:			\$8,697,000	\$11,771,000			\$7,861,800	\$10,707,840	

PEER-REVIEWED TRAINING PROJECTS

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Cost	Annual Project Total Cost	Prog Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Hay J	DOD	DAMD1702-1-11	9/1/2013	8/31/2015	Molecular study of bag domains: A new motif in prostate cancer	\$45,000	\$58,500	T	100	\$45,000	\$58,500
Kahl C	NHLBI	5F32HL069595-02	7/1/2010	6/30/2013	Differentiation of a stem cell population in vivo	\$36,000	\$46,800	T	50	\$36,000	\$46,800
Larson A	NHLBI	5K08HL001711-04	2/1/2012	1/30/2015	Serotonergic mechanisms is stress and anxiety	\$170,000	\$221,000	T	20	\$170,000	\$221,000
Jones B	NCI	1T32CA009579-01	5/1/2008	4/30/2013	Cell adhesion and effects on cell behavior	\$25,000	\$32,500	T	100	\$25,000	\$32,500
			Peer-Reviewed Training Subtotals:			\$276,000	\$358,800			\$276,000	\$358,800

NON-PEER-REVIEWED RESEARCH PROJECTS

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Cost	Annual Project Total Costs	Prog Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Miller L	Breast Cancer Research. Fdn.	3568	10/1/2010	9/30/2015	Breast cancer prevention through nutrition program	\$1,100,000	\$1,430,000	2	100	\$1,100,000	\$1,530,000
Norris C	Am.-Italian Cancer Foundation	4786	7/1/2012	6/30/2017	MicroRNAs as predictors of (pre)malignant phenotype in cystic neoplasms of the pancreas	\$90,000	\$117,000	1	90	\$81,000	\$105,300
Pope B	Vical	N/A	7/1/2014	12/21/2016	Phase II Trial of Allovectin-7 for Metastatic Melanoma	\$250,000	\$325,000	4	100	\$250,000	\$325,000
			Non-Peer-Reviewed Research Subtotals:			\$1,440,000	\$1,872,000			\$1,431,000	\$1,960,300

NON-PEER-REVIEWED TRAINING PROJECTS

PI	Specific Funding Source	Project Number	Project Start Date	Project End Date	Project Title	Annual Project Direct Cost	Annual Project Total Costs	Prog Code	Percent	Annual Program Direct Costs	Annual Program Total Costs
Dinh H	ASCO	CA5463545T	9/1/2011	8/31/2013	Enhancing Donor Cell Engraftment with CXCR4 Antagonist	\$100,000	130,000	T	90	\$90,000	117,000
Roberts E	Prostate Society	T7564	3/1/2012	02/30/15	Calibration and evaluation of a gene expression signature predictive of dasatinib sensitivity	\$23,000	29,900	T	100	\$23,000	29,900
Smith L	Bayer HealthCare	564CAA	7/1/2013	6/30/2015	Reproductive Scientist Career Development Program	\$75,000	97,500	T	80	\$60,000	78,000
			Non-Peer-Reviewed Training Subtotals:			\$198,000	\$257,400			\$173,000	\$224,900
Grand Totals						\$11,111,000	\$14,444,300			\$9,025,800	\$11,759,540

DT 2B

DT 2B describes the total number of cancer-related Research and Training projects and their aggregate total annual direct and total costs.

- For a center-defined reporting date, list the total number of cancer-related Research and Training projects and the sum of annual direct and total costs for each major funding agency category as follows: NCI, other NIH, other Peer-review; and Industry Non Peer-Reviewed and Other Non-Peer Reviewed Projects.
- 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 would (example 9 above) would count as 5 projects.
- Follow the example below:

2P30CA120212-09

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

Specific Funding Source	Project Direct Cost	Project Total Costs	Total Number of Projects
NCI Peer-Reviewed Projects	\$5,180,000	\$6,734,000	13
Other NIH Peer-Reviewed Projects	\$1,916,000	\$2,490,800	9
Other Peer-Reviewed Projects	\$2,377,000	\$3,090,100	5
Subtotal Of Peer Reviewed Projects	\$9,473,000	\$12,314,900	27
Industry Non-Peer-Reviewed Projects	\$325,000	\$422,500	2
Other Non-Peer-Reviewed Projects	\$1,313,000	\$1,706,900	4
Subtotal Of Non-Peer Reviewed Projects	\$1,638,000	\$2,129,400	6
Grand Total (All Projects)	\$11,111,000	\$14,444,300	33

DT 3

DT 3 is intended to provide reviewers with an overview, organized by anatomic cancer site, of 1) the number of cancer cases seen at the Cancer Center, and 2) the participation of the Center's patients in interventional treatment trials devoted to those anatomic sites.

For a center-defined 12-month reporting period, DT 3 therefore reports:

1) the number of newly registered patients at the Cancer Center (registry analytic and non-analytic cases, as defined below), and

2) the number of patients newly enrolled in interventional treatment trials (excluding consented but not enrolled patients, as defined below). In general, the source of newly registered patients and newly enrolled patients should be from the same populations (see table below). As this is intended as an overview, anatomic sites have been grouped for ease of review.

Note: Accrual data in DTs 3 and 4 do not correlate exactly and should not be directly compared.

Use the following definitions to complete the DT 3 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 <http://cancercenters.cancer.gov/Documents/ICD10-508.pdf> 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 http://www.facs.org/cancer/coc/fords/FORDS_for_2011_01012011.pdf (pages 91 and 92);
 - 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
- Patients seen at Center clinical space but who are not eligible for the Center’s clinical trials for non-scientific reasons (ineligible health plan, *etc.*), regardless of registry

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	Include
Center primary clinical arm(s) that report through a separate cancer registry	Include as separate DT3
CCSG peer-reviewed and 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

Total patients newly enrolled in interventional treatment trials: Interventional treatment trials are protocols designed to evaluate one or more interventions for treating a disease, syndrome, or condition. The participants may receive diagnostic, treatment, behavioral, or other types of interventions. **Note:** This equates to therapeutic trials in the previous versions of the guidelines.

Include a patient more than once if he/she participated in more than one interventional treatment trial during the reporting period.

Note: Data in these two columns should match in terms of their institutional source populations, following the criteria stated above. They should reflect the number of patients, not the number of visits.

Example Format:

[Name of] Cancer Center
Reporting Period MM/DD/YYYY – MM/DD/YYYY
Data Table 3 – Newly Registered Patients /Participation in
Interventional Treatment Trials by Anatomic Cancer Site

<i>Name of Reporting Source</i>		
Primary Site*	Newly Registered Patients	Patients newly enrolled in interventional treatment trials
Lip, Oral Cavity and Pharynx	85	0
Esophagus	62	3
Stomach	181	4
Small Intestine	0	0
Colon	728	17
Rectum	50	10
Anus	9	0
Liver	121	6
Pancreas	52	8
Other Digestive Organ	174	8
Larynx	50	2
Lung	1257	50
Other Respiratory and Intrathoracic Organs	105	18
Bones and Joints	25	6
Soft Tissue	35	3
Melanoma, skin	81	15
Kaposi's sarcoma	21	0
Mycosis Fungoides	23	0
Other Skin	6	1
Breast – Female	1203	54
Breast – Male	1	0
Cervix	60	5
Corpus Uteri	602	35
Ovary	49	1
Other Female Genital	33	0
Prostate	382	17
Other Male Genital	22	0
Urinary Bladder	188	12
Kidney	183	1
Other Urinary	10	1
Eye and Orbit	6	0
Brain & Nervous System	932	269
Thyroid	188	0
Other Endocrine System	21	0
Non-Hodgkin Lymphoma	190	41
Hodgkin Lymphoma	10	0
Multiple Myeloma	307	141
Lymphoid Leukemia	37	26
Myeloid and Monocytic Leukemia	154	111
Leukemia, other	1	0

<i>Name of Reporting Source</i>		
Primary Site*	Newly Registered Patients	Patients newly enrolled in interventional treatment trials
Other Hematopoietic	83	37
Unknown Sites	118	0
Ill-Defined Sites	3	13
TOTAL:	7945	924

DT 4

DT 4 serves as a report of the cancer-related hypothesis-driven clinical research studies open at the Cancer Center during a center-defined 12-month reporting period. Consortium centers submit only one DT4. Use the following definitions to complete DT 4:

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 number of participants who have completed or are actively in the process of completing the study. This number includes dropouts. It does not include screen failures.

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.

Table 4-1. Mapping of Previous and Newly Defined Clinical Research Categories

Previous Clinical Research Category	Newly Defined Clinical Research Category
1: Agent or Device	INTERVENTIONAL
2: Trials Involving other Interventions	INTERVENTIONAL
3: Epidemiologic or other Observational Studies	OBSERVATIONAL
4: Ancillary or Correlative Studies	ANCILLARY/CORRELATIVE

Study Source

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

Externally Peer-Reviewed: R01s, SP0RES, U01s, U10s, P01s, CTEP, or any other clinical research study mechanism supported by the NIH or organizations on this list:
<http://cancercenters.cancer.gov/documents/PeerReviewFundingOrganizations508C.pdf>

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.

Anatomic Site: The 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 anatomic sites, enter the term “multiple” in this column.

Protocol ID/IRB Number (Proto ID): Provide the unique identifier for this study. Where available, list the NCT number, as well as 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.

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 DT 1B. 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: For Interventional studies acceptable phases include: pilot, feasibility, 0, I, II, III, IV, or combinations such as I/II. For epidemiologic, cancer control/behavioral, observational, ancillary, correlative, or other biological studies, indicate “N/A.”

Primary Purpose

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

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

Table 4-2. Mapping of Previous Study Type and New Primary Purpose Designations

Previous Study Type Designations	New Primary Purpose Designations
The	TRE
Pre	PRE
Sup	SUP
Scr/Det/Dia Src Det Dia	SCR SCR or DIA (depending on the nature of the study)
Epi/Obs/Out	OTH
Anc	OTH or BAS (depending on the nature of the study)
Cor	BAS
(No existing comparable Study Type)	HSR

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

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 inserting ‘Yes’ in the “Multi-inst study” 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 not a formal part of the Cancer Center (*e.g.*, nearby community hospitals or other Centers that are participating in multi-institution trials led by your Cancer Center).

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.

The following examples illustrate how to report DT 4 data:

Interventional:

INSTITUTIONAL												Total Targeted Accrual		Cancer Center Primary Accrual Institution		Other Accrual Institution(s)	
<i>Ex.</i>	Specific Funding Source	Anatomic Site	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi- Inst study?	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	No	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	Yes	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	Yes		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.

An example of a complete DT 4 follows:

DT 4 Example Format

2P30CA120212-09

[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	Anatomic Site	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst study?	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	Yes		220	82	120		
Alliance	Myeloid leukemia	NCT452761	Kane S	8	4/21/2012		III	TRE	Induction & Consolidation Chemo + Midostaurin v Placebo in Newly Diagnosed FLT3 Mutated AML	Yes		70	28	49		
COG	Myeloid leukemia	NCT665883	Lehr D	4	5/1/2012		I	TRE	Tamibarotene and Arsenic Trioxide for Relapsed Acute Promyelocytic Leukemia	Yes		6	0	4		

EXTERNALLY PEER-REVIEWED												Total Targeted Accrual		Cancer Center: Primary Accrual Institution		Other Accrual Institution(s)	
Specific Funding Source	Anatomic Site	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst study?	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)	Yes	400	60	22	46	70	240	
NCI	Colon, Rectum	NCT4977 29	Shepherd, A	2	12/5/2014		II	PRE	Polyethylene Glycol For ACF Reduction and Biomarker Modulation in Individuals with CRC Risk	No	140	140	34	68			

INSTITUTIONAL												Total Targeted Accrual		Cancer Center: Primary Accrual Institution		Other Accrual Institution(s)	
Specific Funding Source	Anatomic Site	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst trial?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date	
NYU	Breast	NCT990210NYU-1054	Allen T	2	2/14/2013		I/II	SUP	Dose Finding and Tolerability ALA in Paclitaxel Induced Neuropathy Pts.	No	30	30	4	10			
NYU	Lymphoma	NCT9903451	Bates S	4	5/1/2012		I	TRE	Ofatumumab for indolent B-cell lymphomas	Yes	10	6	0	4	2	4	
NYU	Multiple	NCT9901201NYU-1133	Dunn R	1	7/4/2015		II	PRE	Restasis Vs Placebo in Primary Prevention of Ocular GVHD	Yes	14	6	2	5	2	8	
NYU	Multiple	NCT575757	Hook S	10	1/17/2013		II	SUP	Etanercept in Patients With Idiopathic Pneumonia Syndrome After Undergoing a Donor SCT	No	105	105	10	30			

INDUSTRIAL											Total Targeted Accrual		Cancer Center: Primary Accrual Institution		Other Accrual Institution(s)	
Specific Funding Source	Anatomic Site	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst trial?	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	Yes	15	15	6	8		
BMS	Lymphoid leukemia	DRUG 5013	Head R	8	5/1/2014		III	TRE	Lenalidomide as Maintenance Therapy for Patients with B-cell CLL	Yes		113	47	79		

Observational:

EXTERNALLY PEER-REVIEWED											Total Targeted Accrual		Cancer Center: Primary Accrual Institution		Other Accrual Institution(s)	
Specific Funding Source	Anatomic Site	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst trial?	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	Neurocognitive outcomes in pediatric brain tumor survivors following proton beam XRT vs conventional XRT	No	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	Yes	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	No		50	12	49		

INSTITUTIONAL											Total Targeted Accrual		Cancer Center: Primary Accrual Institution		Other Accrual Institution(s)	
Specific Funding Source	Anatomic Site	Protocol ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst study?	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	Yes	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	No		20	6	18		

Ancillary or Correlative:

INSTITUTIONAL											Total Targeted Accrual		Cancer Center: Primary Accrual Institution		Other Accrual Institution(s)	
Specific Funding Source	Anatomic Site	Proto ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Multi-Inst study?	Entire Study	Your Center	12 Months	To Date	12 Months	To Date
NYU	Brain	NCT9981124	Okra S	8	2/23/2016		N/A	BAS	Phase I & 2 drug metabolism polymorphisms & outcome in children with medulloblastoma	No	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	Yes	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	No		206	48	89		

NYU	Other hemapoietic	NCT778 851	Gosden R.	8	2/4/2015		N/A	BAS	Biology Study of Transient Myeloproliferative Disorder (TMD) in Children with Down Syndrome (DS)	No		17	1	3		
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DT 5

DT 5 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 individually. 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.

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)
Professional Personnel		
Senior Leadership		
Program Leaders		
Research Programs (non-salary)		
Cancer Biology		
Experimental Therapeutics		
Administration		
Planning & Evaluation		
Shared Resources and Services		
Flow Cytometry		
Biostatistics		
Clinical Protocol and Data Management		
Protocol Review and Monitoring System (PRMS)		
Early Phase Clinical Research Support		
Developmental funds		

Total Direct Costs		
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*DT 5 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
02/04/2016	DT 3	Changed the reference from ICD 9 to ICD 10
02/04/2015	Overall	Simplified language; brought Data Guide and FAQs into agreement
	Introduction	Added table of describing appropriate DT submission
	DT 1	Simplified column headings; removed embedded symbols from examples
	DT 2A	Simplified examples table; eliminated need to use embedded symbols to denote multi-PI projects or subcontracts; eliminated need to repeat some column data in reporting multi-program and multi-PI projects; examples and FAQ instructions brought into agreement
	DT 3	Clarified definition of newly registered patients; added table describing the appropriate way to report data from consortium partners and affiliates
	DT 4	Simplified column headings; inclusion of NCT numbers
03/12/2015	DT4	To harmonize with CTRP, any Primary Purpose may be assigned to interventional and non-interventional studies (Table 4.3 therefore deleted).