



# NCI Clinical Trials Portfolio Inventory FY2011

Division of Extramural Activities  
Research Analysis Evaluation Branch  
July 10, 2013

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## Introduction

The Clinical Trials Advisory Committee (CTAC) requested that the Research Analysis Evaluation Branch (RAEB), Division of Extramural Activities (DEA), conduct an inventory of NCI clinical trials expenditures for fiscal year (FY) 2011 at its March 7, 2012 meeting. This report provides an update of the report by the Science and Technology Policy Institute (STPI) of FY2006 clinical trials data which was presented to CTAC in 2009.

The Research Analysis Evaluation Branch serves as the NCI's centralized source of science based budget information for NCI supported extramural research. The branch is responsible for the scientific coding of research project grants and contracts. RAEB staff evaluate grant applications and awarded contracts to classify each project for its degree of relevance to Special Interest Categories (SIC) and anatomical sites. SIC coding provides a method that supports reporting of the NCI's and NIH's investments in the major scientific disciplines in a consistent manner.

Over the last five years in collaboration with NCI components RAEB has improved and refined scientific coding for clinical trials research, resulting in more consistent reporting across the Institute. For example, RAEB staff met with staff from the Office of Cancer Centers (OCC) to receive input in the clinical trials coding of center grants. From 2006 to 2008, RAEB conducted a pilot study with the Grants and Contracts Branch (GCB) of the NCI Division of Cancer Treatment and Diagnosis (DCTD) to improve common understanding of the content of clinical trials grants and program project (P01) grants in particular. P01 grants include subprojects and cores that may support multiple clinical trials. Discussions with NCI senior staff involved in clinical trials and clinical research have resulted in more inclusive indexing of grants for clinical trials.

This report presents NCI total expenditures for clinical trials by:

- Intramural and Extramural funding
- NCI Divisions, Offices, and Centers
- Clinical trial categories (e.g., Prevention, Diagnosis, and Therapy, as well as the associated category Other
- Allocation categories, e. g., funding mechanisms, etc.
- Major cancer anatomical sites
- Geographic location

Information on funding by clinical trial phases has not been included since most research project grants do not provide sufficient information for indexing. It should be noted that providing information on NCI clinical trials expenditures presents many challenges since the clinical trials data is not available from one comprehensive source. However, this report presents a broad overview of the clinical trials research portfolio and related investments for FY2011.

## Data Sources for This Report

- Administrative information about grants and contracts and inter-and intra-agency agreements were obtained from NIH IMPAC II and NCI I2E databases.
- Contracts and Inter- and Intra-agency agreements were indexed for clinical trials and the dollar amounts were confirmed in the NCI contracts database.
- Clinical trials percentages and dollar values for P30 Centers grants were provided by the OCC.
- Percentages for clinical trials categories and anatomical sites were obtained from RAEB.
- Clinical Trials Cooperative Group (COOP) and Community Clinical Cooperative Program grants (CCOP) were calculated from data provided by the Cancer Therapy Evaluation Program (CTEP) and were indexed 100% for Clinical Trials.
- Multi-project grants such as P01 (Program Projects), P50 (Specialized Centers), and U54s (Specialized Center Cooperative Agreements) were indexed by subproject and these values are used to automatically calculate the parent project percentages.
- Data for clinical trials extramural funding through the NCI Experimental Therapeutics (NeXT) Program, which supports NCI's drug discovery and development resources, was provided by the Division of Cancer Treatment and Diagnosis.
- Intramural projects and contracts are indexed and provided by the Center for Cancer Research (CCR) and the Division of Cancer Epidemiology and Genetics (DCEG). This includes the SAIC contract at the Frederick National Laboratory for Cancer Research.
- NIH-Reporter was cross-checked for potentially missed projects. NIH Reporter is a database for NIH reporting to Congress and the extramural community which standardizes reporting categories across NIH Institutes.

## What is a Clinical Trial?

The National Cancer Institute Data Safety and Monitoring Committee provides guidelines for conducting clinical trials, including the following "Operational Definition of a Clinical Trial:"

"For purposes of this document, we define a *clinical trial* operationally as a prospective study involving human subjects designed to answer specific questions about the effects or impact of particular biomedical or behavioral interventions; these may include drugs, treatments, devices, or behavioral or nutritional strategies. Participants in these trials may be patients with cancer or people without a diagnosis of cancer but at risk for it.

- In the area of molecular or imaging *diagnostics*, we consider a study to be a clinical trial if it uses the information from the diagnostic test in a manner that somehow affects medical decision-making for the study subject. In this way the information from the diagnostic may have an impact on some aspect of outcome, and assessment of this impact may be a key goal of the trial. By contrast, studies that do not use information from the diagnostic test in any manner that can affect the outcome of study subjects, but whose objective is only the gathering of data on the characteristics of a new diagnostic approach, are not clinical trials and are not covered by this DSM policy, unless performing the diagnostic test itself imposes some risk on study subjects.
- *Behavioral clinical trials* include interventions whose goals are to increase behaviors (e.g. cancer screening, physical activity, fruits and vegetable intake), eliminate or reduce behaviors (e.g., smoking, sun exposure) and/or improve coping and quality of life (e.g., among cancer survivors) and reduce the negative sequelae of treatment. Interventions may pertain to cancer prevention, early detection, treatment, and survivorship. Observational studies and those that do not test interventions are not clinical trials."

For full text of the NCI Data Safety and Monitoring Guidelines, see <http://www.cancer.gov/clinicaltrials/conducting/dsm-guidelines/page2>

In addition to the above definition, this inventory includes projects developing methods specifically for clinical trials (e.g., analyzing or monitoring clinical trial data) but not actually conducting clinical trials, and projects supportive of clinical trials infrastructure.

## NCI Clinical Trials Overview

Of the total FY2011 NCI expenditures of \$5.1 billion, NCI allocated \$771 million to clinical trials representing 15.3% of the total. Of the \$771 million clinical trials allocation, \$701 million (13.9%) was allocated to extramural and \$70.5 million (1.4%) was allocated to intramural.

Fig 1. NCI Clinical Trials Funding as a Proportion of Overall NCI Funding

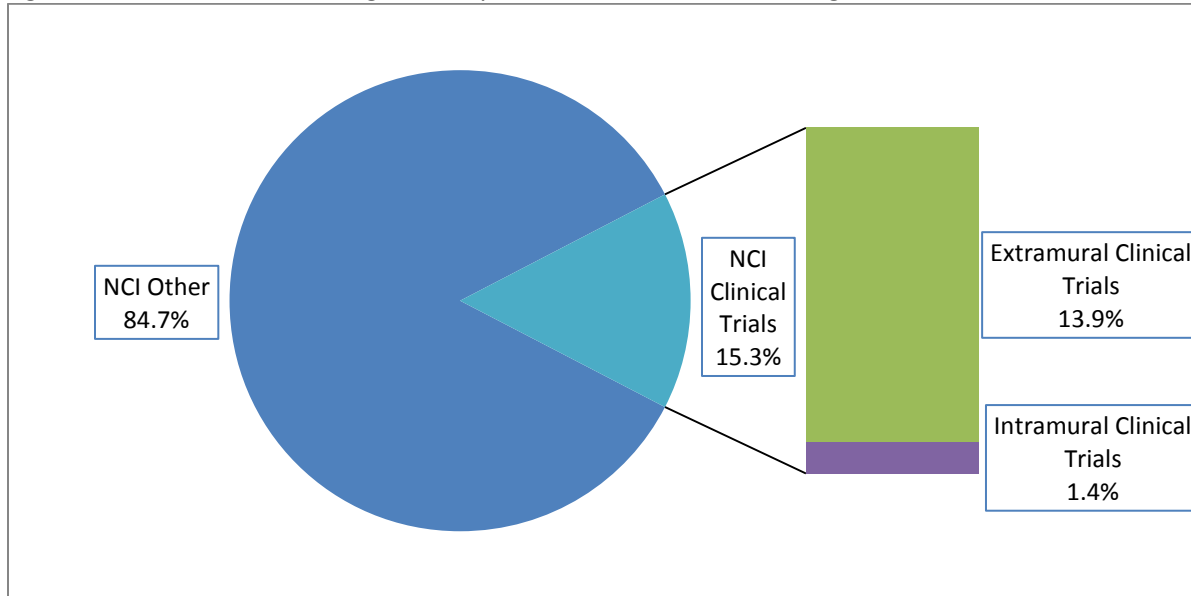


Table1. NCI Clinical Trials Funding as a Proportion of Overall NCI Funding

	Total Dollars	Percentage of NCI Overall Funding		Extramural/ Intramural \$	Percentage of NCI Overall Funding
NCI Clinical Trials Funding	\$771,423,169	15.30%	Extramural Clinical Trials Funding	\$700,855,823	13.90%
			Intramural Clinical Trials Funding	\$70,567,346	1.40%
NCI Other Funding	\$4,286,681,809	84.70%	Extramural Other Funding	\$3,149,101,985	62.20%
			Intramural Other Funding	\$763,102,654*	15.10%
			All other funding	\$374,477,170	7.40%
<b>NCI Overall Funding</b>	<b>\$5,058,104,978</b>	<b>100%</b>		<b>\$5,058,104,978</b>	<b>100%</b>

Includes 107 million NCI Clinical Center Inpatient and Outpatient Operational Costs

# NCI Extramural Clinical Trials Funding

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## NCI Extramural Clinical Trials as a Proportion of Overall Extramural Funding

Of the \$3.8 billion overall extramural funding for grants, contracts, interagency agreements, and the NExT program, \$700.9 million was allocated to clinical trials and \$3.1 billion was allocated for all other extramural funding. Of the 7,393 grants, contracts and interagency agreements, 965 included clinical trials projects.

Fig 2. NCI Extramural Clinical Trials as a Proportion of Overall Extramural Funding

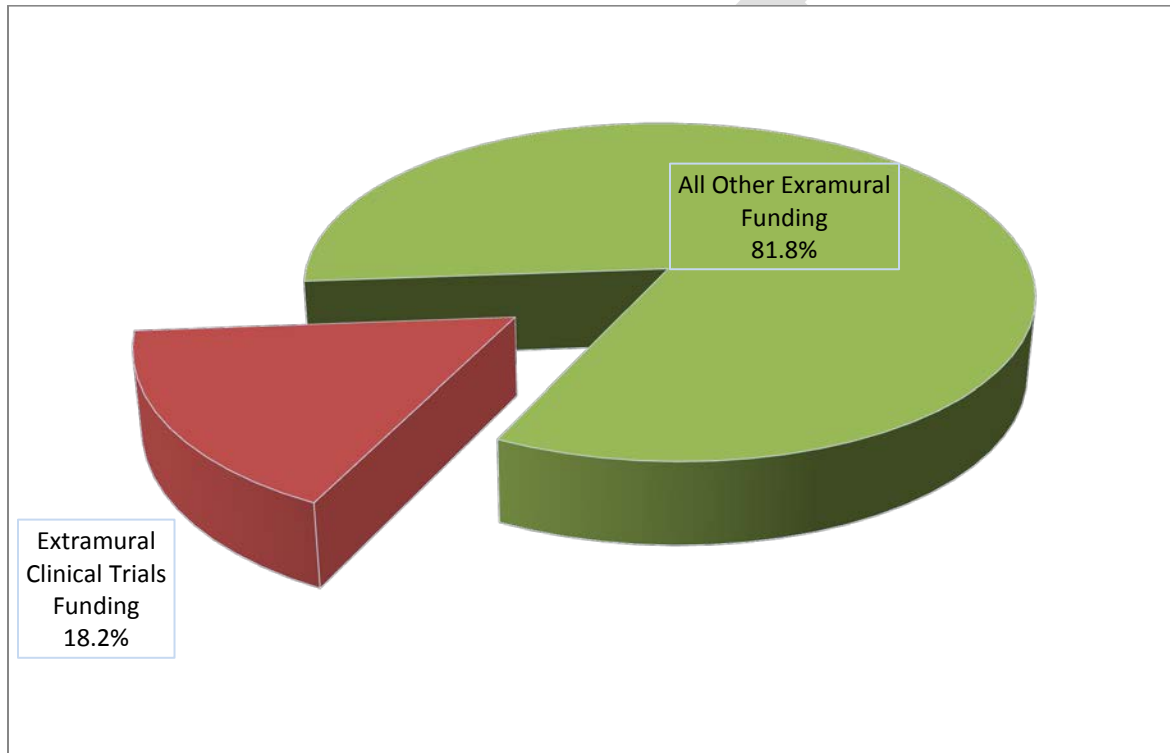


Table 2: NCI Extramural Clinical Trials as a Proportion of Overall Extramural Funding

	FY 2011 Dollars	Percentage of Overall Extramural Funding
Extramural Clinical Trials Funding	\$700,855,823	18.2%
All Other Extramural Funding	\$3,149,101,985	81.8%
<b>Overall Extramural Funding</b>	<b>\$3,849,957,808</b>	<b>100%</b>



## Extramural Clinical Trials Funding (by Division, Office, or Center)

NCI extramural clinical trials research awards are managed by multiple divisions, offices and centers (DOCs). The extramural DOCs included in this report and their website addresses for more information are:

Office of the Director (OD), <http://www.cancer.gov/aboutnci/organization#Office+of+the+Director>

Division of Cancer Biology (DCB), <http://dcb.nci.nih.gov/>

Division of Cancer Control and Population Sciences (DCCPS), <http://cancercontrol.cancer.gov/>

Division of Cancer Prevention (DCP), <http://prevention.cancer.gov/>

Division of Cancer Treatment and Diagnosis (DCTD), <http://dctd.cancer.gov/>

Office of Cancer Centers (OCC), <http://cancercenters.cancer.gov/>

Office of HIV and AIDS Malignancy (OHAM), <http://oham.cancer.gov/>

Center to Reduce Cancer Health Disparities (CRCHD), <http://crchd.cancer.gov/>

Center for Cancer Training (CCT), <http://www.cancer.gov/researchandfunding/cancertraining>

Small Business Innovation Research Development Center (SBIRDC), <http://sbir.cancer.gov>

Fig 3. NCI Extramural Clinical Trials Funding by Division, Office or Center

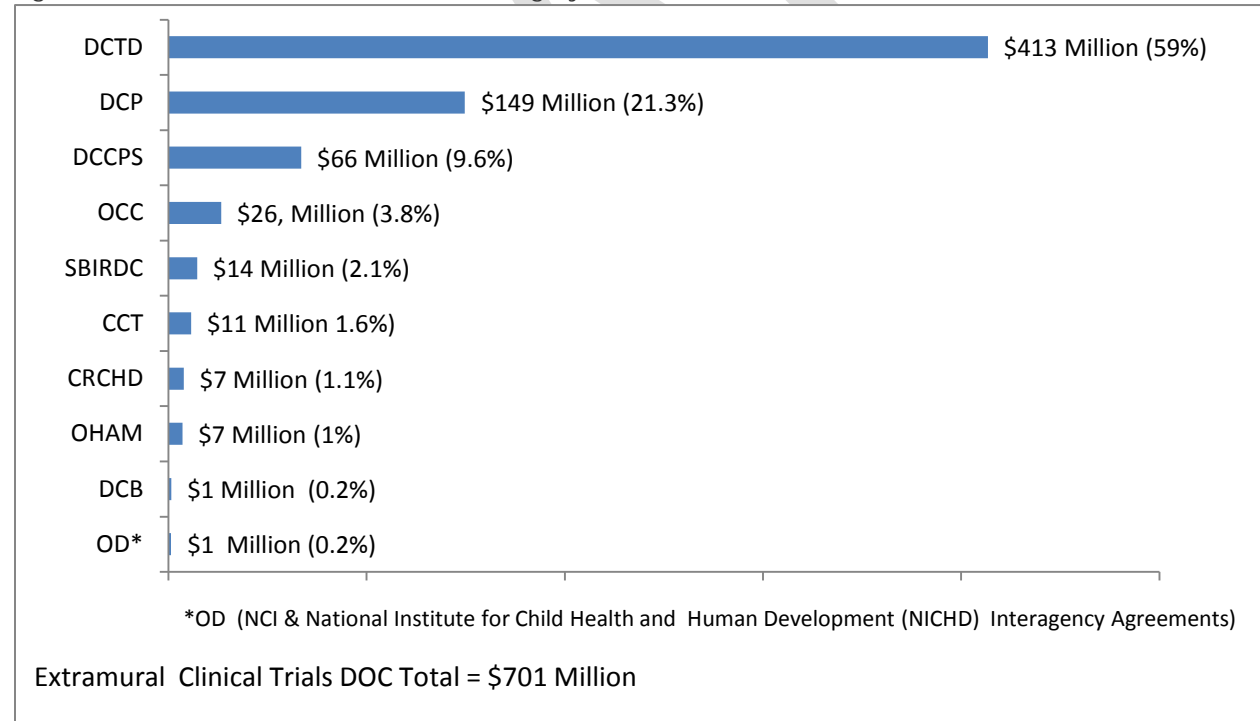


Table 3. NCI Extramural Clinical Trials Funding by Division, Office, or Center

<b>Division, Office, or Center</b>	<b>Clinical Trials Dollars</b>	<b>Percent of Total Extramural Clinical Trials Dollars</b>
DCTD	\$413,490,204	59.0%
DCP	\$149,615,970	21.3%
DCCPS	\$66,997,577	9.6%
OCC	\$26,719,694	3.8%
SBIRDC	\$14,526,240	2.1%
CCT	\$11,531,833	1.6%
CRCHD	\$7,867,926	1.1%
OHAM	\$7,221,360	1.0%
DCB	\$1,468,245	0.2%
OD-Interagency Agreements	\$1,416,780	0.2%
<b>Total Extramural Clinical Trials Dollars</b>	<b>\$700,855,829</b>	<b>100%</b>

## NCI Extramural Clinical Trial Awards, FY2011 (by Mechanism)

Of the extramural Clinical Trials total of \$700.9 million, \$607.4 million was allocated to grants, \$92.8 million to contracts and interagency agreements, and \$0.6 million to the NCI Experimental Therapeutics (NExT) program. The Other Research Programs budget line supports the NCI Clinical Cooperative Group Program (COOP) and the Community Cooperative Oncology Program (CCOP). COOPs and CCOPs account for the major portion of the clinical trials supported by NCI.

Figure 4 and Table 4 display extramural clinical trials allocations by commonly grouped mechanism categories. Table 4a displays extramural clinical trials allocations by individual mechanisms.

Fig 4. NCI Extramural Clinical Trials Funding (by Mechanism)

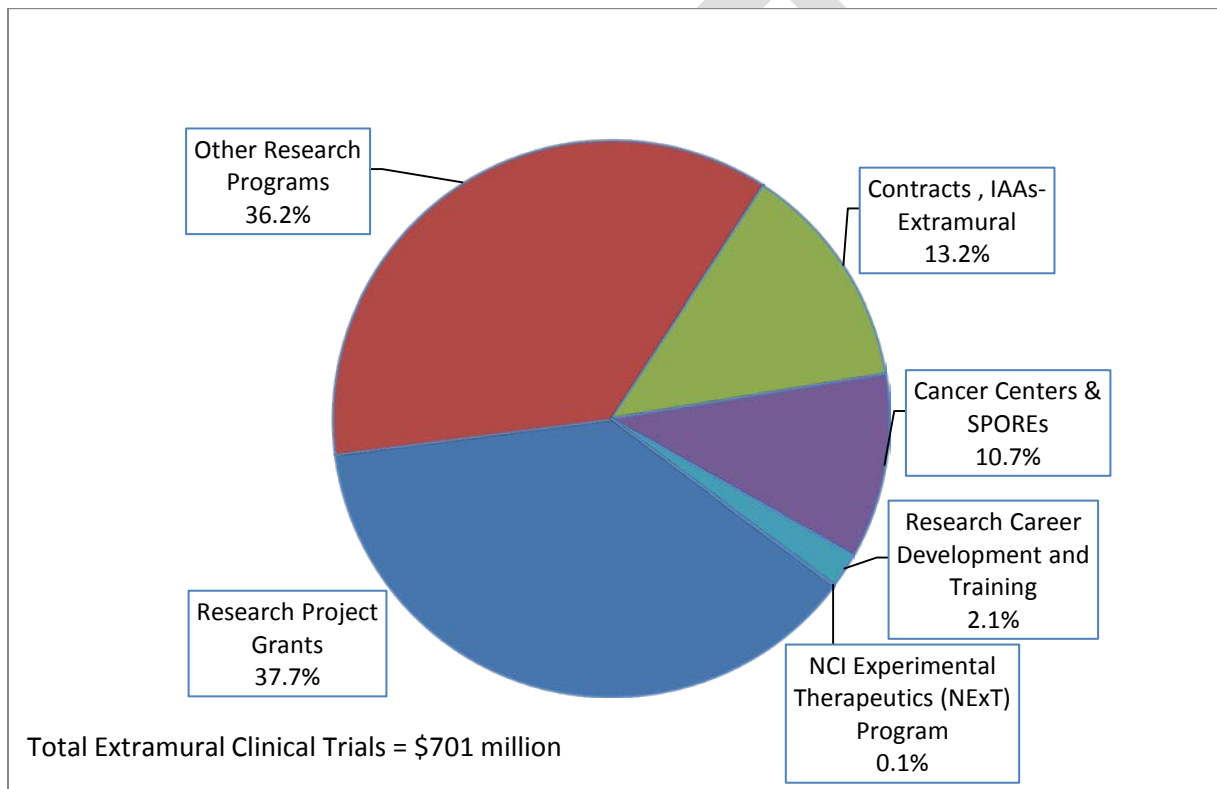


Table 4. Extramural NCI Clinical Trials Funding (by Mechanism)

<b>Mechanism</b>	<b>Number of Grants and Contracts</b>	<b>Clinical Trials Dollars</b>	<b>Percentage of Total Extramural Clinical Trials Dollars</b>
Research Project Grants (P01,R01,R03,R13,R21,R33,R37,R42,R44,U01s)	534	\$264,165,706	37.7%
Other Research Program Grants (U10,U24,U54s)	167	\$253,780,861	36.2%
Contracts , IAAs-Extramural (N01, N02, N43, N44, Y2)	40	\$92,808,898	13.2%
Cancer Center & SPORE Grants (P20,P30,P50s)	127	\$75,119,709	10.7%
Research Career Development and Training Grants (D43,K01,K05,K07,K08,K12,K22,K23,K24,K99,R25,T32)	92	\$14,370,295	2.1%
NCI Experimental Therapeutics (NExT) Program	5	\$610,352	0.1%
<b>Total Extramural Clinical Trials</b>	<b>965</b>	<b>\$700,855,823</b>	<b>100%</b>

## NCI Extramural Clinical Trials Awards by Individual Mechanisms

Table 4a: Extramural NCI Funding for Clinical Trials (by Individual Mechanisms).

Research Project Grants (RPG)	Number	Clinical Trial Dollars	Percentage of RPG Clinical Trial Dollars
Traditional Research Grants - R01	334	\$131,705,003	49.9%
Program Projects - P01	55	\$56,893,576	21.5%
Cooperative Agreements - U01	40	\$42,109,430	15.9%
Exploratory/Developmental Research - R21	75	\$18,759,741	7.1%
SBIR-Phase II - R44	12	\$8,861,596	3.4%
SBIR-Phase I - R42	8	\$4,665,329	1.8%
Phased Innovation Grants - R33	2	\$642,160	0.2%
Small Grants - R03	5	\$288,853	0.1%
Merit Awards - R37	1	\$170,585	0.1%
Conference Grants - R13	2	\$69,433	0.03%
<b>Subtotal RPG Clinical Trials</b>	<b>534</b>	<b>\$264,165,706</b>	<b>100%</b>
<b>Other Research Program Grants</b>			
	Number	Mechanism Clinical Trial Dollars	Percentage of Other Research Clinical Trial Dollars
U10 COOPs-Clinical Cooperative Groups	59	\$150,361,000	59.3%
U10 CCOPs- Community Clinical Oncology Program	75	\$84,810,429	33.4%
Specialized Center Cooperative Agreement U54	27	\$12,234,490	4.8%
Research/Resource Grant - U24	6	\$6,374,942	2.5%
<b>Subtotal, Other Research Program Clinical Trials</b>	<b>167</b>	<b>\$253,780,861</b>	<b>100%</b>

<b>NCI Extramural Contracts and Interagency Agreements</b>	<b>Number</b>	<b>Mechanism Clinical Trial Dollars</b>	<b>Percentage of Contract Clinical Trial Dollars</b>
R & D Contracts - N01	25	\$28,119,642	30.3%
Resource & Support -N02	10	\$62,073,173	66.9%
SBIR Phase I - N43	2	\$449,318	0.5%
SBIR Phase II -N44	1	\$749,985	0.8%
Interagency Agreements – Y2	2	\$1,416,780	1.5%
<b><i>Subtotal, Contracts and Interagency Agreements</i></b>	<b>40</b>	<b>\$92,808,898</b>	<b>100%</b>
<b>SPOREs , Cancer Centers, ICMICs, Planning Grants, Other P50 Centers</b>	<b>Number</b>	<b>Mechanism Clinical Trial Dollars</b>	<b>Percentage of P20, P30, P50 Clinical Trials Dollars</b>
P50s – SPOREs (Specialized Programs Of Research Excellence)	55	\$42,911,905	57.1%
P30s-Cancer Centers	59	\$26,719,694	35.6%
P50 – Other Centers	6	\$3,681,164	4.9%
P50 – ICMIC (In vivo Cellular & Molecular Imaging Centers)	5	\$1,532,179	2.0%
P20s- Planning Grants	2	\$274,767	0.4%
<b><i>Subtotal ,P20, P30, &amp; P50 Clinical Trials Dollars</i></b>	<b>127</b>	<b>\$75,119,709</b>	<b>100%</b>

<b>Research Career Development and Training (RCD&amp;T)</b>	<b>Number</b>	<b>Mechanism Clinical Trial Dollars</b>	<b>Percentage of RCD&amp;T Clinical Trial Dollars</b>
Mentored Patient -Oriented Research Career Development Award - K23	33	\$3,938,703	27.4%
Mentored Career Award - K12	10	\$3,810,272	26.4%
Mid-Career Investigator in Patient-Oriented Research Award - K24	9	\$1,454,137	10.1%
Preventive Oncology Award - K07	12	\$1,380,079	9.6%
NRSA Institutional Award – T32	11	\$1,187,012	8.3%
Cancer Education Awards - R25	3	\$841,517	5.9%
Temin Awards - K01	5	\$581,995	4.0%
International Training Grants in Epidemiology/Infectious Diseases - D43	1	\$499,414	3.5%
Established Investigator Award in Cancer Prevention & Control - K05	4	\$339,774	2.4%
Clinical Research Track - K22	1	\$191,381	1.3%
Mentored Clinical Scientist - K08	1	\$76,302	0.5%
Pathway to Independence - K99	2	\$69,709	0.5%
<b><i>Subtotal, Research Career Development and Training Clinical Trials</i></b>	<b>92</b>	<b>\$14,370,295</b>	<b>100%</b>
<b>NCI Experimental Therapeutics (NExT) Program</b>	<b>5</b>	<b>\$610,352</b>	
<b>Total Extramural Clinical Trials Dollars</b>		<b>\$700,855,823</b>	

## NCI Extramural Clinical Trials Awards by Type of Trial

Of the \$700.8 million extramural clinical trials allocation, \$421.8 million was allocated to Therapeutic, \$149.9 million to Prevention, \$72.1 million to Diagnostic, and \$55 million to other clinical trials.

“Other” includes trials for: behavior, e.g. screening behavior; quality of life or supportive care issues; symptom management; rehabilitation, etc. It also includes projects developing methods specifically for clinical trials (e.g., for analyzing or monitoring clinical trial data) but not actually conducting clinical trials.

Fig 5. NCI Extramural Funding by Clinical Trials Type

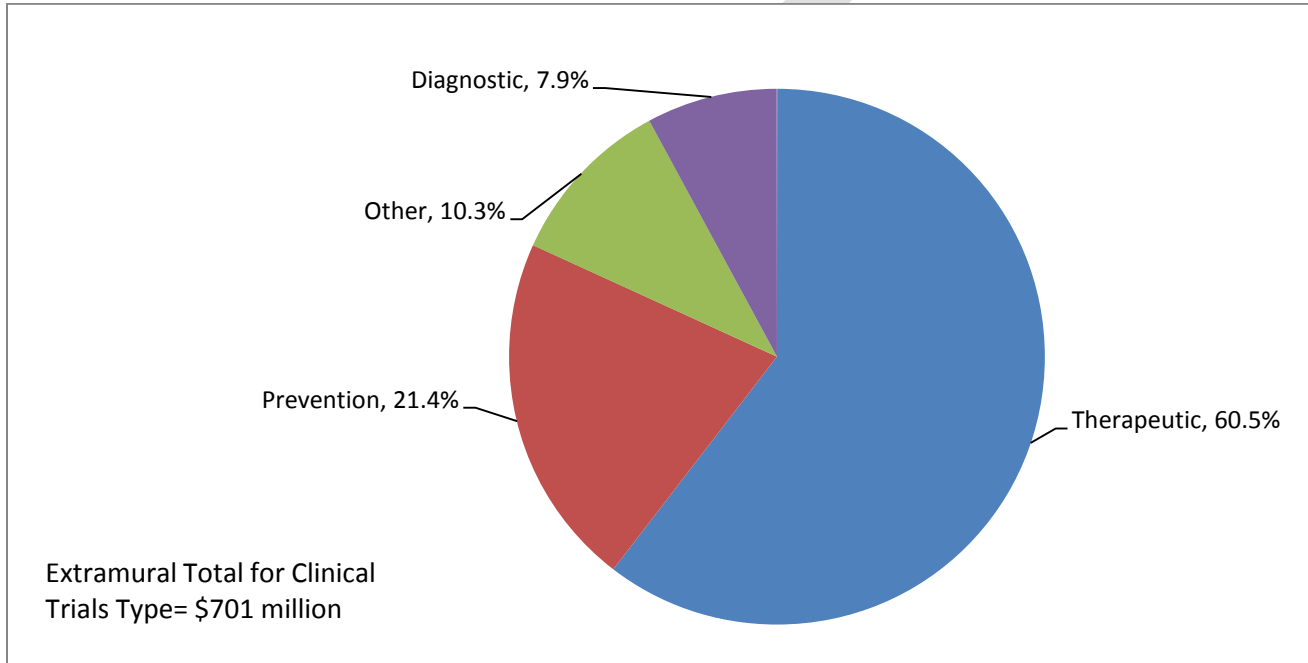


Table 5: NCI Extramural Funding by Type of Trial

Clinical Trial Types	Clinical Trials Dollars	Percentage of Total Clinical Trials Dollars
Therapeutic	\$421,807,088	60.5%
Prevention	\$149,867,600	21.4%
Diagnostic	\$55,033,605	7.9%
Other	\$72,120,404	10.3%
<b>Total Extramural Clinical Trials</b>	<b>\$700,855,829</b>	<b>100%</b>



## NCI Extramural Clinical Trials Funding by Anatomical Site

Extramural clinical trial awards are coded for their percent relevance to specific anatomical sites and funding is calculated by site. Individual extramural awards may include clinical trials relevant to more than one anatomical site. Figure 6 displays the major Site categories in descending order of FY2011 funding. Table 6 displays the anatomical sites being researched in extramural clinical trials projects in FY2011 sorted by major categories.

Fig 6. NCI Extramural Clinical Trial Awards by Site Category

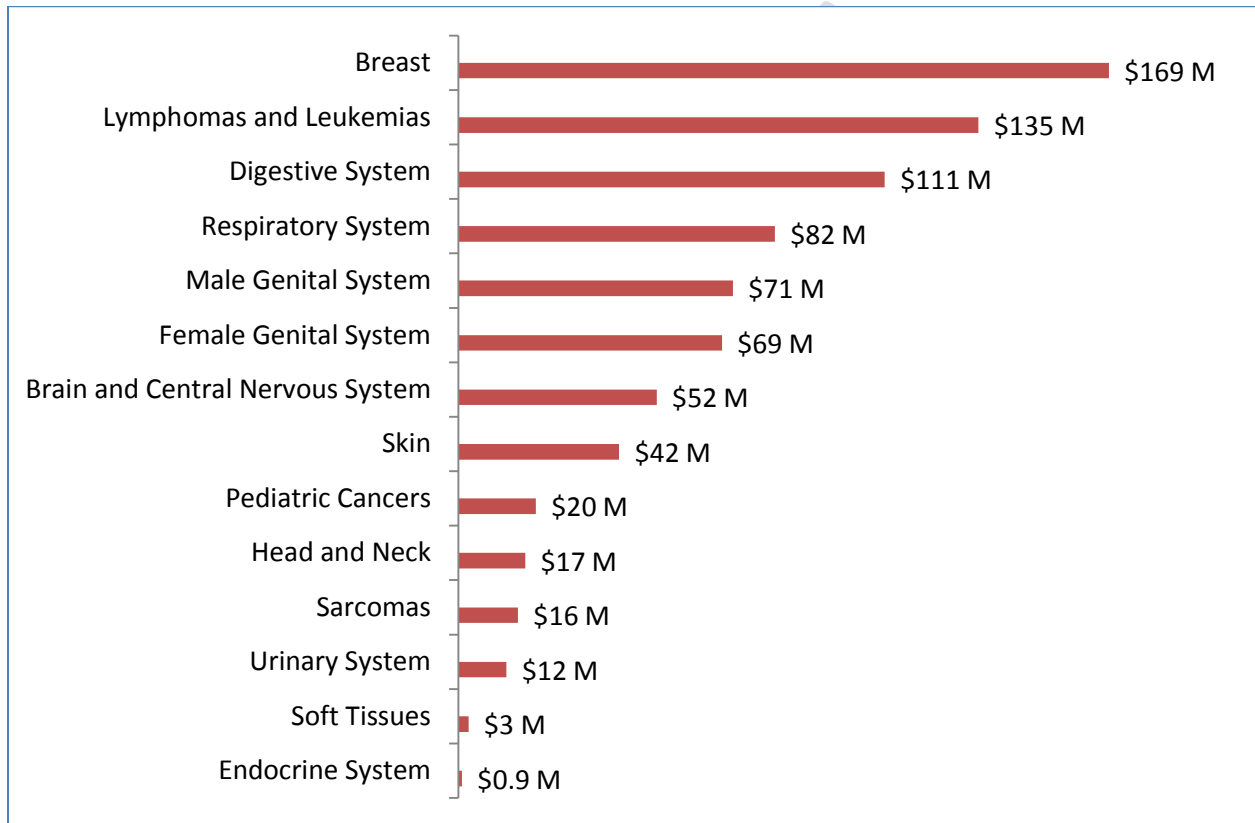


Table 6: Anatomical Sites in NCI Extramural Clinical Trial Awards by Site Category

<b>Site Categories</b>	<b>Individual Site Dollars</b>	<b>Site Category Dollars</b>
<b>Breast</b> BREAST	\$169,289,061	<b>\$169,289,061</b>
<b>Lymphomas and Leukemias</b> HODGKINS LYMPHOMA LEUKEMIA MYELOMA NON-HODGKINS LYMPHOMA RETICULENDOTHELIAL SYSTEM	\$5,142,605 \$76,382,874 \$26,575,525 \$27,265,875 \$8,861	<b>\$135,375,740</b>
<b>Digestive System</b> ANUS COLON, RECTUM ESOPHAGUS GALL BLADDER LIVER PANCREAS SMALL INTESTINE STOMACH	\$1,304,978 \$76,156,906 \$7,237,846 \$199,458 \$8,527,957 \$12,954,969 \$1,383,816 \$3,208,940	<b>\$110,974,869</b>
<b>Respiratory System</b> LUNG TRACHEA, BRONCHUS	\$81,465,501 \$884,177	<b>\$82,349,678</b>
<b>Male Genital System</b> PENIS PROSTATE TESTIS	\$104,818 \$70,566,021 \$765,678	<b>\$71,436,517</b>
<b>Female Genital System</b> CERVIX OVARY UTERUS	\$27,666,368 \$33,205,236 \$7,718,025	<b>\$68,589,629</b>
<b>Brain and Central Nervous System</b> BRAIN CENTRAL NERVOUS SYSTEM	\$48,998,992 \$2,607,340	<b>\$51,606,332</b>
<b>Skin</b> MELANOMA NON-MELANOMA	\$34,161,769 \$7,671,309	<b>\$41,833,078</b>
<b>Pediatric Cancers</b> CHILDHOOD LEUKEMIAS NEUROBLASTOMA RETINOBLASTOMA WILMS TUMOR	\$9,321,589 \$9,750,868 \$202,514 \$913,443	<b>\$20,188,414</b>
<b>Head and Neck</b> HEAD AND NECK ORAL CAVITY PHARYNX	\$15,731,030 \$1,153,452 \$479,419	<b>\$17,363,901</b>

<b>Site Categories</b>	<b>Individual Site Dollars</b>	<b>Site Category Dollars</b>
<b>Sarcomas</b>		<b>\$15,513,815</b>
OSTEOSARCOMA	\$3,671,724	
SOFT TISSUE SARCOMA	\$9,627,829	
KAPOSI SARCOMA	\$2,214,262	
<b>Urinary System</b>		<b>\$12,495,817</b>
BLADDER	\$2,116,226	
KIDNEY	\$10,379,591	
<b>Soft Tissues</b>		<b>\$2,678,880</b>
HEART	\$919,921	
VASCULAR	\$1,758,959	
<b>Endocrine System</b>		<b>\$895,695</b>
ADRENAL	\$57,449	
THYROID	\$838,246	

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## NCI Extramural Clinical Trials Awards, FY2011 (by State)

Four states received more than \$50 million dollars each in FY2011 for clinical trials grants and contracts: California, Maryland, Massachusetts, and Pennsylvania. Four states received no direct NCI clinical trial funding: Alaska, Idaho, North Dakota, and Wyoming. That is, there were no grants paid to institutions in these four states that funded clinical trials, but they indirectly receive funds through subcontracts with Community Clinical Oncology Programs (CCOPs). Eight states and one territory received less than \$1 million each: Kentucky, Maine, Mississippi, Montana, Nevada, Oklahoma, Puerto Rico, Vermont, and West Virginia. The remaining 35 States received between \$1 million and \$50 million in clinical trials dollars in FY2011. Table 7 lists each state alphabetically.

FIG 7: NCI Extramural Funding for Clinical Trials by States

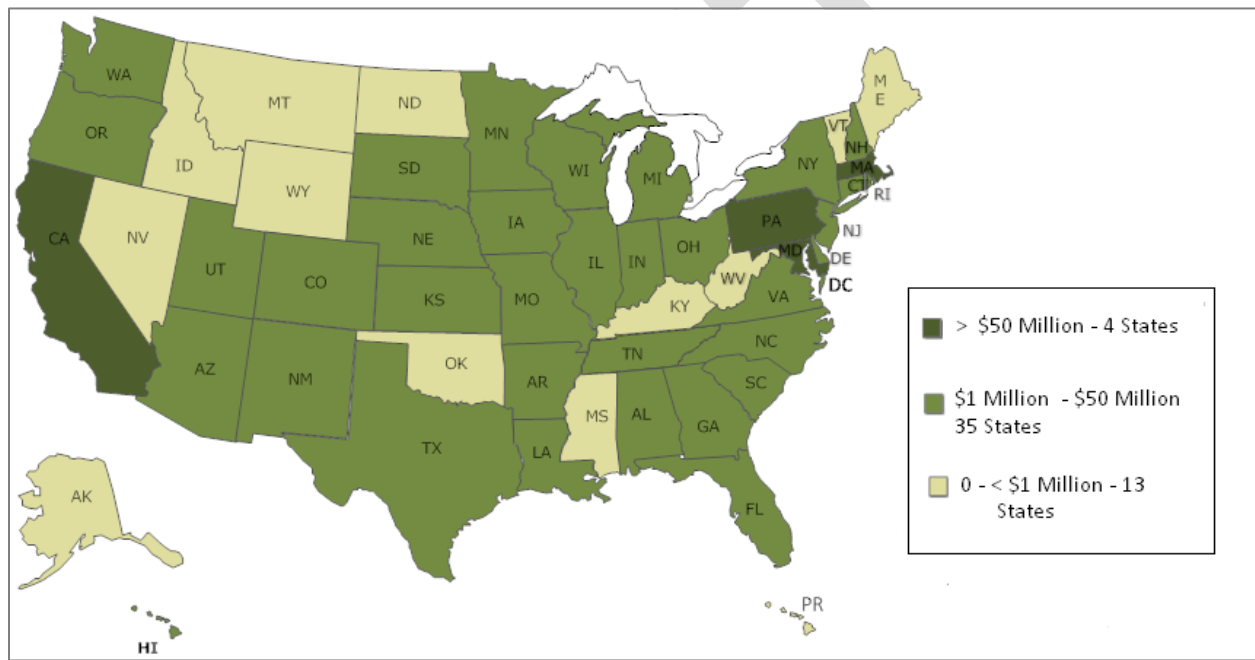


Table 7 NCI Extramural Awards for Clinical Trials (by State)

State	Number of Grants	Number of Contracts	Grants and Contracts Total	Clinical Trials Dollars	Percentage of Total US Extramural Clinical Trials Dollars
ALABAMA	11	1	12	\$6,891,708	1.0%
ARKANSAS	3		3	\$2,109,450	0.3%
ARIZONA	13	1	14	\$7,687,427	1.1%
CALIFORNIA	102	2	104	\$94,096,535	13.5%
COLORADO	11		11	\$5,024,237	0.7%
CONNECTICUT	9		9	\$2,921,963	0.4%

State	Number of Grants	Number of Contracts	Grants and Contracts Total	Clinical Trials Dollars	Percentage of Total US Extramural Clinical Trials Dollars
DISTRICT OF COLUMBIA	9		9	\$2,598,284	0.4%
DELAWARE	1		1	\$1,147,220	0.2%
FLORIDA	32	2	34	\$12,478,684	1.8%
GEORGIA	12		12	\$4,566,728	0.7%
HAWAII	4		4	\$1,086,622	0.2%
IDAHO	0		0	\$0	
IOWA	6		6	\$2,890,053	0.4%
ILLINOIS	35	3	38	\$19,239,253	2.8%
INDIANA	9		9	\$3,768,247	0.5%
KANSAS	8		8	\$5,142,141	0.7%
KENTUCKY	3		3	\$566,943	0.1%
LOUISIANA	6		6	\$2,420,770	0.3%
MASSACHUSETTS	80	1	81	\$72,725,137	10.4%
MAINE	1		1	\$0	
MARYLAND	32	12	44	\$101,219,590	14.5%
MICHIGAN	35		35	\$29,880,332	4.3%
MINNESOTA	40	3	43	\$35,101,113	5.0%
MISSOURI	14	2	16	\$9,488,593	1.4%
MISSISSIPPI	1		1	\$205,176	0.03%
MONTANA	2		2	\$768,085	0.1%
NEBRASKA	4		4	\$2,041,448	0.3%
NEW HAMPSHIRE	4		4	\$1,959,570	0.3%
NEW JERSEY	11	1	12	\$6,254,644	0.9%
NEW MEXICO	3		3	\$1,316,921	0.2%
NEVADA	1		1	\$627,866	0.1%
NEW YORK	71	2	73	\$36,783,052	5.3%
NORTH CAROLINA	37		37	\$23,477,904	3.4%
NORTH DAKOTA	0		0	\$0	

State	Number of Grants	Number of Contracts	Grants and Contracts Total	Clinical Trials Dollars	Percentage of Total US Extramural Clinical Trials Dollars
OHIO	30	2	32	\$14,701,145	2.1%
OKLAHOMA	1		1	\$515,598	0.1%
OREGON	10		10	\$4,245,659	0.6%
PENNSYLVANIA	63		63	\$52,005,554	7.5%
PUERTO RICO	1		1	\$417,931	0.1%
RHODE ISLAND	6		6	\$1,476,348	0.2%
SOUTH CAROLINA	5		5	\$3,033,799	0.4%
SOUTH DAKOTA	3		3	\$1,853,525	0.3%
TENNESSEE	21		21	\$12,352,169	1.8%
TEXAS	81	3	84	\$40,120,906	5.8%
UTAH	10		10	\$4,718,380	0.7%
VIRGINIA	15	1	16	\$29,743,477	4.3%
VERMONT	2		2	\$993,616	0.1%
WASHINGTON	34	1	35	\$24,883,591	3.6%
WISCONSIN	15	1	16	\$8,927,486	1.3%
WEST VIRGINIA	1		1	\$108,244	0.02%
WYOMING	0		0	\$0	
<b>Total US Extramural Clinical Trials Dollars*</b>	<b>907</b>	<b>38</b>	<b>945</b>	<b>\$696,583,117</b>	<b>100%</b>

\*Excludes \$4.3 million in foreign awards.

## NCI Extramural Clinical Trials Awards To US Institutions with a Foreign Component

In FY 2011, 23 NCI clinical trials grants to US institutions had foreign components. The foreign component, e.g., is conducting a trial in a foreign country or has a foreign collaborator on a clinical trial.

**NOTE:** A grant may have more than one country participating with the US Institution.

Fig 8. Countries Participating in NCI Clinical Trials with a U.S. Institution

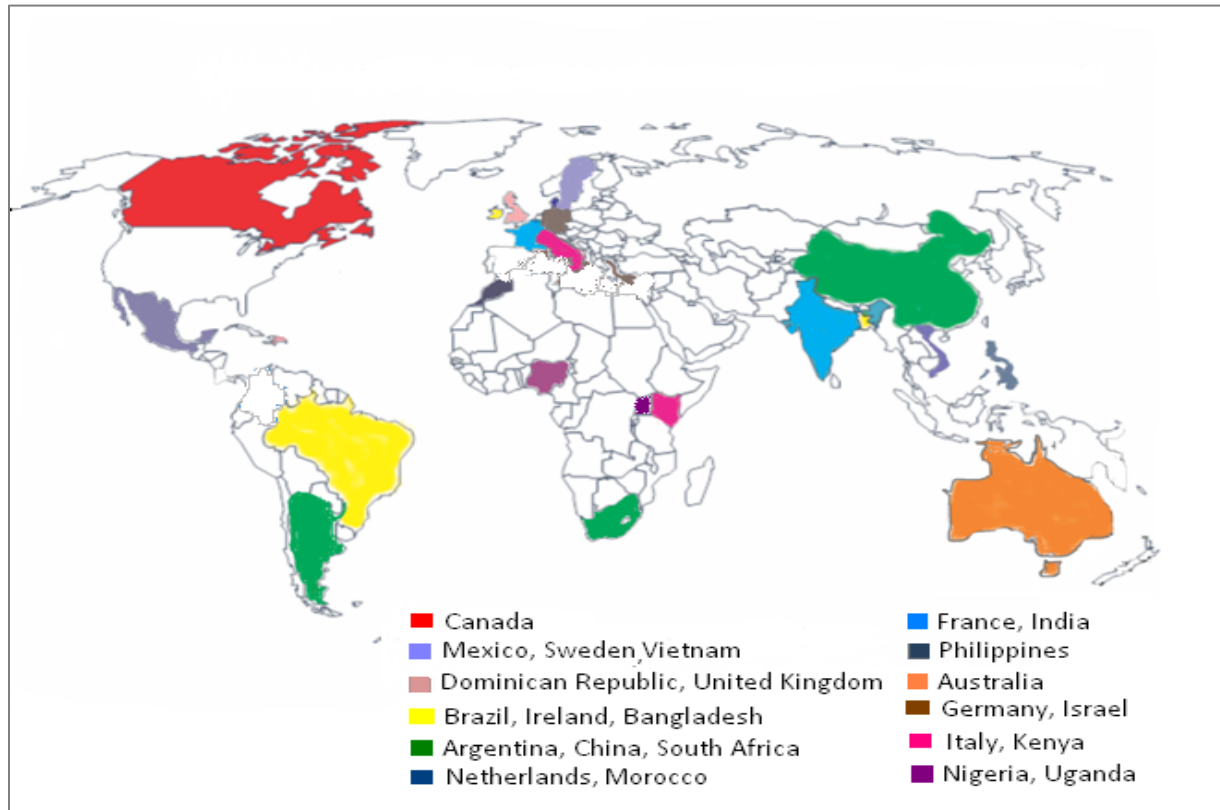


Table 8 Countries Participating in Clinical Trials with a U.S. Institution

Country	Count	Mechanisms	Country	Count	Mechanisms
Australia	1	U24	Israel	1	R01
Argentina	1	U01	Kenya	1	U01
Bangladesh	1	R01	Mexico	1	R01
Brazil	1	U01	Morocco	1	R01
Canada	4	P01,R01,U01,U24	Netherlands	1	R01
China	2	R01,R21	Nigeria	1	D43
Dominican Republic	1	R01	Philippines	1	R01
France	1	P01	South Africa	1	R01
Germany	1	U01	Sweden	1	P01
Italy	1	P01	Uganda	1	U01
India	3	R01, R01, R21	United Kingdom	1	P01
Ireland	1	U24	Vietnam	1	R01

## NCI Extramural Clinical Trials Awards to Foreign Institutions

Fig 9 NCI Clinical Trials Awards to Foreign Institutions

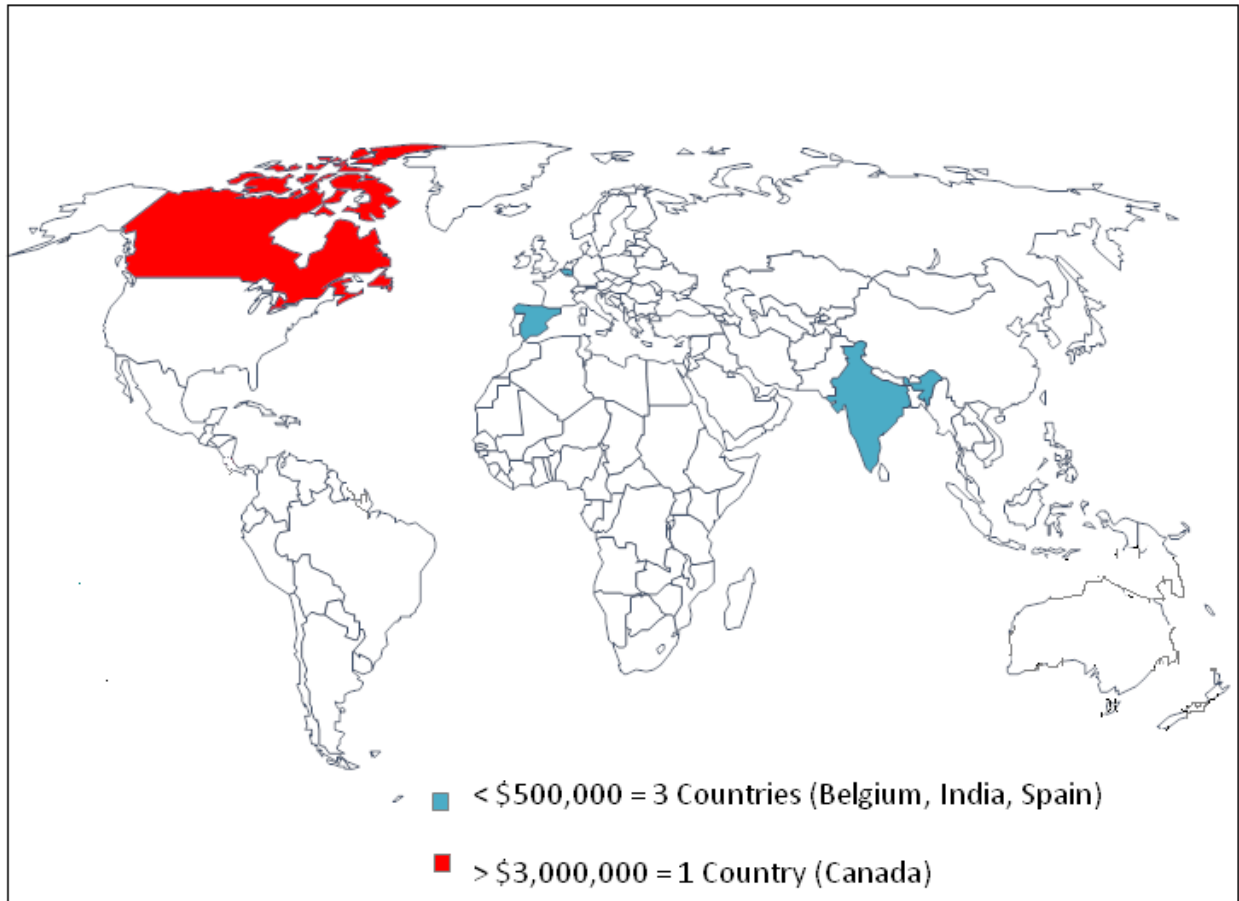


Table 9. NCI Clinical Trials Awards to Foreign Institutions

Countries	Mechanisms	Number of Grants	Foreign Clinical Trials Dollars
Canada	N01	2	\$1,493,798
	R01	2	\$531,866
	R21	2	\$327,411
	U01	2	\$802,355
	U10	4	\$597,717
(subtotal Canada)		12	\$3,753,147
Belgium	U10	1	\$232,518
India	R01	1	\$195,671
Spain	R01	1	\$91,371
<b>Total Foreign Clinical Trials</b>		<b>15</b>	<b>\$4,272,707</b>



# NCI Intramural Clinical Trials Funding

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## NCI Intramural Clinical Trials as a Proportion of Overall NCI Intramural Funding

NCI intramural clinical trials research is conducted by the Center for Cancer Research (CCR), and the Division of Cancer Epidemiology and Genetics (DCEG). More information about their research can be found on their websites: CCR at <http://ccr.cancer.gov/> and DCEG at <http://dceg.cancer.gov/>.

The total intramural funding for FY2011 was \$834 million of which \$70.5 million, or 8% of the total, was allocated to clinical trials.

Fig 10. NCI Intramural Clinical Trials Funding as a Proportion of Overall NCI Intramural Funding

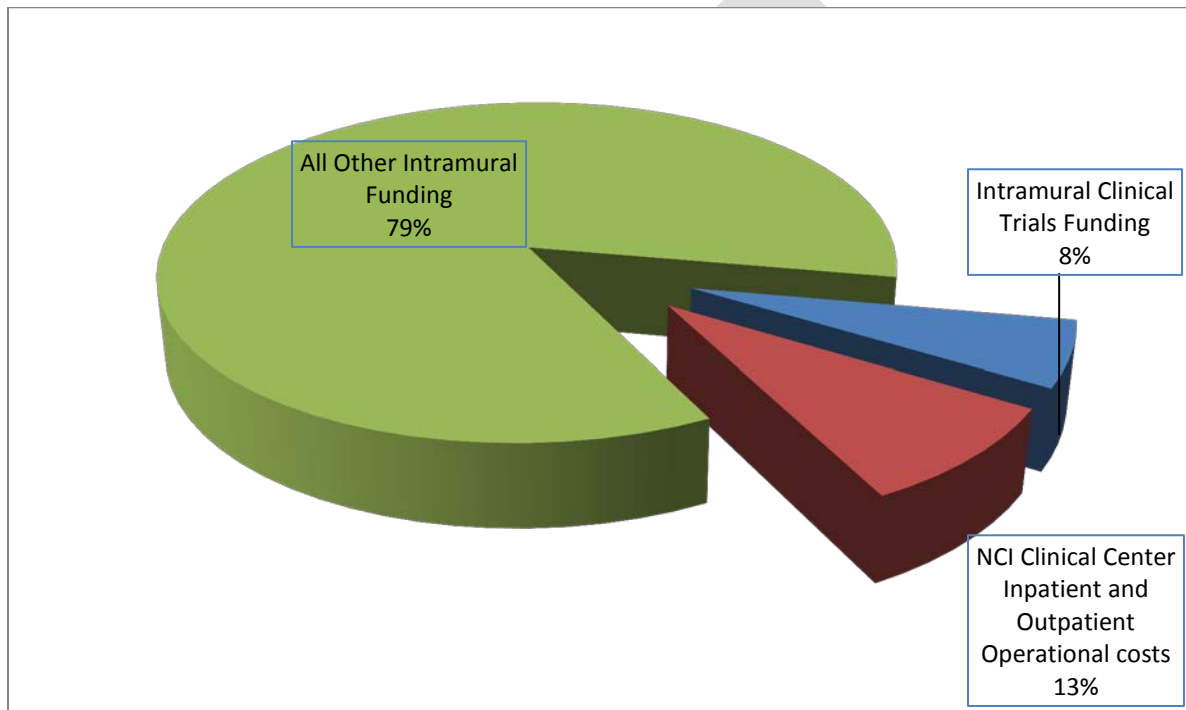


Table 10. Clinical Trials Funding as a Proportion of Overall Intramural Funding

	FY 2011 Dollars	Percentage of Total Intramural Funding
Intramural Clinical Trials Funding	\$70,567,346	8%
NCI Clinical Center Inpatient and Outpatient Operational Costs	\$106,986,000	13%
All Other Intramural Funding	\$656,116,654	79%
<b>Total Intramural funding</b>	<b>\$833,670,000</b>	<b>100%</b>

## NCI Intramural Clinical Trial Funding by Type of Trial

Of the \$70.5 million intramural clinical trials allocation, \$48.5 million was allocated to Therapeutic, \$12.9 million to Prevention, \$0.13 million to Diagnostic, and \$9.7 million to Other Clinical Trials.

“Other” includes trials for: behavior, e.g. screening behavior; quality of life or supportive care issues; symptom management; rehabilitation, etc. It also includes projects developing methods specifically for clinical trials (e.g., for analyzing or monitoring clinical trial data) but not actually conducting clinical trials.

Fig 11. NCI Intramural Clinical Trials Funding by Type of Trial

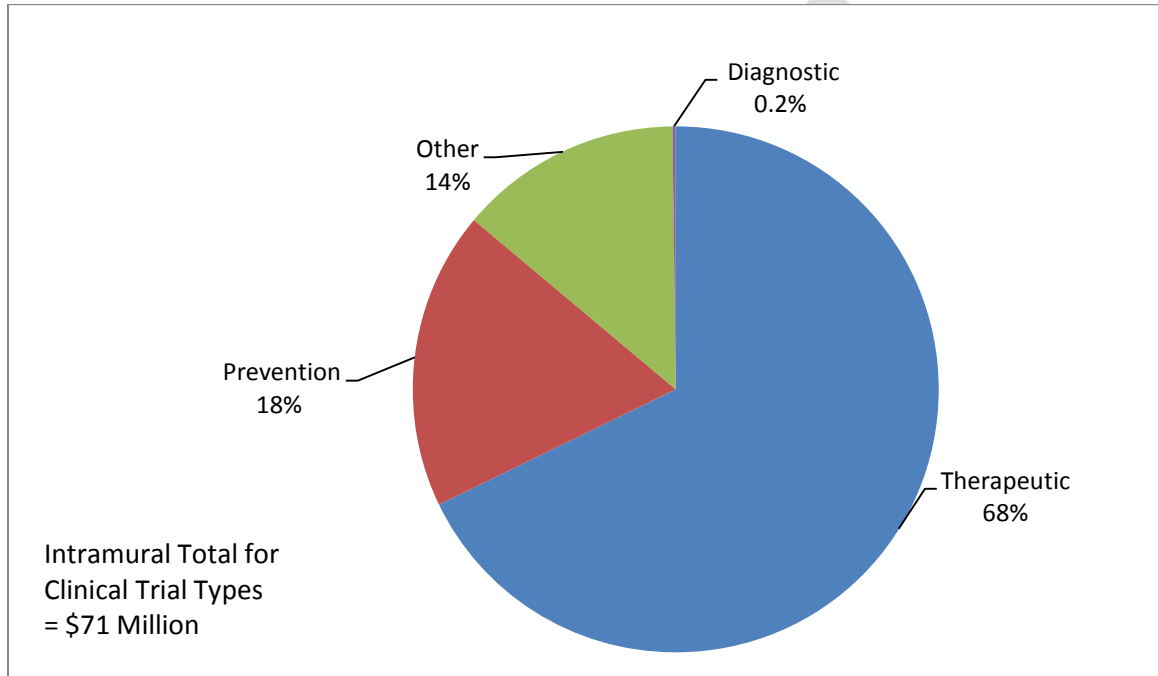


Table 11. Intramural Funding by Type of Trial

Clinical Trial Types	Clinical Trials Dollars	Percentage of Total Intramural Clinical Trials Dollars
Therapeutic	\$47,844,836	67.8%
Prevention	\$12,912,660	18.3%
Diagnostic	\$124,679	0.2%
Other	\$9,685,172	13.7%
<b>Intramural Clinical Trial Dollars Total</b>	<b>\$70,567,346</b>	<b>100%</b>

# NCI Clinical Trials Funding Summary

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## NCI Clinical Trials Funding Summary

Of the \$771 million clinical trials allocation, \$701 million (91%) was allocated to extramural and \$70.5 million (9%) was allocated to intramural.

Fig 12. NCI Funding for Clinical Trials, Intramural and Extramural

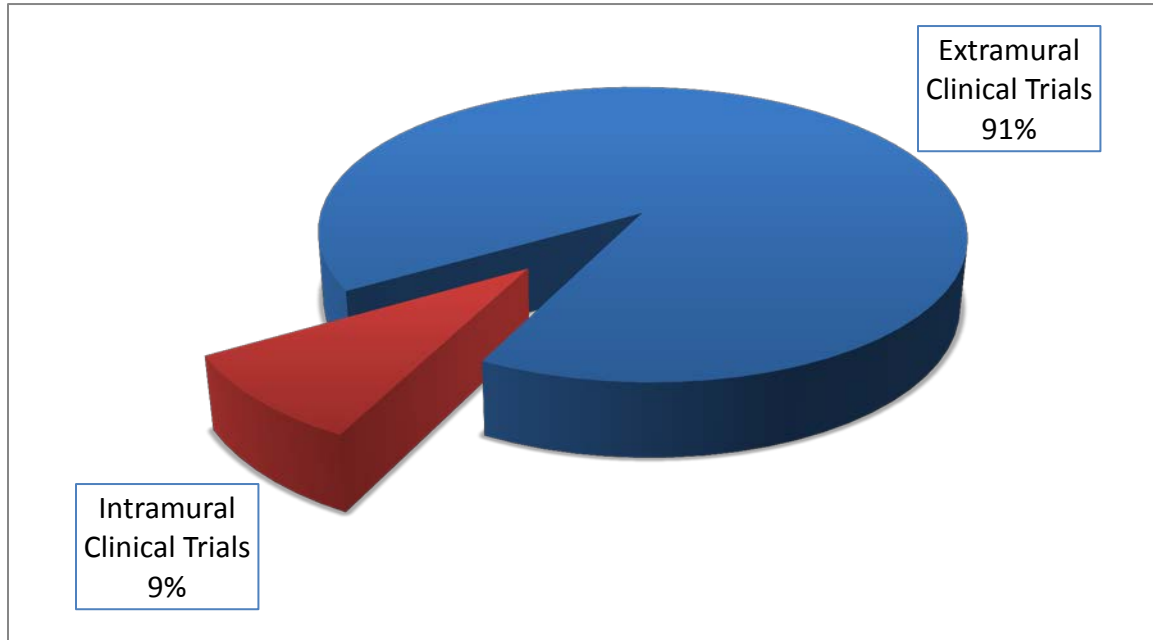
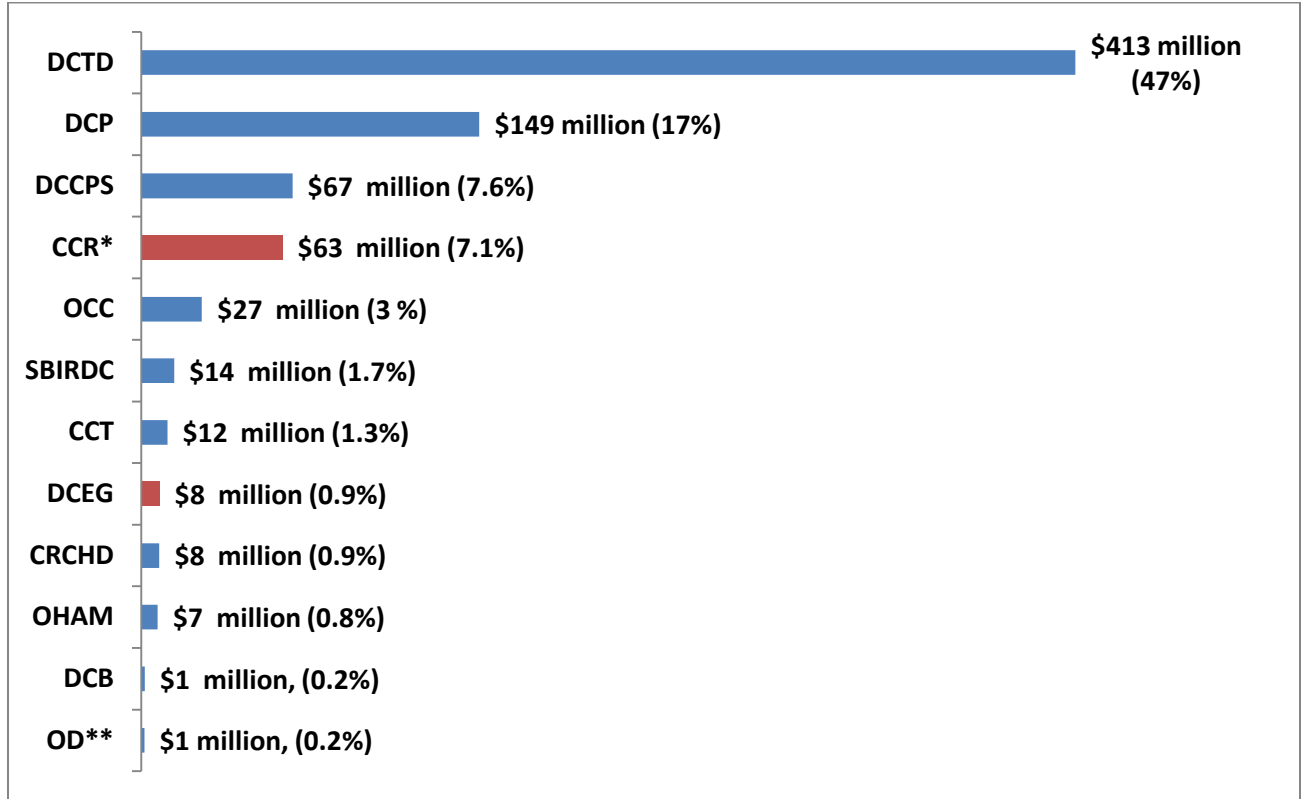


Table 12. NCI Funding for Clinical Trials, Intramural and Extramural

	Extramural/ Intramural \$	Percentage of NCI Clinical Trials Total
<b>Extramural Clinical Trials</b>	<b>\$700,855,823</b>	<b>91%</b>
<b>Intramural Clinical Trials</b>	<b>\$70,567,346</b>	<b>9%</b>
<b>NCI Clinical Trials Total</b>	<b>\$771,423,169</b>	<b>100%</b>

## NCI Clinical Trials Funding by Division, Office, or Center

Fig 13. NCI Clinical Trials Funding by Division, Office, or Center



OD\*\* (NCI & National Institute for Child Health & Human Development Interagency Contract Agreement)

NCI Clinical Trials DOC Total = \$771 Million

## NCI Clinical Trials by Funding Allocation

The \$771 million NCI Overall Clinical Trials funding is broken down into Intramural and Extramural allocation areas in Table 17, illustrated in Figure 17.

Fig 14. NCI Clinical Trials (by Funding Allocation)

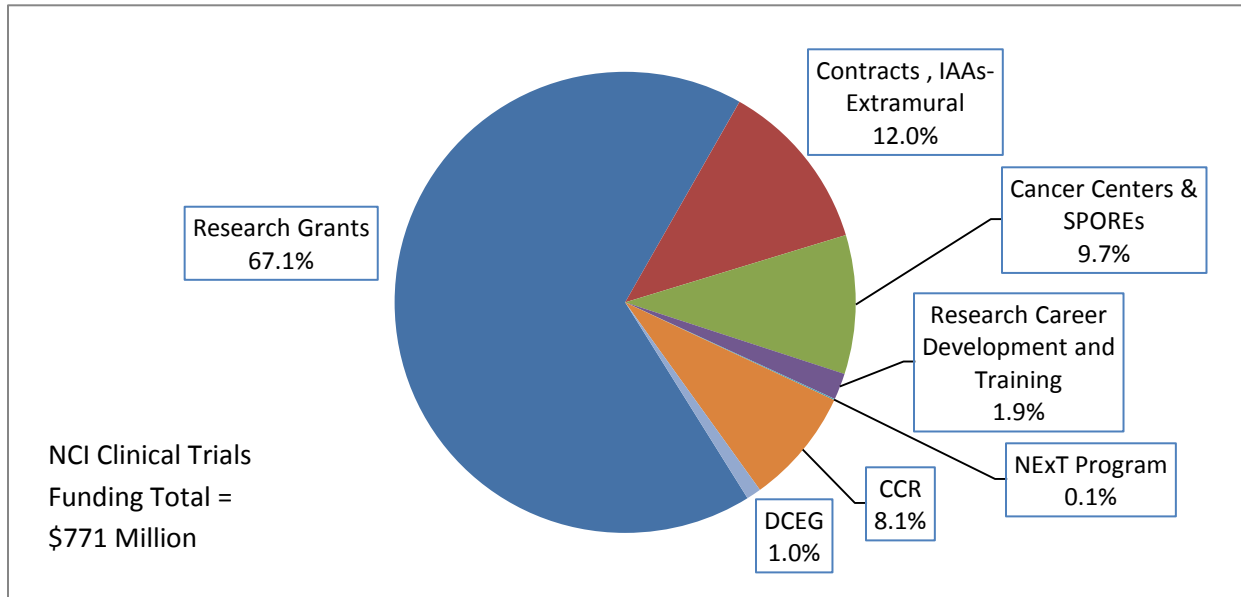


Table 14. NCI Clinical Trials (by Funding Allocation)

Funding Allocation	Number of Projects	Clinical Trials Dollars	Percentage of Total NCI Clinical Trials Dollars
<b>Extramural</b>			
Research Grants	701	\$517,946,567	67.0%
Contracts , IAAs-Extramural	40	\$92,808,898	12.0%
Cancer Centers & SPOREs	127	\$75,119,709	9.8%
Research Career Development and Training	92	\$14,370,295	1.9%
NCI Experimental Therapeutics (NExT) Program	5	\$610,352	0.1%
<b>Intramural</b>			
CCR	141	\$62,560,100	8.2%
DCEG	9	\$8,007,247	1.0%
<b>NCI Total Clinical Trials</b>	<b>1115</b>	<b>\$771,423,169</b>	<b>100.0%</b>

## NCI Clinical Trials by Type of Trial

Clinical Trials funding is indexed by four clinical trial types: Prevention, Diagnostic, Therapeutic, and Other. Other includes trials for: behavior, e.g. screening behavior; quality of life or supportive care issues; symptom management; rehabilitation; as well as projects developing methods specifically for clinical trials (e.g., analyzing or monitoring clinical trial data) but not actually conducting clinical trials.

Of the total NCI FY2011 Clinical Trial funding (\$771 million), 61% (\$470 million) was allocated to Therapeutic trials, 21% (\$163 million) to Prevention trials, 11% (\$82 million) to other trials and 7% (\$55 million) was allocated to Diagnostic trials.

Fig 15. NCI Funding by Type of Trial

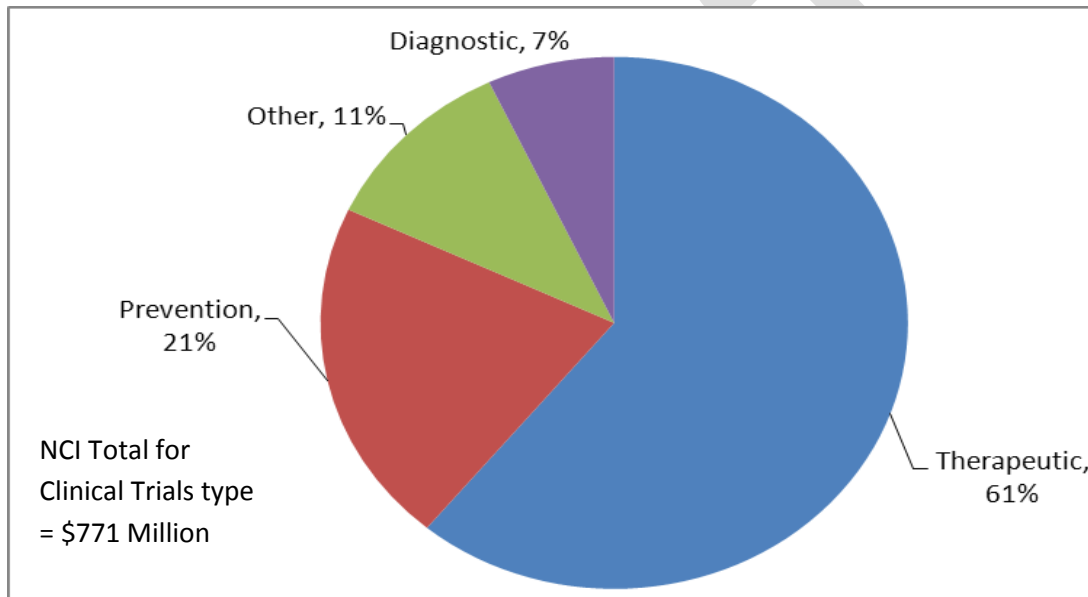


Table 15. NCI Funding for Clinical Trials Type

NCI Clinical Trial Types	Clinical Trials Dollars	Percentage of Total Clinical Trials Dollars
Therapeutic	\$469,651,924	61%
Prevention	\$162,780,260	21%
Diagnostic	\$55,158,284	7%
Other	\$81,805,576	11%
<b>NCI Clinical Trials Total</b>	<b>\$771,423,175</b>	<b>100%</b>



## Summary

Of the total FY2011 NCI expenditures of \$5.1 billion, NCI allocated 17.4% (\$771 million) to clinical trials. Similarly, 18.2% (\$700.9 million) of the \$3.8 billion overall extramural funding was allocated to clinical trials. 8.5% (\$70.5 million) of the total intramural funding for FY2011 of \$834 million was allocated to clinical trials.

Fig 16. Comparison of Extramural, Intramural and NCI Overall Clinical Trials Allocations

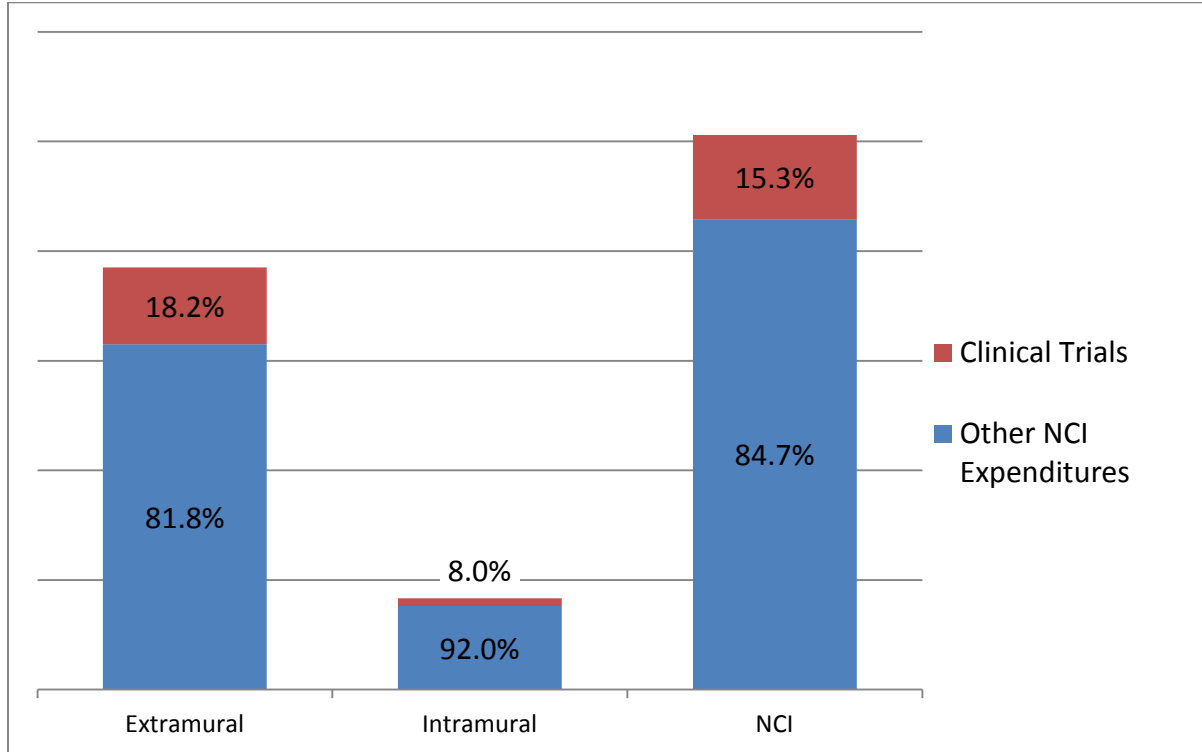


Table 15. Comparison of Extramural, Intramural and NCI Overall Clinical Trials Allocations

	Extramural Dollars	Extramural Percent	Intramural Dollars	Intramural Percent	NCI Dollars	NCI Percent
<b>Clinical Trials</b>	\$700,855,823	18.2%	<b>\$70,567,346</b>	8.00%	\$771,423,169	15.30%
<b>Other NCI Expenditures</b>	\$3,149,101,985	81.8%	<b>\$763,102,654*</b>	92.0%	\$4,286,681,809	84.70%
<b>Total</b>	<b>\$3,849,957,808</b>	100%	<b>\$833,670,000</b>	100%	<b>\$5,058,104,978</b>	100%

\*Includes NCI Clinical Center Inpatient and Outpatient Operational Costs

Documenting NCI clinical trials costs is a difficult process since the data is not available from one comprehensive source. The current NCI clinical trials databases document intervention trials, but this does not represent all of the costs of conducting clinical trials. For example, this portfolio inventory includes projects developing methods specifically for clinical trials (e.g., analyzing or monitoring clinical trial data) but not actually conducting clinical trials.

It is recommended that a database be developed to collect all clinical trials costs, to differentiate between types of trials, clinical trials phases, major anatomical sites, and to include associated costs. Until a standardized process for recording clinical trials costs can be developed, NCI CTROC proposes that the Research Analysis Evaluation Branch (RAEB) repeat this inventory every five years.

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**Thank you:**

- Office of Cancer Centers
- Cancer Therapy Evaluation Program
- Center for Cancer Research
- Division of Cancer Epidemiology and Genetics
- Gail Pitts, M. S.
- Rajasri Roy, Ph. D.
- Marilyn Gaston
- Diane Bronzert

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