DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE
20th CLINICAL TRIALS AND TRANSLATIONAL RESEARCH
ADVISORY COMMITTEE (CTAC) MEETING (WEBINAR)

Summary of Meeting
July 10, 2013

Building 31 C, Conference Room 10
National Institutes of Health
Bethesda, Maryland

CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE
BETHESDA, MARYLAND
Summary of Meeting
July 10, 2013

The 20th meeting of the Clinical Trials and Translational Research Advisory Committee (CTAC) of the National Cancer Institute (NCI) was held on Wednesday, July 10, 2013, at 10:00 a.m. via webinar. Some members participated in the webinar in Conference Room 10, C-Wing, 6th floor, Building 31, on the National Institutes of Health (NIH) main campus in Bethesda, MD. The CTAC Chair, Dr. James L. Abbruzzese, Chairman, Department of Gastrointestinal Medical Oncology, The University of Texas M.D. Anderson Cancer Center, presided. The meeting was adjourned at 12:00 p.m.

Chair
James L. Abbruzzese

CTAC Members
Peter C. Adamson
Susan G. Arbuck
Monica M. Bertagnolli (absent)
Susan G. Braun (absent)
Curt I. Civin
Kevin J. Cullen
Nancy E. Davidson
Olivera J. Finn (absent)
J. Phillip Kuebler
Scott M. Lippman
Mary S. McCabe
Edith P. Mitchell
Nikhil C. Munshi
Lisa A. Newman
Nancy Roach
Daniel J. Sargent
Mitchell D. Schnall
Peter G. Shields
George W. Sledge, Jr.
Chris H. Takimoto
Joel E. Tepper
Gillian M. Thomas
Frank M. Torti
Miguel A. Villalona-Calero (absent)
George J. Weiner

***Ex Officio* Members**
James H. Doroshow, NCI
Paulette S. Gray, NCI
Rosemarie Hakim, CMS
Lee J. Helman, NCI
Michael J. Kelley, VA (absent)
Richard Pazdur, FDA (absent)
Alan S. Rabson, NCI (absent)

Executive Secretary
Sheila A. Prindiville, NCI

TABLE OF CONTENTS

WEDNESDAY, JULY 10, 2013

I. CALL TO ORDER AND OPENING REMARKS—DR. JAMES L. ABBRUZZESE

Dr. Sheila A. Prindiville, Director, Coordinating Center for Clinical Trials (CCCT), NCI, welcomed CTAC members to the webinar meeting. She reviewed the logistics of joining the meeting via webinar and confirmed which members were present. Dr. Prindiville reminded members that the meeting was being videocast by NIH Events Management and that the videocast would be available for review following the meeting at: http://videocast.nih.gov/.

Dr. Abbruzzese called the 20th meeting of the CTAC to order and then reviewed the confidentiality and conflict-of-interest practices required of Committee members during their deliberations. Members of the public were invited to submit written comments related to items discussed during the meeting to Dr. Prindiville within 10 days of the meeting. Any written statements by members of the public will be given careful consideration and attention.

Motion. A motion to accept the minutes of the 19th meeting of the CTAC held on March 13, 2013, was approved unanimously.

II. NCI UPDATE—DR. JAMES H. DOROSHOW

Dr. James H. Doroshow, Deputy Director, Clinical and Translational Research, NCI, noted changes to NCI policy on meeting costs. The restrictions on the dollar amount spent per meeting have recently expanded to include Federal Advisory Committee Act (FACA)-approved official advisory committees. There may be some difficulties in planning future CTAC meetings, and Dr. Doroshow asked for Committee members' support and forbearance in light of these recent changes.

Dr. Doroshow reported that the NCI National Clinical Trials Network (NCTN) Working Group met last week to complete the review of the portfolios of the gynecologic oncology, symptom management, head and neck, and the imaging steering committees. Formal recommendations resulting from these reviews will be presented at the November 2013 CTAC meeting. Once these recommendations are received, CTAC will discuss how to utilize and prioritize the recommendations across the entire NCI clinical trials system. NCI is actively engaged in developing a series of new molecularly driven studies based on genomic characterization for the adjuvant treatment of lung adenocarcinoma and the treatment of squamous cell lung cancer. These types of studies require additional funds to support new tissue biopsy and genomic characterization. Dr. Doroshow asked CTAC members to consider such studies from a budget perspective while prioritizing NCI's research portfolio.

Dr. George W. Sledge, Jr., Chief, Division of Oncology, Stanford University, reiterated that the NCTN Working Group reviewed the portfolios of several individual disease groups at its recent meeting. In the future, the Working Group will progress from looking at individual disease portfolios to a more collective view of priorities and prioritization of trials between the disease groups.

NCI will be moving forward with publishing a notice in the *Federal Register* communicating that applications for randomized phase III trials using the R01 grant mechanism will no longer be accepted. As discussed at the March 2013 CTAC meeting, this policy will help NCI focus its efforts on optimal utilization of the new clinical trials network.

The Pancreatic Cancer Working Group's report, *Pancreatic Cancer: Scanning the Horizon for Focused Interventions*, identifies four recommended research initiatives. This Working Group report will form the basis for the full report required by the Recalcitrant Cancer Research Act. The full report should be submitted to Congress later this year. The Small Cell Lung Cancer Working Group met in early July to develop a set of recommendations that will be presented to CTAC at an upcoming meeting.

Dr. Doroshow noted that a group of external peer reviewers will be reviewing NCTN grant applications next week. NCI will report back to CTAC on the results of the review.

The NIH Clinical Trials Working Group is evaluating clinical-trials-related changes that have been instituted by NCI for their applicability to other Institutes. There is interest across NIH in having an NIH-wide central institutional review board (IRB) and a platform for ongoing reporting of clinical trial accrual beyond what is available on clinicaltrials.gov.

Questions and Discussion

Dr. Peter Adamson, Chair of the Children's Oncology Group and Chief, Division of Clinical Pharmacology and Therapeutics, Children's Hospital of Philadelphia, asked how much money is in the R01 grant pool for phase III randomized trials. Dr. Doroshow said about $4-5 million dollars per year has been spent on phase III trials. He noted that the NCI Clinical Trials Portfolio Analysis (fiscal year [FY] 2011) presentation will provide a better understanding of clinical trials funding allocation across NCI.

Dr. Edith P. Mitchell, Clinical Professor of Medicine and Medical Oncology, Kimmel Cancer Center, Thomas Jefferson University, asked how much funding in the R01 grant pool is devoted to clinical trials. Dr. Doroshow said that the NCI Clinical Trials Portfolio Analysis presentation will provide a dollar figure for R01 grants that were primarily clinical-trials-related for FY2011. The FY2011 figure is similar to the amount of money spent in FY2008.

III. LEGISLATIVE UPDATE—MS. MK HOLOHAN

Ms. MK Holohan, Deputy Director, Office of Government and Congressional Relations, NCI, reported on the status of appropriations and gave an update on legislation of interest.

Appropriations Status. Sequestration took effect March 1, 2013, which reduced each budget line for all discretionary spending programs by 5.1 percent in FY2013. Sequestration will cut $109 billion per year through FY2021 (the next eight fiscal years). After FY2013, the cuts will not be determined by each budget line item but, rather, by the spending caps for each spending bill. The 50/50 budget cut split between defense and nondefense spending will no longer be in effect, and the House and Senate will set spending levels for each bill to arrive at the overall $109 billion cut.

For FY2014, the President's budget request proposed an increase of $471 million ($31.1 billion total) for NIH from pre-sequester budget levels. Currently, the House and Senate budget committees are $91 billion apart overall, and $42.5 billion apart for the Labor, Health and Human Services, Education,

and Related Agencies bill (a 25.9 percent difference). This bill is the largest discretionary spending bill, and is often the last bill Congress approves in the appropriations process. On July 9, the Senate Labor-H appropriations subcommittee passed the spending bill with $30.955 billion for NIH (a $307 million increase from FY2012). The full Senate appropriations committee votes on the bill today. The House does not yet have a Labor-H bill, but they are starting 25.9 percent lower than the Senate. The Senate released a statement on this spending difference:

"Applying an across-the-board cut of 25.9 percent to the Senate mark, the House bill would produce the following results. NIH funding would be slashed by roughly $8 billion below the Senate level. To put that figure in perspective, $8 billion is more than the entire amount that NIH spends on research on cancer and cardiovascular diseases combined. If the House chose to cut any of these programs by less than 25.9 percent, other programs in the bill would have to be reduced by a greater percentage."

At the May 15 Senate Committee on Health, Education, Labor, & Pensions (HELP) Hearing, NIH Director Dr. Francis Collins told Committee members that the NIH budget's purchasing power has declined by 22 percent in the last 10 years. Senate Appropriations Chair Barbara Mikulski, and Senators Jerry Moran (R-KS) and Richard Shelby (R-AL), are strong advocates for NIH and voiced their desire to increase NIH funding.

Congress Members' Visits to NIH. On February 8, Senator Ben Cardin (D-MD) held a Town Hall meeting with staff on the NIH campus. Senator Mikulski (D-MD) visited NIH on February 20 and held a press conference to discuss sequestration. On May 9, House Majority Leader Eric Cantor led a bipartisan group to visit NIH to meet with Dr. Collins and a few other Institute Directors. They toured Dr. Lou Staudt's laboratory and learned about advances in lymphoma research. Senate Majority Leader Harry Reid visited NIH on June 17.

Legislation of Interest. The Kids First Research Act prioritizes pediatric research to assist children with autism and other diseases. The Kids First Research Act will eliminate taxpayer financing of presidential campaigns and the Republican and Democratic party conventions and instead use these funds to expand pediatric research at NIH through the NIH Common Fund. (The Common Fund supports transformative research that involves the coordination of multiple NIH research Institutes and Centers.) The Triple-Negative Breast Cancer Research and Education Act of 2013 directs NIH to expand, intensify, and coordinate research on triple-negative breast cancer. The Caroline Pryce Walker Conquer Childhood Cancer Reauthorization added a new component that relates to biorepositories for childhood cancers. Representative Brian Higgins (D-NY) reintroduced the Cancer Drug Coverage Parity Act of 2013, which requires that insurers provide benefits for oral chemotherapy that are equal to those provided for intravenous chemotherapy.

Questions and Discussion

Dr. Prindiville asked Ms. Holohan for her thoughts on the Supreme Court decision on gene patenting. Ms. Holohan said that the decision has been well received by many patient rights groups. She can provide a detailed summary on the decision to CTAC members, if desired.

IV. NCI CLINICAL TRIALS PORTFOLIO ANALYSIS (FY2011)—DR. PAULETTE GRAY

Dr. Paulette Gray, Director, Division of Extramural Activities (DEA), NCI, presented a portfolio analysis of NCI clinical trials. At the March 2012 CTAC meeting, the Committee requested that the DEA's Research Analysis and Evaluation Branch (RAEB) conduct an inventory of NCI clinical trials expenditures for FY2011. This inventory includes: intramural and extramural clinical trials funding distribution by NCI Division, Office, and Center (DOC); clinical trials category (i.e., prevention, diagnosis, therapy, other); allocation category (funding mechanisms); major anatomic site; and geographic location; and overall NCI clinical trials funding.

The portfolio analysis was conducted based on the following operational definitions of a clinical trial. A clinical trial is a prospective study involving human subjects that is 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. A clinical trial is a diagnostic trial if it uses the information from the diagnostic test in a manner that affects medical decision-making for the study subject. 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. Studies whose objective is only the gathering of data on the characteristics of a new diagnostic approach are not clinical trials. Behavioral clinical trials are interventions whose goals are to increase behaviors, eliminate or reduce behaviors, and/or improve coping and quality of life 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. In addition to these definitions, the inventory includes projects developed as methods to be used specifically for clinical trials; for example, analysis or monitoring of clinical trials data.

NCI's budget was $5.1 billion in FY2011. NCI allocated $771 million to clinical trials, representing 15.3 percent of its total budget; 13.9 percent ($700.9 million) was allocated to extramural trials and 1.4 percent ($17.5 million), to intramural trials. The extramural trial inventory includes grants, contracts, and interagency agreements. Of the 7,393 grants, contracts, and interagency agreements awarded in FY2011, 965 included clinical trials projects. The $700.9 million that was allocated to these 965 grants, contracts, or interagency agreements was 18.2 percent of the overall NCI extramural funding. The two NCI DOCs that received the most NCI extramural clinical trials funding were the Division of Cancer Treatment and Diagnosis (DCTD) with $413 million (59 percent), and the Division of Cancer Prevention (DCP) with $149 million (21.3 percent).

NCI extramural clinical trials funding also was analyzed by mechanism. Research project grants received $264 million (37.7 percent); other research programs, $254 million (36.2 percent); contracts and interagency agreements, $93 million (13.2 percent); Cancer Centers and Specialized Programs of Research Excellence (SPOREs), $75 million (10.7 percent); Research Career Development and Training, $14 million (2.1 percent); and the NCI Experimental Therapeutics (NExT) program, $610,000 (0.1 percent). Over 60 percent of NCI-supported extramural trials were therapeutic trials; 21.4 percent were prevention trials; 7.9 percent were diagnostic trials; and 10.3 percent were other trial types.

In reviewing the analysis of extramural trials by major anatomic site, Dr. Gray noted that extramural awards are coded for their percent relevance to specific anatomic sites for determining funding levels. Individual awards may include clinical trials relevant to more than one anatomic site. Funding for

breast cancer trials was $169 million; lung cancer, $81 million; ovarian cancer, $33 million; and pancreatic cancer, $13 million.

Extramural funding also was analyzed by geographic location. Four states received funding greater than $50 million; 35 states received $1 million to $50 million; and 13 states received less than $1 million. One country (Canada) received greater than $3 million; three countries (Belgium, India, and Spain) received less than $500,000. Twenty-two extramural grants that received funding for clinical trials had a foreign component.

Intramural clinical trials funding comprised 8 percent ($70.5 million) of the total NCI intramural budget ($834 million). NCI inpatient and outpatient operational costs comprised 13 percent ($107 million) of the total intramural budget. Sixty-eight percent of intramural clinical trial funding was for therapeutic trials; 18 percent, prevention trials; 14 percent, other trial types; and 0.2 percent was for diagnostic trials.

In FY2011, NCI spent $771 million on clinical trials; 91 percent of that funding was allocated to extramural clinical trials and 9 percent was allocated to intramural trials. DCTD distributed the majority of the overall NCI clinical trials funding: $413 million, or 47 percent of the total budget. DCP distributed $149 million (17 percent), and the Center for Cancer Research (CCR) received $63 million (7.1 percent). By funding mechanism, research project grants were allocated $518 million (67.1 percent); contracts and Interagency Agreements (IAAs), $93 million (12 percent); Cancer Centers and SPOREs, $75 million (9.7 percent); Research Career Development and Training, $14 million (1.9 percent); CCR, $62.5 million (8.1 percent); the Division of Cancer Epidemiology and Genetics (DCEG), $8 million (1 percent); and the NExT program, $610,000 (0.1 percent). Sixty-one percent of overall clinical trials funding was allocated to therapeutic clinical trials; 21 percent, to prevention trials; 7 percent, to diagnostic trials; and 11 percent, to other trial types.

Two recommendations were developed based on these analyses. It is recommended that a database be developed to track all clinical trials costs, including information on type of trial, clinical trial phase, and major anatomic site, and that associated costs be included. The NCI Clinical and Translational Research Operations Committee (CTROC) recommended that RAEB, the official source of science-based budget information for NCI-supported extramural research, repeat this inventory every five years.

Questions and Discussion

Dr. Gray noted the amount of funding allocated to R01 grants in FY2011. It is indicated on page 13 of the report that NCI funded a total of 334 R01s in the amount of $131,705,000.

Dr. Abbruzzese asked whether it is possible to conduct an analysis of the impact of NCI-supported clinical trials. Dr. Doroshow responded that that type of analysis has never been done before. It would be possible, given the appropriate timeframe, for a working group of CTAC to select one or two disease sites to conduct a more in-depth analysis of the impact of supported trials. Dr. Gray added that if such a working group were to be created, an identified set of criteria to analyze the grants would be necessary. A clear understanding of what constitutes a successful trial is needed. Dr. Abbruzzese noted that one simple metric that could be used is the degree to which the research has led to practice changes.

Ms. Nancy Roach, Consumer Advocate, C3: Colorectal Cancer Coalition, asked for clarification regarding the funding allocated to the Cancer Centers and SPOREs. Dr. Gray explained that only the funding associated with clinical trials was considered.

Dr. Adamson asked whether it is possible to get an estimate of how much of the R01 clinical trials pool was allocated to phase III studies in FY2011. It would be helpful to break down the R01 clinical trials funding by phase. Dr. Doroshow agreed that those numbers would be of interest to the greater clinical trials community.

Dr. Nikhil Munshi, Associate Director, Jerome Lipper Myeloma Center, Dana-Farber Cancer Center, suggested that CTAC members recognize that clinical trials have broader implications than reaching diagnostic or therapeutic endpoints when evaluating the impact of research studies.

Dr. J. Phillip Kuebler, Principal Investigator, Columbus Oncology Associates, Inc., commented that it would be interesting to break down the extramural trials by trial type even further; for example, the percent of cancer control trials versus therapeutic trials.

Dr. Mitchell D. Schnall, Eugene P. Pendergrass Professor and Chairman, University of Pennsylvania Medical Center, asked about the global outcomes that are being sought for the clinical trials program across all mechanisms. How can a determination be made regarding the appropriate size of the various components of the program? Dr. Doroshow responded that if NCI does not know exactly what type of research is being supported, it is hard to evaluate the funding allocations for each clinical trial mechanism. He asked the group to consider whether, in order to discuss prioritizing and allocating resources, it would be important to first get more detailed information on the sizes of the various components of the program or to first think more conceptually about where the emphases should be.

Dr. Gillian M. Thomas, Professor, Department of Radiation Oncology, University of Toronto, commented that understanding the yield from all of the research that is being done and whether it is cost-effective is a conceptual issue. Putting parameters on defining the outcomes of successful clinical trials is a difficult task. It could be done by looking at high-level measures such as life years saved or at whether a specific laboratory research project advanced something to phase II or III studies.

Dr. Lee Helman, Chief, Pediatric Oncology Branch and Deputy Director, CCR, stated that change of practice is the obvious outcome of a successful trial. However, if change of practice is the metric used, they will be looking only at phase III studies in the Cooperative Groups. Dr. Abbruzzese agreed that there are other outcomes that are important to consider. He commented that some outcomes may be disease specific. Dr. Kuebler added that it is difficult to consider only practice change as an outcome as some practices are not adopted.

Ms. Roach commented that there is a paper published by Dr. Robert Kalish showing that there are many small, single-institution phase II trials being conducted with low-impact outcomes. NCI's clinical trials system needs to promote an integrated process that moves things through from the preclinical phase to appropriate phase I and II trials and then phase III, resulting in clinical impact.

Dr. Jeffrey S. Abrams, Associate Director, Cancer Therapy Evaluation Program (CTEP), NCI, expressed concern over the number of NCI groups evaluating the current clinical trials portfolio. The allocation of NCI clinical trials funding will not change unless NCI and its advisors decide that it needs to change. If that is the case, it would be necessary to put some caps in certain areas to redirect funding to other areas.

Dr. Lori Minasian, Deputy Director, DCP, commented that the peer review system favors those disease sites where there is availability and access to tissues and the ability to conduct analyses. In thinking about the conceptual framework for developing metrics for the outcomes of the clinical trials program, it is necessary to know how the money has been spent, but also the desired outcome. Therefore, the question is not only the percentage of trials in the portfolio that were early pilot versus later phase studies, but also the percentage of those studies that provided the basic information that led to a different framework for putting the drug into practice. She expressed concern that over structuring the framework for funding clinical trials might inhibit the ability to support novel studies.

Ms. Roach asked whether it is possible to fund novel studies in the current system. Dr. Minasian responded that the system is based upon peer review and one would hope that really novel ideas would fare well, but that she cannot answer that question.

Dr. Helman noted that Table 4A of the report shows that over 50 percent of NCI clinical trials funding goes through the research project grant pool. He asked CTAC members whether this is something that should be considered. Dr. Adamson agreed but stated that they need to understand what actually is being funded in that pool before drawing any conclusions. For example, it would be helpful to know the success rates for early-phase trials. Dr. Abrams suggested that it would be interesting if CTAC were to look at the R01 and P01 projects and, possibly, the R21s in addition to the current process of looking at the Cooperative Group structure. Dr. Gray clarified that the funds allocated to the R01s and P01s are not 60 percent of the extramural dollars but are actually the percentage of funds in the Research Project Grant pool, which is closer to 30 percent.

Dr. Adamson stated that there seems to be an underestimate for pediatric cancers in Table 6 of the report. He asked how the disease site translates to pediatrics since pediatrics is not actually a site.

Dr. Mitchell commented that it might be helpful to determine some relative outcomes of groups of trials (e.g., if trials ended early with no real conclusion or if the initial intent was completed).

Ms. Roach added that it also would be helpful to know whether the results of publicly funded trials have been presented or published. She also suggested that CTAC might need to make recommendations on which disease sites require more focus and funding.

Dr. Abbruzzese suggested that the role of CTAC should be to look at the process rather than the relative percentages between the different disease sites—the way in which decisions on allocations of funding are made to help determine how well each type of study has accomplished the overall goals of driving science, changing practice, and improving outcomes for patients. Dr. Mitchell agreed that the question should be whether the overall program is providing outcomes that are relevant to the progression of science and are of clinical relevance.

Dr. Prindiville read comments from Dr. Curt Civin, Associate Dean of Research, University of Maryland School of Medicine, who was having difficulties accessing the audio features of the webinar. Dr. Civin noted the need to consider metrics, as substantial cost, time, and effort are involved in implementing them. He also suggested that when analyzing the return on investment in clinical trials, CTAC identify examples of successful clinical trials that would highlight the statistical analyses in a way that the lay public and Congress could appreciate.

Dr. Abbruzzese commented that today's discussions will be brought to the CTAC Program Planning Working Group to discuss the approach that CTAC will take in assisting NCI in assessing its clinical trials and translational research program overall.

V. NEW BUSINESS AND ANNOUNCEMENTS—DR. JAMES L. ABBRUZZESE

Dr. Abbruzzese expressed thoughts on the role of CTAC in the next one to two years. Dr. Abbruzzese would like the Committee to have greater impact in helping NCI given the difficult issues surrounding funding. He asked CTAC members to identify specific barriers to clinical and translational research that could be presented and discussed at a future meeting.

Dr. Abbruzzese asked for feedback on the use of the webinar to conduct the meeting. There were some issues with connecting on the computer; some people had to call in to the meeting. Ms. Roach commented that it is difficult to have a productive discussion with a large group on line.

VI. ADJOURNMENT—DR. JAMES L. ABBRUZZESE

There being no further business, the 20th meeting of the CTAC was adjourned at 12:00 p.m. on Wednesday, July 10, 2013.

National Cancer Institute

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

NCI Legislative Update

Clinical Trials and Translational Research Advisory Committee

July 10, 2013

M.K Holohan, J.D.

Deputy Director, Office of Government and Congressional Relations

mholoha@mail.nih.gov

Discussion Topics

Budget Impasse

- In search of a “Grand Bargain”

Appropriations Status

- FY13 post-sequestration
- FY 2014

Legislation of Interest

Appropriations Status – FY 2013

Where are we?

- FY13: Sequestration took effect March 1
- Cut 5% or $1.55 billion of FY13 budget
  - Reduces each budget line by 5.1%
  - 700 fewer grants issued by NIH

What's next?

2014 -2021: $109 billion will be cut each year by spending caps (not "each budget line")

Appropriations Status – FY 2014

- President's Budget request prosed $31.1 B for NIH (increase of $471M from pre-sequester level)
- Budget Resolutions: House & Senate are $91B apart overall, and $42.5 billion apart for the Labor-H bill (25.9% difference)
- Still no conference (12 weeks post-deadline)
- Showdown in September – Shutdown?

Labor-H Bill

- Senate: passed subcommittee 7/9
  - $30.955 billion for NIH (+ $307 million from FY12)
  - 7/11- full committee vote.
- House: no bill yet, but starting 25.9% lower

Appropriations Status – FY 2014

Senate Bill as Compared to the House Bill

Because the House of Representatives has yet to mark up its Labor-HHS bill, it is impossible to provide a direct comparison. However, the House allocation for Labor-HHS is $121.8 billion, or 25.9 percent lower than the Senate level.

Applying an across-the-board cut of 25.9 percent to the Senate mark, the House bill would result in NIH funding being slashed by roughly $8 billion below the Senate level. To put that figure in perspective, $8 billion is more than the entire amount that NIH spends on research on cancer and cardiovascular diseases combined.

If the House chose to cut any of these programs by less than 25.9 percent, other programs in the bill would have to be reduced by a greater percentage.

Appropriations Status – FY 2014

Senate HELP Appropriations Chair Tom Harkin:

"I will not get engaged in pitting NIH against other worthwhile endeavors in this appropriations bill."

I can promise you, if sequestration stays in effect next year, there's no chance that we will get close to the president's request for NIH, let alone back to fiscal year 2012 levels. It just won't happen."

Member visits to NIH

Feb. 8

- Senator Cardin visits NIH; holds Town Hall meeting with staff

Feb. 20

- Senator Mikulski visits NIH; holds press conference

May 9

- House Majority Leader Eric Cantor led a bipartisan group to visit NIH, great interest in touring Lou Staudt's lab and learning about advances in lymphoma research

June 17

- Senate Majority Leader Harry Reid visits NIH

Want to see how we kill cancer cells?

National Cancer Institute

"Short-sighted cuts to research funding today will cost us valuable cures tomorrow, and while those costs may not be felt this month, this year, or even this decade, their long-term consequences will be grave."

Appropriations Hearing

May 15: Senate HELP Hearing

NIH Director Francis Collins told the committee members that the NIH budget's purchasing power had declined by 22% in the last 10 years.

Senate Appropriations Chair Barbara Mikulski: "I'm going to work my earrings off to make sure that [NIH gets the funding it needs]."

Senators Jerry Moran (R-KS) and Richard Shelby (R-AL), both strong advocates for the NIH, also voiced their strong desire to increase funding for the NIH.

Legislation

Kids First Research Act

Triple-Negative Breast Cancer Research and Education Act of 2013

Caroline Pryce Walker Conquer Childhood Cancer Reauthorization

Cancer Drug Coverage Parity Act of 2013

NATIONAL® CANCER INSTITUTE

July 10, 2013

Legislative Update

for the

Clinical Trials and Translational Research Advisory Committee

Activities of the 113th Congress-

First Session

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http://legislative.cancer.gov

I. Appropriations

The President's Budget was announced April 10 providing $ 31.3 billion for the NIH, and of that amount, NCI would receive $5.1 billion. At this point, the House and Senate are proceeding along contradictory tracks for FY14 appropriations, with the House using a post-sequestration overall spending limit of $967 billion, while the Senate has formally adopted a $1.058 trillion limit, based on the assumption that Congress will repeal the automatic spending cuts that began on March 1 when the sequester took effect. Last month, House Appropriators adopted a top-level budget allocation of $967 billion and individual spending levels for each of the 12 spending bills. Appropriations Chairman Hal Rogers chose to protect and increase funding for the Defense, Military-Construction/VA, and Homeland Security bills, but sharply cut spending limits for non-defense discretionary bills such as Labor-Health-Education, Interior and Environment, and Energy and Water. For example, the Defense bill would increase 5.4%, while the Labor-H bill (funds HHS/NIH) would be cut by 18.6% below the current, post-sequestration level (a $35 billion cut).

On June 20th, the Senate Appropriations Committee, led by Senator Barbara Mikulski, adopted a spending plan that allocates a pre-sequestration level of $1.058 trillion among the 12 annual spending bills – about $91 billion more than the House numbers. With a 15-14 party-line vote, Senator Mikulski won approval of her approach, which she describes as "not willing to accept sequester as the new normal." Allocations for the individual spending bills were close to the numbers in the President's Budget Request, including a $7.7 billion increase for the Labor-H bill over the FY13 enacted level. If GOP senators maintain their united opposition on the Senate floor, they would effectively block approval of any spending plan by denying Democrats the 60 votes needed to move the bills.

Despite this impasse, the appropriations committees have continued to move FY14 spending bills. As of July 8, the House Appropriations Committee has advanced six spending bills out of committee, and two of these - Military Construction-VA and Homeland Security (DHS) – have been passed by the House. The Labor-Health-Education bill (Labor-H) that provides funding for NIH is likely to be among the last bills moving in the House, although Majority Leader Cantor maintains that he plans to bring all 12 bills to the floor for a vote. The White House has threatened to veto the House bills unless the GOP will conduct meaningful budget negotiations for the entirety of the budget, getting back to the needed "grand bargain" negotiation. House Speaker John Boehner has dismissed the veto threat, and insists that the appropriations bills must be kept separate from budget talks, suggesting the possibility of a government shutdown in the fall. In contrast, Rep. Tom Price, vice-chair of the House Budget Committee, stated in mid-June that any budget agreement would inevitably be tied to the debt ceiling.

The Senate Appropriations Committee has advanced four spending bills out of committee, none of these have gone to the Senate floor for a vote. The Labor-H bill is set for subcommittee mark-up on July 9th and is scheduled for full committee consideration on July 11th.

A group of GOP Senators have been meeting with WH staff in recent weeks to work on a deficit reduction agreement, but major disagreements are said to remain. If an agreement is not reached, sequestration will continue into FY14, requiring annual cuts of $109.3 billion from the budget.

II. Congressional Briefings and Visits

Briefing on NCI Office of Communication and Education Spending (5/20/13): At the request of Alan Slobodin, Chief Investigative Counsel, Energy and Commerce Subcommittee on Oversight and Investigations, and John Bartrum, Professional Staff Member of the House Appropriations Subcommittee on Labor, HHS and Education, Dr. Varmus, briefed Mr. Slobodin and Mr. Bartrum on NCI Office of Communication and Education spending.

Senate Appropriations Subcommittee Hearing (5/15/13): Dr. Varmus accompanied Dr. Francis Collins, Director, NIH, at a hearing before the Senate Labor, HHS, Education Subcommittee [Tom Harkin (D-IA), Chair] about the President's FY2014 Budget. Other Institute Directors in attendance were Anthony Fauci, National Institute of Allergy

and Infectious Diseases (NIAID); Gary Gibbons, National Heart, Lung, and Blood Institute (NHLBI); Story Landis, National Institute of Neurological Disorders and Stroke (NINDS); and Richard Hodes, National Institute on Aging (NIA).

Majority Leader Eric Cantor Visit to NIH (5/9/13): Majority Leader Eric Cantor (R-VA) led a bipartisan delegation consisting of Earl Blumenauer (D-OR), Michael Burgess (R-TX), Renee Ellmers (R-NC), Eliot Engel (D-NY), Chaka Fattah (D-PA), Andy Harris (R-MD), Tim Murphy (R-PA), and Ted Yoho (R-FL). The delegation met with the NIH Director and other NIH senior leadership and toured the Clinical Center. The delegation toured Dr. Louis Staudt's Laboratory of Molecular Biology of Lymphoid Malignancies, NCI.

NCI Staff Spoke at Multiple Myeloma Event (4/11/13): At the request of the Congressional Black Caucus, Dr. Nelson Aguila, Program Director, Center to Reduce Cancer Health Disparities, NCI, spoke about multiple myeloma research and health disparities.

NIH Staff Briefed Congressional Staff on Human Subject Protections in NIH-Supported Studies (3/20/13): Ted Trimble, Director, Center for Global Health, NCI, joined with Sarah Carr, NIH Office of Science Policy, Ann Hardy, NIH Extramural Human Research Protection Officer, Sherry Mills, Director, NIH Office of Extramural Programs, Cliff Lane, Deputy Director for Clinical Research and Special Projects, NIAID, to brief House Energy and Commerce Committee staff members, Anne Morris Reid and Wendell Primus about the oversight of NIH-supported international projects to prevent noncompliance with HHS Human Subjects Protection regulations.

Sen. Benjamin Cardin (D-MD), NIH Town Hall (2/8/13): Senator Cardin gave a Town Hall address at NIH and met with Dr. Varmus, as well as Dr. Francis Collins, NIH Director and Dr. Tony Fauci, NIAID Director. He toured Dr. Linehan's lab and met with his research team. He also visited the Urologic Oncology Branch, CCR, and talked with Branch Chief Dr. W. Marston Linehan, Dr. Ramaprasad Srinivasan, and one of their patients who was on a clinical trial for papillary renal cell cancer. During the Town Hall following the meeting, Sen. Cardin commented about meeting the patient he had met, saying, "*It's interesting, the person [patient] I had the chance to meet with who is here for [on Dr. Linehan's study] told us quite frankly that he never thought he would need government help. He never [even filed for] unemployment. He was employed, living his life, thinking everything was going fine. And then they discovered a disease in which only the work done here would give him the chance to enjoy a future. He's now a strong advocate for the NIH.*" In addition, Sen. Cardin discussed the impending sequester cuts, stating that the cuts were never supposed to take effect. He mentioned efforts to avert the cuts, stating that "*we need a rational plan for these irrational cuts*".

III. Supreme Court Decisions of Interest

Negating Gene Patents (6/13/2013) : The Supreme Court unanimously ruled that naturally-occurring human genes cannot be patented. Myriad Genetics claimed exclusive rights to the BRCA 1 and 2 genes, which are linked to increased risk for breast and ovarian cancer. The court ruled that because Myriad "did not create anything", they were not entitled to patent protection. Supporters of the ruling anticipate lower cost and wider access for the test for these genes, and many others, for patients, as well as the elimination of a previous barrier to scientific research. The ability to patent synthetic DNA (for example, cDNA) lessened, somewhat, concerns about intellectual property protection and a potential negative impact on innovation in the biotech industry.

Pay-for-Delay is an Anti-trust Violation (6/17/2013): In a 5 – 3 decision, the Supreme Court ruled that federal regulators may challenge in court arrangements made between drug companies and their competitors to avoid patent challenges and delay introduction of generic versions of patented drugs. Without competing generic versions, brand name drug makers can charge considerably more for medicines, and in the so-called pay-for-delay agreements, potential competitors could share in those profits rather than introduce generic versions. Drug manufacturers argued that the practice is necessary to offset the costs incurred in bringing drugs to market, and that the finding by the court will impede innovation. A study released by the Federal Trade Commission concluded that pay-for-delay settlements cost the American public approximately $3.5 billion annually.

IV. Legislation of Interest

The following resolutions and bills were selected for inclusion in this update due to anticipated interest among the CTTRAC membership. More detailed information about these bills and others are available on our website under Legislative Topics: http://legislative.cancer.gov/topics

Selected Bills With Recent Activity or Interest (113th Congress)

Triple-Negative Breast Cancer Research and Education Act of 2013 (HR 80; 113th Congress)

- This bill would provide for research and education with respect to triple-negative breast cancer, and for other purposes.
- Under this bill, the Director of NIH would be required expand, intensify, and coordinate programs for the conduct and support of research with respect to triple-negative breast cancer through the appropriate institutes, offices, and centers.
    - For the purposes of carrying out this section, $500,000 would be appropriated for each of the fiscal years 2014 through 2016.
- This bill would also require the Centers for Disease Control to carry out an education program and HRSA would be required to develop information for health care providers.
- The bill does not mention the National Cancer Institute.
- H.R. 80 was introduced by Rep. Sheila Jackson Lee (D-TX) on 1/3/2013 and was referred to the House Committee on Energy and Commerce.
- STATUS UPDATE:
    - Rep. Sheila Jackson Lee offered language similar to that contained in this bill as an amendment to the defense authorization bill (HR 1960) on 6/13/2013. The amendment was adopted during floor debate and the revised bill passed the House on 6/14/2013.
    - The amendment directs the DoD to collaborate with the NIH to identify molecular targets and biomarkers for triple-negative breast cancer, and provide information about related discoveries for patients and potential developers of targeted therapeutic agents.

Selected New Bills (113th Congress)

Caroline Pryce Walker Conquer Childhood Cancer Reauthorization Act (H.R. 2607/S. 1251; 113th Congress)

- This bill is a reauthorization of the original Carolyn Pryce Walker Conquer Childhood Cancer Act that was passed unanimously in the House and the Senate in 2008 (named in honor of former Representative Deborah Pryce's daughter, Caroline).
- The bill would renew the authorization of $30 million per year for five years, but changes the authorized activities, substituting the following:
    - The bill would expand on existing childhood cancer biorepository resources to include specimens and clinical and demographic information from children, adolescents, and young adults (CAYA) diagnosed with cancer (not just those enrolled in NCI-sponsored studies) in comprehensive pediatric cancer biorespositories with the goal of including 90 percent of CAYA in the effort.
    - The bill would also authorize the CDC to award grants for state cancer registries to enhance and expand infrastructure for identifying and tracking incidences of CAYA cancers.
    - The bill would direct a GAO study to investigate the feasibility of expanding FDA requirements for pediatric studies of adult oncologic drugs and make recommendations for overcoming any research barriers.
- H.R. 2607 was introduced by Rep. Chris Van Hollen (D-MD) on 6/27/13 and was referred to the House Energy and Commerce Committee; S. 1251 was introduced by Sen. Jack Reed (D-RI) on 6/27/13 and referred to the Senate Committee on Health, Education, Labor, and Pensions

- *Additional Information:* This bipartisan reauthorization was introduced in the House by Rep. Chris Van Hollen (D-MD) and Rep. Michael McCaul (R-TX), co-chairs of the Childhood Cancer Caucus.

Pediatric, Adolescent, and Young Adult Cancer Survivorship Research and Quality of Life Act (S. 1247; 113th Congress) and Childhood Cancer Survivors' Quality of Life Act of 2013 (H.R. 2058; 113th Congress)

- Both bills would authorize $15 million each year for five years for the HHS Secretary to award grants for pilot programs to develop or evaluate model systems for monitoring and caring for childhood cancer survivors
- Both bills would authorize an additional $5 million each year for five years for the HHS Secretary to establish a Workforce Development Collaborative on Medical and Psychosocial Care for Pediatric Cancer Survivors. The collaborative would include educators, consumer and family advocates, and providers of psychosocial and biomedical health services.
- The House bill would also authorize $10 million each year for five years for the NIH Director to award grants for research on the causes of health disparities in pediatric cancer survivors and conduct or support research on follow-up care for pediatric cancer survivors
- The Senate bill was Introduced by Sen. Jack Reed (D-RI) on 6/27/13 and referred to the Committee on Health, Education, Labor, and Pensions; H.R. 2058 was introduced by Rep. Jackie Speier (D-CA) on 5/20/13 and has 9 cosponsors. The bill was referred to the Energy and Commerce Committee.
- *Additional Information:* Both bills similar to the Pediatric, Adolescent, and Young Adult Cancer Survivorship Research and Quality of Life Act of 2011 which was introduced by Rep. Speier and Sen. Reed in the 112th Congress. The legislation was never considered in the House or the Senate in the 112th Congress.

National Pediatric Research Network Act of 2013 (S. 424/H.R. 225; 113th Congress)

- While both bills would establish a National Pediatric Research Network, there are a number of differences between the two bills. For example, S. 424 does not specifically mention childhood cancers.
- Both bills would authorize a National Pediatric Research Network – a group of pediatric research consortia comprised of public and private entities - to be established and funded by the NIH Director and/or the NICHD Director.
- Both bills direct a specific research focus on rare pediatric diseases and unmet pediatric research needs and would support multi-site clinical trials of therapeutic, diagnostic, and preventive strategies. S. 424 would require that a minimum of one consortium prioritize collaboration with institutions serving rural areas; this provision is *not* included in H.R. 225.
- The House proposal requires the NIH Director to establish a data coordinating center, and provide assistance to CDC for the establishment or expansion of patient registries and other surveillance systems; the Senate version lacks this directive.
- Sen. Sherrod Brown (D-OH) introduced S. 424 on 2/28/13 and the bill was referred to the HELP Committee. Sens. Wicker (R-MS), Blumenthal (D-CT), Blunt (R-MO), Collins (R-ME), Portman (R-OH), and Whitehouse (D-RI) signed on as original cosponsors.
- H.R. 225 was introduced by Rep. Lois Capps (D-CA) on 1/14/13 and was referred to the House Committee on Energy and Commerce, which voted the bill out of committee on 1/22/13. The House passed the bill by a vote of 375-27 on 2/4/13. The bill was then referred to the Senate HELP committee on 2/7/13.
- Sen. Brown introduced a slightly different draft of this bill in the 112th Congress, but it never made it out of the HELP Committee. The version introduced in the 112th Congress included language similar to H.R. 225 regarding a proposed data coordinating center and related reporting.

Fair Access to Science and Technology Research (FASTR) Act of 2013 (S. 350/H.R. 708; 113th Congress)

- The proposal would require Federal agencies funding more than $100,000,000 in extramural research to develop, within one year of enactment, public access policies relating to research conducted by employees of that agency and other research supported (in whole or in part) by that agency.

- S.350 was introduced by Sen. John Cornyn (R-TX), along with co-sponsor Sen. Ron Wyden (D-OR) on 2/14/13 and was referred to the Committee on Homeland Security and Governmental Affairs.
- H.R. 708 was introduced by Rep. Michael Doyle (D-PA) along with co-sponsors Reps. Zoe Lofgren (D-CA) and Kevin Yoder (R-KS), and was referred to the House Committee on Oversight and Government Reform.
- *Related Executive Action:* Independent of the legislative proposals, the White House Office of Science and Technology Policy (OSTP), issued a memo on 2/22/13, to the heads of Executive Departments and Agencies, titled "Increasing Access to the Results of Federally Funded Scientific Research." The memo does not address the FASTR Act, but does direct Federal agencies with over $100 million in annual conduct of research and development expenditures to develop a plan to support increased public access. Draft plans are due to OSTP within six months. OSTP encourages coordination, where appropriate, between agencies; and directs those agencies that already have policies in place to adapt their policies, as necessary, to fully meet the requirements set out in the memo.

Prostate Research, Outreach, Screening, Testing, Access, and Treatment Effectiveness (PROSTATE) Act of 2013 (S.516; 113th Congress)

- The intent of S. 516 is to reduce disparities and improve access to effective and cost- efficient diagnosis and treatment of prostate cancer through advances in testing, research, and education, including through telehealth, comparative effectiveness research, and identification of best practices in patient education and outreach, particularly with respect to underserved racial, ethnic and rural populations and men with a family history of prostate cancer.
- The bill proposes to establish a directive on what constitutes clinically appropriate prostate cancer imaging; to convene an Interagency Prostate Cancer Coordination and Education Task Force (Task Force); and to create a prostate cancer scientific advisory board for the Office of the Chief Scientist at the Food and Drug Administration. Among its responsibilities, the Task Force would be required to submit recommendations to Congress regarding any appropriate changes to relevant research and health care programs, including recommendations to improve the research portfolio of the VA, NIH, and other federal agencies to ensure strategic coordination of efforts and avoid unnecessary duplication.
- The Veterans Affairs Administration (VA) is designated as the lead on most provisions. Several provisions require that the VA work with HHS and other agencies.
- Sen. Jon Tester (D-MT) introduced S.516 on 3/11/13, and it was referred to the Committee on Health, Education, Labor, and Pensions. Sen. Tester introduced similar version of the bill in the 111th and 112th Congresses.

Taxpayers' Cancer Research Funding Act of 2013 (H.R. 1293; 113th Congress)

- The bill would amend the Internal Revenue Code to establish a Breast and Prostate Cancer Research Fund and allow taxpayers to designate on their tax returns a five dollar contribution to the fund (ten dollars for joint returns).
- The bill proposes that resources from the fund be made available through the appropriations process for qualified research grants, as selected by the NCI through the NIH peer review process.
- H.R. 1293 was introduced by Rep. Peter King (R-NY) on 3/20/13 and was referred to the Committees on Ways and Means and Energy and Commerce.

Kids First Research Act of 2013 (H.R. 1724/H.R. 2019; 113th Congress)

- H.R. 2019 is the current version of the previously introduced H.R. 1724. Both versions propose to eliminate taxpayer financing of presidential campaigns and party conventions and reprogram that mechanism to provide funds for a 10-year pediatric research initiative.
- The measure would authorize $13 million annually from FY2014 through FY2023 from the Pediatric Research Initiative Fund for pediatric research administered through the Common Fund and requires such funds to supplement, not supplant, funds otherwise allocated by NIH for pediatric research.
- The original version, H.R. 1724, included a prohibition against NIH research on helath economics, but this provision has been stripped from the current version of the bill

- H.R. 1724 was introduced by Reps. Gregg Harper (R-MS) and Tom Cole (R-OK) on 4/25/13 and was referred to the Committees on Energy and Commerce, House Administration, and Ways and Means.
- H.R. 2019 is the amended version of H.R. 1724 and was introduced by Rep. Harper on 5/16/13, The bill has 108 cosponsors and was referred to the Committees on Energy and Commerce, House Administration, and Ways and Means. Recent news items indicate that Rep. Eric Cantor (R-VA) is championing the bill and seeking Democratic support to augment lackluster Republican backing.
- *Additional Information:* This bill seems to be aimed at intellectual disorders, such as autism and Fragile-X associated disorders, more than any other pediatric illnesses. Rep. Harper's son suffers from Fragile X Syndrome and he serves as co-chairman of the Congressional Fragile X Caucus.

Cancer Drug Coverage Parity Act of 2013 (H.R. 1801; 113th Congress)

- The bill proposes to require group and individual health insurance coverage and group health plans to provide for coverage of oral anticancer drugs on terms no less favorable than the coverage provided for anticancer medications administered by a health care provider.
- H.R. 1801 was introduced by Rep. Brian Higgins (D-NY) on 4/26/13 and has 45 cosponsors. The bill was referred to the Committees on Energy and Commerce, Ways and Means, and Education and the Workforce.
- Rep. Higgins introduced a similar bill in the 112th Congress, but it did not move out of committee.

Accelerating the End of Breast Cancer Act of 2013 (H.R. 1830/S. 865; 113th Congress)

- The bill calls for the President to establish a Commission to Accelerate the End of Breast Cancer, with a mission of helping to "end breast cancer by 2020." The Commission would be tasked with identifying opportunities that have been "overlooked" by government and the private sector. The Commission's responsibilities would include issuing recommendations for research projects, approving research projects, and developing criteria to assess projects' progress.
- Commission members are to be appointed by the President (8), the Speaker of the House (1), and the Majority Leader of the Senate (1).
- S. 865 would authorize appropriations, - $8 million for FY 2013, $12 million for FY 2014 and FY 2015, and such sums necessary for following fiscal years through termination of the commission on June 1, 2020; H.R. 1830 does not include an authorization of appropriations.
- S. 865 was introduced by Sen. Sheldon Whitehouse (D-RI) on 5/6/13 and has 22 cosponsors. The bill was referred to the Senate HELP Committee.
- H.R. 1830 was introduced by Rep. Shelley Moore Capito (R-WV) on 5/6/13 and has 150 cosponsors. The bill was referred to the Energy and Commerce Committee.
- Similar proposals were introduced in the 112th Congress by Rep. Karen Bass (CA) and Sen. Sheldon Whitehouse (D-RI). The House proposal had 235 cosponsors, and the Senate had 26, but neither made it out of committee.

Breast Cancer Patient Education Act of 2013 (S. 931/H.R. 1984; 113th Congress)

- This bill proposes to raise awareness of, and to educate breast cancer patients anticipating surgery, especially patients who are members of racial and ethnic minority groups, regarding the availability and coverage of breast reconstruction, prostheses, and other options through the Secretary's implementation of an education campaign.
- The bill would require this information to be posted on the web sites of relevant Federal agencies as well as biannual reports to Congress describing the activities carried out under this section, including an evaluation of the extent to which such activities have been effective in improving the health and well-being of racial and ethnic minority groups.
- S. 931 was introduced by Sen. Roy Blunt (R-MO) on 5/13/13 and was referred to the Senate HELP Committee.
- H.R. 1984 was introduced by Rep. Leonard Lance (R-NJ) on 5/15/13 and was referred to the Energy and Commerce Committee.
- Sen. Blunt and Rep. Lance introduced similar proposals during the 112th Congress, which did not make it out of committee.

Clinical Trial Cancer Mission 2020 Act (H.R. 2301; 113th Congress)

- The bill proposes to enhance the clinical trial registry data bank reporting requirements and enforcement measures by revising the Clinical Trial Registry Data Bank requirements to apply whether or not a clinical trial results in a positive or negative outcome.
- The bill also proposes to restrict funding for a grantee and hold the grantee liable for repayment of any grant amount provided, if the grantee has not submitted clinical trial information within the 30-day correction period for noncompliance.
- The bill was introduced by Rep. Tom Reed (D-NY) on 6/6/13 and was referred to the Energy and Commerce Committee. The bill has 2 cosponsors.
- Rep. Reed introduced an identical bill in the 112th Congress, which did not move out of committee and had no cosponsors.

Selected Recent Resolutions (113th Congress)

This section highlights resolutions introduced to raise awareness about specific diseases. It is important to note that resolutions are different than bills, in that they are used to express the sentiment of one chamber (House or Senate) on an issue. As such, resolutions do no not require concurrence of the other chamber or approval by the president, and they do not have the force of law.

Passed

Designating September 26, 2013 as National Pediatric Brain Cancer Awareness Day (S. Res. 116; 113th Congress)

- This resolution designates September 26, 2013 as National Pediatric Brain Cancer Awareness Day.
- S. Res. 116 was introduced by Sen. Deb Fischer (R-NE), along with Sen. Amy Klobuchar (D-MN), on 4/25/13 and was adopted by unanimous consent.

Introduced

Expressing Support for Designation of April 15, 2013 through April 21, 2013 as National Minority Cancer Awareness Week (H. Res. 154; 113th Congress)

- This resolution expresses support for designating April 15, 2013 through April 21, 2013 as National Minority Cancer Awareness week.
- H. Res. 154 was introduced by Rep. Ami Bera (D-CA) on 4/12/13 and was referred to the House Committee on Oversight and Government Reform.

Preventing Duplicative and Overlapping Government Programs Resolution (S. Res. 110; 113th Congress)

- This resolution expresses support for preventing the creation of duplicative and overlapping Federal programs and calls for the report accompanying each bill or joint resolution to include analysis by the Congressional Research Service to determine if any duplicative Federal program, office, or initiative would be created.
- S. Res. 110 was introduced by Sen. Tom Coburn (R-OK) on 4/24/13 and was referred to the Committee on Rules and Administration.

113th Congress Committee Rosters

APPROPRIATIONS COMMITTEE:
Chair: Barbara Mikulski (MD) [new to the position this year]
Ranking: Richard Shelby (AL) [new position]

LABOR, HHS, EDUCATION SUBCOMMITTEE:
Chair: Tom Harkin (IA)
Ranking: Jerry Moran (KS) [new to position this year]
Patty Murray (D-WA)
Mary Landrieu (D-LA)
Richard Durbin (D-IL)
Tim Johnson (D-SD)
Jack Reed (D-RI)
Mark Pryor (D-AR)
Barbara Mikulski (D-MD)
Jon Tester (D-MT)
Jeanne Shaheen (D-NH) [new to committee this year]
Jeff Merkley (D-OR) [new to committee this year]
Thad Cochran (R-MS)
Richard Shelby (R-AL)
Lamar Alexander (R-TN)
Lindsey Graham (R-SC)
Mark Kirk (R-IL)
Mike Johanns (R-NE) [new to committee this year]
John Boozman (R-AR) [new to committee this year]

HEALTH, EDUCATION, LABOR AND PENSIONS COMMITTEE:
Chair: Tom Harkin (IA)
Ranking: Lamar Alexander (TN) [new position this year]
Barbara Mikulski (D-MD)
Patty Murray (D-WA)
Bernard Sanders (D-VT)
Bob Casey (D-PA)
Kay Hagan (D-NC)
Al Franken (D-MN)
Michael Bennet (D-CO)
Sheldon Whitehouse (D-RI)
Tammy Baldwin (D-WI)[new to committee this year]
Christopher Murphy (D-CT) [new to committee this year]
Elizabeth Warren (D-MA) [new to committee this year]
Richard Burr (R-NC)
Johnny Isakson (R-GA)
(Dr.) Rand Paul (R-KY)
Orrin Hatch (R-UT)
Pat Roberts (R-KS)
Lisa Murkowski (R-AK)
Mark Kirk (R-IL)
Tim Scott (R-SC) [new to committee this year]

HOUSE

APPROPRIATIONS COMMITTEE:
Chair: Hal Rogers (KY)
Ranking: Nita Lowey (NY) [new position]

LABOR, HHS, EDUCATION SUBCOMMITTEE:
Chair: Jack Kingston (GA)
Ranking: Rosa DeLauro (CT)
Rodney Alexander (R-LA)
Mike Simpson (R-ID)
Steve Womack (R-AR) [new to subcommittee this year]
Chuck Fleischmann (R-TN) [new to committee this year]
David Joyce (R-OH) [new to committee this year]
(Dr.) Andy Harris (R-MD) [new to committee this year]
Lucille Roybal-Allard (D-CA)
Barbara Lee (D-CA)
Mike Honda (D-CA) [new to subcommittee this year]

ENERGY AND COMMERCE COMMITTEE:
Chair: Fred Upton (MI)
Ranking: Henry Waxman (CA)

HEALTH SUBCOMMITTEE:
Chair: Joe Pitts (PA)
Ranking: Frank Pallone (NJ)
Vice Chairman: (Dr.) Michael Burgess (R-TX)
Ralph Hall (R-TX) [new to committee this year]
Ed Whitfield (R-KY)
John Shimkus (R-IL)
Mike Rogers (R-MI)
Tim Murphy (R-PA)
Marsha Blackburn (R-TN)
(Dr.) Phil Gingrey (R-GA)
Leonard Lance (R-NJ)
(Dr.) Bill Cassidy (R-LA)
Brett Guthrie (R-KY)
Morgan Griffith (R-VA) [new to subcommittee this year]
Gus Bilirakis (R-FL) [new to committee this year]
Renee Ellmers (R-NC) [new to committee this year]
Joe Barton (R-TX)
Fred Upton (R-MI)
John Dingell (D-MI)
Eliot Engel (D-NY)
Lois Capps (D-CA)
Jan Schakowsky (D-IL)
Jim Matheson (D-UT) [new to subcommittee this year]
Gene Green (D-TX) [new to subcommittee this year]
G.K. Butterfield (D-NC) [new to subcommittee this year]
John Barrow (D-GA) [new to subcommittee this year]
(Dr.) Donna Christensen (D-VI) [new to committee this year]
Kathy Castor (D-FL) [new to committee this year]

John Sarbanes (D-MD) [new to committee this year]
Henry Waxman (D-CA)

National Cancer Institute

NCI Clinical Trials Portfolio Inventory FY 2011

Division of Extramural Activities

July 10, 2013

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

NCI Clinical Trials Portfolio Inventory FY 2011

At the March 2012 Clinical Trials Advisory Committee (CTAC) meeting, CTAC requested that DEA's Research Analysis Evaluation Branch (RAEB) conduct an inventory of NCI clinical trials expenditures for FY2011.

NCI Clinical Trials Portfolio Inventory FY 2011

- This report includes:
  - Intramural and extramural clinical trials funding
  - NCI divisions, offices, and centers
  - Clinical trials categories (Prevention, Diagnosis, Therapy, and Other)
  - Allocation categories (funding mechanisms)
  - Major anatomical sites
  - Geographic location
  - Overall NCI clinical trials funding

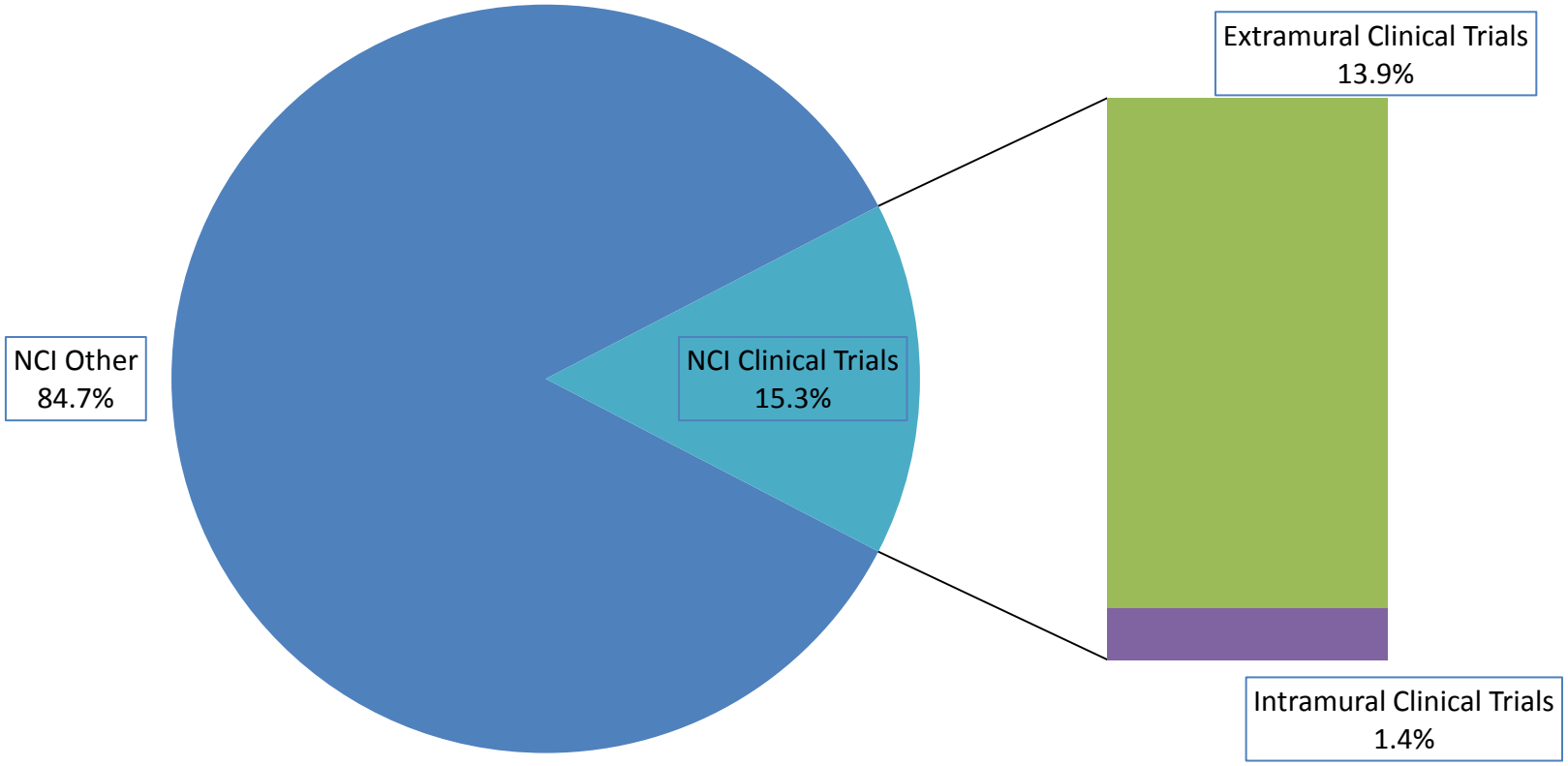
Operational Definition of a Clinical Trial

A clinical trial is 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.

Diagnostic Clinical Trials: a clinical trial if it uses the information from the diagnostic test in a manner that affects medical decision-making for the study subject 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. Studies whose objective is only the gathering of data on the characteristics of a new diagnostic approach, are not clinical trials.

Behavioral clinical trials: interventions whose goals are to increase behaviors, eliminate or reduce behaviors and/or improve coping and quality of life 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.

Clinical Trials Expenditures as a Proportion of Total FY2011 NCI Budget ($5.1 billion)



FY2011 NCI Total Budget= $5.1 billion

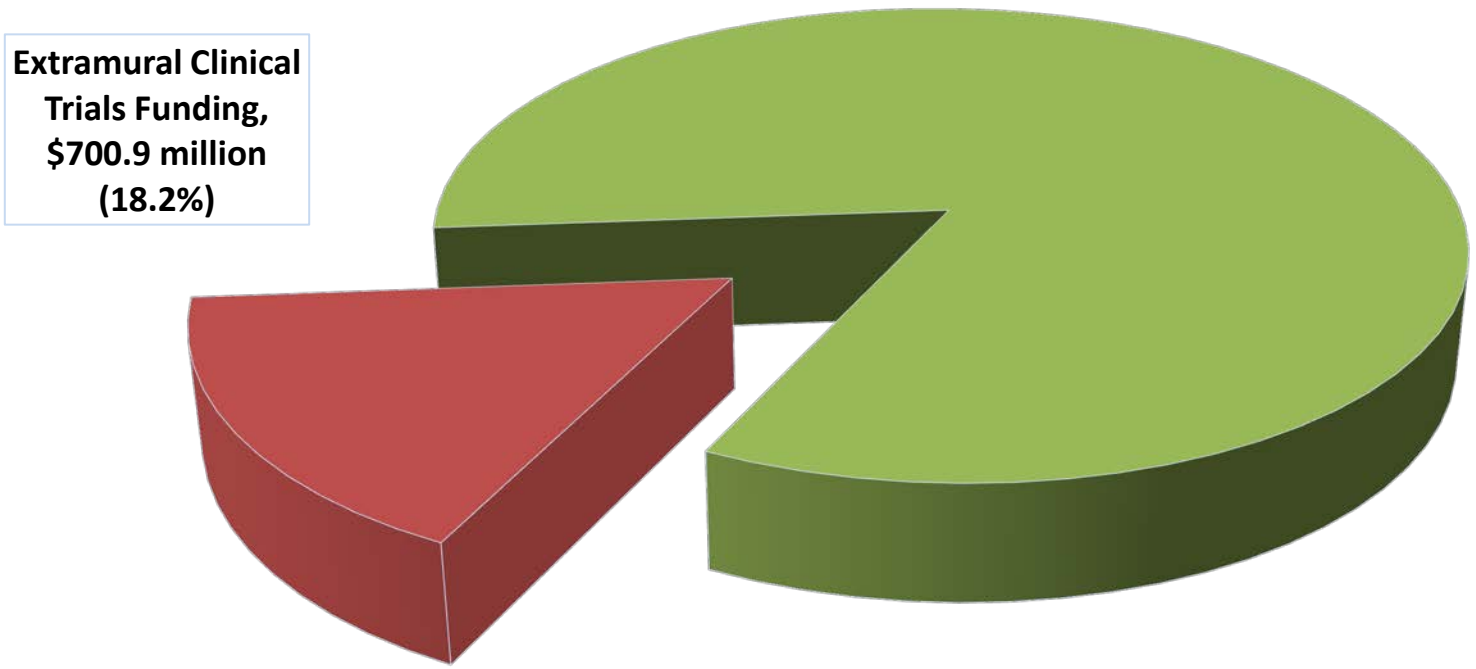
National Cancer Institute

EXTRAMURAL CLINICAL TRIALS INVENTORY

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

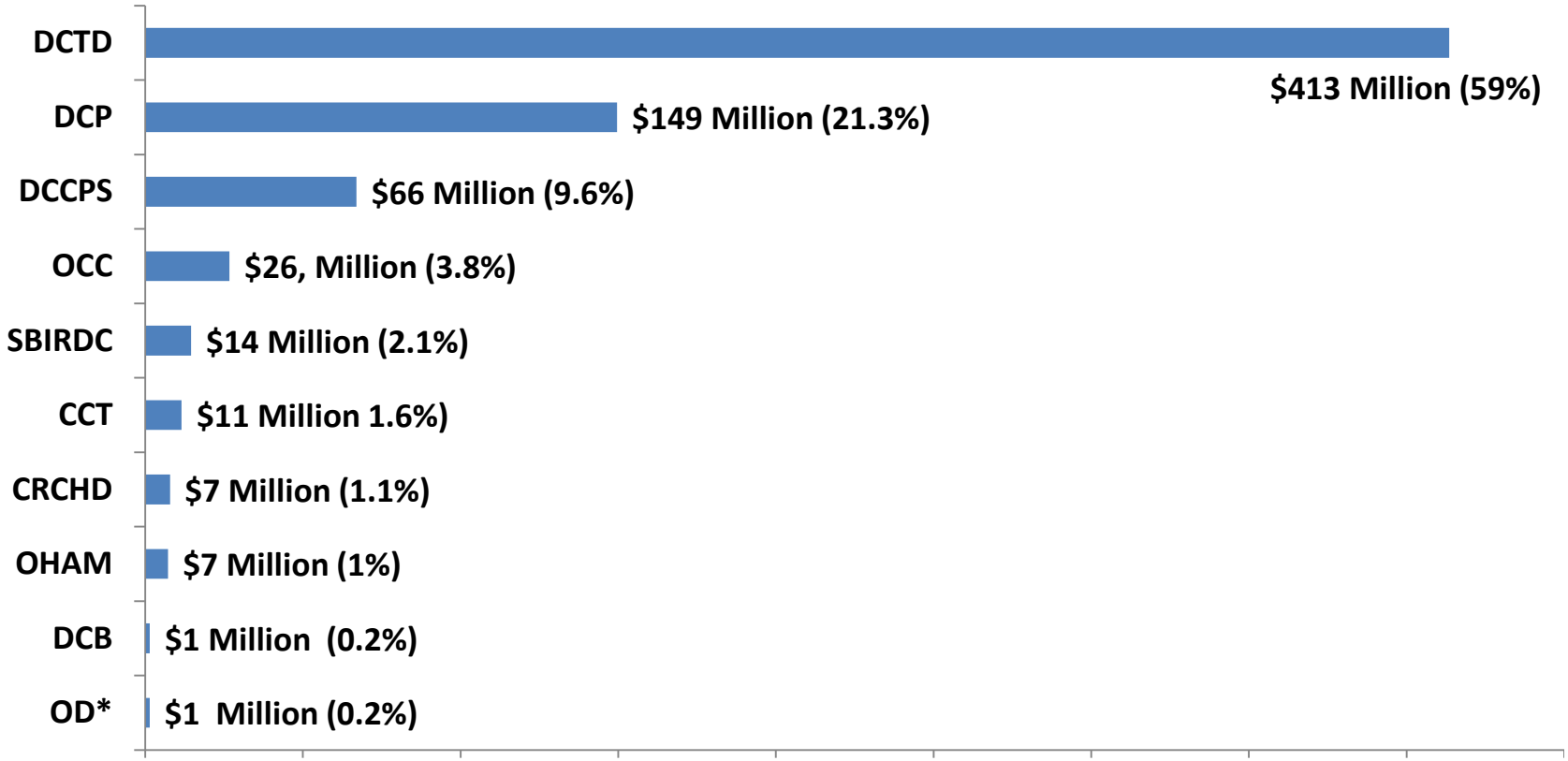
National Institutes of Health

NCI Extramural Clinical Trials as a Proportion of Overall Extramural Funding ($3.8 billion)



FY2011 Overall NCI extramural funding = $3.8 billion

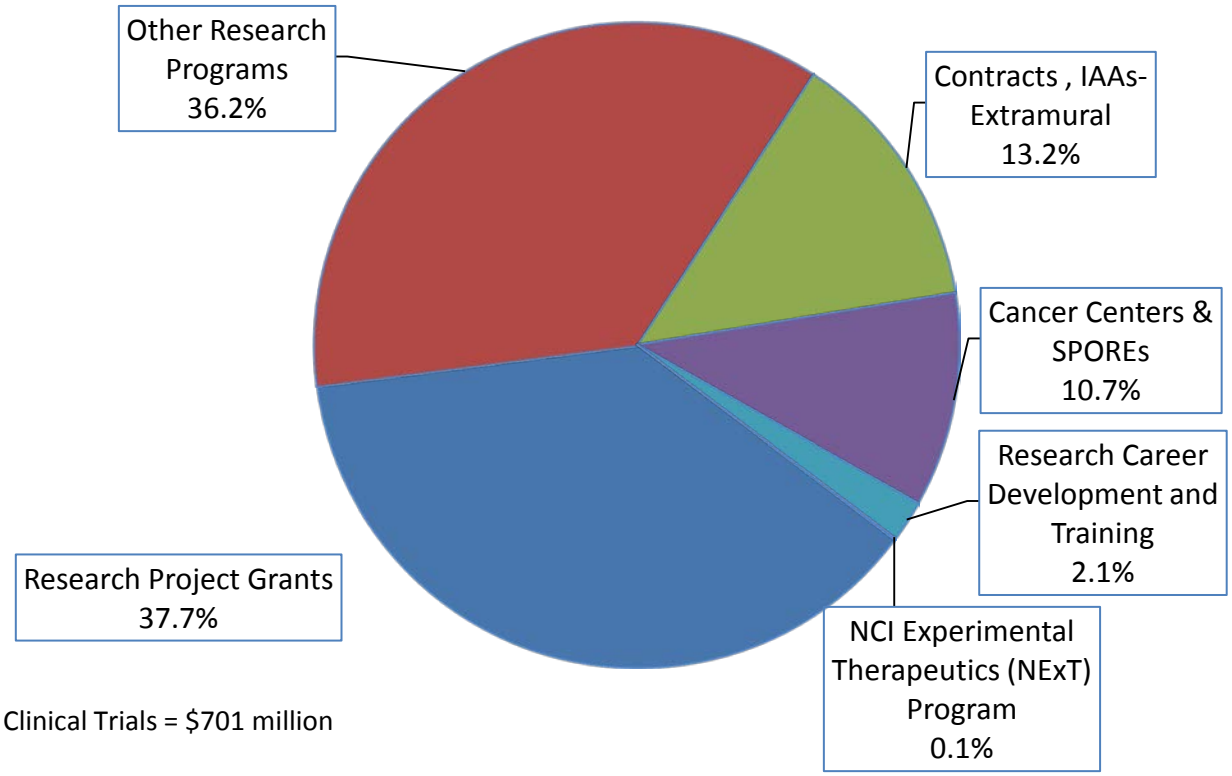
FY2011 NCI Extramural Clinical Trials Funding by Division, Office or Center



*OD (NCI & National Institute for Child Health and Human Development (NICHD) Interagency Agreements)

FY2011 Extramural Clinical Trials DOC Total = $701 Million

FY2011 NCI Extramural Clinical Trials Funding by Mechanism



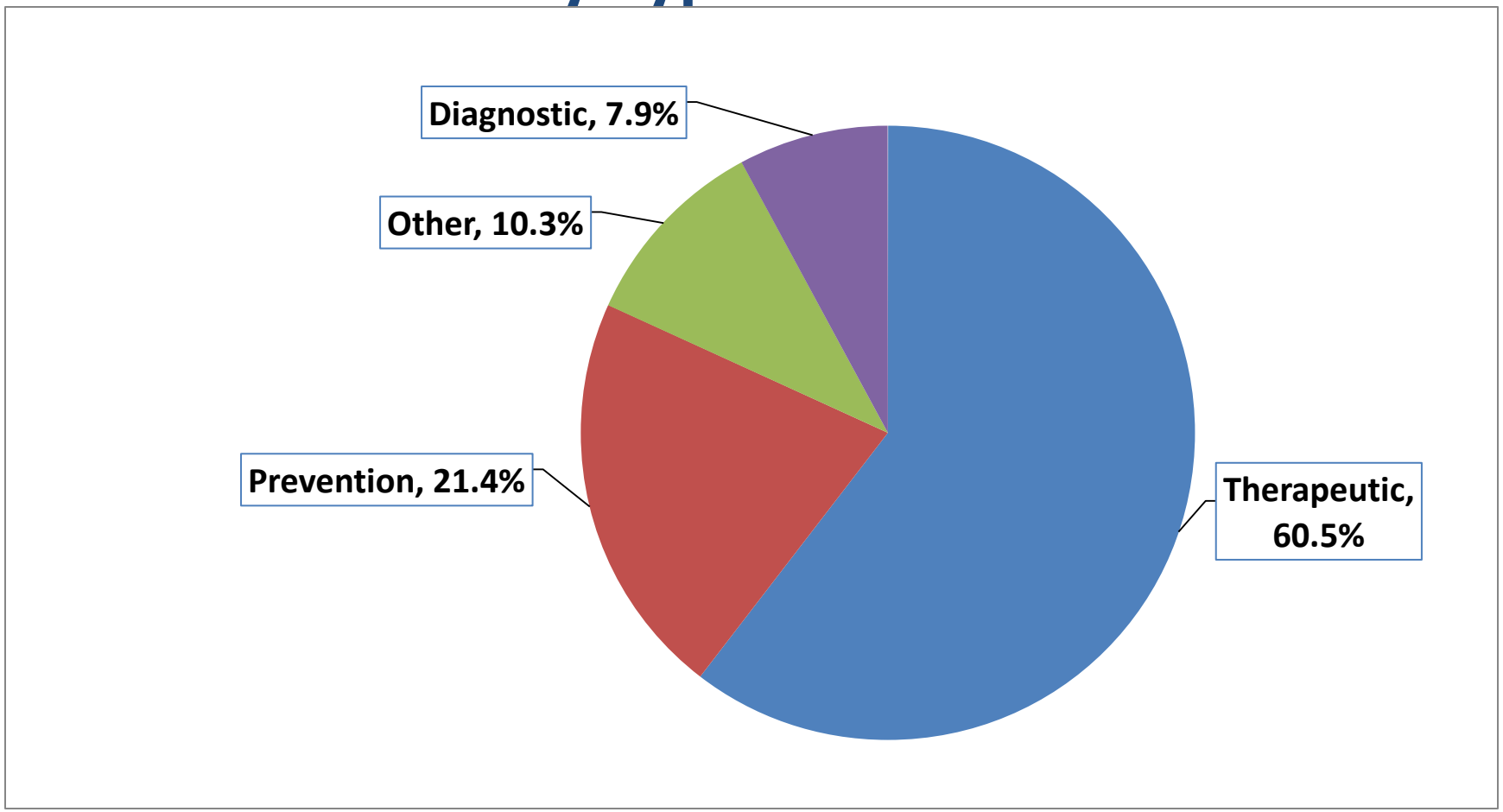
Total Extramural Clinical Trials = $701 million

Total FY2011 Extramural Clinical Trials = $701 million
Research Project Grants = $264 million, Other RPGs = $254 million, Contracts & IAAs = $93 million, Cancer Centers & SPOREs = $75 million, Research Career Dev. & Training =$14 million, NExT Program=$610 thousand

FY2011 NCI Extramural Clinical Trials Funding by Type of Trial

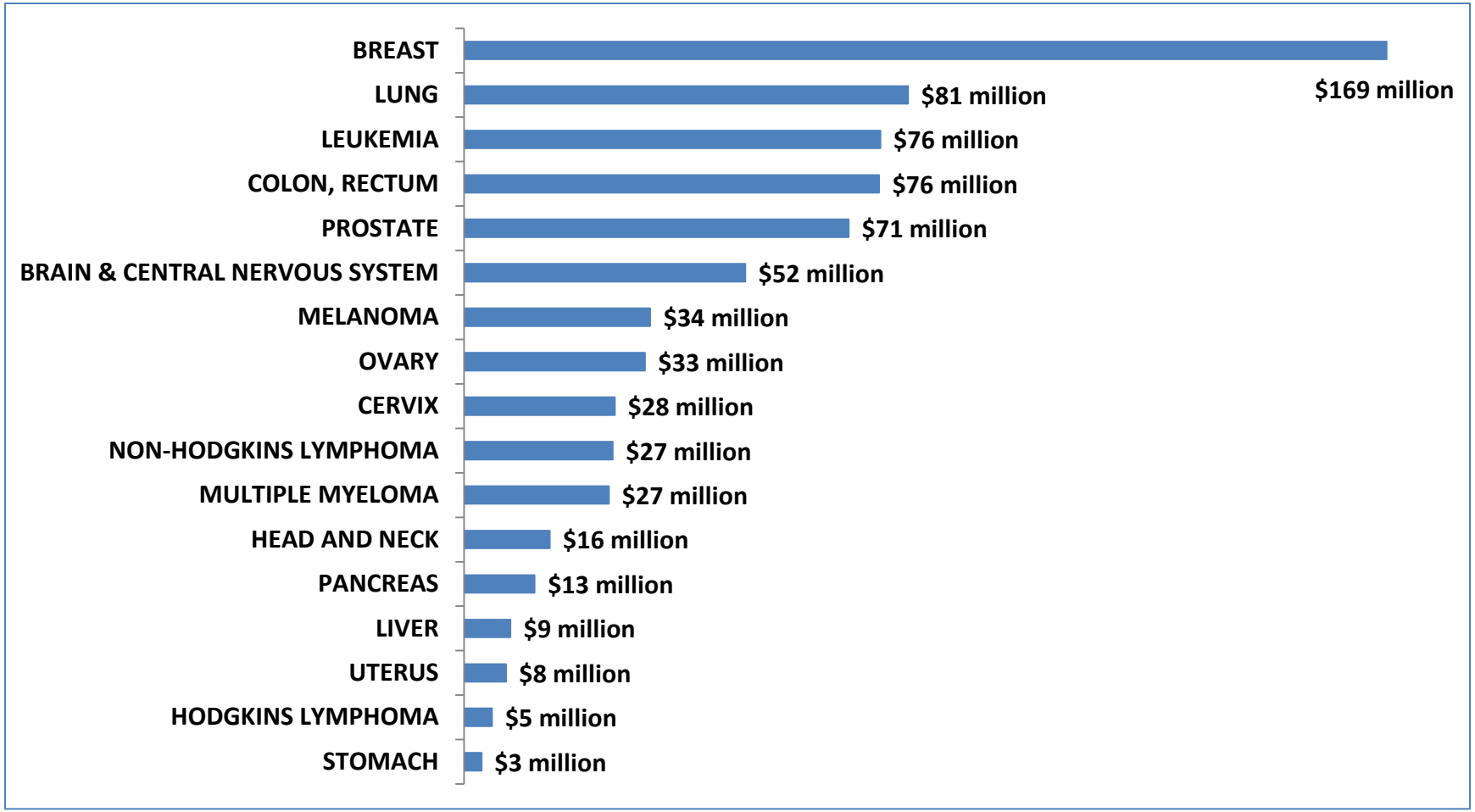
- Therapeutic
- Prevention
- Diagnostic
- Other - includes trials for: behavior, e.g. screening behavior; quality of life or supportive care issues; symptom management; rehabilitation, etc. It also includes projects developing methods specifically for clinical trials (e.g., analyzing or monitoring clinical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

FY2011 NCI Extramural Clinical Trials Awards by Type of Trial



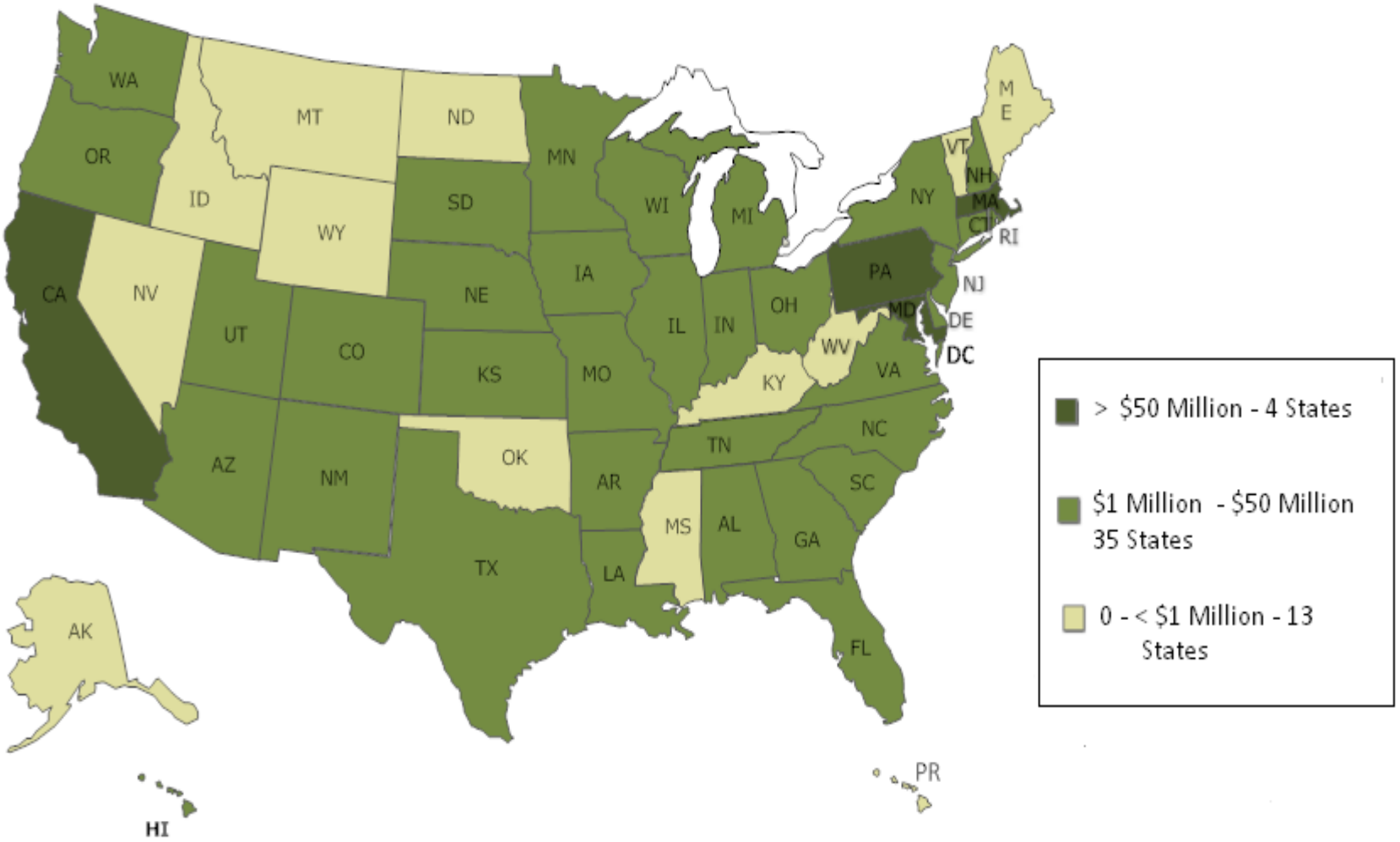
Total FY2011 Extramural Clinical Trials = $701 million
Therapeutic = $422 million, Prevention = $150 million, Diagnostic = $55 million, Other = $72 million

NCI Extramural Clinical Trials Funding for FY2011 by Major Anatomical Sites



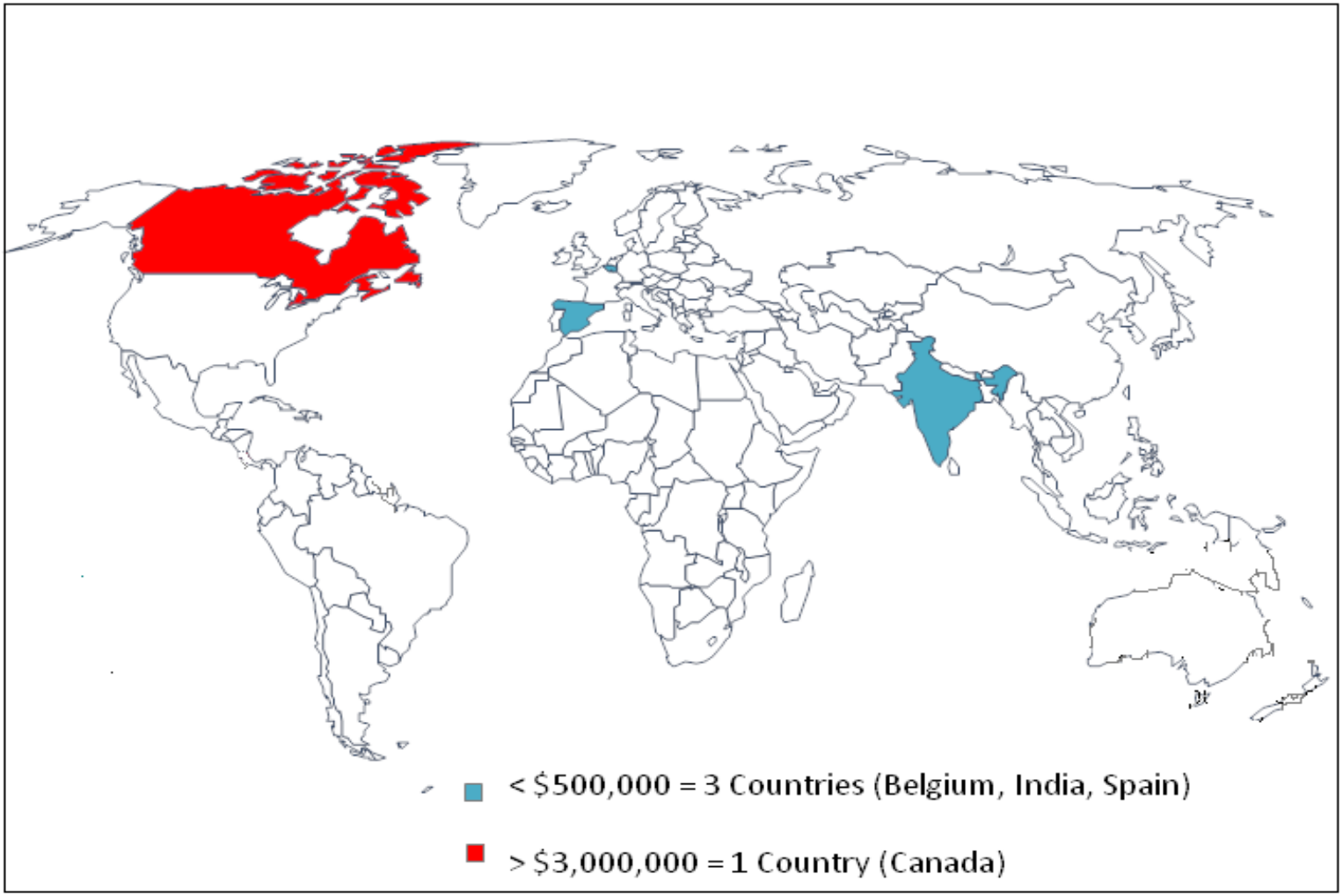
FY2011

NCI Extramural Awards for Clinical Trials by States



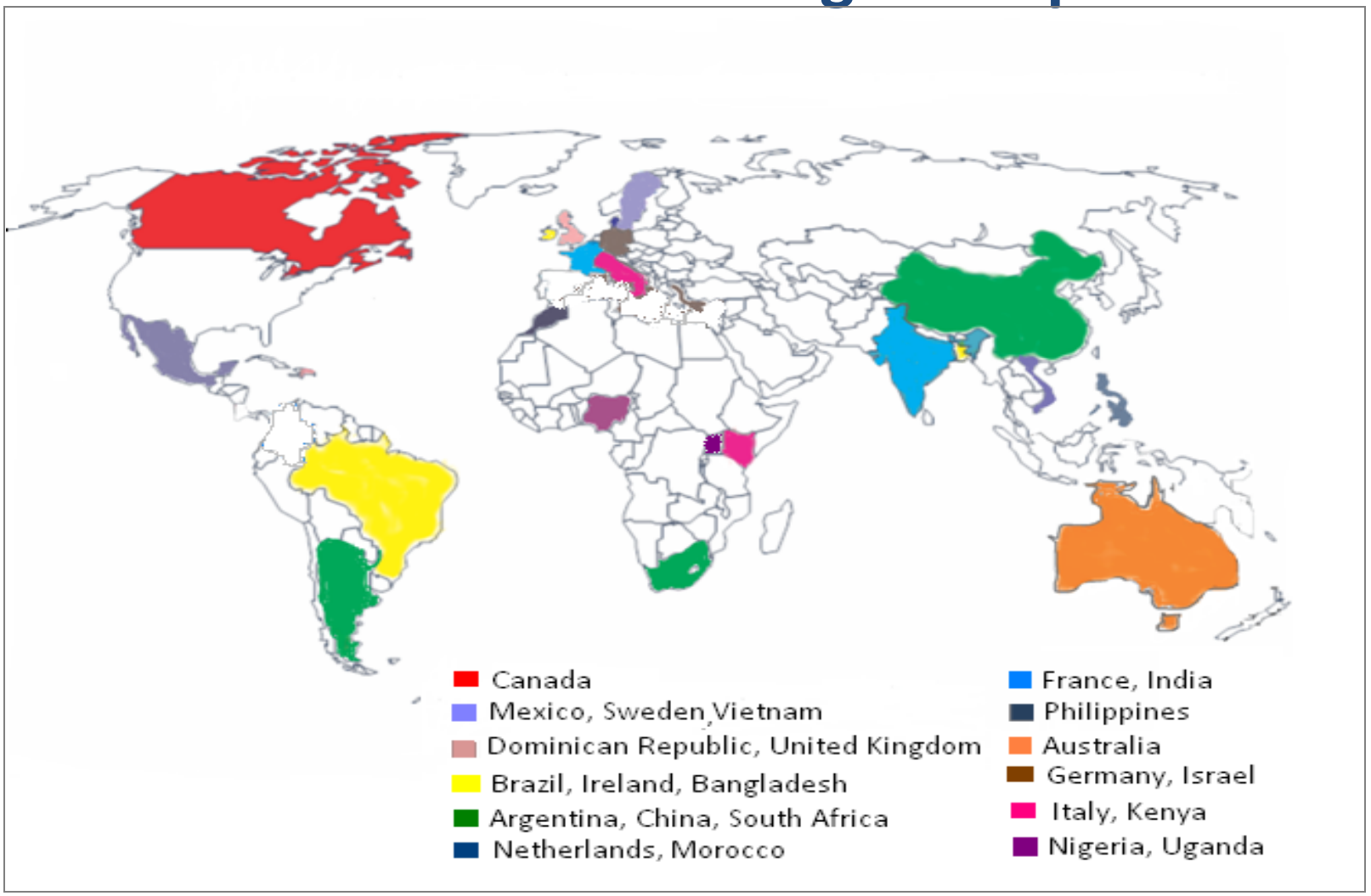
FY2011

NCI Extramural Clinical Trials Awards to Foreign Institutions



FY2011

NCI Extramural Clinical Trials Awards to US Institutions with a Foreign Component



FY2011

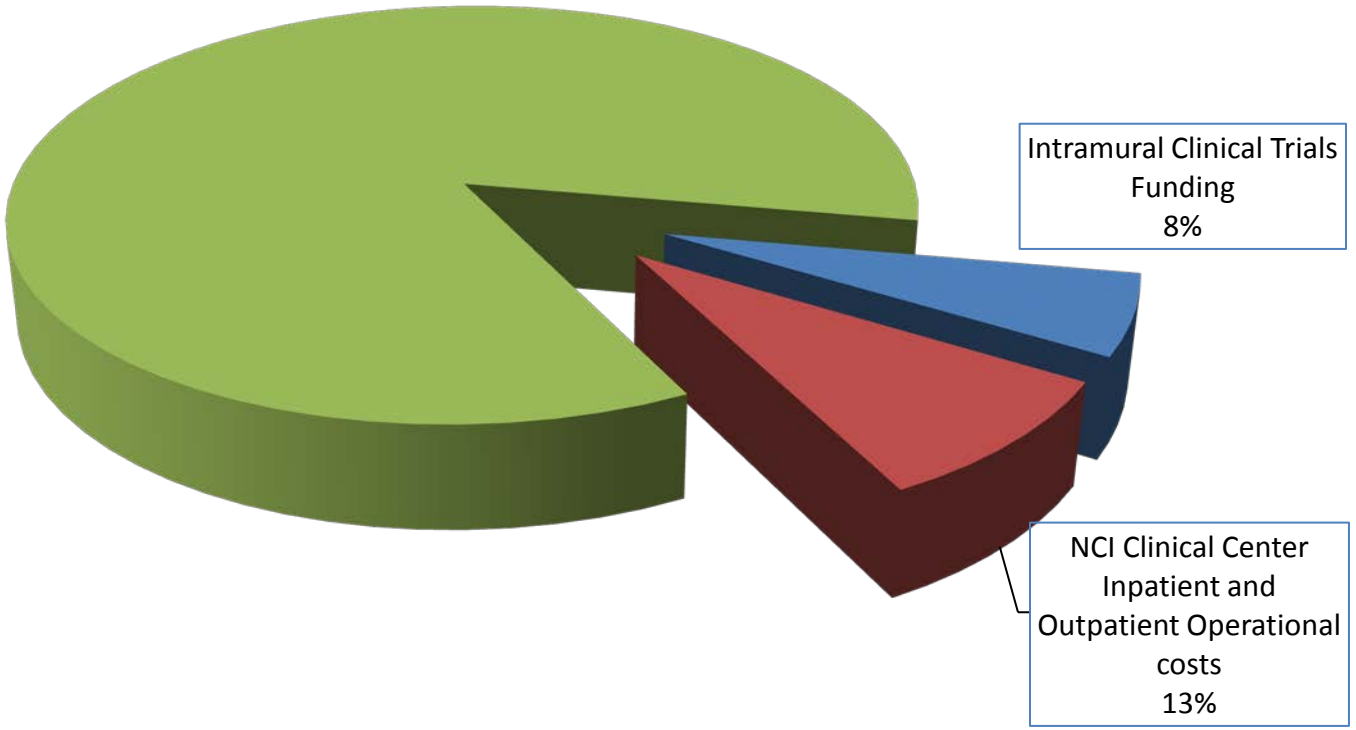
National Cancer Institute

INTRAMURAL CLINICAL TRIALS INVENTORY

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

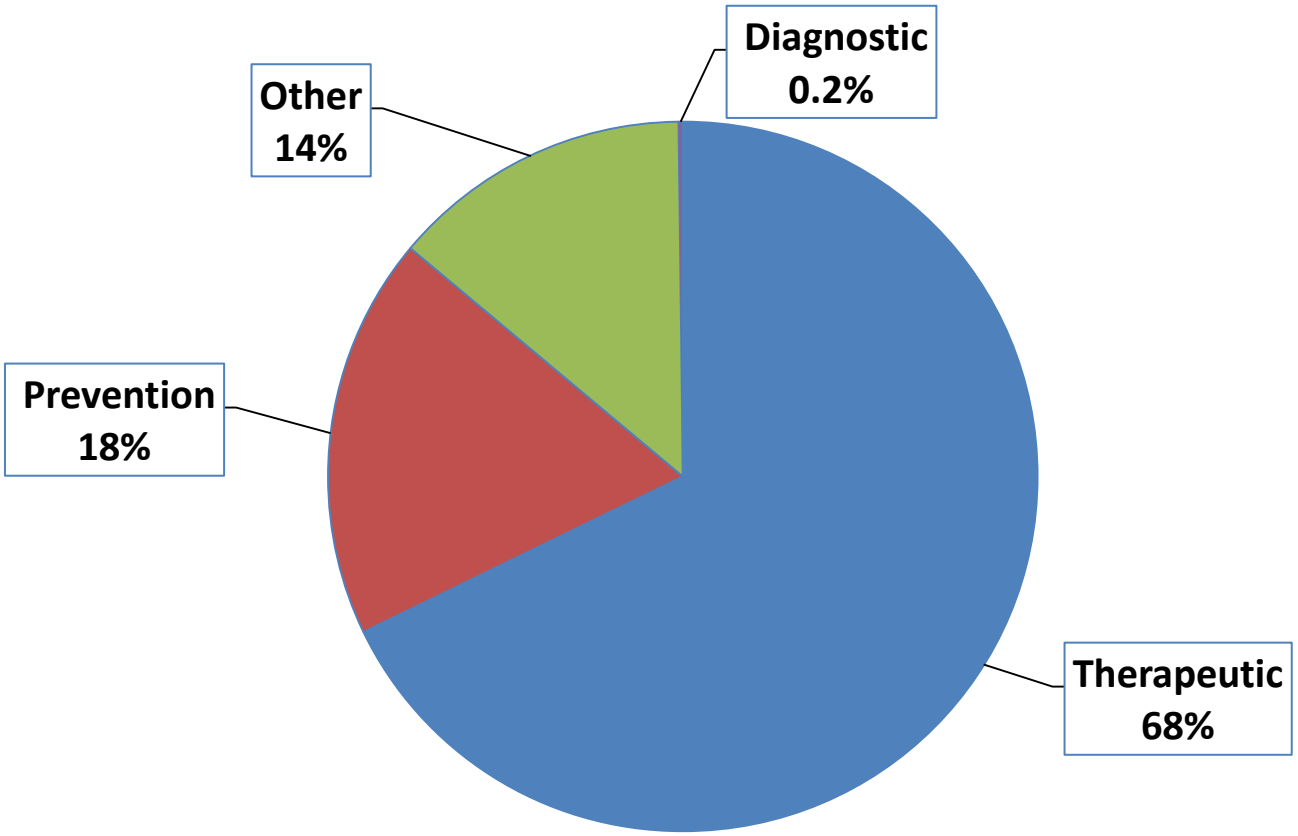
National Institutes of Health

NCI Intramural Clinical Trials as a Proportion of Overall NCI Intramural Funding ($834 million)



FY2011 Overall NCI intramural funding = $834 million
Intramural clinical trials = $70.5 million, NCI inpatient and outpatient operational costs = $107 million, all other intramural = $763 million

FY2011 NCI Intramural Clinical Trials Awards by Type of Trial



FY2011 Intramural Clinical Trials Funding= $70.5 million
Therapeutic = $48 million, Prevention = $13 million,
Diagnostic = $125 thousand, and Other = $10 million

National Cancer Institute

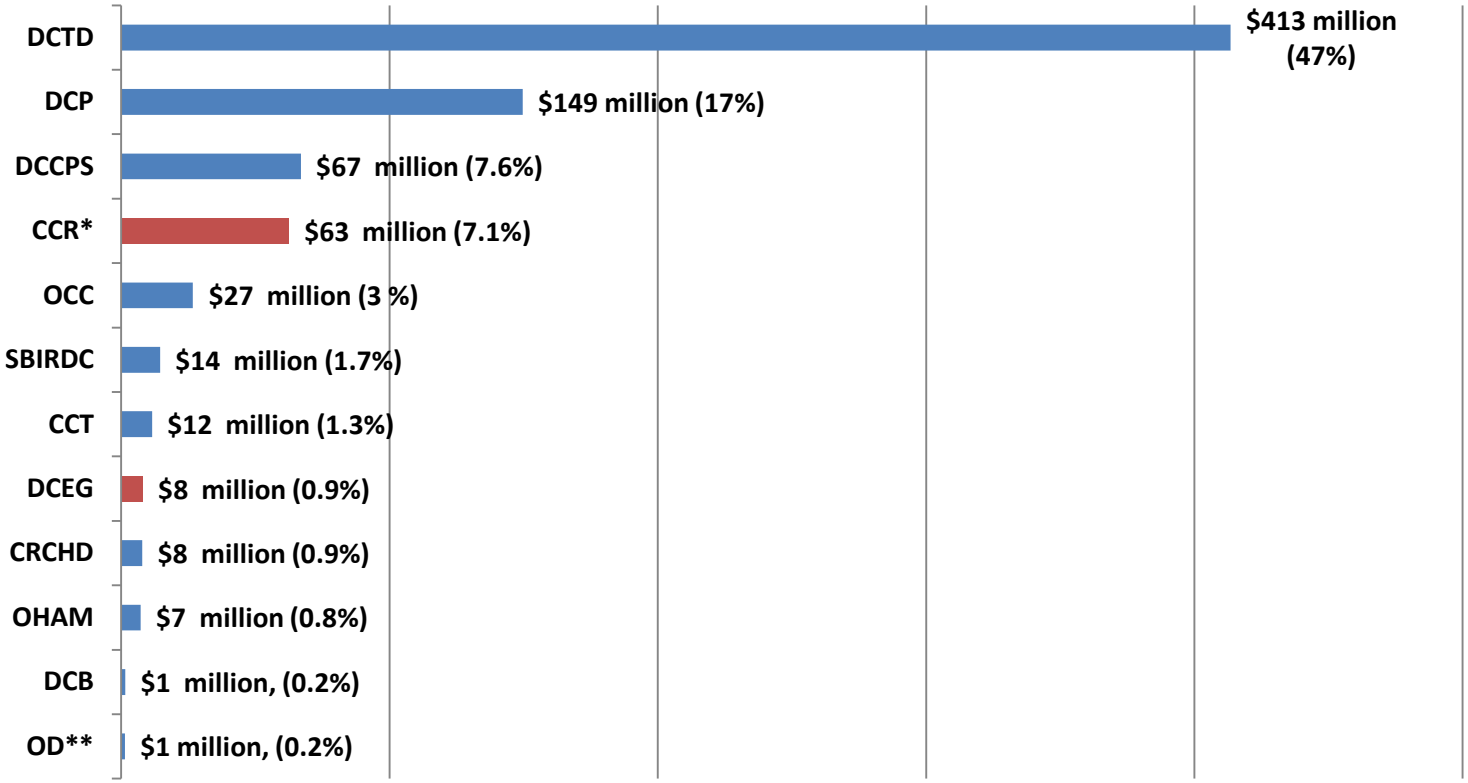
NCI OVERALL CLINICAL TRIALS INVENTORY

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

NCI Overall Clinical Trials Funding (FY2011 $771 million)

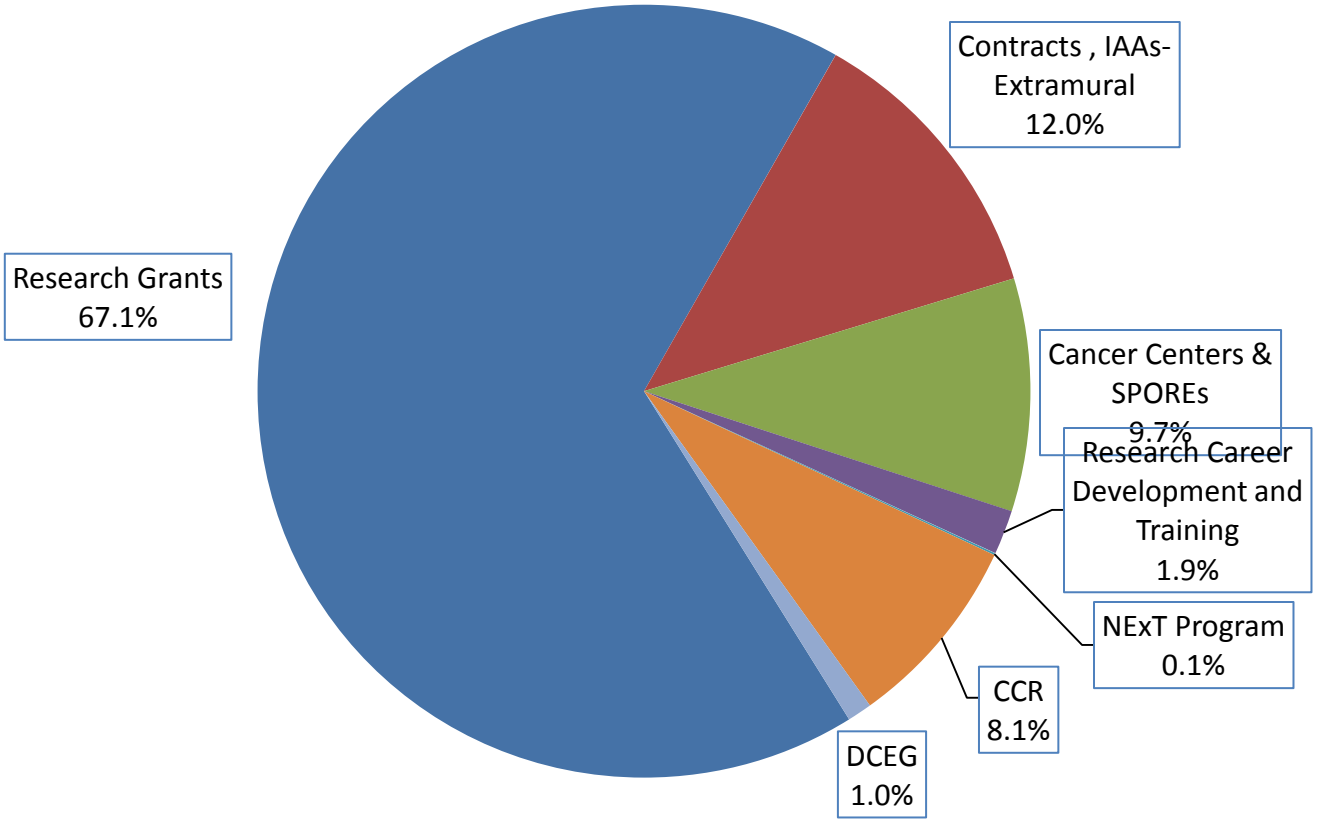
NCI Clinical Trials Total = $771 million
Extramural Clinical Trials = $700.9 million
Intramural Clinical Trials = $70.5 million

FY2011 NCI Clinical Trials Funding by Division, Office, or Center



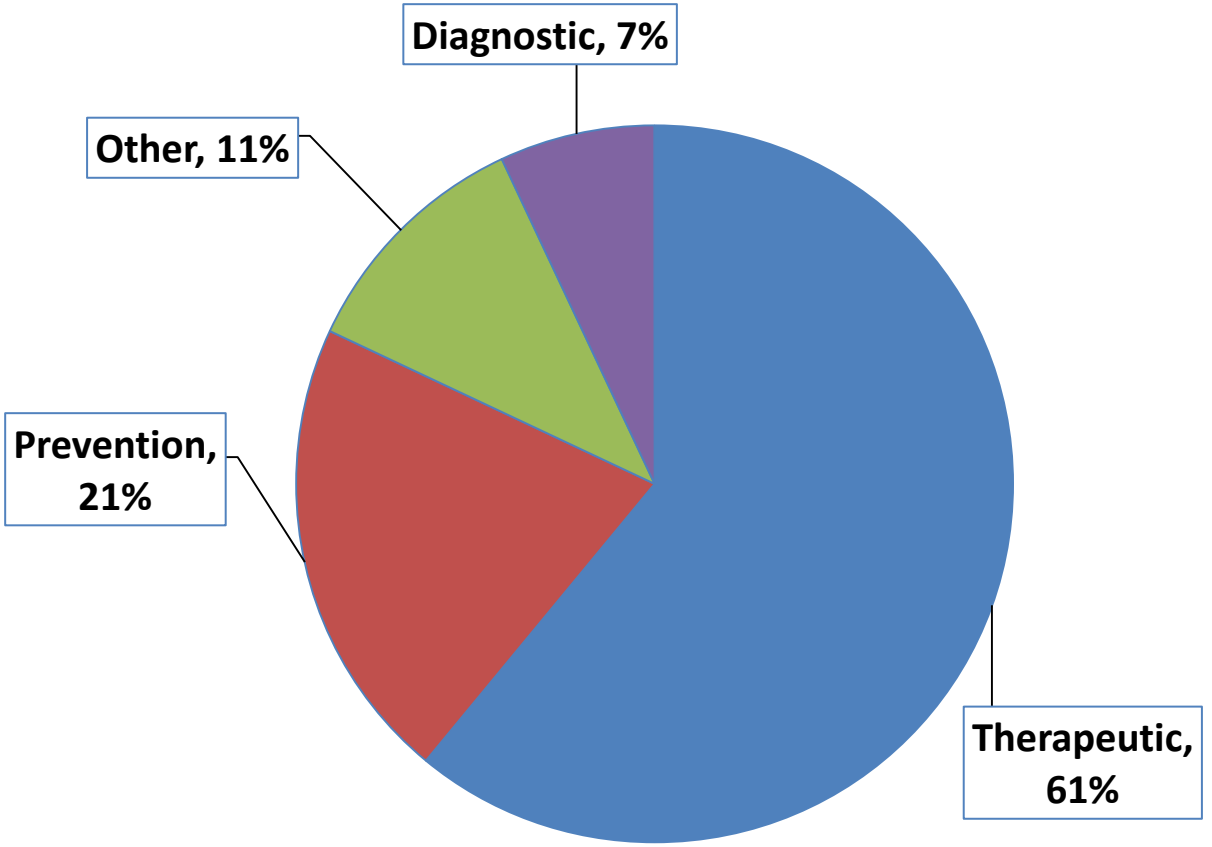
OD** (NCI & National Institute for Child Health & Human Development Interagency Contract Agreement)
NCI Clinical Trials Total = $771 Million

NCI Overall Clinical Trials by Funding Mechanism



FY2011 NCI Overall Clinical Trials = $771 million
Research Project Grants = $518 million, Contracts & IAAs = $93 million,
Cancer Centers & SPOREs = $75 million, Research Career Dev. & Training =$14 million,
CCR = $62.5 million, DCEG = $8 million, Next Program $610 thousand

FY2011 NCI Clinical Trials by Type of Clinical Trial



FY2011 NCI Overall Clinical Trials Funding= $771 million
Therapeutic = $470 million, Prevention = $163 million,
Diagnostic = $55 million, and Other = $82 million

Recommendations

- 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.
- NCI CTROC recommends that the RAEB, the official source of science based budget information for NCI supported extramural research, repeat this inventory every five years.

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

NCI Clinical Trials Portfolio Inventory FY2011

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

Table of Contents

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 Center s (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

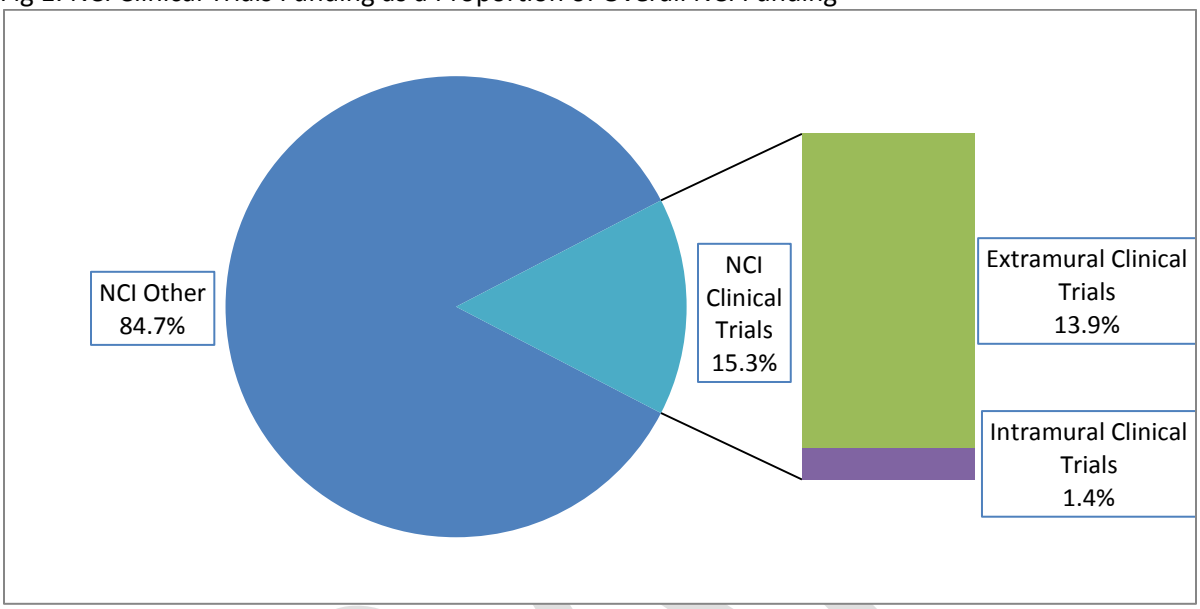


Table1. NCI Clinical Trials Funding as a Proportion of Overall NCI Funding

	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%**
NCI Overall Funding	**$5,058,104,978**	**100%**		**$5,058,104,978**	**100%**

Includes 107 million NCI Clinical Center Inpatient and Outpatient Operational Costs

NCI Extramural Clinical Trials Funding

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

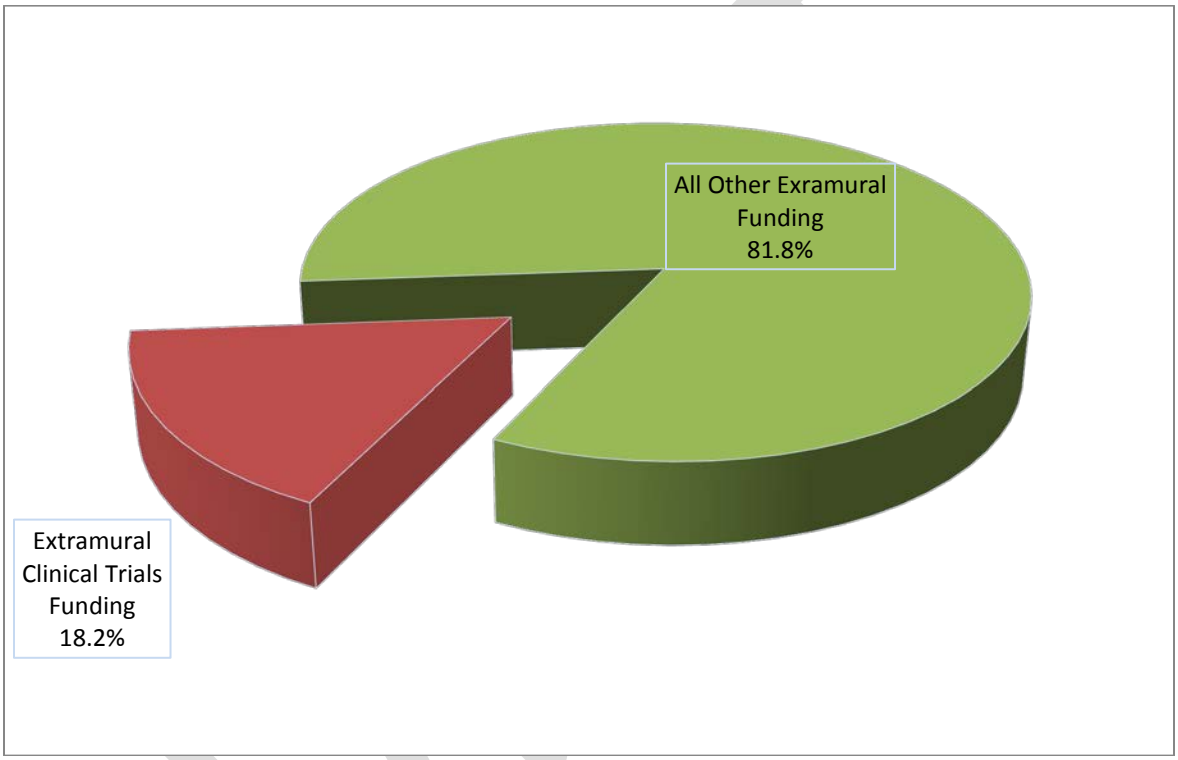


Table 2: NCI Extramural Clinical Trials as a Proportion of Overall Extramural Funding

	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%
Overall Extramural Funding	**$3,849,957,808**	**100%**

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

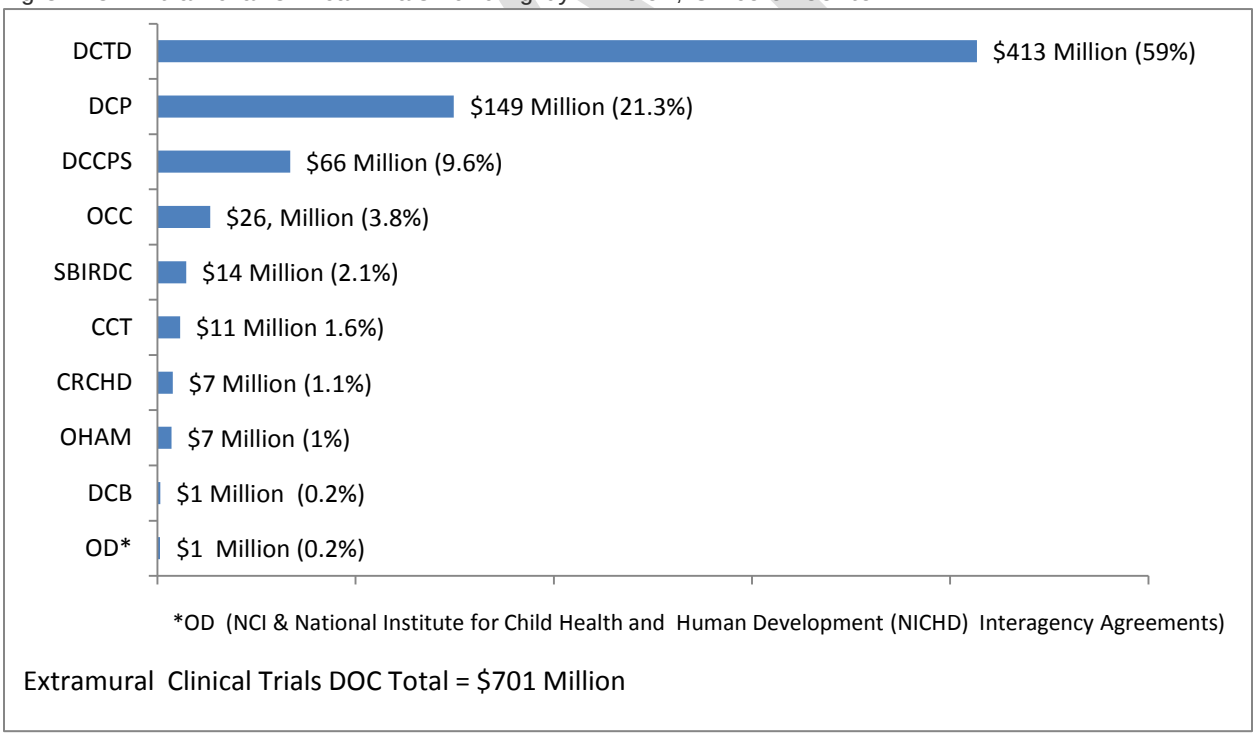


Table 3. NCI Extramural Clinical Trials Funding by Division, Office, or Center

Division, Office, or Center	Clinical Trials Dollars	Percent of Total Extramural Clinical Trials Dollars
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%
Total Extramural Clinical Trials Dollars	**$700,855,829**	**100%**

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)

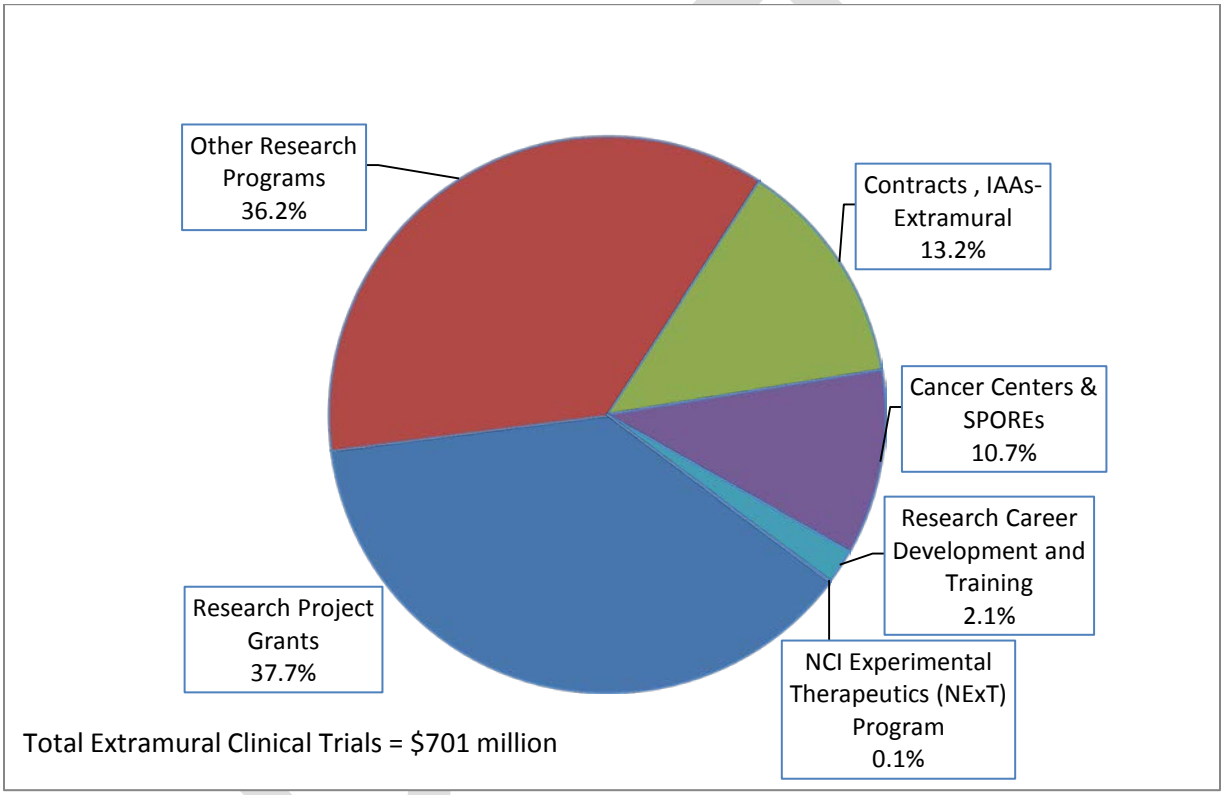


Table 4. Extramural NCI Clinical Trials Funding (by Mechanism)

Mechanism	**Number of Grants and Contracts**	**Clinical Trials Dollars**	**Percentage of Total Extramural Clinical Trials Dollars**
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%
Total Extramural Clinical Trials	965	**$700,855,823**	**100%**

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%
Subtotal RPG Clinical Trials	***534***	***$264,165,706***	***100%***
Other Research Program Grants	**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%
Subtotal, Other Research Program Clinical Trials	***167***	***$253,780,861***	***100%***

NCI Extramural Contracts and Interagency Agreements	**Number**	**Mechanism Clinical Trial Dollars**	**Percentage of Contract Clinical Trial Dollars**
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%
Subtotal, Contracts and Interagency Agreements	***40***	***$92,808,898***	***100%***
SPOREs , Cancer Centers, ICMICs, Planning Grants, Other P50 Centers	**Number**	**Mechanism Clinical Trial Dollars**	**Percentage of P20, P30, P50 Clinical Trials Dollars**
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%
Subtotal ,P20, P30, & P50 Clinical Trials Dollars	***127***	***$75,119,709***	***100%***

Research Career Development and Training (RCD&T)	**Number**	**Mechanism Clinical Trial Dollars**	**Percentage of RCD&T Clinical Trial Dollars**
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%
Subtotal, Research Career Development and Training Clinical Trials	***92***	***$14,370,295***	***100%***
NCI Experimental Therapeutics (NExT) Program	**5**	**$610,352**	
Total Extramural Clinical Trials Dollars		**$700,855,823**	

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

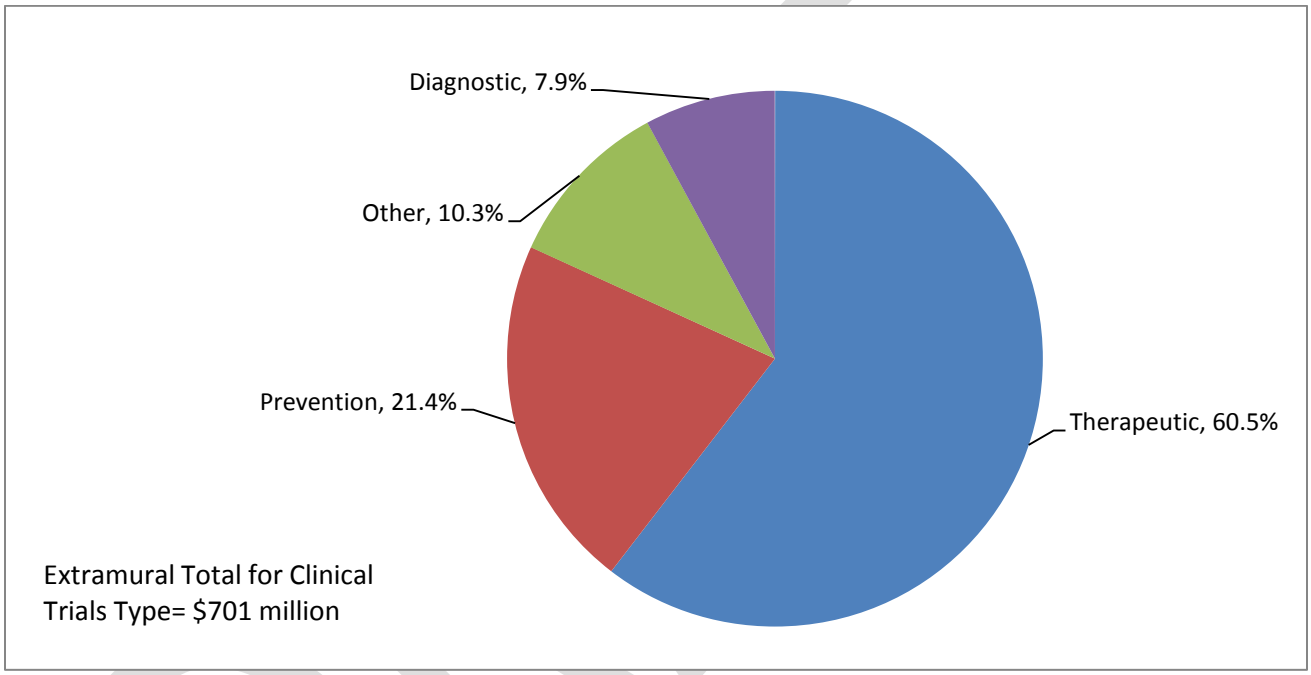


Table 5: NCI Extramural Funding by Type of Trial

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%
Total Extramural Clinical Trials	**$700,855,829**	**100%**

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

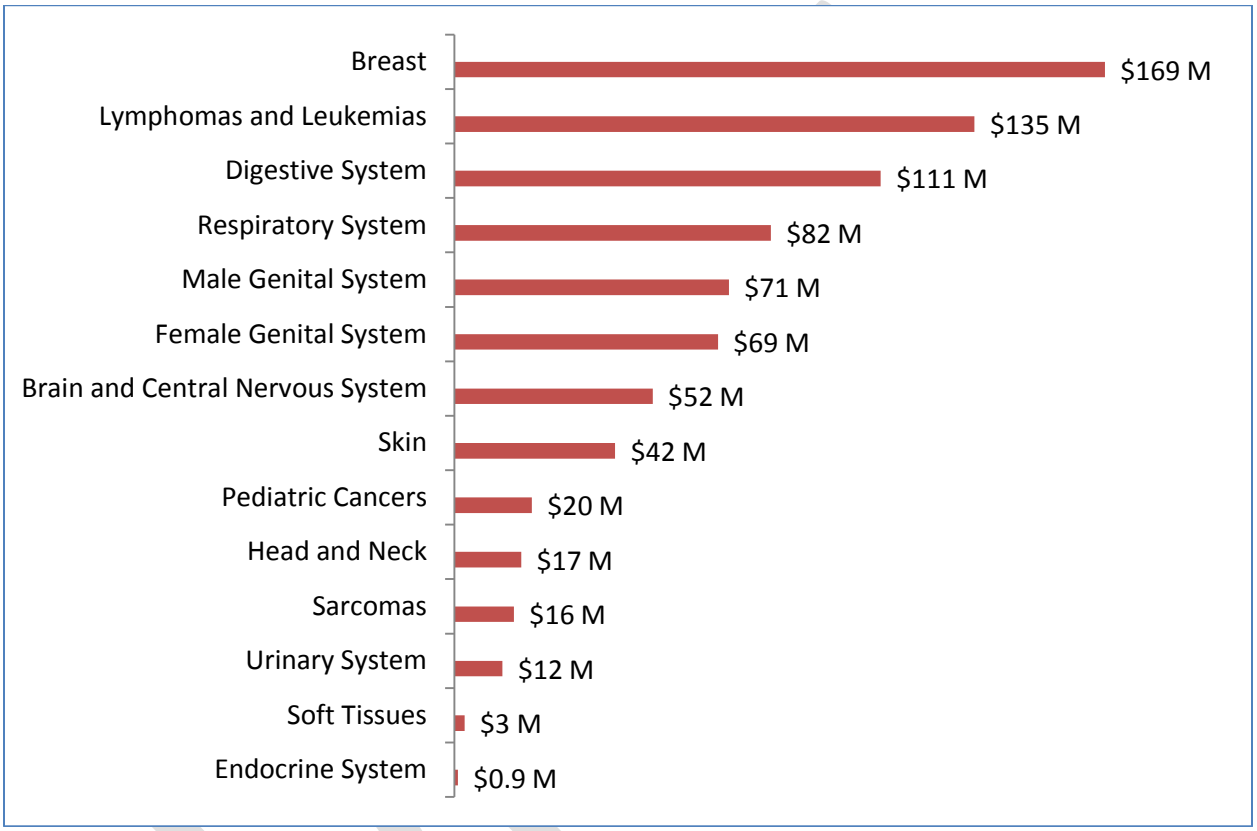


Table 6: Anatomical Sites in NCI Extramural Clinical Trial Awards by Site Category

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

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

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

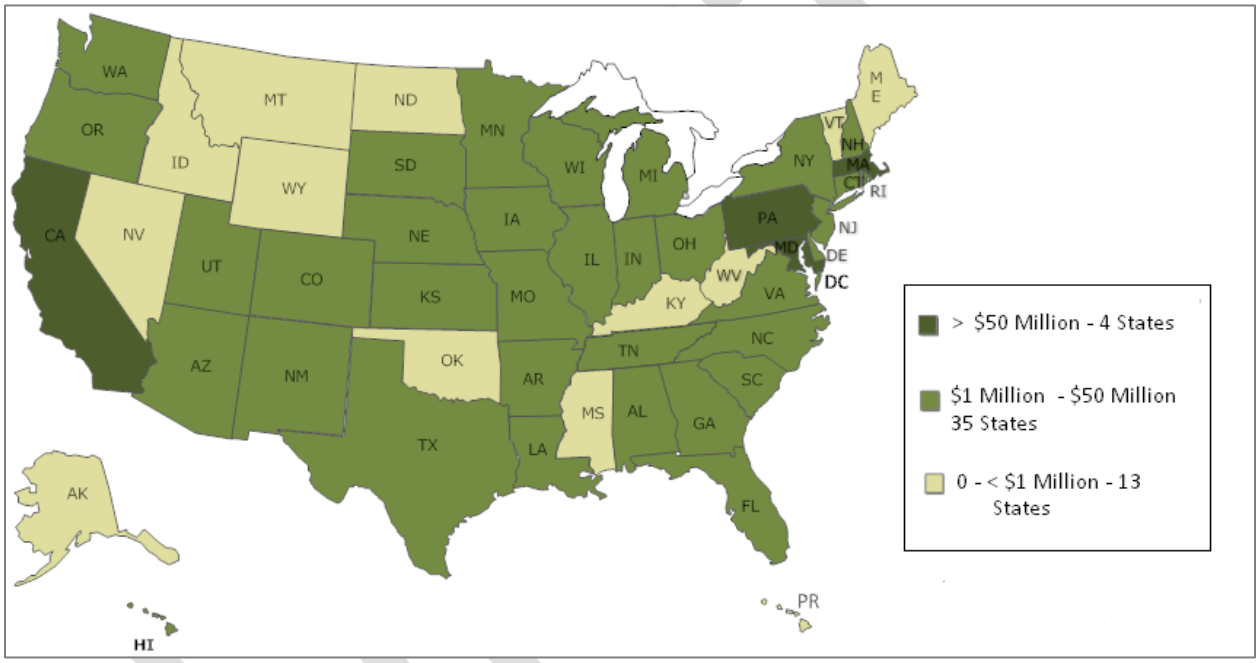


Table 7 NCI Extramural Awards for Clinical Trials (by State)

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 VIRGINIIA	1		1	$108,244	0.02%
WYOMING	0		0	$0	
Total US Extramural Clinical Trials Dollars*	**907**	**38**	**945**	**$696,583,117**	**100%**

*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

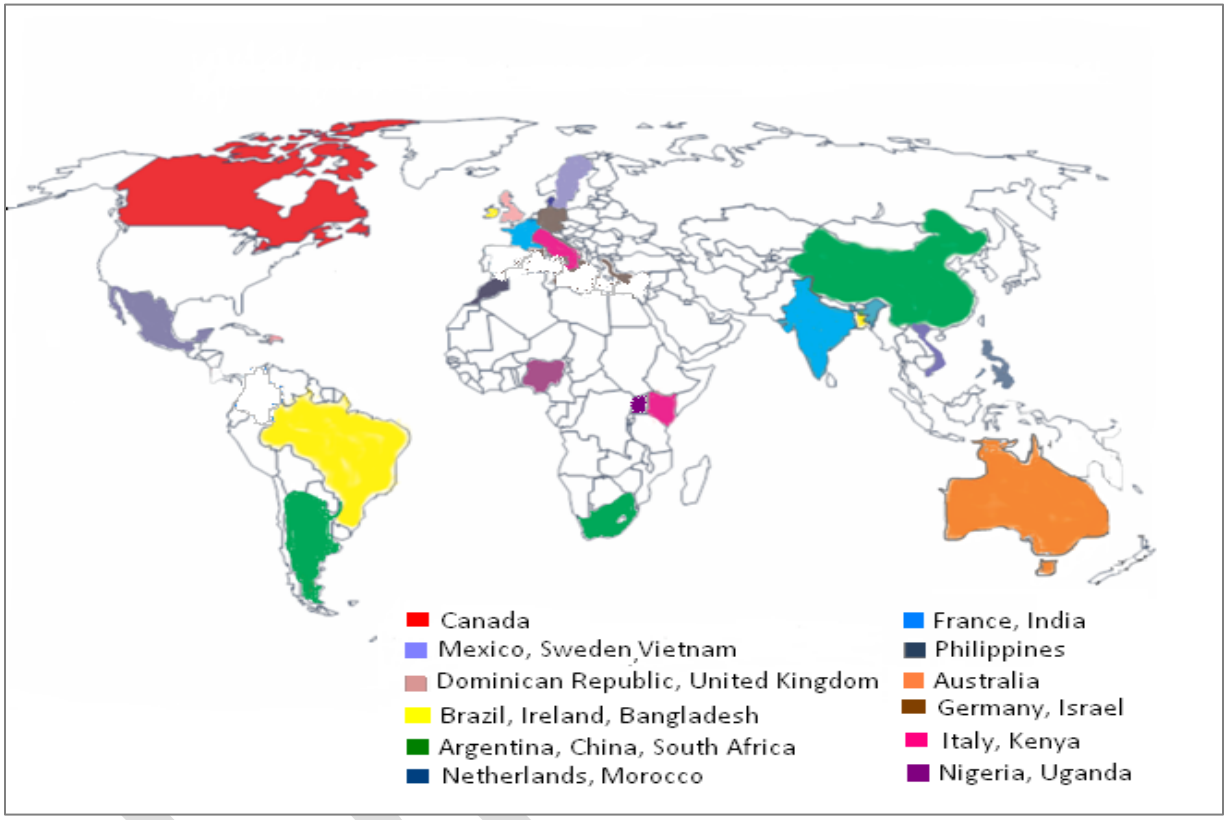


Table 8 Countries Participating in Clinical Trials with a U.S. Institution

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

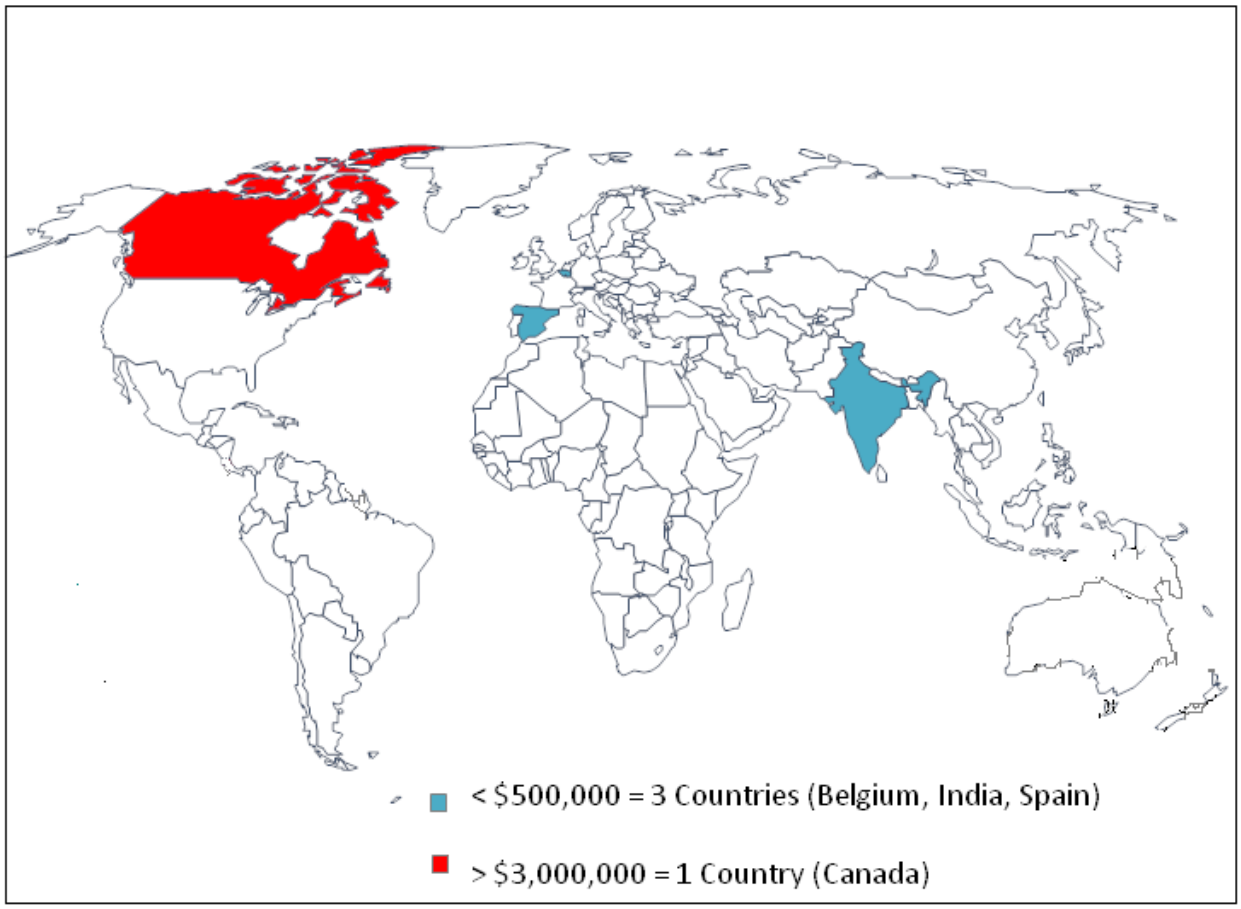


Table 9. NCI Clinical Trials Awards to Foreign Institutions

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
Total Foreign Clinical Trials		**15**	**$4,272,707**

NCI Intramural Clinical Trials Funding

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

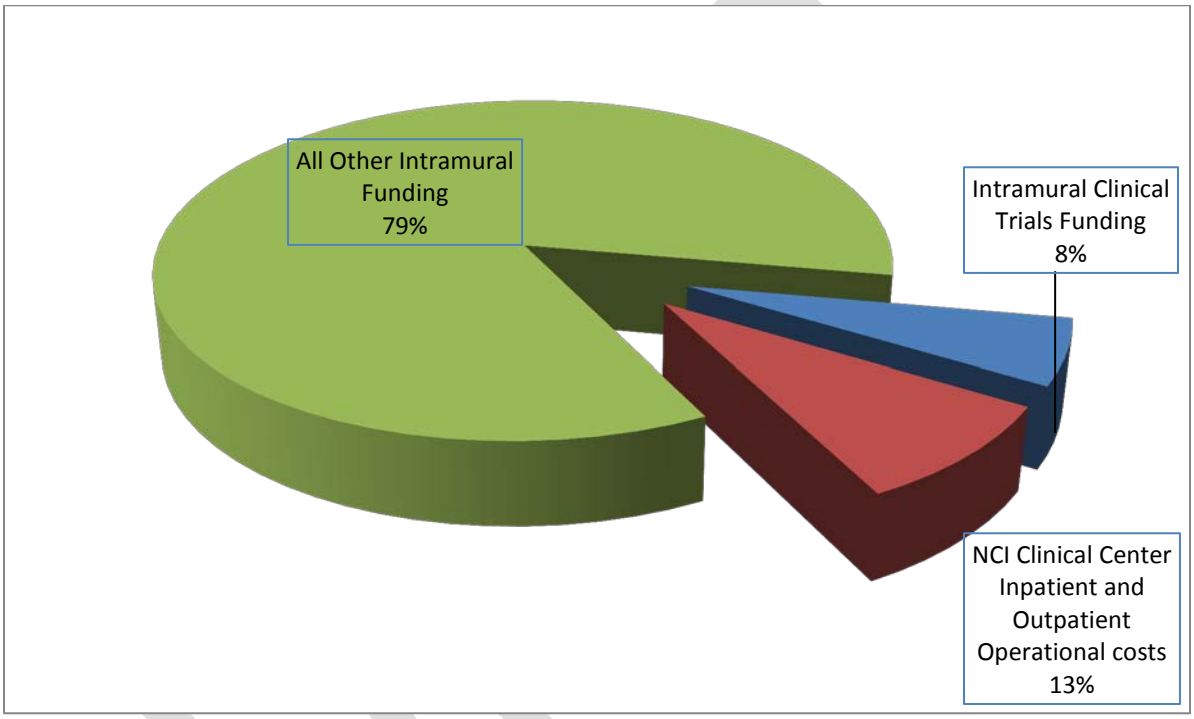


Table 10. Clinical Trials Funding as a Proportion of Overall Intramural Funding

	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%
Total Intramural funding	**$833,670,000**	**100%**

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

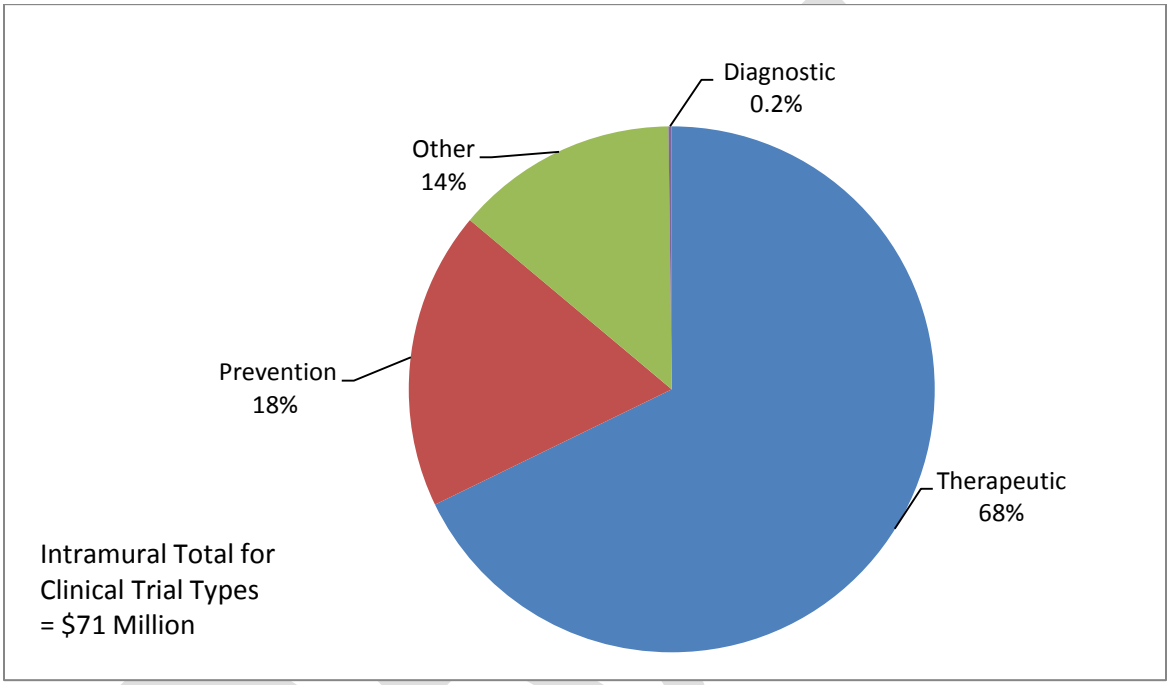


Table 11. Intramural Funding by Type of Trial

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%
Intramural Clinical Trial Dollars Total	**$70,567,346**	**100%**

NCI Clinical Trials Funding Summary

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

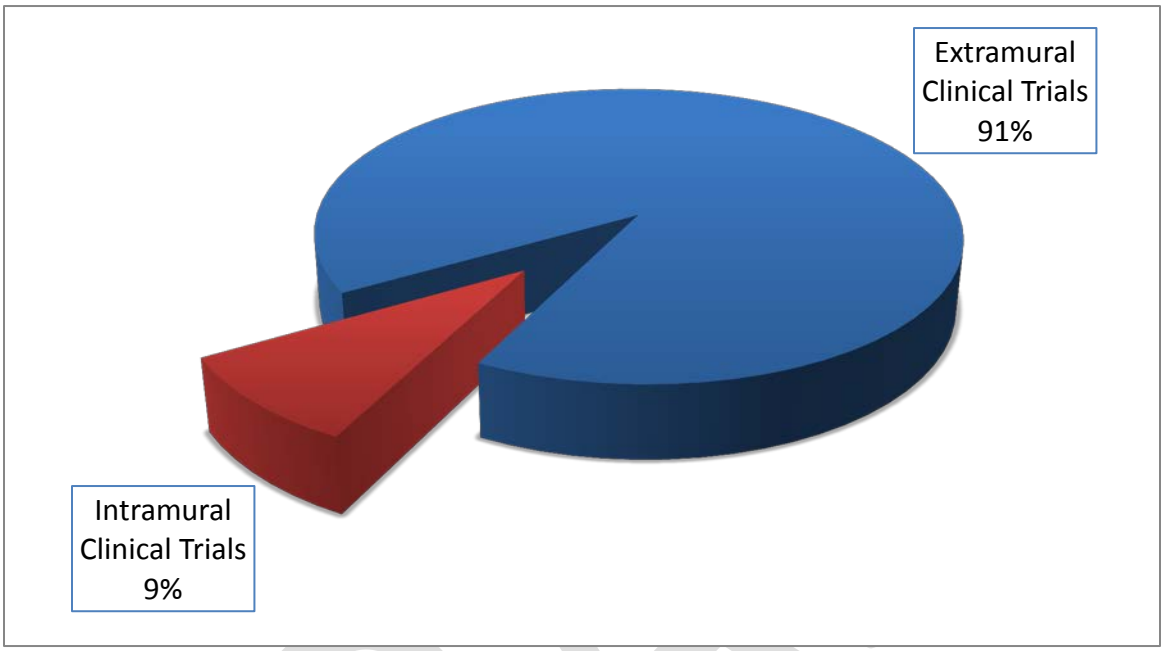
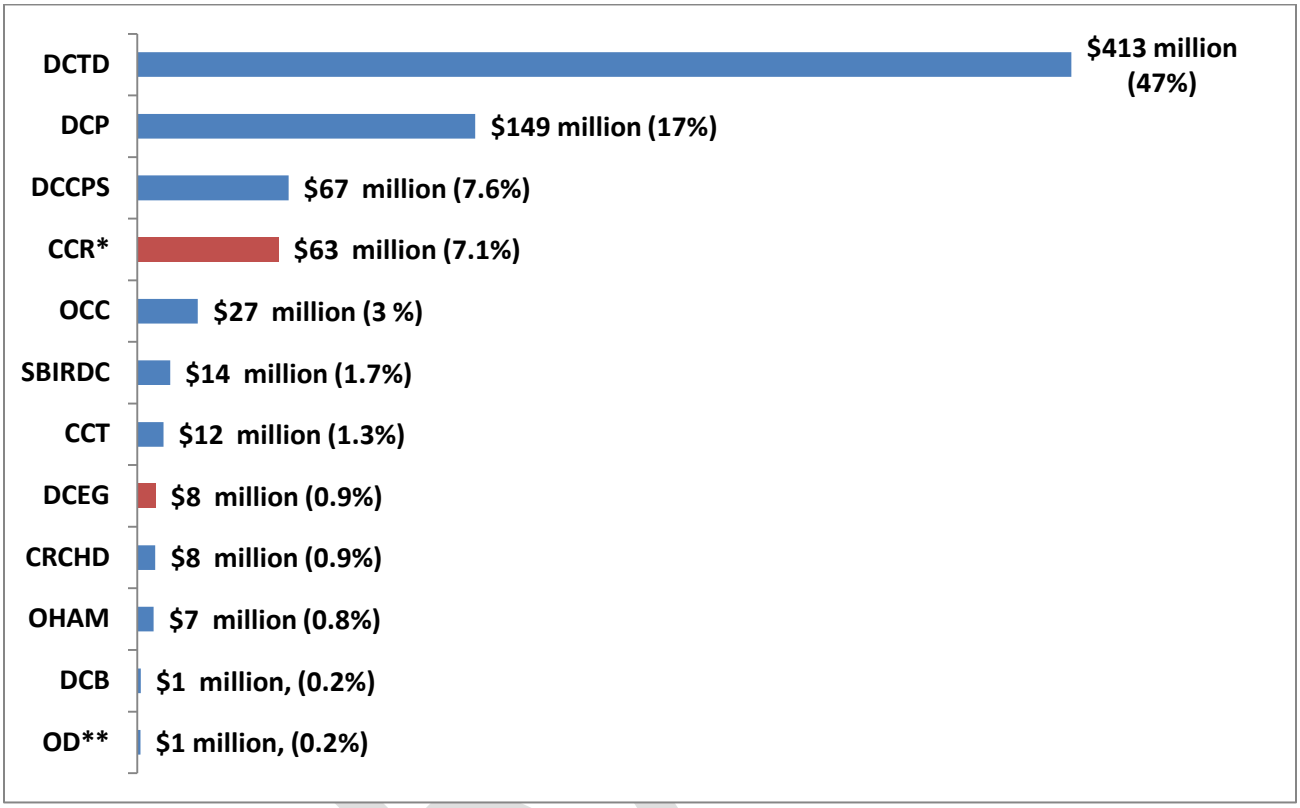


Table12. NCI Funding for Clinical Trials, Intramural and Extramural

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

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)

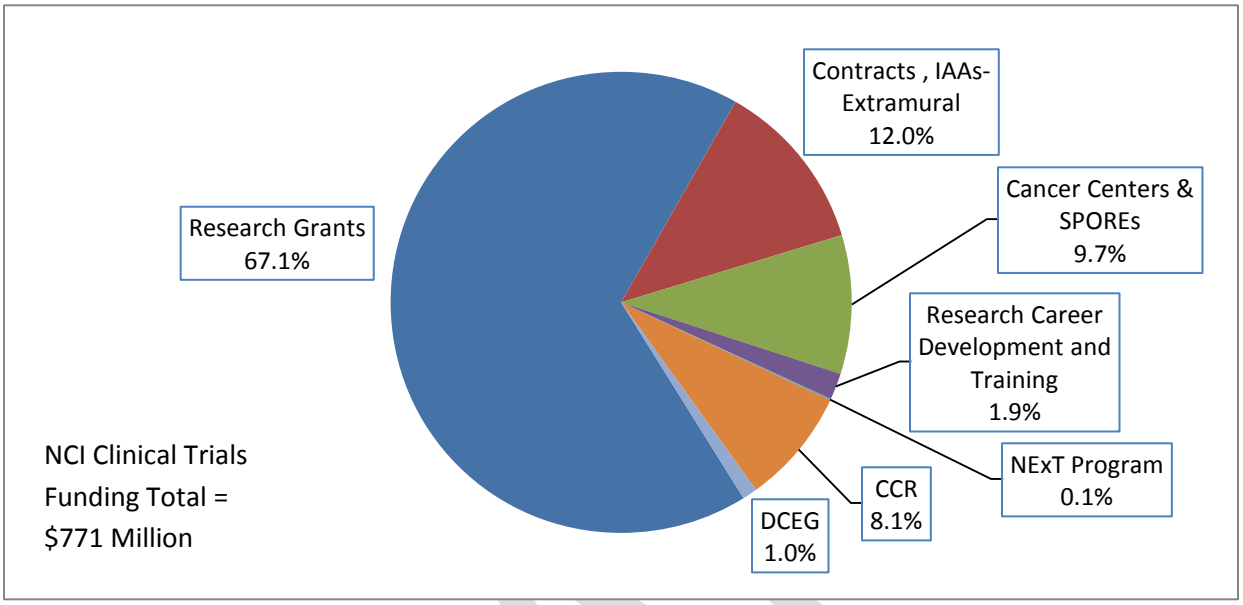


Table 14. NCI Clinical Trials (by Funding Allocation)

Funding Allocation	Number of Projects	Clinical Trials Dollars	Percentage of Total NCI Clinical Trials Dollars
Extramural			
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%
Intramural			
CCR	141	$62,560,100	8.2%
DCEG	9	$8,007,247	1.0%
NCI Total Clinical Trials	**1115**	**$771,423,169**	**100.0%**

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

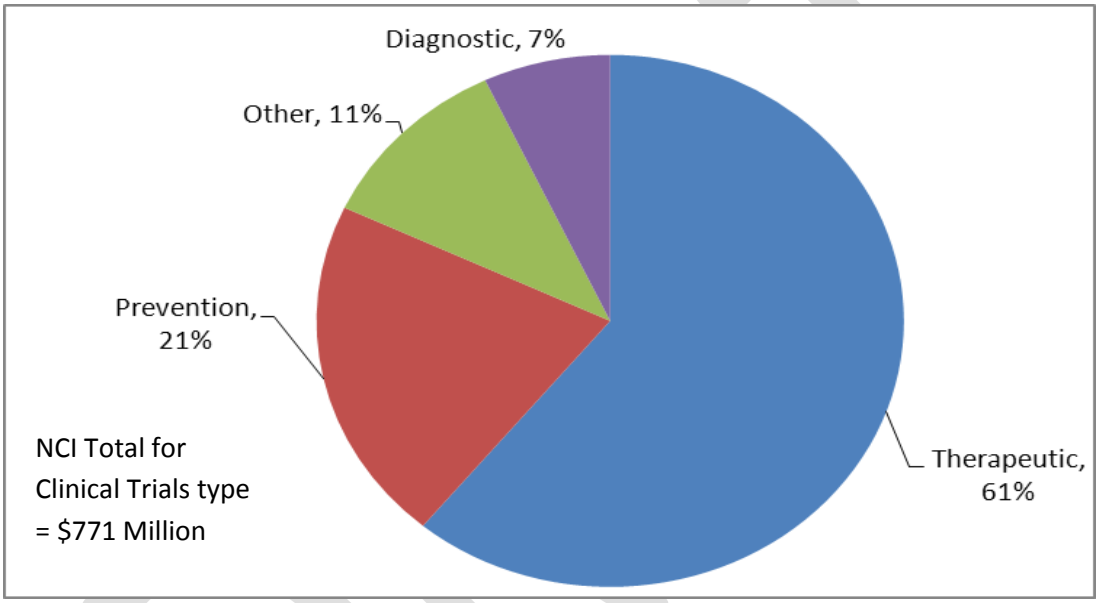


Table 15. NCI Funding for Clinical Trials Type

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%
NCI Clinical Trials Total	**$771,423,175**	**100%**

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

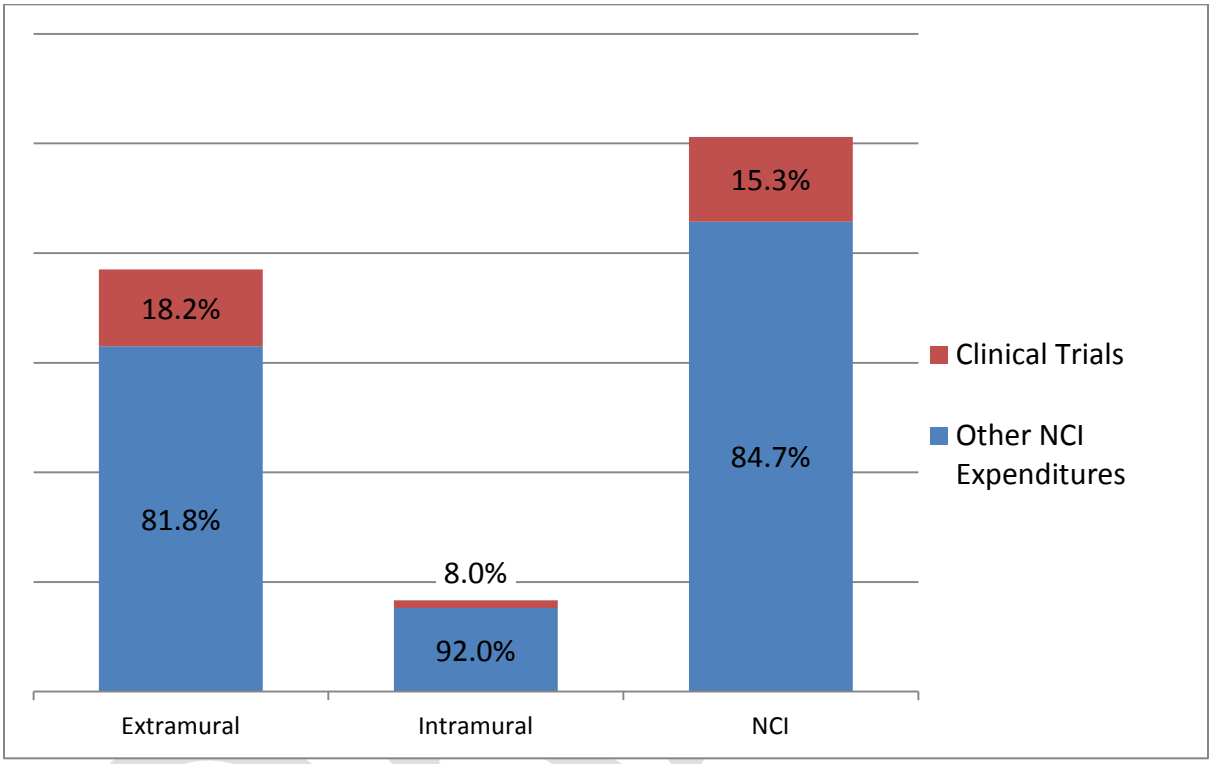


Table 15. Comparison of Extramural, Intramural and NCI Overall Clinical Trials Allocations

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

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

Cooperative Group/ Document Number	Phase	Status	Document Name	Principal Investigator	Date Received in PIO (for SC evaluation)	Date Original Reviewed in SC	Date of Re-Review in SC (if applicable)	Date Protocol Approved by NCI	*Date Protocol Open to Accural*	*Accural Total as of 5/31/13*	*BIQSFP Assay/ Test/ Tool*
Breast Cancer Steering Committee (BCSC)											
ACOSOG_Z11103 (A011106)	**2&3**	**APPROVED; Pending with Revisions**	ALTernate approaches for clinical stage II and III Estrogen Receptor positive breast cancer NeoAdjuvant TrEatment (ALTERNATE) Study (w/ BIQSFP)	Cynthia X. Ma, MD, PhD	3/30/2011; 5/23/2011 (rev 1); 06/08/211 (rev 2)	4/20/2011	6/15/2011	In Review 06/27/2012			***Ki67***
ALLIANCE_A011202	**3**	**APPROVED**	A Randomized Phase III Trial Evaluating the Role of Axillary Lymph Node Dissection in Breast Cancer Patients (cT1-3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant	Judy C. Boughey, MD	3/26/2012	4/18/2012	N/A				*N/A*
NSABP/RTOG #9353	**3**	**APPROVED; Pending with Revisions**	A Randomized Phase III Clinical Trial Evaluating the Role of Post-Mastectomy Chest Wall and Regional Nodal XRT and Post-Lumpectomy Regional Nodal XRT in Patients with Documented Positive Axillary Nodes Before Neoadjuvant Chemotherapy Who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy	Eleftherios Mamounas, MD, MPH (NSABP) Julia White, MD (RTOG)	3/27/2012; 5/31/2012	4/18/2012	6/20/2012				*N/A*
ECOG_E2108	**3**	**APPROVED; Pending with Revisions**	A Randomized Trial of the Value of Early Local Therapy for the Intact Primary Tumor in Women with Metastatic Breast Cancer	Seema Khan, MD	4/30/2009	6/16/2009	N/A	10/26/2010	***2/8/2011***	***102***	*880*
NCIC CTG_MA.32	**3**	**APPROVED; Pending with Revisions**	A Phase III Randomized Trial of the Effect of Metformin versus Placebo on Recurrence and Survival in Early Stage Breast Cancer (w/ BIQSFP)	Pam Goodwin, MD	3/25/2009; 07/14/2009 (rev)	4/23/2009	7/23/2009	3/26/2010	***6/25/2010 [Closed to Accrual]***	***3649***	***Fatigue, Behavioral, & Health Outcomes***
NSABP B-48 (8708)	**3**	**APPROVED; Pending with Revisions**	A Randomized Phase III Clinical Trial Evaluating Pathologic Complete Response in Patients with Palpable and Operable, Triple-Negative Breast Cancer Treated with Docetaxel and Cyclophosphamide Followed by Gemcitabine and Carboplatin with or without the PARP1 Inhibitor BSI-201	Steven A, Limentani, MD	10/28/2009	11/19/2009	2/17/2010	**Withdrawn 06/22/2011**			*N/A*
(NSABP B-49 (#9186)	**3**	**APPROVED; Pending with Revisions**	A Phase III Clinical Trial Comparing the Combination of Docetaxel Plus Cyclophosphamide to Anthracycline-Based Regimens for Women with Node-Positive or High-Risk Node-Negative, HER2-Negative Breast Cancer	Patrick J. Flynn, MD	9/28/2011	10/19/2011	12/21/2011	2/28/2012	***4/4/2012***	***1089***	*N/A*
RTOG-1005	**3**	**APPROVED; Pending with Revisions**	A Phase III Trial of Accelerated Whole Breast Irradiation with Hypofractionation plus Concurrent Boost Versus Standard Whole Breast Irradiation with Conventional Fractionation plus Sequential Boost for Early-Stage Breast Cancer	Frank A. Vicini, MD, FACR	7/22/2010 10/13/2010 (rev)	8/18/2010	10/20/2010	5/2/2011	***5/24/2011***	***970***	*N/A*
RTOG-1119	**2**	**APPROVED**	Phase II Randomized Study of Whole Brain Radiotherapy in Combination With Concurrent Lapatinib in Patients with Brain Metastasis From HER2-Positive Breast Cancer – A Collaborative Study of RTOG and KROG	Kim In Ah, MD, PhD	8/8/2011	9/15/2011	N/A	6/11/2012	***7/26/2012***	***5***	*N/A*
SWOG_S1007	**3**	**APPROVED; Pending with Revisions**	A Phase III, Randomized Clinical Trial of Standard Adjuvant EndocrineTherapy +/- Chemotherapy in Patients with 1-9 Positive Nodes, Hormone-responsive and HER2-negative Breast Cancer according to Recurrence Score (RS) (w/ BIQSFP)	Ana Maria Gonzalez-Angulo, MD	2/24/2010; 5/25/2010 (rev)	3/18/2010	6/16/2010	1/3/2011	***01/15/2011***	***2695***	***Onco Type DX***
SWOG_S1207	**3**	**APPROVED**	Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer (w/ BIQSFP)	Mariana Chavez Mac Gregor, MD, MSc	12/27/2011	1/19/2012	N/A	8/3/2012	***8/3/2012***	***0***	***N/A***

Cooperative Group/ Document Number	Phase	Status	Document Name	Principal Investigator	Date Received in PIO (for SC evaluation)	Date Original Reviewed in SC	Date of Re-Review in SC (if applicable)	Date Protocol Approved by NCI	*Date Protocol Open to Accural*	*Accural Total as of 5/31/13*	*BIQSFP Assay/ Test/ Tool*
NSABP #9432	**3**	**APPROVED; Pending with Revisions**	A Randomized Phase III Trial Evaluating Pathologic Complete Response Rates in Patients with Hormone Receptor-Positive, HER2-Positive, Large Operable and Locally Advanced Breast Cancer Treated with Neoadjuvant Therapy of Docetaxel, Carboplatin, Trastuzumab, and Pertuzumab (TCHP) with or Without Estrogen Deprivation	Mothaffar Rimawi, MD	6/28/2012; 10/10/2012	7/19/2012	10/24/2012				*N/A*
ECOG_E2112	**3**	**APPROVED; Pending with Revisions**	A Randomized Phase III Trial of Endocrine Therapy plus Entinostat/Placebo in Patients with Hormone Receptor-Positive Metastatic Breast Cancer	Roisin Connolly, MB, BCh	9/4/2012; 12/11/12	10/17/2012	12/19/2012				*N/A*
Brain Malignancy Steering Committee (BMSC)											
ALLIANCE_A071101	**2**	**APPROVED; Pending with Revisions**	A Phase 2 Multicenter, Randomized, Double Blind, Placebo-Controlled Trial Comparing Efficacy of Heat Shock Protein-Peptide Complex-96 (HSPPC-96) Vaccine or Placebo in Combination with Bevacizumab (Avastin®) in the Therapy of Surgically Resectable Recurrent Glioblastoma Multiforme (GBM)	Andrew Parsa, MD, PhD	12/22/2011; 2/27/2012	1/12/2012	3/8/2012	In Review 06/07/2012	***5/22/2013***	***0***	*N/A*
COG_ACNS1022	**2**	**APPROVED; Pending with Revisions**	A Phase II Trial of Lenalidomide in Pediatric Patients with Recurrent, Refractory or Progressive Low-Grade CNS Gliomas	Kathy Warren, MD	12/27/2010	1/13/2011	3/10/2011	3/2/2012	***3/19/2012***	***16***	*N/A*
COG_ACNS1123	**2**	**APPROVED; Pending with Revisions**	Phase 2 Trial of Response-Based Radiation Therapy for Patients with Localized Central Nervous System Germ Cell Tumors	Ute Bartels, MD	5/25/2011; 8/31/2011	7/14/2011	9/8/2011	5/15/2012	***5/29/2012***	***43***	*N/A*
PBTC-033 (C9073)	**2**	**APPROVED; Pending with Revisions**	A Feasibility and Phase II Study of ABT888, an oral poly(ADP-ribose) polymerase inhibitor, and concurrent radiation therapy, followed by ABT888 and temozolomide, in children with newly diagnosed high-grade or diffuse pontine gliomas (DIPG)	Jack Meng-Fen Su, MD	05/04/2011 (rev1)	3/10/2011	5/12/2011	In Review 11/14/2011	***11/17/2011***	***7***	*N/A*
RTOG-1205	**2**	**APPROVED; Pending with Revisions**	Randomized Phase II Trial of Concurrent Bevacizumab and Re-Irradiation Versus Bevacizumab Alone as Treatment for Recurrent Glioblastoma	Christina Tsien, MD	12/15/2011	1/12/2012	3/8/2012	In Review 07/16/2012	***12/20/2012***	***0***	*N/A*
RTOG-1125	**2&3**	**APPROVED; Pending with Revisions**	Phase II/III Randomized, Double Blinded Placebo Controlled Trial Comparing Adjuvant Temozolomide and Ipilimumab with Adjuvant Temozolomide in Patients with Newly Diagnosed Glioblastoma After Successful Completion of Concurrent Radiation and Temozolomide	Mark R. Gilbert, MD	7/20/2011; 10/06/2011 (rev)	8/11/2011	10/13/2011	6/22/2012			*N/A*
PBTC #9425/C106	**2**	**APPROVED; Pending with Revisions**	A Molecular Biology and Phase II Study of Imetelstat (GRN163L) in Children with Recurrent High-Grade Glioma, Ependymoma, Medulloblastoma/Primitive Neuroectodermal Tumor (PNET) and Diffuse Intrinsic Pontine Glioma	Kathleen Dorris, MD	6/21/2012; 9/13/2012	7/12/2012	9/21/2012				*N/A*
COG_ACNS1221	**2**	**APPROVED**	A Phase II Study for the Treatment of Non-Metastatic Desmoplastic Medulloblastoma in Children Less Than 4 Years of Age	Lucie LaFay-Cousin, MD	8/21/2012	9/21/2012	N/A				*N/A*
PBTC #9514	**2**	**APPROVED**	Phase II study of pegylated interferon α-2b for pediatric patients with unresectable or recurrent craniopharyngioma	Regina Jakacki, MD	11/13/2012	12/13/2012	N/A				*N/A*

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Clinical Imaging Steering Committee (CISC)											
9175 (ACRIN_6698)	**3**	**APPROVED**	Diffusion Weighted MR Imaging Biomarkers for Assessment of Breast Cancer Response to Neoadjuvant Treatment: A Sub-study of the I-SPY 2 TRIAL (Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging And MoLecular Analysis)	Nola Hylton, PhD.	8/15/2011	9/13/2011	N/A	3/15/2012	***8/27/2012***	***52***	*N/A*
CALGB_71101 (A211201)	**3**	**APPROVED**	Change in Mammographic Density with Metformin Use: A Companion Study to NCIC study MA.32	Jennifer Eng-Wong, MD, MPH	7/25/2011	8/9/2011	N/A		***8/22/2012***	***36***	*N/A*
ACRIN_6702	**2**	**APPROVED; Pending with Revisions**	A Multi-Center Study Evaluating the Utility of Diffusion Weighted Imaging for Detection and Diagnosis of Breast Cancer	Savannah Partridge, PhD	8/30/2012; 2/12/2013	10/16/2012	2/19/2013				*N/A*
Gynecologic Steering Committee (GCSC)											
GOG_DTM0708	**2**	**WITHDRAWN; Approved**	A Randomized Phase II Evaluation of Volociximab (M200) plus Weekly Paclitaxel vs. Weekly Paclitaxel Alone in the Third-line Treatment of Recurrent or Persistent Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer (GOG-0186 series)	Linda A. Duska, MD	N/A - sent directly to Uterine TF	9/11/2007	N/A	N/A	WD	NA	N/A
SWOG_S0903	**2**	**WITHDRAWN; Approved**	Randomized Phase II Study Evaluating Carboplatin/Paclitaxel Compared with Carboplatin/Paclitaxel and Everolimus in Patients with Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer in First Relapse	Lainie P. Martin, MD	3/29/2010	4/20/2010	N/A	In Review 07/29/2010	WD	NA	N/A
GOG_DTM0929	**2**	**WITHDRAWN; Approved**	A Phase II Study Of The Potent, Highly Selective Poly(Adp-Ribose) Polymerase (Parp) -1 And -2 Inhibitor Mk-4827 In The Treatment Of Persistent Or Recurrent High-Grade Serous Ovarian Cancer	Robert L. Coleman, MD	10/21/2010	11/16/2010	N/A	N/A	WD	NA	N/A
GOG_OVM0606	**3**	**WITHDRAWN; Approved**	A Randomized Phase III Trial of Neoadjuvant Carboplatin/ Paclitaxel vs. Carboplatin/Weekly Abraxane in Performance Status Challenged and Geriatric Patients	Thomas J. Herzog, MD	N/A - sent directly to Ovarian TF	11/6/2007	N/A	N/A	WD	NA	N/A
GOG-0238	**2**	**APPROVED**	A Randomized Trial of Pelvic Irradiation with or without Concurrent Weekly Cisplatin In Patients with Pelvic-Only Recurrence of Carcinoma of the Uterine Corpus	Higinia R. Cardenes, MD, PhD	NOT A CONCEPT; Study came to PIO as Protocol; 12/12/2006	2/23/2007	N/A	5/11/2007	***2/25/2008***	***63***	*N/A*
LOI 8093 (GOG-0248)	**2**	**APPROVED**	Randomized Phase II Trial of Temsirolimus or the Combination of Hormonal Therapy Plus Temsirolimus in Women with Advanced or Recurrent Endometrial Carcinoma	Gini Fleming, MD	Not a CONCEPT; LOI; 4/6/2007	5/8/2007	N/A	7/28/2008	***9/29/2008*** ***[Closed to Accrual]***	***73***	*N/A*
DTM0801 (GOG - 0186G)	**2**	**APPROVED**	A Randomized Phase II Evaluation of Oral Everolimus (RAD001) plus Bevacizumab vs. Oral Placebo plus Bevacizumab in the Treatment of Recurrent or Persistent Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer	William P. Tew, MD	8/7/2008; 10/28/08 (rev)	11/18/2008	N/A	4/6/2009	***12/27/2010*** ***(Closed to Accrual)***	***150***	*N/A*
DTM0905 (GOG - 0186I)	**2**	**APPROVED**	A Randomized Phase II Evaluation of Single Agent Bevacizumab (NSC #704865) and Combination Bevacizumab with Fosbretabulin in the Treatment of Persistent or Recurrent Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Carcinoma	Bradley J. Monk, MD	9/29/2009	10/20/2009	N/A	2/22/2011	***3/21/2011*** ***[Closed to Accrual]***	***101***	*N/A*

Cooperative Group/ Document Number	Phase	Status	Document Name	Principal Investigator	Date Received in PIO (for SC evaluation)	Date Original Reviewed in SC	Date of Re-Review in SC (if applicable)	Date Protocol Approved by NCI	*Date Protocol Open to Accural*	*Accural Total as of 5/31/13*	*BIQSFP Assay/ Test/ Tool*
GOG-0213	**3**	**APPROVED; Pending with Revisions**	A Phase 3 Randomized Controlled Clinical Trial of Carboplatin and Paclitaxel Alone or in Combination with Bevacizumab Followed by Bevacizumab or in Combination with Bevacizumab Followed by Bevacizumab and Erlotinib and Secondary Cytoreductive Surgery in Platinum-Sensitive, Recurrent Ovarian and Peritoneal Primary Cancer	Robert L. Coleman, MD	10/26/04; revision 1 - 6/14/05; revision 2 - 7/5/05; 8/16/06	9/28/2006	1/9/2007	10/19/2007	***12/6/2007***	***742***	*N/A*
UC-0704 (GOG-0258)	**3**	**APPROVED**	A Randomized Phase III Trial of Cisplatin and Tumor Volume Directed Irradiation Followed by Carboplatin and Paclitaxel vs. Carboplatin and Paclitaxel for Optimally Debulked, Advanced Endometrial Carcinoma	Daniela Matei, MD	5/29/2007	7/9/2007	N/A	6/29/2009	***6/29/2009***	***578***	*N/A*
GOG-0204R-CVM-0704 (GOG-0240)	**3**	**APPROVED**	A Randomized Phase III Trial of Cisplatin plus Paclitaxel with and without Bevacizumab versus the Non-Platinum Doublet, Topotecan plus Paclitaxel, with and without Bevacizumab, in Stage IVB, Recurrent or Persistent Carcinoma of the Cervix	Krishnansu S. Tewari, MD	NOT A CONCEPT; Protocol; 05/31/07	6/25/2007	N/A	11/21/2008	***4/6/2009 [Closed to Accrual]***	***452***	*N/A*
UC-0701 (GOG-0261)	**3**	**APPROVED**	Randomized Phase III Trial of Carboplatin plus Paclitaxel versus Ifosfamide plus Taxol in Patients with Advanced, Persistent or Recurrent Carcinosarcoma (Mixed Mesodermal Tumors) of the Uterus	Matthew A. Powell, MD	7/31/2007	8/7/2007	N/A	7/23/2009	***8/17/2009***	***472***	*N/A*
UC-0604 (2007) (GOG-0249)	**3**	**APPROVED**	Phase III Trial of Pelvic Radiation Therapy versus Vaginal Cuff Brachytherapy Followed by Paclitaxel/Carboplatin Chemotherapy in Patients with High Risk, Early Stage Endometrial Cancer (w/ BIQSFP)	Scott McMeekin, MD	08/21/06; 10/09/07 (rev)	11/6/2007	N/A	12/1/2008	***3/23/2009 [Closed to Accrual]***	***578***	***PROMIS 7 (HRQOL)***
OVM0705 (GOG-0252)	**3**	**APPROVED**	Phase III Clinical Trial of Bevacizumab with IV versus IP Chemotherapy in Ovarian, Fallopian Tube and Primary Peritoneal Carcinoma	Joan L. Walker, MD	12/14/2007	1/8/2008	N/A	7/20/2009	***7/27/2009 [Closed to Accrual]***	***1548***	*N/A*
OVM0703 (GOG-0255)	**3**	**APPROVED**	A Randomized Phase III Trial in Patients with Epithelial Ovarian, Fallopian Tube, or Peritoneal Cancer with a Polyvalent Vaccine-KLH Conjugate + QS-21 versus QS-21	Paul Sabbatini, MD	4/22/2008	5/13/2008	N/A	2/19/2009	***7/26/2010 [Closed to Accrual]***	***171***	*N/A*
GOG-0241	**3**	**APPROVED; Pending with Revisions**	A Randomized Phase III Evaluation of Capecitabine and Oxaliplatin (Xelox) versus Carboplatin and Paclitaxel in Mucinous Adenocarcinoma of the Ovary	David M. Gershenson, MD	01/04/08; 04/16/08 (rev); 12/30/08 (rev); 02/04/10 (rev)	5/13/2008	1/20/2009	9/8/2010	***10/12/2010***	***13***	*N/A*
CVM0801 (GOG 0263)	**3**	**APPROVED**	Randomized Clinical Trial for Adjuvant Chemo-radiation in Post-operative Cervical Cancer Patients with Intermediate Risk Factors	Sang Young Ryu, MD	03/26/08; 04/24/08 (rev); 01/30/09 (rev)	2/17/2009	N/A	4/1/2010	***4/12/2010***	***122***	*N/A*
OVM0813 (GOG 0262)	**3**	**APPROVED; Pending with Revisions**	A Randomized Phase III Trial of Every-Three-Weeks versus Dose Dense Weekly Paclitaxel and Carboplatin plus Concurrent Bevacizumab in the Treatment of Primary Suboptimal Stage III or IV Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Carcinoma	John K. Chan, MD	11/10/2008; 3/10/2009 (rev)	12/1/2008	1/20/09; 3/17/09; 4/7/09	7/2/2010	***9/27/2010***	***773***	*N/A*

Cooperative Group/ Document Number	Phase	Status	Document Name	Principal Investigator	Date Received in PIO (for SC evaluation)	Date Original Reviewed in SC	Date of Re-Review in SC (if applicable)	Date Protocol Approved by NCI	*Date Protocol Open to Accural*	*Accural Total as of 5/31/13*	*BIQSFP Assay/ Test/ Tool*
CVM1004 (ANZGOG-0902; GOG-0274)	**3**	**APPROVED**	A Phase III Trial of Adjuvant Chemotherapy Following Chemoradiation as Primary Treatment for Locally Advanced Cervical Cancer Compared to Chemoradiation Alone: GOG COLLABORATION WITH THE OUTBACK TRIAL (ANZGOG 0902)	Kathleen Moore, MD	3/30/2010 7/2/2010 (rev)	4/20/2010	7/20/2010	7/22/2011	***1/9/2012***	***64***	*N/A*
GOG -UC1009 (GOG-0277)	**3**	**APPROVED; Pending with Revisions**	A Phase III Randomized Trial of Gemcitabine plus Docetaxel followed by Doxorubicin v. Letrozole for Early Stage High Grade Uterine Leiomyosarcoma	Martee L. Hensley, MD	3/23/2011; 06/22/2011 - (rev)	4/19/2011	7/12/2011	2/6/2012	***6/4/2012***	***1***	*N/A*
GOG - UC1005 (GOG-0275)	**3**	**APPROVED**	A Phase III Randomized Trial of Pulse Actinomycin-D versus Multi-day Methotrexate for the Treatment of Low-risk Gestational Trophoblastic Neoplasia	Julian C. Schink, MD	4/28/2011	5/17/2011	N/A	2/8/2012	***6/18/2012***	***9***	*N/A*
DTM0720 (GOG-0250)	**2b**	**APPROVED**	Randomized Phase IIB Evaluation of Gemcitabine-Docetaxel with or without Bevacizumab for Advanced or Recurrent Uterine Leiomyosarcoma	Martee L. Hensley, MD	2/25/2008; 03/17/2006 (rev)	4/7/2008	N/A	10/19/2009	***11/9/2009***	***106***	*N/A*
RTM0602 (GOG 0264)	**2b**	**APPROVED; Pending with Revisions**	A Phase II Trial of Paclitaxel and Carboplatin vs. Bleomycin, Etoposide, and Cisplatin for Newly Diagnosed Advanced Stage Sex Cord-Stromal Tumors of the Ovary	Jubilee Brown, MD	4/28/2009	5/19/2009	N/A	12/29/2009	***2/8/2010***	***14***	*N/A*
DTM1003 (GOG-0186J)	**2b**	**APPROVED**	A Randomized Phase IIB Evaluation of Pazopanib versus Weekly Paclitaxel plus Pazopanib versus Weekly Paclitaxel in the Treatment of Persistent or Recurrent Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Carcinoma	Debra L. Richardson, MD	6/15/2010	7/20/2010	N/A	11/02/2011	***12/12/2011*** *[Closed to Accrual]*	***102***	*N/A*
GOG - 0270		**APPROVED; Pending with Revisions**	Groningen International Study on Sentinal Nodes in Vulvar Cancer (Groinss-V) II: An Observational Study	Brian M. Slomovitz, MD	11/24/2010 05/10/11 (rev)	1/18/2011	5/31/2011	12/15/2011	***1/3/2012***	***26***	*N/A*
NCIC CTG_OV.21	**3**	**APPROVED**	A Phase II/III study of intraperitoneal (IP) plus intravenous (IV) chemotherapy versus IV carboplatin plus paclitaxel in patients with epithelial ovarian cancer optimally debulked at surgery following neoadjuvant intravenous chemotherapy	Helen Mackay, MD	11/9/2009	11/17/2009	N/A	11/1/2010	***9/11/2009***	***151***	*N/A*
RTOG-0724	**3**	**APPROVED; Pending with Revisions**	Phase III Randomized Study of Concurrent Chemotherapy and Pelvic RT with or Without Adjuvant Chemotherapy in High-Risk Patients with Early-Stage Cervical Carcinoma Following Radical Hysterectomy	Anuja Jhingran, MD	9/25/2007; 3/24/2009	6/9/2008	9/9/2008	8/10/2009	***9/16/2009***	***62***	*N/A*
SWOG_S0904	**2**	**APPROVED**	Randomized Phase II Study of Docetaxel Followed by ZD6474 (Vandetanib) vs. Docetaxel plus ZD6474 in Patients with Persistent or Recurrent Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Carcinoma	Robert L. Coleman, MD	8/19/2008; 10/28/2008 (rev)	11/18/2008	N/A	3/17/2009	***3/15/2010*** *[Closed to Accrual]*	***131***	*N/A*

Cooperative Group/ Document Number	Phase	Status	Document Name	Principal Investigator	Date Received in PIO (for SC evaluation)	Date Original Reviewed in SC	Date of Re-Review in SC (if applicable)	Date Protocol Approved by NCI	*Date Protocol Open to Accural*	*Accural Total as of 5/31/13*	*BIQSFP Assay/ Test/ Tool*
GOG_RTM1104	**2 & 3**	**APPROVED**	A Randomized Phase II/III Study to Assess the Efficacy of MEK Inhibitor GSK1120212 in Patients with Recurrent or Progressive Low-Grade Serous Ovarian Cancer or Peritoneal Cancer	David M. Gershenson, MD	8/2/2012	8/21/2012	N/A				*N/A*
GOG_DTM1212	**2 & 3**	**APPROVED; Pending with Revisions**	A Randomized Phase II/III Evaluation of Paclitaxel/Carboplatin/Metformin versus Paclitaxel/Carboplatin/Placebo in Advanced and Recurrent Endometrial Cancer Patients	Victoria Bae-Jump, MD	8/31/2012; 11/02/2012	9/18/2012	11/20/2012				*N/A*
Gastrointestinal Steering Committee (GISC)											
ACOSOG Z6051	**3**	**APPROVED; Pending with Revisions**	A Phase III Trial Comparing Laparoscopic-Assisted Rectal Resection (LARR) to Open Resection for Rectal Cancer	James Fleshman, MD	4/2/2007	5/21/2007	7/16/2007	7/22/2008	***8/15/2008***	***462***	*N/A*
CALGB-80701	**2**	**APPROVED; Pending with Revisions**	A Phase II Randomized Study of Temozolomide or Temozolomide + Bevacizumab in Patients with Advanced Pancreatic Neuroendocrine Tumors	Matt Kulke, MD	12/3/2007; 05/12/08 (rev)	12/17/2007	5/19/2008	10/15/2010	***10/15/2010 [Closed to Accrual]***	***148***	*N/A*
CALGB-80803	**2**	**APPROVED; Pending with Revisions**	Phase II Trial of PET Scan-Directed Combined Modality Therapy in Esophageal Cancer (w/ BIQSFP)	Kathryn A. Goodman, MD	4/20/2010	6/21/2010	8/16/2010	4/4/2011	***7/15/2011***	***61***	*Central pathology & PET/CT*
CALGB-81003	**2**	**APPROVED**	Phase IB/Randomized Phase II Study of Folfirinox plus AMG-479 or placebo in Patients with Previously Untreated, Metastatic Pancreatic Adenocarcinoma	Brian M. Wolpin, MD, MPH	2/17/2011	3/28/2011	N/A	11/4/2011	***8/2/2012 (administratively complete)***	***0***	*N/A*
CALGB-81103	**2**	**APPROVED**	Prospective Randomized Phase II Trial of Pazopanib Versus Placebo in Patients with Progressive Carcinoid Tumors	Emily Bergsland, MD	12/13/2011	1/30/2012	N/A				*N/A*
CALGB-80802	**3**	**APPROVED; Pending with Revisions**	Phase II/III Randomized Study of Sorafenib plus Doxorubicin Versus Sorafenib in Patients with Advanced Hepatocellular Carcinoma (HCC)	Abou-Alfa Ghassan, MD	4/10/2008; 08/07/08 (rev)	5/19/2008	8/18/2008	11/2/2009	***2/15/2010***	***207***	*N/A*
CALGB-80702	**3**	**APPROVED; Pending with Revisions**	A 2 x 2 Phase III Trial of Celecoxib and Vitamin D in Addition to Standard Chemotherapy for Stage III Colon Cancer	Jeffrey A. Meyerhardt, MD	7/7/2008, 10/13/2008, 2/21/2009	7/21/2008	11/17/2008; 2/27/2009	6/15/2010	***6/22/2010***	***1092***	*N/A*
ECOG_E7208	**2**	**APPROVED; Pending with Revisions**	A Randomized Phase II Study of Irinotecan with Cetuximab Plus/Minus IMC-1121B in Metastatic Colorectal Cancer Patients Progressing on Bevacizumab-Containing Chemotherapy	Howard S. Hochster, MD	2/3/2009	2/27/2009	5/18/2009	2/22/2010	***10/8/2010 (Temporarily closed to Accrual)***	***35***	*N/A*
ECOG_E1208	**3**	**APPROVED; Pending with Revisions**	A Phase III Randomized Trial of Chemoembolization with or without Sorafenib in Unresectable Hepatocellular Carcinoma (HCC) in Patients with and without Vascular Invasion.	John Kauh, MD	5/27/2008; 6/9/2008 (rev); 9/8/2007 (rev)	6/16/2008	9/15/2008	10/5/2009	***10/28/2009***	***158***	*N/A*
NCCTG_N0949	**3**	**APPROVED; Pending with Revisions**	Randomized Phase III Trial of mFOLFOX7 Plus Bevacizumab Versus 5-Fluorouracil or Capecitabine Plus Bevacizumab as First-line Treatment in Elderly Patients (≥75Years Old) with Metastatic Colorectal Cancer	Alex Grothey, MD	3/29/2010	4/19/2010	6/21/2010	12/23/2010	***01/21/2011 [Closed to Accrual]***	***30***	*N/A*

Cooperative Group/ Document Number	Phase	Status	Document Name	Principal Investigator	Date Received in PIO (for SC evaluation)	Date Original Reviewed in SC	Date of Re-Review in SC (if applicable)	Date Protocol Approved by NCI	*Date Protocol Open to Accural*	*Accural Total as of 5/31/13*	*BIQSFP Assay/ Test/ Tool*
ECOG_E2211	**2**	**APPROVED; Pending with Revisions**	A Randomized Study of Temozolomide or Temozolomide + Capecitabine in Patients with Advanced Pancreatic Neuroendocrine Tumors	Pamela L. Kunz, MD	2/28/2012	3/19/2012	5/21/2012	In Review 7/27/2012	***5/2/2013***	*1/1/1904*	*N/A*
NCCTG N1048/ CALGB 81001/ ACOSOG Z6092	**2&3**	**APPROVED; Pending with Revisions**	A Phase II/III trial of Neoadjuvant FOLFOX, with Selective Use of Combined Modality Chemoradiation versus Preoperative Combined Modality Chemoradiation for Locally Advanced Rectal Cancer Patients Undergoing Low Anterior Resection with Total Mesorectal Excision	Deborah Schrag MD (CALGB) , Alessandro Fichera (ACOSOG) Robert McWilliams Mayo Clinic (NCCTG)	1/20/2011	2/28/2011	4/4/2011	10/14/2011	***1/13/2012***	***37***	*N/A*
NSABP-C-11 (8358)	**3**	**APPROVED; Pending with Revisions**	Phase III Trial Evaluating the Role of Perioperative Chemotherapy and Bevacizumab in Patients with Potentially Resectable Hepatic Colorectal Metastases	Michael Choti, MD	12/22/2008; 04/13/09 (rev)	1/26/2009	4/20/2009	7/29/2010	***8/23/2010 [Administratively Complete)***	***8***	*N/A*
RTOG-0436	**3**	**APPROVED; Pending with Revisions**	A Phase III Trial Evaluating the Addition of Cetuximab to Paclitaxel, Cisplatin and Radiation for Patients with Locally Advanced Esophageal Cancer	Mohan Suntharalingam, MD	09/20/06 (rev); 12/12/06 (rev2)	10/16/2006	12/18/2006	10/27/2007; 12/11/2007	***6/30/2008 [Closed to Accrual]***	***344***	*N/A*
RTOG-0848	**3**	**APPROVED; Pending with Revisions**	Gemcitabine, With and Without Erlotinib, Followed By a Second Randomization With and Without Chemoradiation, as Adjuvant Treatment For Pancreatic Head Cancer: A Phase III RTOG/SWOG/NCIC/EORTC Study	Ross Abrams, MD	8/8/2008; 11/10/2008	8/18/2008	11/17/2008	10/23/2009	***11/17/2009***	***264***	*N/A*
RTOG-1010	**3**	**APPROVED; Pending with Revisions**	A Phase III Trial Evaluating the Addition of Trastuzumab to Trimodality Treatment of HER2 Overexpressing Esophageal Adenocarcinoma (w/ BIQSFP)	Howard Safran, MD	09/25/2009; 10/23/2009 (rev)	11/16/2009	1/11/2010	8/11/2010	***12/30/2010***	***286***	***HER2***
RTOG-1112	**2&3**	**APPROVED; Pending with Revisions**	Randomized Phase II/III Study of Sorafenib versus Sorafenib and Stereotactic Body Radiation Therapy in Hepatocellular Carcinoma	Laura A. Dawson, MD	7/25/2011; 10/07/2011 (rev)	8/15/2011	10/17/2011	In Review 5/25/2012	***4/24/2013***	***0***	*N/A*
SWOG_S1115	**2**	**APPROVED; Pending with Revisions**	Randomized Phase II Clinical Trial of AZD-6244 and MK-2206 vs. mFOLFOX in Patients with Metastatic Pancreatic Cancer after Prior Chemotherapy	Vincent Chung, MD	6/1/2011	7/18/2011	8/15/2011	7/27/2012	***8/15/2012***	***14***	*N/A*
SWOG_S1201	**2**	**APPROVED**	A Randomized Phase II Pilot Study Prospectively Assigning Treatment for Patients Based on ERCC1 for Advanced/Metastatic Gastric Cancer or Gastroesophageal (GE) Junction Cancer (w/ BIQSFP)	Syma Igbal, MD	6/27/2011	8/15/2011	N/A	12/14/2011	***2/8/2012***	***59***	***ERCC-1***
USMCI_8214	**3**	**APPROVED**	A Phase III Trial Comparing Best Available Systemic Therapy to Cytoreduction + Hyperthermic Intraperitoneal Mitomycin-C + Best Available Systemic Therapy in Patients with Limited Peritoneal Dissemination of Colon Adenocarcinoma	Alex Stojadinovic, MD, Jesus Esquivel, MD	12/5/2007	12/17/2007	N/A	7/7/2010	***8/23/2010 [Closed to Accrual)***	***1***	*N/A*
RTOG-1201	**2**	**APPROVED; Pending with Revisions**	A SMAD4-driven Phase II Randomized Trial of High Versus Standard Intensity Local or Systemic Therapy for Unresectable Pancreatic Cancer (w/ BIQSFP)	Edgar Ben-Josef, MD	5/25/2012; 8/29/2012	6/18/2012	9/24/2012				***SMAD-4***

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ECOG_E1212	**2**	**APPROVED**	Randomized Phase II Study of mFOLFOX6 +/- Tivantinib (ARQ 197) in the First Line Treatment of Patients with Her2Neu Negative and High c-Met Expressing Advanced Gastric and Gastroesophageal Junction (GEJ) Adenocarcinoma	Lakshmi Rajdev M.D., M.S	6/26/2012	7/16/2012	N/A				*N/A*
ECOG_E2212	**2**	**APPROVED; Pending with Revisions**	A Randomized, Double-Blinded, Placebo-Controlled Phase II Study of Adjuvant Everolimus Following the Resection of Metastatic Pancreatic Neuroendocrine Tumors to the Liver	Steven K. Libutti, MD, FACS	9/24/2012; 12/10/2012	10/15/2012	12/21/2012				*N/A*
SWOG_S1313	**2**	**APPROVED**	A Phase Ib/II Randomized Study of Modified FOLFIRINOX + Pegylated Recombinant Human Hyaluronidase (PEGPH20) versus Modified FOLFIRINOX Alone in Patients with Good Performance Status Metastatic Pancreatic Adenocarcinoma	Ramesh K. Ramanathan, MD	1/25/2013	2/25/2013	N/A				*N/A*
Genitourinary Steering Committee (GUSC)											
CALGB-90802	**3**	**APPROVED**	Randomized Phase III Trial Comparing Everolimus Plus Placebo versus Everolimus Plus Bevacizumab for Advanced Renal Cell Carcinoma Progressing After Treatment with Tyrosine Kinase Inhibitors.	George K. Philips, MD	7/21/2008	9/17/2008	N/A	8/19/2010	***9/15/2010 [Closed to Accrual]***	***75***	*N/A*
ECOG_E2810	**3**	**APPROVED; Pending with Revisions**	Randomized, double-blind phase III study of pazopanib vs. placebo in subjects with metastatic renal cell carcinoma who have no evidence of disease following metastasectomy	Leonard J. Appleman, MD, PhD	3/30/2011; 6/8/2011 (rev)	4/20/2011	7/20/2011	3/19/2012	***8/8/2012***	***4***	*N/A*
CALGB_90901	**3**	**WITHDRAWN; Approved**	A Randomized Phase III Study of ixabepilone, mitoxantrone and prednisone versus mitoxantron and prednisone alone in patients with castration resistant prostrate cancer previously treated with docetaxel chemotherapy.	Charles Ryan, MD	4/1/2009	6/17/2009	8/19/2009	No protocol rec'd	***WD***	***N/A***	*N/A*
RTOG 0815	**3**	**APPROVED; Pending with Revisions**	A Phase III Prospective Randomized Trial of Dose-Escalated Radiotherapy With or Without Short-Term Androgen Deprivation Therapy for Patients With Intermediate-Risk Prostate Cancer	Alvaro A. Martinez, MD	7/11/08 11/7/08	8/20/2008	11/19/2008	6/18/2009	***9/14/2009***	***913***	*N/A*
RTOG-0924	**3**	**APPROVED; Pending with Revisions**	Androgen Deprivation Therapy and High Dose Radiotherapy With or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial	Mack Roach III, MD	6/2/2010; 10/14/2010 (rev)	7/21/2010	10/20/2010	5/24/2010	***7/7/2011***	***341***	*N/A*
RTOG-1115	**3**	**APPROVED**	Phase III Trial of Dose Escalated Radiation Therapy and Standard Androgen Deprivation Therapy (ADT) with a GnRH Agonist vs. Dose Escalated Radiation Therapy and Enhanced ADT with a GnRH Agonist and TAK-700	M. Dror Michaelson, MD	2/14/2011	5/4/2011	N/A	2/28/2012	***5/1/2012***	***50***	*N/A*
SWOG_S0931	**3**	**APPROVED**	**EVEREST**: EVErolimus for Renal Cancer Ensuing Surgical Therapy, A Phase III Study	Christopher Ryan, MD	4/3/2009	5/20/2009	N/A	3/15/2010	***4/1/2011***	***413***	*N/A*
SWOG_S1011	**3**	**APPROVED**	Prospective Evaluation Of The Benefit Of A Standard Versus An Extended Pelvic Lymphadenectomy Performed At Time Of Radical Cystectomy For Bladder Cancer With Adjuvant Chemotherapy Administration For Node Positive Disease	Seth Paul Lerner, MD	3/31/2010	4/21/2010	N/A	09/30/2010; 01/07/2011 (rev)	***8/1/2011***	***173***	*N/A*
SWOG_S1216	**3**	**APPROVED**	A Phase III Randomized Trial Comparing LHRHa + TAK-700 with LHRHa + Bicalutamide in Patients with Newly Diagnosed Metastatic Hormone Sensitive Prostate Cancer	Neeraj Agarwal, MD	3/1/2012	3/21/2012	N/A		***3/6/2013***	***9***	*N/A*

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ALLIANCE_ A031201	**3**	**APPROVED (with recommendations)**	A Phase III Trial of MDV3100 vs. MDV3100 and Abiraterone and Prednisone for Castration Resistant Metastatic Prostate Cancer (w/ BIQSFP)	Michael J. Morris	6/26/2012	7/18/2012	N/A				***PET/CT***
RTOG-1218	**2**	**APPROVED; Pending with Revisions**	Conventional versus Hypofractionated Postprostatectomy Radiotherapy for Adverse Pathologic Features or PSA Recurrence	Mark K. Buyyounouski, MD., MS	11/26/2012; 02/13/2013	12/19/2012	3/20/2013				*N/A*
SWOG_S1314	**2**	**APPROVED**	A Randomized Phase II Study of CO-eXpression ExtrapolatioN (COXEN)-Directed Neoadjuvant Chemotherapy for Localized, Muscle-Invasive Bladder Cancer (w/BIQSFP)	Thomas W. Flaig, MD	2/27/2013	3/20/2013	N/A				*COXEN-Co-eXpression ExtrapolatioN & Whole - Genome DASL HT*
Head & Neck Steering Committee (HNSC)											
ACRIN_6685 (#8270)	**2**	**APPROVED; Pending with Revisions**	FDG PET/CT Staging of Head and Neck Cancer and its Impact on the N0 Neck	Val Lowe, MD	4/30/2008	11/3/2008	2/23/2009	9/2/2009	***4/1/2010***	***167***	*N/A*
ECOG_E1311	**2**	**APPROVED; Pending with Revisions**	A Randomized Phase II Trial of Afatinib (BIBW2992) as Adjuvant Therapy Following Chemoradiation in Patients with Head and Neck Squamous Cell Carcinoma at High Risk of Recurrence	Christine H. Chung, MD	3/12/2012	4/9/2012	8/6/2012				*N/A*
RTOG-1008	**2**	**APPROVED**	A Randomized Phase II Study of Adjuvant Concurrent Chemotherapy and Radiation in Resected High-Risk Malignant Salivary Gland Tumors	Cristina P. Rodriguez, MD; David Adelstein, MD	2/1/2010	5/3/2010	N/A	9/17/2010	***11/3/2010***	***61***	*N/A*
RTOG-0920	**3**	**APPROVED**	Phase III Randomized Study of Adjuvant Intensity-Modulated Radiotherapy With Versus Without Cetuximab in Patients With Locally Advanced Resected Squamous Cell Carcinoma of the Head and Neck	Mitchell Machtay, MD	1/9/2008; 5/8/2008	2/1/2008	5/5/08; 8/4/08	7/22/2009	***11/5/2009***	***281***	*N/A*
RTOG-1016	**2&3**	**APPROVED; Pending with Revisions**	Phase II-III Trial of Moderate De-Escalation of Chemotherapy and Radiation in Favorable Risk, Locally Advanced, HPV-Associated Oropharynx Cancer (w/ BIQSFP)	Andy Trotti, MD	3/22/2010	4/12/2010	7/12/2010	2/15/2011	***6/9/2011***	***613***	***p16***
RTOG-1216	**2&3**	**APPROVED**	Randomized Phase II/III Trial of Surgery and Postoperative Radiation Delivered with Concurrent Cisplatin Versus Docetaxel Versus Cetuximab and Docetaxel for High-Risk Squamous Cell Cancer of the Head and Neck (w/ BIQSFP)	Paul Harari, MD; David Rosenthal	4/16/2012	5/23/2012	N/A		***3/18/2013***	***1***	***p16 + EGFR***
ECOG_E3311	**2**	**APPROVED; Pending with Revisions**	Phase II Randomized Trial of Transoral Surgical Resection Followed by Low-Dose or Standard-Dose IMRT with Biomarker Correlatives in Resectable p16+ Locally Advanced Oropharynx Cancer	Robert L. Ferris, MD, PhD	5/15/2012; 9/24/2012	6/25/2012	10/22/2012				*N/A*
RTOG-1221	**2**	**APPROVED**	Randomized Phase II Trial of Transoral Endoscopic Head and Neck Surgery Followed by Risk-Based IMRT and Weekly Cisplatin Versus IMRT and Weekly Cisplatin for HPV Negative Oropharynx Cancer (w/ BIQSFP)	Floyd Christopher Holsinger, MD, FACS	8/20/2012	9/24/2012	N/A				***MBS***
RTOG-1305	**2&3**	**APPROVED**	Randomized Phase II and Phase III Studies of Individualized Treatment for Nasopharyngeal Carcinoma Based on Biomarker Epstein Barr Virus (EBV) Deoxyribonucleic Acid (DNA)	Nancy Lee, MD	3/11/2013	4/1/2013	N/A				*N/A*

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Leukemia Steering Committee (LKSC)											
CALGB-11002	**2**	**APPROVED**	A Randomized Phase II Trial of Decitabine-based Induction Strategies for Patients ≥ 60 Years Old with Acute Myeloid Leukemia	Gail J. Roboz, MD	6/24/2010; 9/20/2010 (Rev)	7/27/2010	9/28/2010	8/15/2011	***11/16/2011 [Closed to Accrual]***	***126***	*N/A*
SWOG_S1203	**3**	**APPROVED; Pending with Revisions**	A Randomized Phase III Study of Standard Cytarabine Plus Daunomycin (7+3) Therapy Versus Idarubicin with High Dose Cytarabine (IA) with or Without Vorinostat in Younger Patients with Previously Untreated Acute Myeloid Leukemia (AML) (w/ BIQSFP)	Guillermo Garcia-Manero, MD	3/7/2012; 5/2/2012	3/27/2012	5/22/2012		***2/12/2013***	***12***	***FISH and Cytogenetics for t(8;21), inv (16)/t(16;16), and t(15;17)***
SWOG_S1117	**2**	**APPROVED**	A Randomized Phase II Study of Azacitidine in Combination with Lenalidomide vs. Azacitidine in Combination with Vorinostat vs. Azacitidine Alone for Higher-Risk Myelodysplastic Syndromes (MDS)	Mikkael A. Sekeres, MD	6/8/2011	6/28/2011	N/A	1/20/2012	***3/1/2012***	***93***	*N/A*
ECOG_E1912	**2&3**	**APPROVED**	A Randomized Phase II/III Study of PCI-32765 Based-Therapy Versus Standard Fludarabine, Cyclophosphamide, and Rituximab (FCR) Chemoimmunotherapy in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL)	Tait Shanafelt, MD	4/3/2012	4/24/2012	N/A	In Review 8/6/2012			*N/A*
ALLIANCE_ A041202	**3**	**APPROVED**	A Randomized Phase III Study of Chlorambucil Plus Rituximab Versus Ibrutinib Plus Rituximab Versus Ibrutinib Alone in Untreated Older Patients with Chronic Lymphocytic Leukemia (CLL)	Jennifer Woyach, MD	5/29/2012	6/26/2012	N/A				*N/A*
ECOG_E1910	**3**	**APPROVED**	A Phase III Randomized Trial of Blinatumomab for Newly Diagnosed BCR-ABL Negative B Acute Lymphoblastic Leukemia in Adults (w/ BIQSFP)	Mark R. Litzow, MD	6/5/2012	6/26/2012	N/A				***PET/CT***
Lymphoma Steering Committee (LYSC)											
CALGB-51101	**2**	**APPROVED**	Randomized trial of myeloablative versus non-myeloablative consolidation chemotherapy for newly diagnosed primary CNS B-cell lymphoma	Tracey Batchelor, MD	5/23/2011	7/8/2011	N/A	12/27/2011	***6/15/2012***	***3***	*N/A*
ECOG_E2410	**2**	**APPROVED**	Phase II Trial of Response-Adapted Therapy Based on Positron Emission Tomography (PET) for Bulky Stage I and II Classical Hodgkin Lymphoma (HL)	Ranjana Advani, MD	1/21/2011	2/11/2011	N/A	6/21/2011	***4/2/2012***	***0***	*N/A*
E1411 [formerly ECOG E1410]	**2**	**APPROVED**	Intergroup Randomized Phase 2 Four Arm Study In Patients ≥ 60 With Previously Untreated Mantle Cell Lymphoma Of Therapy With: Arm A = Rituximab+ Bendamustine Followed By Rituximab Consolidation (RB → R); Arm B = Rituximab + Bendamustine + Bortezomib Followed By Rituximab Consolidation (RBV→ R), Arm C = Rituximab + Bendamustine Followed By Lenalidomide + Rituximab Consolidation (RB → LR) or Arm D = Rituximab + Bendamustine + Bortezomib Followed By Lenalidomide + Rituximab Consolidation (RBV → LR)	Mitchell Smith, MD, PhD	2/18/2011	3/11/2011	N/A	7/29/2011	***5/22/2012***	***27***	*N/A*

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ECOG_1410	2	WITHDRAWN; Approved	Intergroup Randomized Phase 2 Three-Arm Study In Patients ≥ 60 With Previously Untreated Mantle Cell Lymphoma Of Therapy With: Arm A = Rituximab+ Bendamustine (R – B), Arm B = Rituximab + Bendamustine + Bortezomib (R - B – V), or Arm C = Rituximab + Bendamustine Followed By Lenalidomide + Rituximab Consolidation (R - B → L – R)	Mitchell Smith, MD, PhD	9/1/2010	10/8/2010	N/A	N/A	***WD***	***N/A***	*N/A*
SWOG_S1001	2	APPROVED; Pending with Revisions	A Phase II Trial of PET-directed Therapy for Early Stage Diffuse Large B-cell Lymphoma	Daniel O. Persky, MD	10/6/2010; 01/24/2011	12/10/2010	2/11/2011	5/16/2011	***7/18/2011***	***40***	*N/A*
SWOG_S1106	2	APPROVED	A Randomized Phase II Trial of R-HCVAD-MTX/ARA-C Induction Followed by Consolidation With an Autologous Stem Cell Transplant vs. R-Bendamustine Induction Followed by Consolidation With an Autologous Stem Cell Transplant for Previously Untreated Patients </= 65 Years of Age With Mantle Cell Lymphoma	Steven H. Bernstein, MD	1/28/2011	3/11/2011	N/A	7/29/2011	***10/1/2011***	***43***	*N/A*
ECOG_E1412	2	APPROVED; Pending with Revisions	Randomized Phase II Study of Lenalidomide R-CHOP (R2CHOP) vs RCHOP (Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone) in Patients with Newly Diagnosed Diffuse Large B Cell Lymphoma	Grzegorz S. Nowakowski MD	5/18/2012; 7/6/2012	6/8/2012	8/10/2012				*N/A*
Myeloma Steering Committee (MYSC)											
ECOG_E1A10	2	APPROVED; Pending with Revisions	A Randomized Selection Phase II Study of Rituximab, Bortezomib, and Dexamethasone and Rituximab, RAD001, and Dexamethasone in Previously Untreated, Symptomatic Waldenstrom's Macroglobulinemia	Leonard T. Heffner, Jr.	5/13/2010; 5/28/2010	7/6/2010	9/7/2010	5/27/2011	***7/20/2011***	***3***	*N/A*
ECOG_E1A11	3	APPROVED; Pending with Revisions	Randomized Phase 3 Trial of Bortezomib, Lenalidomide and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide, Dexamethasone (CRd) in Patients with Newly Diagnosed Symptomatic Multiple Myeloma	Shaji Kumar, MD	1/19/2012; 4/24/2012	3/6/2012	5/1/2012	In Review 7/31/2012			*N/A*
SWOG_S1304	2	APPROVED	A Phase II Randomized Study Comparing Two Doses of Carfilzomib (NSC-XXXX) with Dexamethasone for Multiple Myeloma Patients with Relapsed or Refractory Disease	Sikander Ailawadhi, MD	9/11/2012	10/2/2012	N/A				*N/A*
ALLIANCE_A061202	1&2	APPROVED; Pending with Revisions	A Phase 1/2 study of Pomalidomide, Dexamethasone and MLN9708 vs. Pomalidomide and Dexamethasone for Patients with Relapsed and Relapsed/Refractory Multiple Myeloma Previously Treated with Proteasome Inhibitor-Based Therapy and Resistant to or Intolerant of Lenalidomide	Peter Voorhees, MD	9/13/2012; 12/07/2012	11/6/2012	1/8/2013				*N/A*
Pediatric & Adolescent Solid Tumor Steering Committee (PASTSC)											
COG_ADVL1122	2	APPROVED	A Phase II Trial of Pazopanib (NSC# 737754, IND# 75648) in Children with Refractory Solid Tumors	Alice Lee, MD	8/19/2011	9/26/2011	N/A				*N/A*
COG_ANBL1221	2	APPROVED	Phase II Randomized Trial of Irinotecan/Temozolomide with Temsirolimus or Chimeric 14.18 Antibody (ch14.18) in Children with Relapsed/Refractory Neuroblastoma	Rajen Mody, MD, MS	1/5/2012	1/23/2012	N/A	In Review 5/18/2012	***2/12/2013***	***2***	*N/A*
COG_ANBL12P1	obs	APPROVED	Pilot Study Using Myeloablative Busulfan/Melphalan (BuMel) Consolidation Following Induction Chemotherapy for Patients with Newly Diagnosed High-Risk Neuroblastoma	Meaghan Granger, MD	2/1/2012	2/27/2012	N/A	In Review 5/04/2012	***4/8/2013***	***0***	*N/A*
COG_ANBL1122	2	WITHDRAWN; Approved	Phase II Randomized Trial of Irinotecan/Temozolomide with Temsirolimus or Bevacizumab (Avastin) in Children with Relapsed Neuroblastoma	Rajen Mody, MD, MS	6/29/2011	7/25/2011	N/A	N/A	***WD***	***N/A***	*N/A*

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COG_ARST1221	**2**	**APPROVED; Pending with Revisions**	A Feasibility Study of Ifosfamide and Doxorubicin (ID) and Radiotherapy with or without Pazopanib in Patients with Newly Diagnosed Unresected Intermediate- or High-Risk Non-Rhabdomyosarcoma Soft Tissue Sarcoma (NRSTS)	Aaron Weiss, DO	1/3/2012; 5/21/2012	1/23/2012	5/29/2012				*N/A*
COG_AEWS1221	**2**	**APPROVED**	Randomized Phase II Selection Trial Evaluating the Addition of the IGF-1R Monoclonal Antibody AMG 479 to Multiagent Chemotherapy for Patients with Newly Diagnosed Metastatic Ewing Sarcoma	Steven DuBois, MD	3/5/2012	4/9/2012	N/A				*N/A*
COG_ANBL1232	**3**	**APPROVED; Pending with Revisions**	Response- and Biology-Based Therapy for Patients with Non-High-Risk Neuroblastoma (w/ BIQSFP)	Holly Meany, MD	1/7/2013; 4/8/2013	2/6/2013	4/22/2013				***MYCN FISH, DNA FLOW, SNP array, central path review***
COG_ARET12P1	**2**	**APPROVED; Pending with Revisions**	A Multi-institutional Feasibility Study of Intra-Arterial Chemotherapy Given in the Ophthalmic Artery of Children with Retinoblastoma	Murali Chintagumpala, MD	2/1/2013; 5/21/2013	2/25/2013	5/30/2013				*N/A*
COG_ADVL1321	**2**	**APPROVED**	A Phase II Trial of Imetelstat (GRN163L, NSC# 754228, IND# 110934) in Children with Refractory Solid Tumors	Patrick A. Thompson, MD	2/4/2013	2/25/2013					*N/A*
Pediatric Leukemia & Lymphoma Steering Committee (PLLSC)											
COG_ANHL1131	**2&3**	**APPROVED; Pending with Revisions**	Intergroup Trial for Children or Adolescents with B-cell Non-Hodgkin Lymphoma (NHL) or Mature B-cell Leukemia (B- AL): Evaluation of Rituximab Efficacy and Safety in High Risk Patients.	Thomas G. Gross, MD, Ph.D	4/29/2011; 7/22/2011	6/3/2011	8/5/2011	4/24/2012	***6/11/2012***	***17***	*N/A*
COG_ASCT1221	**2**	**APPROVED; Pending with Revisions**	A Randomized Phase II Study Comparing Two Different Conditioning Regimens Prior to Allogeneic Hematopoietic Cell Transplantation (HCT) for Children with Juvenile Myelomonocytic Leukemia (JMML) (w/ BIQSFP)	Adam Peterson, MD	1/17/2012; 3/30/2012	2/3/2012	4/6/2012	In Review 6/27/2012			***DNA sequencing***
COG_ANHL12P1	**2**	**APPROVED; Pending with Revisions**	A Pilot Study of Brentuximab Vedotin (NSC# 749710, IND pending) and Crizotinib (NSC#749005, IND pending) in Patients with Newly Diagnosed Anaplastic Large Cell Lymphoma (ALCL)	Eric Lowe, MD	7/13/2012; 9/28/2012	8/3/2012	10/5/2012				*N/A*
Symptom Management & Quality of Life Steering Committee (SxQOLSC)											
GOG 0257	**3**	**APPROVED; Revise & Resubmit**	A Randomized, Double-Blind, Placebo Controlled Trial Using Acetyl L-Carnitine (ALCAR) for the Prevention of Chemotherapy-Induced Peripheral Neuropathy in Patients with Recurrent Ovarian, Primary Pertitoneal or Fallopian Tube Cancer	David Kushner, MD	9/26/2008	11/18/2008	4/14/2009	12/6/2011	***4/16/2012***	***0***	*N/A*
HLMCC-0806 SCUSF-0806	**2**	**APPROVED; Revise & Resubmit**	Phase II Placebo-controlled Trial of Lisinopril and Coreg CR to Reduce Cardiotoxicity in Patients with Breast Cancer Recieving (neo)Adjuvant Chemotherapy with Trastuzumab (Herceptin)	Maya Guglin, MD	8/25/2008	10/14/2008	1/13/2009	8/31/2009	***3/1/2010***	***279***	*N/A*
NCCTG_N08C3	**3**	**APPROVED**	Phase III Double-Blind, Placebo Controlled Study of Gabapentin for the Treatment of Delayed CINV (Chemotherapy Induced Nausea and Vomiting) in Patients Receiving Highly or Moderately Emetogenic Chemotherapy	Deborah Barton, RN, PhD	2/12/2008	3/11/2008	N/A	1/28/2009	***4/17/2009 [Closed to Accrual]***	***430***	*N/A*

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NCCTG_N08C7	**3**	**APPROVED**	Phase III, Randomized, Placebo-controlled, Double-Blind Trial of Flaxseed for the Treatment of Hot Flashes	Deborah Barton, RN, PhD	5/14/2008	6/10/2008	N/A	5/27/2009	***10/9/2009 [Closed to Accrual & Treatment)***	***210***	*N/A*
NCCTG-N08CB	**3**	**APPROVED; Revise & Resubmit**	A Phase III Randomized, Placebo-Controlled, Double-Blind Study of Intravenous Calcium/Magnesium in Two Different Versions to Prevent Oxaliplatin-Induced Sensory Neurotoxicity	Charles Loprinzi, MD	9/12/2008	10/14/2008	1/13/2009	3/29/2010	***6/22/2010 [Closed to Accrual]***	***362***	*N/A*
NCCTG_N09C6	**3**	**APPROVED; Revise & Resubmit**	Phase III Double-Blind Cross-over Study of Doxepin Rinse versus Placebo in the Treatment of Acute Oral Mucositis Pain in Patients Receiving Radiotherapy and/or Chemotherapy	James L. Leenstra MD; Robert C. Miller, MD	7/24/2009	9/8/2009	12/8/2009	6/9/2010	***12/17/2010***	***162***	*N/A*
NCCTG_N10C1	**3**	**APPROVED**	Vaginal DHEA for Vaginal Dryness: A Phase III Randomized, Double Blind, Placebo-Controlled Study	Debra Barton MD	5/7/2010	5/11/2010	N/A	5/18/2011	***7/29/2011 [Closed to Accrual]***	***464***	*N/A*
NCCTG_N10C2	**3**	**APPROVED; Revise & Resubmit**	Phase III Double-Blind, Placebo-Controlled Study of Magnesium Supplements to Reduce Menopausal Hot Flashes	Haeseong Park, MD, MPH	8/12/2010; 3/3/2011 (rev 1)	9/14/2010	3/8/2011	9/1/2011	***9/30/2011 [Closed to Accrual]***	***289***	*N/A*
NCCTG_N10CB	**3**	**APPROVED; Revise & Resubmit**	A Phase III, Randomized, Double-Blind Placebo Controlled Study of the Probiotic Preparation VSL#3® versus Placebo in the Prevention of Acute Radiation Enteritis in Patients Receiving Abdominal and/or Pelvic Radiation Therapy	Robert C. Miller MD & Christopher L. Hallemeier, MD	12/20/2011; 3/16/2011 (rev)	1/11/2011	4/12/2011	10/31/2011			*N/A*
NCCTG_N10C3-A	**3**	**APPROVED; Revise & Resubmit**	The Use of Armodafinil (Nuvigil) To Reduce Severe Cancer-Related Fatigue in Patients with Glioblastoma Multiforme: A Randomized, Novel Adaptive Design Study.	Charles Loprinzi, MD	4/29/2011; 8/26/2011	6/14/2011	10/11/2011				*N/A*
NCCTG_N11C5	**3**	**APPROVED**	Phase III, Randomized, Double-Blind Study of Lactobacillus brevis CD2 Lozenges versus Placebo in the Prevention of Acute Oral Mucositis in Patients with Head and Neck Cancer Receiving Concurrent Radiotherapy and Chemotherapy	Charles Loprinzi, MD	8/31/2011	10/11/2011	N/A	2/27/2012			*N/A*
NCCTG_N10C7	**2&3**	**APPROVED; Revise & Resubmit**	A Randomized Double-blind Placebo Controlled, Phase II/III, Study of Aromatase Inhibitors and Transdermal Testosterone in the Adjuvant Treatment of Postmenopausal Women with Aromatase Inhibitor Induced Arthralgiass	Stephen Birrell, MD, PhD	1/14/2011; 06/13/2011	3/8/2011	7/12/2011	3/29/2012			*N/A*
RTOG-1012	**2**	**APPROVED**	Phase II Randomized Dose Seeking Trial of the Prophylactic Use of Manuka Honey for the Reduction of Chemoradiation Therapy Induced Esophagitis During the Treatment of Lung Cancer	Lawrence B. Berk, MD	10/20/2009	12/8/2009	N/A	11/23/2010	***2/28/2012 [Temporarily closed to Accrual]***	***27***	*N/A*
RTOG 0938	**2**	**APPROVED; Revise & Resubmit**	A Randomized Phase II Trial of Hypofractionated Radiotherapy for Favorable Risk Prostate Cancer	Jean-Paul Bahary, MD	3/8/2010; 8/18/2010 (rev)	4/20/2010	9/14/2010	11/23/2010	***9/29/2011***	***102***	*N/A*
RTOG-1203	**2**	**APPROVED; Revise & Resubmit**	A Randomized Phase II Study of Three-Dimensional vs. IMRT Pelvic Radiation for Endometrieal and Cervial Cancer (TIME-C)	Ann Klopp, MD, PhD	8/18/2011; 11/28/2011	10/11/2011	1/24/2012	2/28/2012	***11/28/2012***	***7***	*N/A*
SWOG_S0927	**2**	**APPROVED; Revise & Resubmit**	Randomized Placebo-Controlled Trial of Omega-3-Fatty Acid for the Control of Aromatase Inhibitor-Induced Musculoskeletal Pain in Women with Early Stage Breast Cancer	Dawn Hershman, MD, MS	4/3/2009	5/12/2009	11/10/2009	10/4/2010	***2/1/2012***	***262***	*N/A*

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SWOG_S1202	**3**	**APPROVED**	Phase III Study of Duloxetine for Treatment of Aromatase Inhibitor-Associated Musculoskeletal Symptoms in Women with Early Stage Breast Cancer	Norah L. Henry, MD, PhD	11/1/2011	12/13/2011	N/A	4/10/2012			*N/A*
URCC-09005 (URCC-10054)	**2**	**APPROVED; Revise & Resubmit**	Curcumin for the Prevention of Radiation-Induced Dermatitis in Breast Cancer Patients	Julie Ryan, PhD, MPH	2/19/2009	4/14/2009	12/8/2009	10/25/2010	***10/25/2010***	***695***	*N/A*
WFU-08-03-06	**2**	**APPROVED; Revise & Resubmit**	Phase II Randomized Placebo Controlled Study of Armodafinil on Fatigue in Brain Tumor Patients Receiving Brain Radiation Therapy	Edward G. Shaw, MD	3/12/2008	4/8/2008	7/8/2008	12/3/2009	***8/5/2010 [Closed to Accrual &Treament]***	***54***	*N/A*
WFU-08-08-08	**2**	**APPROVED; Revise & Resubmit**	Yoga during Breast Cancer Treatment: Establishing Community-Based Partnerships	Suzanne Danhauer, PhD	8/18/2008	9/9/2008	1/13/2009	6/22/2009	***10/21/2009 [Closed to Accrual)***	***40***	*N/A*
WFU-08-08-09	**2**	**APPROVED; Revise & Resubmit**	A Randomized Phase II Dose Finding Study of ArginMax with or without Phosphodiesterase-5 Inhibitors for Its Effect on Erectile Function and Quality of Life in Survivors of Prostate Cancer Previously Treated with Radiotherapy	James Urbanic, MD	8/14/2008	9/9/2008	2/10/2009	3/26/2010	***10/18/2010***	***123***	*N/A*
WFU 10-05-16	**2**	**APPROVED**	A Feasibility Study of Donepezil in Breast Cancer Survivors with Chemotherapy-Related Self-Reported Cognitive Dysfunction	Julia Lawrence, DO	5/12/2010	8/10/2010	N/A	10/18/2011	***6/6/2012***	***62***	*N/A*
URCC-12048	**2**	**APPROVED; Revise & Resubmit**	Feasibility, Acceptability and Mechanisms of Brief Behavioral Therapy (BBT) for Sleep Problems During Chemotherapy: A Phase II Randomized Controlled Trial (response to URCC 12021)	Oxana Palesh, PhD., MPH	??; 9/19/2012	7/24/2012	10/23/2012				*N/A*
ALLIANCE_A221 301		**APPROVED**	Olanzapine for the Prevention of Chemotherapy Induced Nausea and Vomiting (CINV) in Patients Receiving Highly Emetogenic Chemotherapy (HEC)	Rudolph M. Navari	3/22/2013	4/23/2013	N/A				*N/A*
Thoracic Malignancy Steering Committee (TMSC)											
ACOSOG Z41102 (A081105)	**3**	**APPROVED**	Personalized Adjuvant Therapy In Patients With Completely Resected Non-small Cell Lung Cancer (NSCLC)	Ramaswamy Govindan, MD	3/29/2011	5/5/2011	N/A	In Review 5/3/2012		***0***	*N/A*
ECOG_E2511	**2**	**APPROVED; Pending with Revisions**	Phase II Randomized Double Blind Clinical Trial of Cisplatin and Etoposide in Combination with Veliparib (ABT-888) or Placebo as Frontline Therapy for Extensive Stage Small Cell Lung Cancer	Taofeek K. Owonikoko, MD, PhD	7/20/2011; 10/17/2011 (rev)	8/18/2011	11/10/2011	7/6/2012	***9/28/2012***	***3***	*N/A*
RTOG-1106	**2**	**APPROVED; Pending with Revisions**	Randomized Phase II Trial of Individualized Adaptive Radiation Using During-Treatment FDG-PET/CT and Modern Radiation Technology to Dose Escalate in Locally Advanced Non-Small Cell Lung Cancer (NSCLC)	Feng Ming (Spring) Kong, MD, PhD	1/4/2011; 4/14/2011 (rev1);	2/17/2011	5/5/2011	In Review 07/08/2011	***2/22/2012***	***10***	*N/A*
RTOG 1021 (formerly ACOSOG Z4099)	**3**	**APPROVED**	A Randomized Phase III Study of Sublobar Resection versus Stereotactic Body Radiation Therapy in High Risk Patients with Stage I Non-Small Cell Lung Cancer (NSCLC)	Hiran C. Fernando, MD (ACOSOG); and Robert Timmerman, MD (RTOG)	2/22/2010	3/18/2010	N/A	4/11/2011	***5/2/2011 [Closed to Accrual]***	***12***	*N/A*
RTOG 0937	**2**	**APPROVED; Pending with Revisions**	Randomized Phase II Study Comparing Prophylactic Cranial Irradiation Alone to Prophylactic Cranial Irradiation and Consolidative Extra-Cranial Irradiation for Extensive Disease Small Cell Lung Cancer (ED-SCLC)	Elizabeth Gore, MD	5/7/2009 7/30/2009	5/21/2009	8/20/2009	1/12/2010	***3/18/2010***	***44***	*N/A*

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RTOG 1306/ Alliance 31101	**2**	**APPROVED**	A Randomized Phase II Study of Individualized Combined Modality Therapy for Stage III Non-small Cell Lung Cancer (NSCLC)	Ramaswamy Govindan, MD (Alliance); Hak Choy, MD	7/18/2012	9/20/2012	N/A				*N/A*
ECOG-E4512	**3**	**APPROVED; Pending with Revisions**	Individualized therapy for surgically resected early stage non-small cell lung cancer: Crizotinib versus placebo for patients with tumors harboring the anaplastic lymphoma kinase (ALK) fusion protein	Suresh S. Ramalingam, MD	9/21/2012; 12/07/2012	10/18/2012	12/20/2012				*N/A*
RTOG-1308	**3**	**APPROVED; Pending with Revisions**	Phase III Randomized Trial Comparing Overall Survival After Photon Versus Proton Radiochemotherapy for Inoperable Stage II-IIIB NSCLC	Zhongxing Liao, MD	10/25/2012; 12/18/2012	11/15/2012	1/17/2013				*N/A*
SWOG-S1300	**2**	**APPROVED; Pending with Revisions**	A Randomized, Phase II Trial of Crizotinib Plus Pemetrexed Versus Pemetrexed Monotherapy in ALK-Positive Non-Squamous NSCLC Patients who have Progressed Systemically after Previous Clinical Benefit from Crizotinib Monotherapy (w/ BIQSFP)	D. Ross Camidge, MD, PhD	11/30/2012 03/04/2013	12/20/2012	3/21/2013				*DNA sequencing ALK kinase, ALK FISH, SNaPshot*