ClinicalTrials.gov Results Database

Results Database Objectives

- Satisfy legal requirements
- Promote objective, standardized reporting
- Facilitate "good reporting practices", including publishing and regulatory guidelines
- Provide structured data entry to ensure complete reporting, efficient quality review, and consistent display of data elements
- Support detailed searches with the use of database structure and other NLM functions

Adapted from Table 2 in *N Engl J Med* 2011;852-860.

Sample Posted Record* and Results Modules

*Adapted from NCT00312208

Docetaxel in Breast Cancer

This study is ongoing, but not recruiting participants.

Sponsor:
Sanofi

Collaborator:
Cancer International Research Group

Information provided by (Responsible Party):
Sanofi

ClinicalTrials.gov Identifier:
NCT00312208

First received: April 5, 2006
Last updated: September 13, 2012
Last verified: September 2012
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: October 29, 2009

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Breast Cancer
Interventions:	Drug: docetaxel, doxorubicin, cyclophosphamide Drug: Docetaxel,doxorubicin, cyclophosphamide

Participant Flow

Overall Study

	Doxorubicin + Cyclophosphamide Followed by Docetaxel (AC → T)	Docetaxel + Doxorubicin and Cyclophosphamide (TAC)
STARTED	1649	1649
COMPLETED	1477	1526
NOT COMPLETED	172	123
Adverse Event	97	61
Protocol Violation	5	3
Death	2	1
Lack of Efficacy	7	4
Lost to Follow-up	3	5
Withdrawal by Subject	53	42
Not Specified	5	7

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Adapted from NCT00312208

Baseline Measures – Default Required

	Doxorubicin + Cyclophosphamide Followed by Docetaxel (AC → T)	Docetaxel + Doxorubicin and Cyclophosphamide (TAC)	Total
Number of Participants [units: participants]	1649	1649	3298
Age, Customized [units: participants]			
>= 65 years	85	83	168
65 to 50 years	784	783	1567
49 to 35 years	689	710	1399
<= 35 years	91	73	164
Age [units: years] Median (Full Range)	50 (22 to 74)	50 (24 to 72)	50 (22 to 74)
Gender [units: participants]			
Female	1649	1649	3298
Male	0	0	0

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Adapted from NCT00312208

Baseline Measures – User-Specified/Study Specific

	Doxorubicin + Cyclophosphamide Followed by Docetaxel (AC → T)	Docetaxel + Doxorubicin and Cyclophosphamide (TAC)	Total
Hormonal Receptor Status [units: participants]			
Positive	1348	1346	2694
Negative	301	303	604
Number of Positive Lymph Nodes [units: participants]			
[0]	0	1	1
[1 to 3]	1010	1005	2015
[4 to 10]	462	456	918
> 10	177	187	364
At least one surgery [units: participants]			
Mastectomy	955	973	1928
Lumpectomy	283	276	559
Quadrantectomy/Segmental	411	400	811

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Adapted from NCT00312208

Primary Outcome Measure

Measure Title	Local, Regional or Metastatic Relapse, or Second Primary Cancer, or Death From Any Cause
Measure Description	The primary event is the local, regional or metastatic relapse or the date of second primary cancer or death from any cause (whichever occurs first). The primary efficacy analysis is performed on the time from randomization to this primary event. The Measured Values table below presents the numbers of patients with the event at the end of the study period.
Time Frame	Median follow-up 65 months

Measured Values

	Doxorubicin + Cyclophosphamide Followed by Docetaxel (AC → T)	Docetaxel + Doxorubicin and Cyclophosphamide (TAC)
Number of Participants Analyzed	1649	1649
Local, Regional or Metastatic Relapse, or Second Primary Cancer, or Death From Any Cause *[units: participants]*	356	352

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Adapted from NCT00312208

Serious Adverse Events

	Doxorubicin + Cyclophosphamide Followed by Docetaxel (AC → T)	Docetaxel + Doxorubicin and Cyclophosphamide (TAC)
Total, serious adverse events # participants affected / at risk	331/1634 (20.26%)	520/1635 (31.80%)
Blood and lymphatic system disorders		
Anemia †1 # participants affected / at risk	3/1634 (0.18%)	5/1635 (0.31%)
Coagulation disorders †1 # participants affected / at risk	1/1634 (0.06%)	0/1635 (0.00%)
Hemorrhage Vaginal †1 # participants affected / at risk	1/1634 (0.06%)	0/1635 (0.00%)
Leukopenia †1 # participants affected / at risk	18/1634 (1.10%)	56/1635 (3.43%)
Lymphadenopathy †1 # participants affected / at risk	0/1634 (0.00%)	1/1635 (0.06%)
Lymphedema †1 # participants affected / at risk	0/1634 (0.00%)	2/1635 (0.12%)

† Events were collected by systematic assessment
1 Term from vocabulary, COSTART

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Adapted from NCT00312208

Certain Agreements

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

☑ **Restriction Description:** If no publication has occurred within 12 months of the completion of the study, the investigator shall have the right to publish/present independently the results of the study. The Investigator shall provide the Sponsor with a copy of any such presentation/publication for comment at least 30 days before any presentation/submission for publication. If requested by the Sponsor, any presentation/submission shall be delayed up to 90 days, to allow the Sponsor to preserve its proprietary rights.

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Experience with Results Database

- Entering results is similar to writing a journal article
- Data provider must be able to understand the study design and data analysis
  - Typically, the investigator and/or a statistician will need to be involved

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Protocol and Results Review

- Protocol and results must be clear and informative
- Review focuses on:
  - Logic and internal consistency
  - Apparent validity
  - Meaningful entries
  - Formatting
- Note: Review is NOT "peer review"

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Examples of Incoherent Entries

- 823.32 mean hours sleep/day
- "time to survival"
- 36 eyeballs in study of 14 people
- "mean time to seizure" = 18 people

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Who is the Audience?

PI and Clinical Research Team

Other Medical Researchers in same field

Other Medical Researchers in other fields

Other Readers of the medical literature

Science Writers

Lay Public (readers of consumer health literature)

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Conceptual Framework – Specification in Reporting OMs

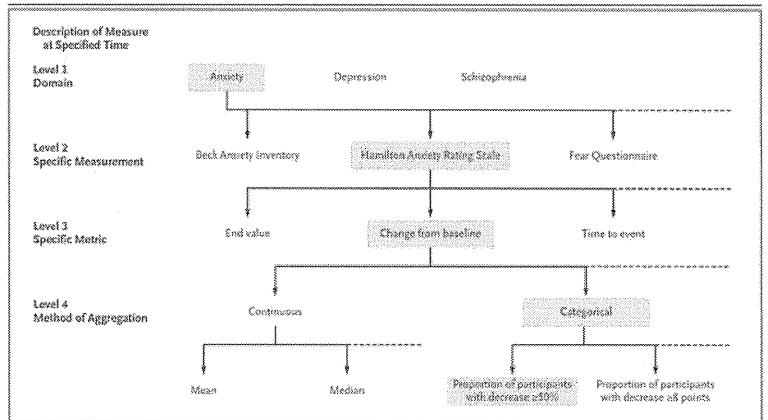

Figure 1. An Example of the Four Levels of Specification in Reporting Outcome Measures.

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N *Engl J Med* 2011;364:852-60

Results - Specification of Outcome Measures

Level	POMs (% Total)
1 – Domain (only)	36%
2 – Specific Measurement	25%
3 – Specific Metric	26%
4 – Method of Aggregation	13%
Included Specific Timeframe	63%

Lower "levels" of prespecification permit:
- *Post hoc* selection of "metric" and "method of aggregation"
- Mask multiple comparisons
- Cherry-picking of positive results

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N Engl J Med. 2005 Dec 29;353(26):2779-87.

Finding Results Submitted to ClinicalTrials.gov

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Finding Results

- From Homepage (http://clinicaltrials.gov) "Search for Studies"
  - Select "Advanced Search"
  - Study Results field - Select "Studies with Results" from the menu
  - Select study record from results list
  - Click "Study Results" tab
- Step-by-step screen shots on next slides

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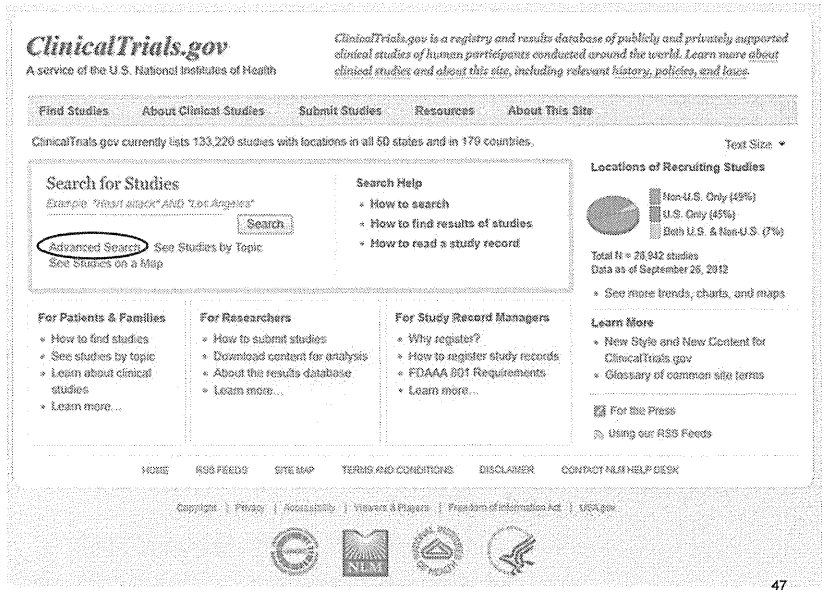

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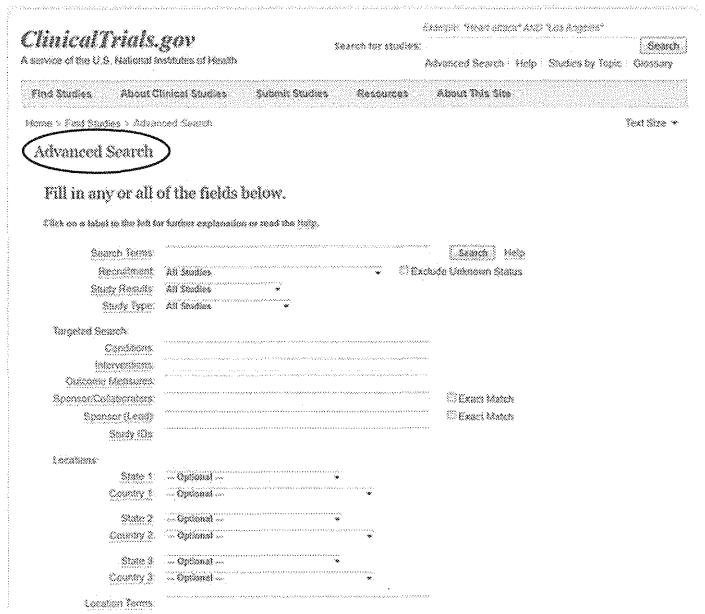

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Advanced Search

Fill in any or all of the fields below.

Click on a label to the left for further explanation or read the Help.

Search Terms: Search Help
Recruitment: All Studies Exclude Unknown Status
Study Results: Studies With Results
Study Type: All Studies

Targeted Search:
Conditions:
Interventions:
Outcome Measures:
Sponsor/Collaborators: Exact Match
Sponsor (Lead): Exact Match
Study IDs:

Locations:
State 1: -- Optional --
Country 1: -- Optional --

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List | By Topic | On a Map | Search Details

Show Display Options Download Subscribe to RSS

Include only open studies Exclude studies with unknown status

Rank	Status	Study
1	Terminated, Has Results	Phase III Randomized Study of Lucinactant in Full Term Newborn Infants With Meconium Aspiration Syndrome Condition: Meconium Aspiration Interventions: Drug: Lucinactant; Other: Standard Care
2	Completed, Has Results	Effects of Exenatide and Insulin Glargine in Subjects With Type 2 Diabetes Condition: Type 2 Diabetes Mellitus Interventions: Drug: exenatide; Drug: insulin glargine
3	Completed, Has Results	BAY43-9006 - Phase II in Advanced Breast Cancer Conditions: Breast Neoplasms; Breast Cancer Intervention: Drug: Sorafenib (Nexavar, BAY43-9006)
4	Completed, Has Results	Effectiveness of D-Cycloserine as an Aid to Enhance Learning for Individuals With OCD Receiving Behavior Therapy Condition: Obsessive-Compulsive Disorder Interventions: Drug: seromycin; Behavioral: Behavior Therapy
5	Completed, Has Results	Ophthalmologic Safety Study of Pramipexole IR Versus Ropinirole in Early Parkinson's Disease Patients Condition: Parkinson Disease Interventions: Drug: Mirapex; Drug: Requip

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BAY43-9006 - Phase II in Advanced Breast Cancer

This study has been completed.

Sponsor:
Bayer

Information provided by:
Bayer

ClinicalTrials.gov Identifier:
NCT00101400

First received: January 10, 2005
Last updated: November 9, 2011
Last verified: November 2011
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Purpose

The purpose of this study is to evaluate the anti-cancer activity and safety of BAY43-9006 (Sorafenib) in patients, who suffer from an advanced breast tumour, which has spread to other organs of body despite treatment that the patient has received so far.

Condition	Intervention	Phase
Breast Neoplasms Breast Cancer	Drug: Sorafenib (Nexavar, BAY43-9006)	Phase 2

Study Type: Interventional
Study Design: Allocation: Non-Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Phase II Multicenter Uncontrolled Trial of BAY43-9006 in Subjects With Metastatic Breast Cancer.

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BAY43-9006 - Phase II in Advanced Breast Cancer

This study has been completed.

Sponsor:
Bayer

Information provided by:
Bayer

ClinicalTrials.gov Identifier:
NCT00101400

First received: January 10, 2005
Last updated: November 9, 2011
Last verified: November 2011
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: January 30, 2009

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Conditions:	Breast Neoplasms Breast Cancer
Intervention:	Drug: Sorafenib (Nexavar, BAY43-9006)

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
Subjects were enrolled from 03 Feb 2004 to 29 Jul 2004 by 3 centers in Germany and 4 centers in Italy.

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No Study Results Posted

- Results may not be posted for any of the following reasons:
  - The study is still ongoing
  - The study may not be required to submit results
  - The study is completed, but the deadline for results submission has not been reached
  - The results have been submitted, but have not yet been posted (e.g., pending review by ClinicalTrials.gov)
  - Submission of results information has been delayed with certification
  - A request for extending the submission deadline has been submitted to NIH

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Uses of ClinicalTrials.gov

For those concerned with human subjects protections…

- Complete list of ongoing and completed trials of relevance
- Assurance that information about the trial of interest
  - is in the public domain
  - for some trials, results will become public

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For those with medical conditions…

- Finding a trial in which to participate
- Finding an expanded access drug
- Finding a center of research for a given condition/intervention

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For those concerned with research integrity…

- Relatively complete list of trials
- Description of protocol
- Tracking of changes to protocols
- Identifying all outcome measures
- Providing results, regardless of journal publication status

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For those seeking study results…

- Linkages to PubMed
- Summary Results in database
- Results for all prespecified outcome measures
- Standardized format facilitating comparisons

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For those studying the "clinical research enterprise"

- Search engine allows one to identify all trials that meet certain criteria
  - Search results are listed by relevance
- Must understand nuances of database
- May be best to call for help
- Other site for ClinicalTrials.gov aggregate data by the Clinical Trials Transformation Initiative (CTTI)
  - AACT Database
  - https://www.ctti-clinicaltrials.org/project-topics/clinical-trials.gov/ctgov

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Characteristics of Clinical Trials Registered in ClinicalTrials.gov, 2007-2010

Robert M. Califf, MD
Deborah A. Zarin, MD
Judith M. Kramer, MD, MS
Rachel E. Sherman, MD, MPH
Laura H. Aberle, BSPH
Asba Tasneem, PhD

CLINICAL TRIALS ARE THE CENtral means by which preventive,

Context Recent reports highlight gaps between guidelines-based treatment recommendations and evidence from clinical trials that supports those recommendations. Strengthened reporting requirements for studies registered with ClinicalTrials.gov enable a comprehensive evaluation of the national trials portfolio.

Objective To examine fundamental characteristics of interventional clinical trials registered in the ClinicalTrials.gov database.

Methods A data set comprising 96 346 clinical studies from ClinicalTrials.gov was downloaded on September 27, 2010, and entered into a relational database to analyze aggregate data. Interventional trials were identified and analyses were focused on 3 clinical specialties—cardiovascular, mental health, and oncology—that together

"Conclusion: Clinical trials registered in ClinicalTrials.gov are dominated by small trials and contain significant heterogeneity in methodological approaches, including reported use of randomization, blinding, and DMCs."

JAMA. 2012;307(17):1838-1847

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The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

The ClinicalTrials.gov Results Database — Update and Key Issues

Deborah A. Zarin, M.D., Tony Tse, Ph.D., Rebecca J. Williams, Pharm.D., M.P.H., Robert M. Califf, M.D., and Nicholas C. Ide, M.S.

Table 4. Characteristics of Interventional Study Records Posted at ClinicalTrials.gov as of September 27, 2010.*

Variable	Registry Records (N=79,413)	Results Records (N=2178)
Outcome measures reported per trial — no.		
Primary		
Median		1
Interquartile range		1–2
Full range		1–71
Secondary		
Median		3
Interquartile range		1–7
Full range		0–122

N Engl J Med. 2011;364(9):852-60.

ANALYSIS CMAJ

Registration of observational studies: Is it time?

Rebecca J. Williams PharmD MPH, Tony Tse PhD, William R. Harlan MD, Deborah A. Zarin MD

Appendix 2: Observational studies first received Nov. 1, 2007 through Mar. 26, 2010

		Time perspective*					
		Prospective	Cross-Sectional	Retrospective		Missing	Total
Study design†	Cohort	2 617	265	305		95	3 282
	Case only	995	191	140		39	1 365
	Case–Control	848	232	102		41	1 223
	Other‡	136	78	25		14	253
	Missing	752	97	91		672	1 612
	Total	5 348	863	663		861	7 735

*Time perspective and study design (ClinicalTrials.gov data element – Observational Study Model) definitions available at: http://prsinfo.clinicaltrials.gov/definitions.html.
†Includes: case-crossover, ecologic or community, family based, and other.

CMAJ. 2010;182(15):1638-42.

Select Publications

Califf RM, Zarin DA, Kramer JM, Sherman RE, Aberle LH, Tasneem A. Characteristics of clinical trials registered in ClinicalTrials.gov, 2007-2010. *JAMA.* 2012;307(17):1838-47.

Wong E, Williams R. ClinicalTrials.gov: Requirements and implementation strategies. *Regulatory Focus.* 2012 May.

Ross JS, Tse T, Zarin DA, Xu H, Zhou L, Krumholz HM. Publication of NIH funded trials registered in ClinicalTrials.gov: cross-sectional analysis. *BMJ.* 2012;344:d7292.

Zarin DA, Tse T, Williams RJ, Califf RM, Ide NC. The ClinicalTrials.gov results database – update and key issues. *N Engl J Med* 2011;852-860.

Tse T, Williams RJ, Zarin DA. Reporting basic results in ClinicalTrials.gov. *Chest* 2009;136:295-303.

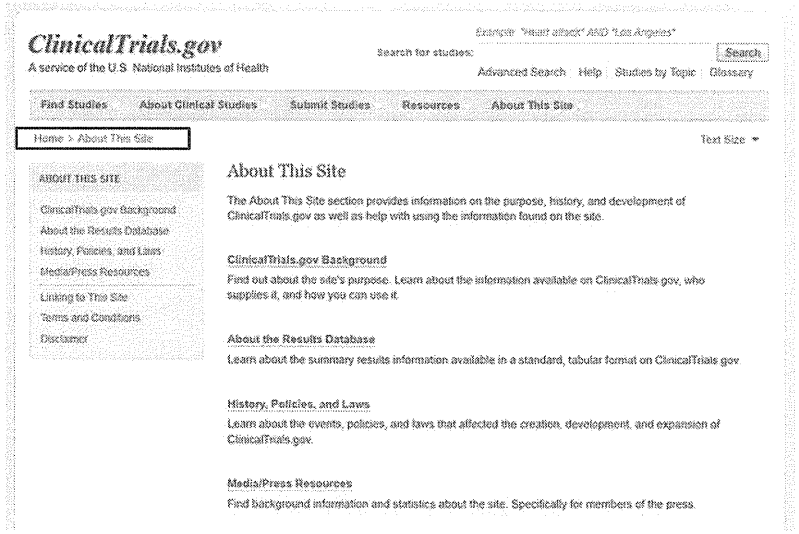
Additional Information

General ClinicalTrials.gov information:
http://clinicaltrials.gov/ct2/about-site

FDAAA related information:
http://clinicaltrials.gov/ct2/manage-recs/fdaaa

Office of Extramural Research (OER)
http://grants.nih.gov/Clinicaltrials_fdaaa/

Questions?
register@clinicaltrials.gov



http://clinicaltrials.gov/ct2/about-site

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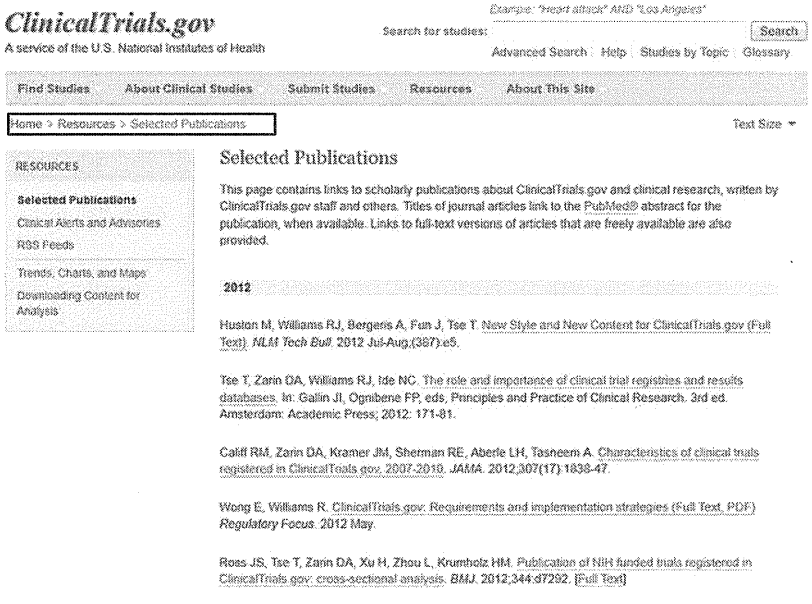


National Cancer Institute and Program Overviews

Office of Communications and Education

February 11, 2013

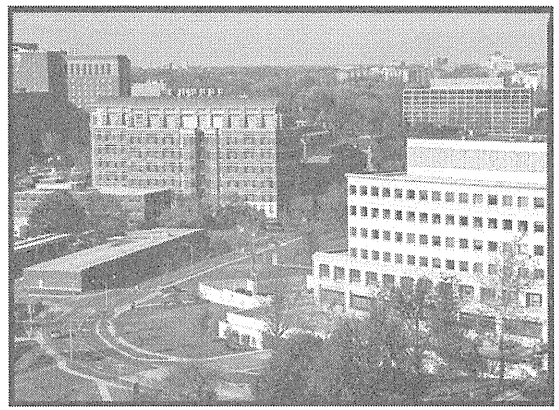
National Institutes of Health

- NIH is the world's premier medical research organization supporting over 38,000 research projects nationwide in diseases including cancer, Alzheimer's, diabetes, arthritis, heart ailments and AIDS
- 27 separate Institutes and Centers

The Department of Health and Human Services

- The U.S. government's principal agency for protecting the health of all Americans and providing essential services especially for those least able to help themselves
- DHHS includes more than 300 programs

NIH Campus



National Institutes of Health

- Employees – 17,138
- Director – Francis Collins, MD, PhD
- FY Annual Budget - $29.5 billion
- Established in 1887 in Staten Island, NY
- Headquarters – Bethesda, MD

National Cancer Institute

- Established in 1937
- National Cancer Act of 1971
- Employees – ~ 4,000
- Director – Harold Varmus, MD
- Annual Budget - $4.8 billion
- Location: Bethesda, MD with satellite offices in the area

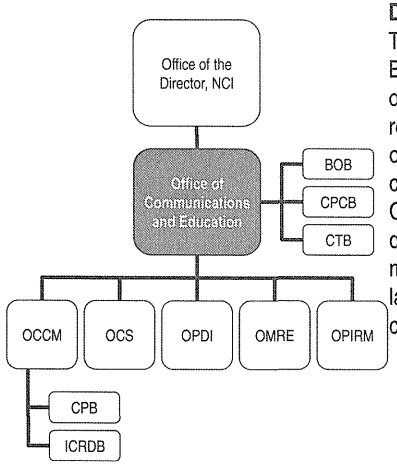
National Cancer Institute

- The world's largest organization solely dedicated to cancer research
- Leader of the National Cancer Program
  - Vision and leadership to the global cancer community
  - International research
  - Training
  - Health Information Dissemination

The NCI Intramural and Extramural Programs

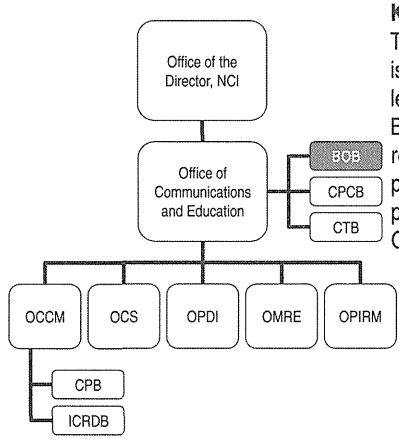
- **Intramural**
  - **Clinical Center**
  - **Center for Cancer Research**
- **Extramural**
  - Funded research, education and training across the US and abroad

Office of Communications and Education



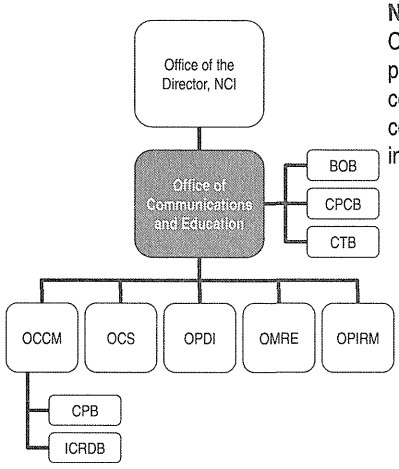
Dr. Lenora Johnson, Director
The Office of Communications and Education (OCE) advances the mission of NCI by disseminating research results to the public to improve the lives of those affected by cancer. Working closely with scientists and partners, OCE uses effective methods to reach diverse audiences and meet their needs for the latest, evidence-based cancer information.

Business Operations Branch



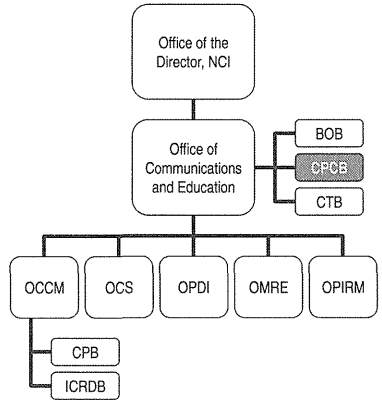
Kevin Davis, Chief
The Business Operations Branch (BOB) is designed and structured to direct and lead the operational aspects of OCE. BOB is responsible for all staffing resources, budgetary, financial, procurement, travel, and records and property tracking related functions within OCE.

Multicultural and International Communications



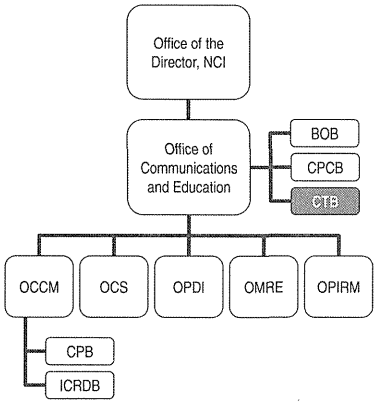
Nelvis Castro, Associate Director
Communicates NCI's global impact by providing culturally-appropriate strategic communications counsel and coordination to NCI's multicultural and international programs.

Communications Planning and Coordination Branch



Sabrina Islam-Rahman, Acting Chief
CPCB's team of seven Communication Program Managers serves as the main point of contact for NCI programs seeking communication support from OCE. They advise clients on communication strategy, develop communication plans and budgets, and manage projects to completion.

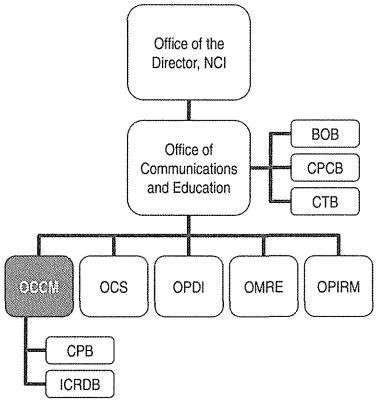
Communications Technology Branch



Jonathan Cho, Chief

The Communications Technology Branch (CTB) provides management oversight, technical support, and both strategic and tactical guidance for OCE's communications technologies; designs, develops, and operates web sites and information management systems that support communications-related programs; designs, develops, and disseminates NCI video and multimedia content; defines, implements, and manages the OCE Enterprise content strategy; and keeps abreast of the most current communication, education, dissemination, Network interaction, and web/digital technologies.

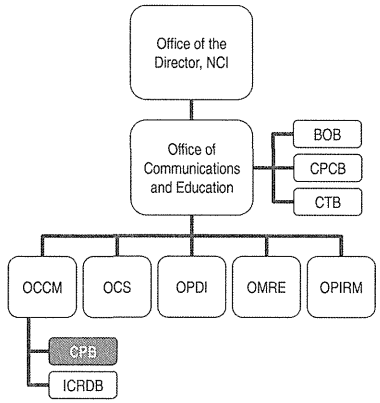
Office of Cancer Content Management



Dr. Rick Manrow, Associate Director

The Office of Cancer Content Management (OCCM) advances the missions of OCE and NCI by developing accurate, authoritative, evidence-based cancer information and education products to meet the needs of health professionals, patients, and the general public. OCCM works closely with NCI researchers and others to translate complex biomedical concepts and research findings into high-quality, cancer-related Information products that are written in plain language, directed to diverse audiences, and distributed through multiple channels.

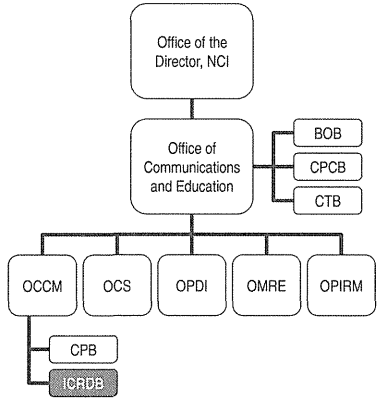
Cancer Publications Branch



Dr. Rebecca Chasan, Chief

The Cancer Publications Branch (CPB), part of the Office of Cancer Content Management (OCCM), creates and maintains cancer-related information and education products for Cancer.gov and a range of NCI print publications designed to reach a wide variety of audiences, including patients and their families, health professionals, researchers, and the general public. CPB also manages the clearance process for OCE and NCI and serves as the Institute's point-of-contact for requirements specified under the Office of Management and Budget's Information Quality Bulletin for Peer Review, helping to ensure that NCI content is accurate and consistent with Institute, NIH, and DHHS positions and policies.

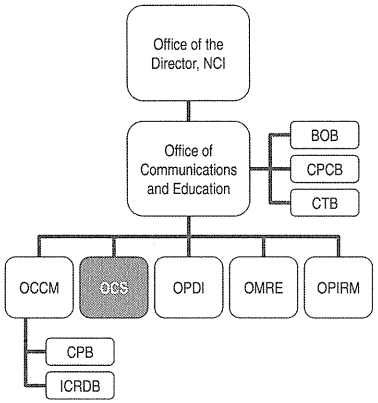
International Cancer Research Databank Branch



Margaret Beckwith, Chief

The International Cancer Research Databank Branch (ICRDB), part of the Office of Cancer Content Management (OCCM), coordinates all information management activities associated with NCI's Physician Data Query (PDQ®) comprehensive cancer information database, including information collection and synthesis, editorial processes, and data exchanges. ICRDB also manages the NCI Dictionary of Cancer Terms (for patients), the NCI Drug Dictionary (for health professionals), NCI's Drug Information Summaries (for patients), NCI's Cancer Genetics Services Directory, and NCI's List of Cancer Clinical Trials for the Cancer.gov Web site.

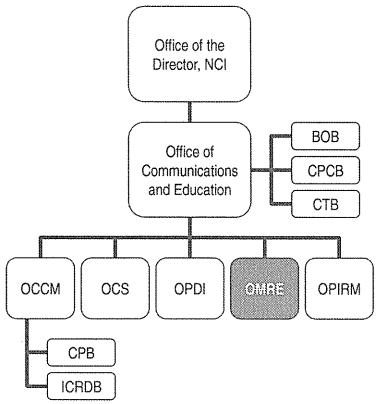
Office of Communications Services



As the creative production arm of NCI, the Office of Communications Services (OCS) creates and maintains the visual image of the NCI as it brings information to the Institute's various audiences:

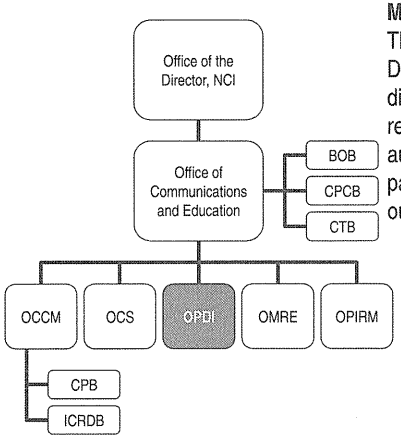
- With its custom designed NCI corporate branding and visuals, the internal and public-facing image of the Institute is consistently upheld as OCS provides creative services to NCI Divisions, Offices, and Centers that result in products and activities of the highest professional quality.
- Through the design and management of major NCI outreach efforts such as the NCI National Exhibit Program and the Publication Fulfillment Center, NCI information and materials reach stakeholders and the public worldwide.

Office of Market Research and Evaluation



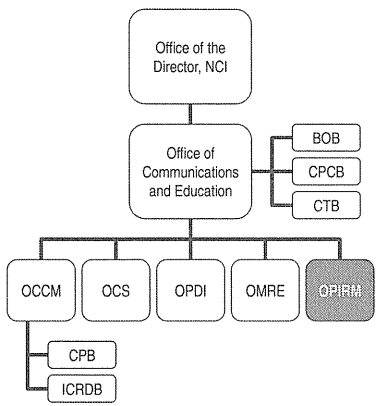
Dr. Anita Ousley, Act. Assoc. Director
The Office of Market Research and Evaluation (OMRE) ensures that the National Cancer Institute's communication and education resources are appropriate, useful, and effective. OMRE uses scientific methods to: identify the cancer-related needs of diverse audiences; inform the design and development of NCI resources; monitor audience trends; and assess the impact of resources and activities.

Office of Partnerships and Dissemination Initiatives



Madeline La Porta, Associate Director
The Office of Partnerships and Dissemination Initiatives (OPDI) disseminates cancer research findings, resources, and programs to targeted audiences through strategic partnerships, multicultural media outreach, education, and training.

Office of Public Information and Resource Management



Mary Anne Bright, Associate Director
OPIRM supports NCI's mission by communicating credible, research-based cancer information to the public and cancer research community and by informing NCI about public information needs.

NCI's Physician Data Query (PDQ®) Cancer Information

Richard E. Manrow, Ph.D.
Associate Director, Office of Cancer Content Management

Margaret Beckwith, Ph.D.
Chief, International Cancer Research Databank Branch (ICRDB)

Office of Communications and Education
National Cancer Institute

Legislative Foundation for PDQ

- National Cancer Act of 1971

SEC. 407. (b)

In carrying out the National Cancer Program, the Director of the National Cancer Institute shall:

"Collect, analyze, and disseminate all data useful in the prevention, diagnosis, and treatment of cancer, including the establishment of an international cancer research data bank [ICRDB; later called PDQ] to collect, catalog, store, and disseminate insofar as feasible the results of cancer research undertaken in any country for the use of any person involved in cancer research in any country."

Additional Legislation Supporting PDQ

- **Health Research Extension Act, 1985**
- **Health Omnibus Programs Extension Act, 1988**
- **Public Health Service Act, 1996:***

"…provide physicians and the public with state-of-the-art information on the treatment of particular forms of cancers, and to identify those clinical trials that might benefit patients…"

"…maintain and operate the International Cancer Research Data Bank [ICRDB/PDQ] …"

"…to the extent practical, in disseminating the results of such cancer research and treatment, utilize information systems available to the public."

*Provisions still current

What's in PDQ?

- Evidence-based, peer-reviewed cancer information summaries
  - Cancer Treatment (Adult and Pediatric)
  - Supportive & Palliative Care
  - Screening & Prevention
  - Cancer Genetics
  - Complementary & Alternative Medicine
- List of active/open and closed cancer clinical trials (U.S. and international)
- Clinical and basic biomedical terminology (data source for NCI's online dictionaries)
- Cancer-related drug information
- Cancer Genetics Services Directory
- Biomedical images (to support PDQ and other NCI cancer information products, e.g., patient education publications)

PDQ Cancer Information Summaries: Current Totals

PDQ Editorial Board	English		Spanish	
	Health Professional	Patient	Health Professional	Patient
Adult Treatment	73	72	73	72
Pediatric Cancer Treatment	25	24	25	24
Supportive Care	26	25	26	25
Screening & Prevention	31	30	5	4
Cancer Genetics	8	–	–	–
Cancer Complementary & Alternative Medicine	20	20	–	1
Total	183	171	129	126
Total/Language	354		255	
Overall Total	609			

The PDQ Editorial Boards

- Meet 4-8 times/year, depending on the Board
- Attendance at Board meetings can be in person, by videoconferencing, or by teleconferencing
- The use of WebEx as an alternative to face-to-face Board meetings is increasing
- Board meetings vary in length from 2 hrs to 2-day "retreats"
- In addition to Board meetings, several Boards have working groups that meet more often
- Each Editorial Board has a larger external Editorial Advisory Board that peer-reviews the PDQ summaries every 2 years

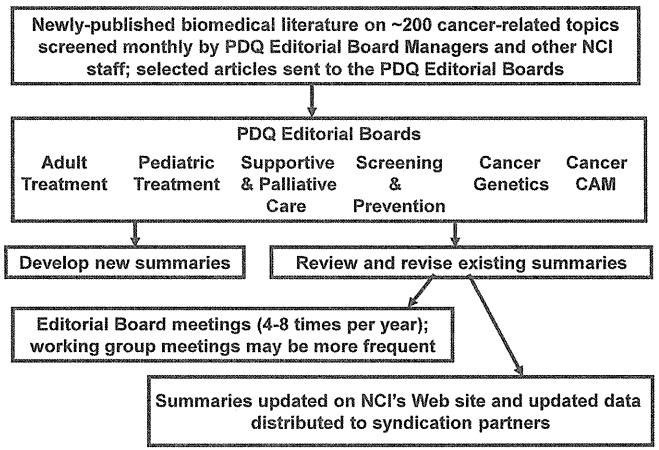
The PDQ Editorial Boards

Editorial Board	Editor-in Chief
Adult Treatment	**Franco Muggia, M.D.** New York University Medical Center
Pediatric Cancer Treatment	**A. Kim Ritchey, M.D.** Children's Hospital of Pittsburgh
Supportive Care	**Deborah Barton, Ph.D.** Mayo Clinic, Rochester, MN
Screening & Prevention	**Barnett S. Kramer, M.D., M.P.H.** Division of Cancer Prevention, NCI
Cancer Genetics	**Mary Daly, M.D., Ph.D.** Fox Chase Cancer Center Philadelphia, PA
Cancer CAM	**Jeffrey White, M.D.** Office Of Cancer Complementary and Alternative Medicine, NCI

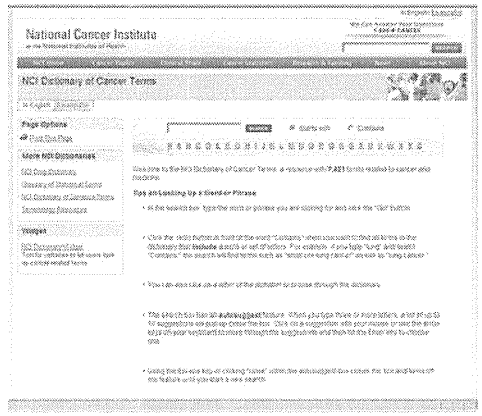
The PDQ Editorial Boards

- Evaluate published results of cancer research conducted around the world and assess the strength of the evidence regarding cancer-related interventions
- Summarize their evaluations in the PDQ Cancer Information Summaries for Health Professionals, which are documents reflecting the consensus opinion of the entire authoring Editorial Board
- Do not formulate practice guidelines or make treatment recommendations
- Are not formal advisory boards to NCI and do not formulate policy for Institute

PDQ Health Professional Summary Process



NCI Dictionary of Cancer Terms

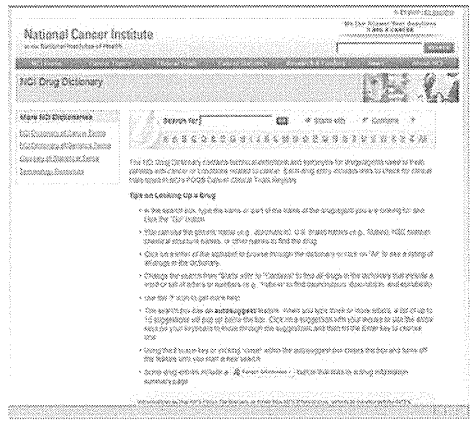


- **Contains more than 7,400 scientific and medical terms defined for the general public**
- **Terms and definitions translated into Spanish**

PDQ List of Cancer Clinical Trials

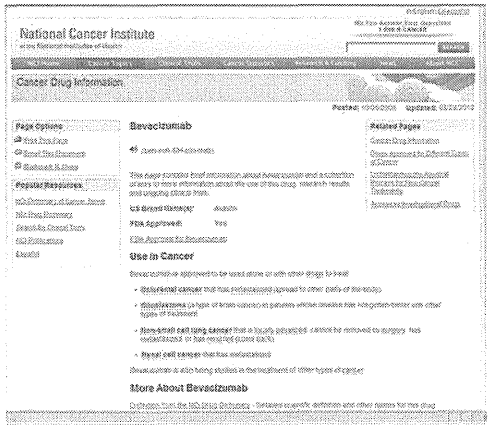
- >12,000 active clinical trials (accepting patients)
- >26,000 closed or completed clinical trials
- Searchable via a large number of parameters at http://www.cancer.gov/clinicaltrials/search.
- Many trial summaries have links to published results (reference citations in NLM's PubMed database and proceedings abstracts from ASCO annual meetings)

NCI Drug Dictionary



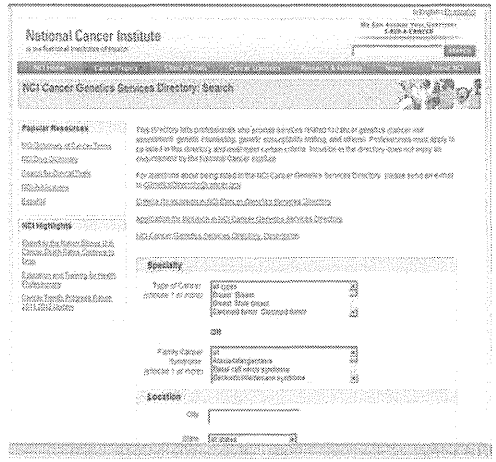
Health professional resource that contains information on more than 3,200 drugs and agents used in cancer-related care

NCI Drug Information Summaries



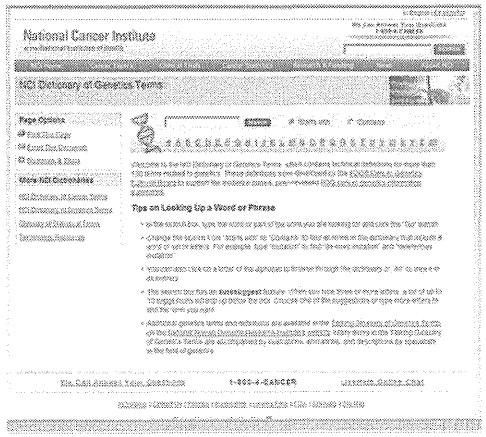
Lay-oriented information on more than 126 drugs and 32 drug combinations used in cancer-related care

NCI Cancer Genetics Services Directory



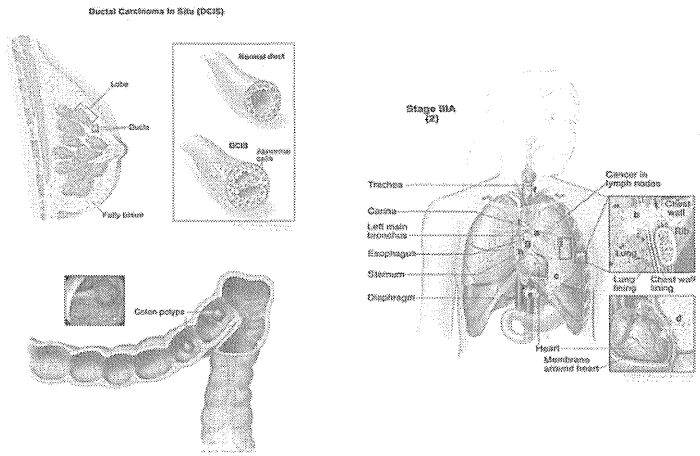
Information on more than 500 professionals who provide risk assessment, genetic testing, genetic counseling, and other services

NCI Dictionary of Genetics Terms

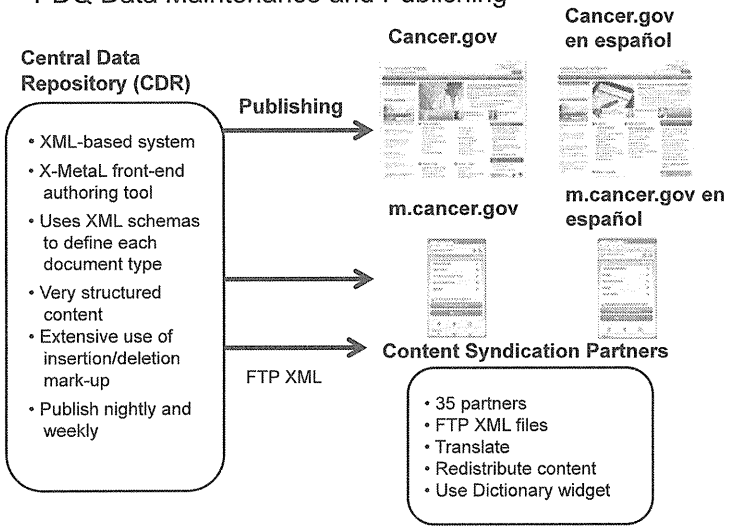


Health professional resource that contains more than 170 genetics terms and definitions

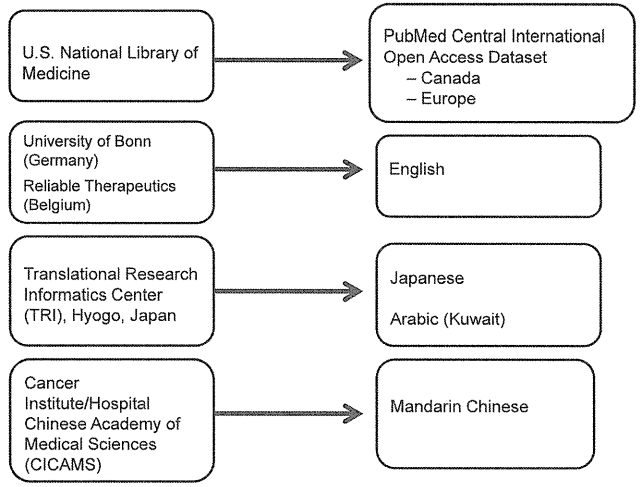
PDQ Biomedical Images



PDQ Data Maintenance and Publishing



International Reach of PDQ



Cancer.gov Page Views/Month (English)

Cancer Topics Portal	3,716,371
PDQ Summaries	1,639,024
NCI Dictionary of Cancer Terms	348,519
Mobile cancer.gov	356,384