

# Knowledge Acquisition Report

## NCI Clinical Trials Model – IT Initiatives Tracking

**Session Date:** January 31, 2001

**Session Topic:** NCI Clinical Trial Information Technology Initiatives Tracking

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**Organization:** National Cancer Institute

**Type of Session:**

Interview       Task Analysis       Scenario Analysis  
 Concept Analysis       Observation       Structured Interview  
 Other: Analysis of Existing Source Materials

**Documentation:**

Report of the National Cancer Institute Clinical Trials Program Committee (Armitage)  
August 26, 1997

Report of the National Cancer Institute Clinical Trials Implementation Committee  
September 23, 1998

Report of the Long Range Planning Committee. Translating Cancer Research into Cancer Care  
March 1, 2000

EAB Subcommittee on Gender/ Minority Tracking May 14, 1999

MMHCC Pathology Committee Report from the Mouse Models of Human Cancers Consortium  
January 19-21, 2000

Office of Informatics Quarterly Review September 13, 1999

Interagency Agreement Between the Department of Defense and National Cancer Institute for Partnership in Clinical Trials for Cancer March 5, 1996

“Document Development and Management Streamlining Plans” Memo from the Head of the Protocol and Information Office of the Cancer Therapy Evaluation Program (CTEP) to the Associate Director of CTEP. August 31, 1998

## Report Summary

In 1997, the Clinical Trials Program Review Group (known as the Armitage Committee) presented the National Cancer Institute (NCI) with a comprehensive report on the NCI's clinical trials program. The following year, the NCI Implementation Committee presented a follow-up report addressing the Armitage Committee's suggestions.

NCI management has invested significant resources on information technology (IT) activities to address the concerns and recommendations expressed in these review group documents. This report represents the initial steps in documenting and modeling the linkages between IT activities and expressed NCI needs.

This report contains a detailed list of NCI-sponsored information technology resources relevant to the clinical trials space. The list represents the IT resources that ScenPro has identified during its knowledge acquisition activities with NCI, and is not presumed to be an exhaustive compilation of all IT resources available. This report also contains excerpts from seven NCI documents that express NCI needs relevant to clinical trials.

## NCI Sponsored Information Technology Systems Used in the Management of Clinical Trials

### Websites and Systems

Type	Title and URL address	Description	Users
Website	Cancer.gov  <a href="http://www.nci.nih.gov/">http://www.nci.nih.gov/</a>	NCI's website. Comprehensive website providing information on every aspect of cancer research for both patients and health care professionals.	General public, health care professionals, patients general public
System	EVS (Enterprise Vocabulary System)  <a href="http://ncievs.nci.nih.gov/NCI-Metaphrase.html">http://ncievs.nci.nih.gov/NCI-Metaphrase.html</a>	Compiles terminologies from all research communities into one source. Researchers may look up synonyms used by other researchers.	Clinical Researchers
System	EZAccrual Data Entry System  <a href="http://ciiserver3.nci.nih.gov/ezaccrual/index.html">http://ciiserver3.nci.nih.gov/ezaccrual/index.html</a>	Part of EZAccrual, “an application that simplifies the process of reporting, analyzing, and filing NCI grant enrollment data.  LGA, Inc. created the EZ Accrual system. The system provides a mechanism to enter patient accrual data and pass it on the PTDB. CGCB personnel enter accrual information for over 700 protocols using EZ Accrual. EZ Accrual includes some information not found in PTDB. This includes protocol name, protocol phase, and type of clinical trial (therapeutic versus other). EZ Accrual allows CGCB personnel to see miscoded grants immediately and pursue correction without waiting for year end reporting.	NCI Personnel

System	NCI Online Workplace (NOW)  Link on: <a href="http://cii.nci.nih.gov/">http://cii.nci.nih.gov/</a>	User password required to enter. Suite of web applications. Users enter their "IMPACII or GRITS ID". Users have access to: <ul style="list-style-type: none"> <li>• Referral</li> <li>• GAMS (Grants Application and Management System)</li> <li>• Program Activities</li> <li>• Grant Detail Viewer</li> <li>• NCI Enterprise Maintenance</li> <li>• Reports</li> <li>• DCP PIMS</li> <li>• Financial Management</li> </ul>	NCI personnel, clinical researchers
System	CDE (Common Data Elements) <a href="http://cii-server5.nci.nih.gov:8080/pls/cde_public/cde_java.show">http://cii-server5.nci.nih.gov:8080/pls/cde_public/cde_java.show</a>	Provides a hub for clinical researchers to a standardized list of terms. Users check the CDE website to find approved terms to use on a variety of forms associated with clinical research.	Clinical Researchers
System	NCI DIS (Drug Information System) 3D Database  <a href="http://www.dtp.nci.nih.gov/docs/3d_data_base/dis.html">http://www.dtp.nci.nih.gov/docs/3d_data_base/dis.html</a>	The NCI Drug Information System (DIS) was set up in 1980 in order to keep track of acquisition, storage, shipping, and testing of drugs at the National Cancer Institute. The DIS consists of 2 major sub-systems: The Pre-Registry and the Drug sub-systems. The Pre-Registry sub-system handles compound acquisition and only is of interest to those directly involved in the acquisition process. The Drug sub-system is where most of the data is stored and is the system used by most users.	Clinical Researchers
System	CTSU (Cancer Trials Support Unit) website access  <a href="http://www.ctsu.org/">http://www.ctsu.org/</a>	Website portal to this NCI pilot project for the support of a national network of physicians to participate in NCI-sponsored Phase III clinical trials. Objectives: <ul style="list-style-type: none"> <li>• Reduce regulatory/ administrative burden on Cancer Cooperative Groups</li> <li>• Increase physician and patient access to NCI-sponsored</li> </ul>	Clinical researchers

		<p>clinical trials</p> <ul style="list-style-type: none"> <li>Streamline and standardize information collection and reporting</li> </ul>	
System	<p>CancerNet (PQD)</p> <p><a href="http://www.cancer.gov/cancer_information/pdq/">http://www.cancer.gov/cancer_information/pdq/</a></p>	<p>Website containing listing of all NCI sponsored clinical trials as well as comprehensive information about cancer treatment, screening, prevention, genetics, and supportive care.</p>	<p>Clinical researchers, physicians, patients, general public</p>
Website	<p>CIS (Cancer Information Service)</p> <p><a href="http://cis.nci.nih.gov/about/about.html">http://cis.nci.nih.gov/about/about.html</a></p>	<p>National information and education network of general cancer information</p>	<p>Clinical researchers, physicians, patients, general public</p>
System	<p>AdDEERS (Adverse Event Expected Reporting System)</p> <p><a href="http://ctep.cancer.gov/reporting/adeers.html">http://ctep.cancer.gov/reporting/adeers.html</a></p>	<p>CTEP system for submitting reports for serious and/or unexpected patient drug reactions forwarded to designated recipients and the NCI for all trials using a NCI-sponsored investigational agent</p>	<p>Clinical researchers</p>
System	<p>CTMS-AIS (Clinical Trials Monitoring Branch – Auditing Information System)</p> <p><a href="http://ctep.cancer.gov/monitoring/ctmb.html">http://ctep.cancer.gov/monitoring/ctmb.html</a></p>	<p>Web-based information system which permits online submission of all data collected during quality assurance audits of NCI-sponsored Cooperative Group clinical trials. The system consists of three modules which link the Cooperative Groups, CTMB, and the Clinical Trials Monitoring Service to Coordinate audit-related activities.</p> <p>CTMS' ACES® data management system collects clinical trial information such as patient accruals for selected phase I and phase II studies. It contains information that cannot be found in CDUS, and it is updated once every two weeks. In the near</p>	<p>Co-op group personnel, clinical researchers</p>

		future, CDUS will be updated so that CTMS information is loaded into it monthly. Theradex, a contract research organization, maintains the CTMS system.	
Website with database	CANCERLIT <a href="http://www.cancer.gov/search/cancer_literature/">http://www.cancer.gov/search/cancer_literature/</a>	Web access to bibliographic database with more than 1.5 million citations and abstracts from over 4,000 different sources, including biomedical journals, proceedings, books, reports, and doctoral theses.	Clinical researchers
Web-based system	CancerTrials <a href="http://www.cancer.gov/search/clinical_trials/">http://www.cancer.gov/search/clinical_trials/</a>	Provides access to cancer clinical trial registries and NCI cancer center listings  <u>Provides information on study protocol results, legislative and insurance news, and how patients and doctors can participate in clinical trials</u>  Provides inks to NCI information resources helpful to those conducting clinical trials  Provides listserv for updates of information	General public, clinical researchers
Web-based system	Cancer Research Portfolio <a href="http://researchportfolio.cancer.gov/">http://researchportfolio.cancer.gov/</a>	Provides information on approximately 9000 research projects, including grants, contracts, and clinical trials supported through NCI's intramural and extramural programs  Provides access to NCI's research portfolio by type of cancer (breast cancer, prostate cancer) and by type of cancer research (biology, etiology, prevention, treatment etc.)  Provides direct links to research abstracts and PDQ searches of clinical trial protocols  Provides links to NCI information resources including CancerNet, cancer trials, and other resources of interest to scientific investigators, patients, and the public	Clinical researchers
Web-based	CancerNet Search Service <a href="http://www.cancer.gov/search/cancer_literature/">http://www.cancer.gov/search/cancer_literature/</a>	Customized searches of PDQ and CANCERLIT	Clinical researchers

system	<a href="#">rature/</a>		
Website with database	SEER (Surveillance, Epidemiology, and End Results) program database <a href="http://seer.cancer.gov/">http://seer.cancer.gov/</a>	Web access to the SEER Program. SEER is the only comprehensive source of population-based information in the United States that includes stage of cancer at the time of diagnosis and survival rates within each stage	Clinical researchers, policy makers
System	SEER*Prep Software <a href="http://seer.cancer.gov/ScientificSystems/SEERPrep/">http://seer.cancer.gov/ScientificSystems/SEERPrep/</a>	Companion system to SEER*Stat that allows cancer investigators to prepare and format their own cancer incidence, mortality, and population data.	Statisticians
System	SEER*Stat Software <a href="http://seer.cancer.gov/ScientificSystems/SEERStat/">http://seer.cancer.gov/ScientificSystems/SEERStat/</a>	A statistical package for the analysis of SEER and other cancer databases. Provides cancer investigators with a desktop system for the production of statistics useful in studying the impact of cancer on a population.	Statisticians
Website with database	SEER-Medicare Database <a href="http://seer.cancer.gov/">http://seer.cancer.gov/</a>	Links clinical data collected by the SEER registries with claims for health services collected by Medicare for its beneficiaries. These combined datasets can be used for assessing <ul style="list-style-type: none"> <li>• patterns of care for persons with cancer</li> <li>• use of tests and procedures before and after cancer diagnosis</li> <li>• costs of cancer treatment</li> </ul>	Statisticians
System	Rapid Access to Intervention Development (RAID)-Drug Development <a href="http://dtp.nci.nih.gov/docs/raid/raid_pp.html">http://dtp.nci.nih.gov/docs/raid/raid_pp.html</a>	RAID provides access to NCI resources for the preclinical development of drugs and biologics, allowing subsequent clinical trials to proceed. The goal of RAID is clinical "proof of principle" that a new molecule or approach is a viable candidate for expanded clinical evaluation. Tasks supported by RAID include: <ul style="list-style-type: none"> <li>• large-scale synthesis, formulation</li> </ul>	Clinical researchers

		<ul style="list-style-type: none"> <li>• pharmacology and toxicology</li> <li>• in vivo screening</li> <li>• developmental tasks necessary to translate discoveries to the clinic</li> </ul>	
System	Rapid Access to Prevention Intervention Development (RAPID) <a href="http://dtp.nci.nih.gov/docs/raid/raid_index.html">http://dtp.nci.nih.gov/docs/raid/raid_index.html</a>	<p>RAPID supports preclinical development of chemopreventive agents and clinical development through Phase I studies by assisting investigators in the process of bringing discoveries from laboratory to the clinic.</p> <p>Support provided includes:</p> <ul style="list-style-type: none"> <li>• chemical synthesis and GMP manufacturing</li> <li>• preclinical efficacy</li> <li>• GLP toxicology testing</li> <li>• IND preparation</li> <li>• phase 1 support</li> </ul>	Clinical researchers
Software	Breast cancer Risk Assessment Tool <a href="http://bcra.nci.nih.gov/brc/">http://bcra.nci.nih.gov/brc/</a>	The Breast Cancer Risk Assessment Tool is a computer program that women and their health care providers can use to estimate a woman's chances of developing breast cancer based on several recognized risk factors.	Physicians/patients
Web-based system	CANQUES information on cancer statistics <a href="http://seer.cancer.gov/ScientificSystems/Canques/">http://seer.cancer.gov/ScientificSystems/Canques/</a>	A Web-based query system that allows access to over 10 million cancer statistics, created by the SEER program for the SEER Cancer Statistics Review.	Clinical researchers
Website	State of the Science <a href="http://www.webtie.org/sots/index.htm">http://www.webtie.org/sots/index.htm</a>	Reports of disease-specific meetings/workshops; archived video, presentation slides, meeting transcripts are available through the website	Clinical researchers
Website with database	Children's Environmental Health and Safety Inventory of Research (CHEHSIR) <a href="http://oaspub.epa.gov/chehsir/chehsir.page">http://oaspub.epa.gov/chehsir/chehsir.page</a>	<p>Publicly accessible database created and maintained in response to U.S. Presidential Executive Order 13045 (Protection of Children):</p> <ul style="list-style-type: none"> <li>• Developed by EPA/NIEHS (to which NIH/NCI contributes)</li> </ul>	General public/clinical researchers

		<ul style="list-style-type: none"> <li>Details all federally funded research related to environmental and safety risks to children</li> </ul>	
System	Grant Detail Viewer Link through: <a href="http://cii.nci.nih.gov/">http://cii.nci.nih.gov/</a>	Allows users to search for submitted Grant information via a variety of ways.	NCI personnel, clinical researchers
Website with database	NCI Yeast Anti-Cancer Drug Screen Results <a href="http://www.dtp.nci.nih.gov/yacds/default.html">http://www.dtp.nci.nih.gov/yacds/default.html</a>	Results of more than 60,000 compounds screened against yeast panel strains A database of compounds screened for evidence of the ability to inhibit the growth of selected yeast strains. Choose "Public Data" from the left column.	Clinical researchers
System	CTC (Common Toxicity Criteria)  <a href="https://webapps.ctep.nci.nih.gov/ctcv2/plsql/ctc000w\$.startup">https://webapps.ctep.nci.nih.gov/ctcv2/plsql/ctc000w\$.startup</a>	Site containing access to standards used to grade, assign attribution and report side effects experienced by patients on clinical trials	Clinical researchers
System	PIMS (Protocol Information Management System)	Database containing protocol administration information for all Division of Cancer Prevention clinical trials	DCP PIO
System	CTEP-ESYS (The Cancer Therapy Evaluation Program Enterprise System)	Database system containing information on clinical trials conducted under NCI CTEP	CTEP personnel, CCOP Program Analyst
System	PATS (Protocol Administration and Tracking System)	Component of CTEP-ESYS. Contains reported accrual data. The PATS system supports the creation, review, approval, and tracking of clinical trial protocols using NCI-sponsored investigational agents. It includes information such as review dates, investigator contact information, and planned patient accruals.	CTEP personnel, CCOP Program Analyst
System	CDUS (Clinical Data Update System)	Mechanism to be used when submitting specified data for clinical trials approved by CTEP. Also tracks reported accrual data.	CTEP personnel,

		<p>Primary resource for clinical trial data for the Division of Cancer Treatment and Diagnosis (DCTD) and the Division of Cancer Prevention (DCP). CDUS reports are submitted for all DCTD and DCP sponsored trials (Phases 1, 2 and 3), including:</p> <ul style="list-style-type: none"> <li>• DCTD-sponsored Cooperative Group and CCOP Research Base treatment trials utilizing DCTD-supplied investigational agents and trials utilizing non-NCI agents</li> <li>• all DCTD-funded non-Cooperative Group trials utilizing non-NCI agents</li> <li>• DCTD-sponsored Cooperative Group and CCOP Research Base non-treatment trials</li> <li>• DCP-sponsored CCOP Research Base cancer prevention and control trials</li> </ul> <p>The CDUS system supports the collection and reporting of clinical trial information. It includes information such as patient accruals and toxicity results. CDUS reports this information quarterly.</p>	CCOP Program Analyst, clinical researchers
System	<p>Biospecimen Inventory Processing System (BS I-II)</p> <p>(Division of Cancer Epidemiology and Genetics produced)</p>	<p>Designed for use in biospecimen repositories, BS I-II:</p> <ul style="list-style-type: none"> <li>• tracks and controls the acquisition, storage, aliquoting, processing, requisition, and distribution of biological specimens</li> <li>• records a complete description of each vial as a full history</li> <li>• provides both repository-specific and study-specific data</li> </ul>	Clinical researchers
System	IMPAC II Extensions	<p>Component of the National Institutes of Health (NIH) financial management system IMPACT II. IMPACT II Extensions is designed to meet the unique financial management needs of the NCI. Extensions are made up of five parts:</p> <ol style="list-style-type: none"> <li>1. Select for Pay: Automation of the Select for Pay Process.</li> </ol>	NCI personnel

		<p>Integrates data from IMPAC II with NCI management data.</p> <ol style="list-style-type: none"> <li>2. FLARE: Web-based system replacing old mainframe GENIUS system. FLARE integrates with the Enterprise Vocabulary System.</li> <li>3. GAB Specialist Assignment: Application used by GAB Section or Team leaders to manage the assignment of NCI grants.</li> <li>4. Referral: Application provides the DEA Referral Office and the NCI Program staffs with a shared environment for the proper assignment of newly received Grant Applications to NCI Organizations and Staff Members.</li> <li>5. Grants Administration Management System: Application enabling a more timely update of information required to monitor the progress of the funding process performed by GAB and Program staffs.</li> </ol>	
System	Portfolio Analysis Management Module (PAMM)	Provides a framework in which NCI staff are able to model portfolios of grants and analyze them. Integrates with IMPAC II.	NCI Program offices, cancer center personnel, Division of Cancer Control and Population Sciences personnel, MMHCC personnel
System	Drug Authorization and Review Tracking	Application to conduct daily operations of the Pharmaceutical	PMB

	System (DARTS)	Management Branch (PMB). High-level modules of DARTS: Acquisition, Drug In, Inventory Management, Drug Out, Ordering and Authorization, Investigator registration.	personnel
System	Priority Agents Review and Tracking System (PARTS)	Research tool for tracking the development of investigational agents. The system includes modules for supporting assessment and overview of the agents under study.	NCI personnel
System	Cancer Molecular Analysis Project (CMAP)	Prototype web-based system designed to enable researchers to identify and evaluate molecular targets in cancer. Contains: Molecular Profiles; Molecular Targets, Molecular Targeted Agents, and Clinical Trial Information.	Clinical Researchers

## Databases

Title	Description	Users
<p>Protocol Review System (created and maintained by IMS, populated by DCP PIO)</p>	<p>The Protocol Review System provides protocol review information related to Community Clinical Oncology Program (CCOP) studies. PIO uses this Microsoft Access database to perform data maintenance and reporting on CCOP studies.</p> <p style="text-align: center;"><b>Data Maintenance Types</b></p> <ul style="list-style-type: none"> <li>• Cancer Control</li> <li>• Special Cancer Control</li> <li>• CTEP</li> <li>• Addresses</li> </ul> <p style="text-align: center;"><b>Report Types</b></p> <ul style="list-style-type: none"> <li>• Reports</li> <li>• Letters</li> <li>• Frequency Tables</li> </ul>	<p>DCP PIO</p>
<p>CCOP Administrative Database (created and maintained by IMS, populated by CCOP)</p>	<p>The CCOP Administrative Database contains CCOP administrative and funding information.</p> <p>The CCOP Administrative Database provides information related to CCOP protocol funding and administration. The CCOP Program Analyst populates this database via a disc sent quarterly from the CCOP organizations.</p> <p>The CCOP Administrative Database stores administrative information related to CCOP studies and CCOP organizations:</p> <ul style="list-style-type: none"> <li>• Name of organization</li> <li>• Name of clinical trial</li> <li>• Name of Principal Investigator</li> <li>• Affiliates and components that make up a Research Base</li> </ul>	<p>DCP CCOP Program Analyst, DCP PIO personnel</p>

	<ul style="list-style-type: none"> <li>• Patient accrual information by protocol and by organization</li> </ul> <p>The database also houses information about credits awarded to CCOP protocols.</p>	
Chemical Structure Database of Anti-Cancer Screened Compounds	Structures and screening results for compounds tested in anti-cancer screens	Clinical researchers
Database of NCI's 60 Cell Line Anti-cancer Drug Screen	Drug sensitivity of more than 70,000 compounds	Clinical researchers
NCI databases for ChemFinder Pro & SD format	National Cancer Institute Data base with 40 calculated physical properties for over 120,000 chemical structures.	Clinical researchers
NCI Specimen Resource Locator	<p>Database with query tools to locate resources such as tissue banks and tissue procurement services with access to normal, benign, pre-cancerous and/or cancerous human tissue covering a wide variety of organ sites.</p> <p>Specimens include:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Tissue</li> <li><input type="checkbox"/> Serum</li> <li><input type="checkbox"/> DNA/RNA</li> <li><input type="checkbox"/> Other specimens</li> </ul>	Clinical researchers
Cancer Center Branch Internal Database	<p>Contains information on CCB grants and cooperative agreements and NCI contracts.</p> <p>Cancer Centers Branch personnel maintain an internal database for tracking information relevant to its programs. For each center, CCB personnel collect lists of protocol names, protocol phases, target accruals, accruals to date, accruals in past twelve months, and new patient information (by cancer site and by type of protocol). The centers update this information annually.</p>	CCB personnel

	<p>CCB personnel collect information on the following types of clinical trials:</p> <ul style="list-style-type: none"> <li>• Peer review funded trials (such as P01 grants)</li> <li>• Cooperative group trials</li> <li>• Trials developed and funded by research institutions</li> <li>• Trials developed and funded by industry</li> </ul> <p>CCB personnel find it difficult to collect information on the latter two types of trials because reporting to NCI is voluntary.</p>	
Clinical Grants and Contracts Branch Internal database	<p>Contains information on NCI grants, cooperative agreements, and contracts.</p> <p>CGCB maintains an internal MS Access database to track CTEP grants and cooperative agreements. CGCB personnel use this database to produce ad-hoc reports as well as standard reports for program directors.</p> <p>The CGCB Internal Database consists of three tables:</p> <ul style="list-style-type: none"> <li>• Current (data kept on active grants)</li> <li>• Pending (data kept on pending grants)</li> <li>• Tumor Type (data on tumor type and location, linked to both other tables)</li> </ul> <p>These tables are populated by manual data entry of information from grant applications and award notices.</p>	CGCB personnel
State Cancer Legislative database (SCLD)	<p>State legislation and regulation on cancer-related topics.</p> <ul style="list-style-type: none"> <li>• for evaluating the effect of state legislation on public health and on the application of cancer control science</li> <li>• for monitoring legislative trends that may reflect</li> </ul>	Clinical researchers, policy makers

	<p>changing public attitudes and practices</p> <ul style="list-style-type: none"><li>• on legislation and regulation addressing topics such as tobacco, genetics, access to state-of-the-art cancer treatment, cancer registries, diet and nutrition, employment discrimination, environmental exposure, and occupational exposure</li></ul>	
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## Downloadable Software and Databases

Title and URL address	Description	Users
BRB Array Tools (DCTD Biometric Research Branch produced) <a href="http://linus.nci.nih.gov/BRB-ArrayTools.html">http://linus.nci.nih.gov/BRB-ArrayTools.html</a>	Software developed by professional statisticians. The package: <ul style="list-style-type: none"> <li>• Includes a variety of powerful analytic and visualization tools for microarray data analysis</li> <li>• Has a user-friendly Excel front-end</li> </ul>	Clinical researchers
SaTScan-Spatial and Space-Time Scan Statistics (developed by Biometry Research Group) <a href="http://www3.cancer.gov/prevention/bb/satscan.html">http://www3.cancer.gov/prevention/bb/satscan.html</a>	The SaTScan software analyses spatial, temporal and space-time point data using the spatial, temporal, or space-time scan statistic. It is designed for any of the following interrelated purposes: <ul style="list-style-type: none"> <li>- To evaluate reported spatial or space-time disease clusters, to see if they are statistically significant.</li> <li>- To test whether a disease is randomly distributed over space or over time or over space and time.</li> <li>- To perform geographical surveillance of disease, to detect areas of significantly high or low rates.</li> </ul>	Statisticians
Conditional Logistic Regression with Sandwich Estimators (developed by Biometry Research Group) <a href="http://www3.cancer.gov/prevention/bb/sandwich.html">http://www3.cancer.gov/prevention/bb/sandwich.html</a>	This IBM PC program performs conditional logistic regression on clustered data and calculates a sandwich ("robust") estimator of the covariance of the regression coefficients.	Statisticians
Cox Regression for Survey Data (developed by Biometry Research Group)	This IBM PC program fits Cox's proportional hazards model to sample survey data, allowing for time-dependent covariates and left-truncated data (subjects entering at time >0).	Statisticians

<a href="http://www3.cancer.gov/prevention/bb/cox.html">http://www3.cancer.gov/prevention/bb/cox.html</a>		
DevCan software system version 4.0 <a href="http://srab.cancer.gov/DevCan/">http://srab.cancer.gov/DevCan/</a>	Calculates the lifetime and age-conditional estimates of developing or dying of cancer for over 20 different cancer sites by race (white, black) and gender.  Uses age-specific cross-sectional incidence rates from the Surveillance, Epidemiology, and End Results (SEER) Program and mortality rates from data collected by the National Center for Health Statistics.	Clinical researchers
Joinpoint Software <a href="http://srab.cancer.gov/joinpoint/">http://srab.cancer.gov/joinpoint/</a>	The software: <ul style="list-style-type: none"> <li>• takes trend data (e.g. cancer rates) and models them as joined linear segments (on a log or linear scale)</li> <li>• statistically chooses the simplest joinpoint model allowed by the data</li> <li>• estimates where each joined segment begins and ends</li> <li>• graphs the final model</li> </ul>	Clinical researchers
mAdb: Another Microarray Database <a href="http://nciarray.nci.nih.gov/">http://nciarray.nci.nih.gov/</a>	Flat file database designed specifically for microarray data. Runs on any web server that supports PERL.	Clinical researchers

## Other NCI Information Technology Efforts

Type	Title	Description	Users
MS Project-based software	IDB Drug Development Plan	Draws from CTEP-ESYS database. Displays clinical trial progress information in a Gantt chart format	CTEP IDB personnel
Service	CancerMail	Subscribers can receive cancer information such as PDQ's full-text summaries on cancer treatment, supportive care, screening, prevention, and fact sheets on current cancer topics	Clinical researchers
Population studies repository	Computerized Occupational Referent Population System (CORPS)  (Division of Cancer Epidemiology and Genetics produced)	A referent population to be used for epidemiologic studies of employed persons. <ul style="list-style-type: none"> <li>pooled data from cohort studies, providing a referent population of employed persons from a variety of occupations and industries</li> <li>rates or proportions available in a format compatible with user analysis package (i.e., NIOSH, Monson 8th Revision, OCMAP, or O/E)</li> </ul>	Clinical researchers: Epidemiologists
Population studies repository	Datasets from Completed Occupational Epidemiology Studies (Division of Cancer Epidemiology and Genetics produced)	Has links to order forms for datasets not actively being used in studies by the Occupational Epidemiology Branch and available for use in other epidemiological studies	Clinical researchers: Epidemiologists
Stand Alone PC software	CancerHelp	Software runs on PC connected to touch screen monitor. Patients can browse and print cancer information. Updated monthly via CD-ROM. Placed in high traffic areas such as clinics, hospitals, resource centers, CancerHelp collects user statistics from on-screen questionnaires.	Cancer patients, family members, general public
Software	TPS3D	Radiation treatment planning software, dose calculation and dose optimization. Software features real time 3D volume rendering.	Clinical researchers , physicians
Website	Questionnaire Modules (QMOD)	Database of questionnaires with citations to articles describing	Clinical

questionnaires		analysis results. Search for questionnaires by topics, researcher, or study title. A list of references is included to help in creating new questionnaires.	researchers
Software	CTSU Meeting Planner	Application providing a framework in which NCI staff tracks: <ol style="list-style-type: none"> <li>1. Recommendations from Program Review Groups and other oversight committees</li> <li>2. Organizational responses to recommendations- goals and objectives for the future</li> <li>3. Initiatives and grants that address goals, objectives, and initiatives</li> <li>4. Progress against goals</li> </ol>	NCI personnel
Software	IT planning – version 2 (CIT)	Application providing: <ol style="list-style-type: none"> <li>1. Budget information for IT initiatives</li> <li>2. Expense information for IT initiatives</li> <li>3. Tracking IT initiatives to IT portfolio areas</li> <li>4. Tracking acquisitions and associated contracts</li> <li>5. Capabilities for IT five year planning</li> <li>6. Cost benefit estimation capabilities</li> <li>7. Capabilities provided for IC IT roll-ups to NIH repository</li> </ol>	NCICB personnel
Software	Letter of Intent (LOI) Prototype Experiment	Workflow technology to support the collection, distribution, review, and approval of LOIs.	NCI personnel
Software	Generic Protocol Model	The object model is used as a basis of support for protocol authorizing. The model begins to identify some of the building blocks for automating portions of protocol authoring.	Clinical researchers, NCI personnel

**Software Available from the Laboratory of Experimental and Computational Biology (LECB)/ NCI**

Links to all: <http://www.lecb.ncifcrf.gov/Software/>

<b>Type</b>	<b>Title</b>	<b>Description</b>	<b>Users</b>
Downloadable software	Delila	Software for Informational Analysis of Protein and Nucleic-acid Sequences	Clinical researchers
Downloadable software	MicroArray Explorer (MAExplorer)	Java-based microarray data mining system that may be used either as a stand-alone or as an Applet.	Clinical researchers
Downloadable software	Flicker	2-D gel image comparison software is a Java Applet that visually compares two 2-D gel images.	Clinical researchers
Downloadable software	Db Engine	CGI-BIN database engine program for WWW browsers to search tables prepared by spreadsheets or from relational databases	Clinical researchers
Downloadable software	Thethe	Program to catch repeated words in a document	Clinical researchers
Downloadable software	Procdoc	Program to generate macro, typedef, function indices of C programs	Clinical researchers
Downloadable software	Mform	CGI-BIN program for WWW browsers to submit comments or addresses entered via a Mosaic form to different mailees or log files	Clinical researchers

## Website Tools that are part of NCI's The Cancer Genome Anatomy Project (CGAP)

Links to all: <http://cgap.nci.nih.gov/Tools>

Type	Title	Description	Users
Website	Gene Finder	Finds genes based on various search criteria and links to gene information from NCBI and NCI databases.	Clinical researchers
Website	GO Browser	Classifies human and mouse genes by molecular function, biological process, and cellular component.	Clinical researchers
Website	Nucleotide BLAST	Finds genes based on nucleotide sequence similarities.	Clinical researchers
Website	Library Finder	Finds EST and SAGE libraries based on selected criteria. Library construction details are also provided.	Clinical researchers
Website	Gene Library Sorter (GLS)	Generates unique and non-unique gene lists for single cDNA library or library group.	Clinical researchers
Website	cDNA xProfiler	Compares gene expression between two pools of cDNA libraries.	Clinical researchers
Website	Digital Gene Expression Displayer (DGED)	Distinguishes statistically significant differences in gene expression profiles between two pools of libraries (Includes both EST and SAGE library choices).	Clinical researchers
Website	SAGEmap xProfiler	Compares gene expression profiles between selected SAGE (Serial Analysis of Gene Expression) libraries.	Clinical researchers
Website	SAGEmap vNorthern	Identifies SAGE tags and generates a digital gene expression profile.	Clinical researchers
Website	Mitelman Database	CGAP has developed four tools to search the Mitelman Database (a genome-wide map of chromosomal breakpoints in human cancer).	Clinical researchers
Website	Recurrent Aberrations	CGAP has developed a tool to search the Middleman data of Recurrent Aberrations in cancer.	Clinical researchers
Website	FISH-mapped BACs	BAC clones, available to the public, that integrate the cytogenetic and physical maps of the human genome.	Clinical researchers
Website	Expression-Based SNP Imagemaps	Find SNPs based on cancer type and chromosome.	Clinical researchers
Website	Genetic and Physical SNP	Show genetic and physical locations of confirmed, validated, and predicted	Clinical

	Maps	SNPs.	researchers
Website	GeneMap99	Displays a physical map of >35,000 human gene-based markers, constructed by the International Radiation Hybrid Mapping Consortium.	Clinical researchers

# Comments and Recommendations on the Cancer Clinical Trial Program Expressed in National Cancer Institute (NCI) Documents 1997 – 2000

The following sections present excerpts from seven documents ranging in scope from the high-level observations and suggestions of the Armitage Committee Report to the specific actions outlined in a Cancer Therapy Evaluation Program (CTEP) inter-departmental memo.

## High-Level Documents:

- ❑ Report of the National Cancer Institute Clinical Trials Program Review Group (Armitage) August 26, 1997
- ❑ Report of the National Cancer Institute Clinical Trials Implementation Committee September 23, 1998
- ❑ Report of the Long Range Planning Committee. Translating Cancer Research into Cancer Care March 1, 2000
- ❑ EAB Subcommittee on Gender/ Minority Tracking May 14, 1999
- ❑ MMHCC Pathology Committee Report from the Mouse Models of Human Cancers Consortium. January 19-21, 2000

## Documents Enacting Improvements:

- ❑ Interagency Agreement Between the Department of Defense and National Cancer Institute for Partnership in Clinical Trials for Cancer March 5, 1996
- ❑ “Document Development and Management Streamlining Plans“ Memo from the Head of the Protocol and Information Office (PIO) of the Cancer Therapy and Evaluation Program (CTEP) to the Associate Director of CTEP. August 31, 1998

There are two sections to this portion of the report:

1. The first section contains excerpts from NCI documents identifying needed improvements to the clinical trial program.
2. The second section contains excerpts from NCI documents enacting improvements in the clinical trial program.

## Excerpts from NCI Documents Identifying Needed Improvements to the Clinical Trial program

Excerpts are presented in eight categories of expressed needs:

- I. Expressed goals/ concerns related to standardizing terminology and/or collection methods
- II. Expressed goals/ concerns related to reducing administrative redundancy
- III. Expressed goals/ concerns related to making the patient accrual process more efficient
- IV. Expressed goals/ concerns related to increasing funding and better financial management of clinical trials
- V. Expressed goals/ concerns related to NCI Informatics
- VI. Expressed goals/ concerns related to the protocol process
- VII. Expressed goals/ concerns related to disseminating research findings, clinical trial information
- VIII. Expressed goals/ concerns related to improving the general science and support of clinical trials

Below each category, the source material is identified as underlined text. Excerpts are indented below each source material. ***These excerpts are exact quotes from the source material.***

### **I. Expressed goals/ concerns related to standardizing terminology and/or collection methods**

#### Armitage Report

##### **Executive Summary**

Uniformity of data collection for patients on clinical trials in cooperative groups and cancer centers is essential.

##### **Improving Efficiency in Clinical Trial Methodology**

The clinical trials methodologies used by the 11 cooperative groups and 51 cancer centers have created a system described as a "Tower of Babel" by some members of the Review Group, in which protocol format, clinical

endpoints, data collection forms, informed consent, toxicity criteria, and computerization of data differ among groups.

### **Improvement of Intergroup Studies and the Size of the Cooperative Group Enterprise**

Even though managed by one group, each of the groups process the required paperwork, conduct follow up, and even store tissues. This duplication is largely a result of the perceived need for each group to monitor accrual and data quality for its own members. This duplication of effort becomes even more problematic because the group data collection systems are often incompatible. Information collected on investigators, institutional review board reviews, and registration privileges, for example, are not uniform. Specimen tracking and data sharing are not efficient and sometimes ineffective.

MMHCC Pathology Committee Report from Mouse Models of Human Cancers Consortium (1/19-21/2000)

#### **The recommendations of the Pathology Committee:**

2. ...Standard nomenclature and protocols for the sampling, collection, processing, and reporting of specimens should be adopted by MMHCC ...

Long Range Planning Committee Report

#### **Executive Summary**

To move the CII from theory into practice, the Committee recommends that the Office of Informatics

1. Formulate the role of the National Cancer Institute in the national standards development process.

#### **Recommendations**

*Recommendation 1.* **Formulate the role of the National Cancer Institute in the national standards development process.**

- **Ensure that NCI efforts to develop or promote oncology-specific information standards are tightly coordinated with the broader health information standards community.** Coordination needs to extend to include standards development organizations (SDOs), such as HL7 and SNOMED, umbrella organizations such as ANSI HISB and ISO TC 215, and larger communities of interest such as FDA and pharmaceutical industry, NLM's UMLS, and most importantly practicing scientists and clinicians.

## Recommendations

**Recommendation 3. Focus informatics efforts on demonstration and evaluation projects that enhance NCI's ability to carry out its mission, by building on ongoing mainstream informatics initiatives and Internet technologies.**

Implementing the CII is a complex and long-term task, but most of the technologies and applications required to support it are available now.

...NCI should therefore emphasize investments that address issues of future concern, such as support for the evolution of standards, or considerations of issues relating to the scaling-up of the extent of CII development among the diverse participants in NCI activities.

## II. Expressed goals/ concerns related to reducing administrative redundancy

### Armitage Report

#### Executive Summary

The clinical trials system is complex, involves many participants, and requires collaboration at all levels--between investigators and physicians, industry and academia, academia and NCI, and NCI and industry. In its entirety, the clinical trials system is an intricate and large research laboratory without walls. This complexity has bred inefficiencies and eroded the ability of the system to generate new ideas to reduce the cancer burden.

### Clinical Trials Implementation Committee Report

#### Section 2

##### I. Key components of the IC vision included:

##### B. Efficiency and streamlining

- Reduced administrative and operational redundancy across the clinical trials system

#### Section 2

##### II. Key components of an open and flexible clinical trials system:

- C. Consolidated **Clinical Trials Support Unit(s)** to serve 3 main purposes:
- to consolidate redundant administrative tasks
  - to provide linkage of physicians and patients anywhere to the best clinical trials

- to be able to flexibly direct funding for the costs of running clinical trials to wherever the best trials are developed and to the actual sites of patient accrual.

### **III. Expressed goals/ concerns related to making the patient accrual process more efficient**

#### Armitage Report

##### **Executive Summary**

Other challenges to clinical research, such as rapidly diminished opportunities for training, managed care, cost containment, low levels of participation in research, and diminishing levels of financial support for patient care and research have strained the system.

##### **Recruitment of Participants in Clinical Trials**

And even in studies where accrual is good, compliance and retention are not optimal. As a result, slow accrual and retention rates give way to delayed completion of clinical trials, resulting in cost inefficiencies, slowed translation of bench science, and potentially inequitable distribution of the risks and benefits of research.

#### Clinical Trials Implementation Committee Report

##### **Section 2**

###### **I. Key components of the IC vision included:**

###### **B. Efficiency and streamlining**

- Mechanisms to permit broad patient access to protocols not previously widely available

##### **Section 2**

###### **I. Key components of the IC vision included:**

###### **C. Increase accrual and broaden access to patients and physicians**

- Rapid accrual and completion of important clinical trials
- Inclusion of physicians in diverse practice settings not currently participating in clinical trials

#### Long Range Planning Committee Report

##### **Picturing the CII and Its New Model of the Clinical Trial Process**

To make our vision of the CII more "real", we developed a model of what clinical research will look like in 2004. ... Patients are accrued more rapidly since clinical trials are integrated in the standard of care.

### EAB Subcommittee on Gender/Minority Tracking Report

#### Concerns

1. Investigators do not routinely provide all data required for the NIH Population Tracking Database
2. Tracking worksheets do not allow for capturing demographic information for certain types of investigations and may therefore not adequately represent gender and minority accrual.
3. Not all NCI programs have computerized database for their active portfolios and gender/ minority data are not centrally collected
4. Investigators are not required to provide gender/minority accrual for interim or phase-put support.

### **IV. Expressed goals/ concerns related to increasing funding and better financial management of clinical trials**

#### Armitage Report

#### **Executive Summary**

Other challenges to clinical research, such as rapidly diminished opportunities for training, managed care, cost containment, low levels of participation in research, and diminishing levels of financial support for patient care and research have strained the system.

#### **Clinical Trials in a Changing Environment**

This trend in the delivery of health care poses several challenges to the clinical trials system, including access to patients and reimbursement for the costs of care for patients enrolled in clinical trials.

#### **Participation of Minorities and Underserved Populations Recommendations**

The NCI should continue to develop strategies (including necessary data bases) to convince payers that clinical trials are the preferred way to manage patients, that they represent a better standard of care, and ultimately result in decreased costs.

#### Long Range Planning Committee Report

#### **Recommendations**

**Recommendation 3. Focus informatics efforts on demonstration and evaluation projects that enhance NCI's ability to carry out its mission, by building on ongoing mainstream informatics initiatives and Internet technologies.**

Third, the NCI needs to make specific investments that address compelling nearer-term needs. This includes "bootstrapping" new efforts in the development of standards and technology.

## V. Expressed goals/ concerns related to NCI Informatics

### Clinical Trials Implementation Committee Report

#### Section 2

##### I. Key components of the IC vision included:

##### B. Efficiency and streamlining

- Major projects to create uniform informatics systems across all NCI supported clinical research projects (and, potentially, industry-sponsored trials as well)

### Long Range Planning Committee Report

#### Recommendations

**Recommendation 4. Develop a process to strategically and tactically diffuse the products and concepts of recommendations 1, 2, and 3 throughout the cancer community.**

In the cancer community there are a number of early adopters or visionaries of a comprehensive cancer informatics infrastructure and its potential impact on the clinical trials process. There is sometimes a "gap" between these early adopter/visionaries and the majority of others who are working in the cancer area. The goal of this recommendation is to develop systematic demonstration and evaluation efforts that will illustrate the impact to the people in the cancer community that can be called "early majority pragmatists."

## VI. Expressed goals/ concerns related to the protocol process

### Armitage Report

#### Reforming the Cancer Therapy Evaluation Program

The protocol review process of CTEP, which serves as an extension of its role as a clearinghouse for clinical trials, is an excellent service for the cooperative groups. However, the process has become cumbersome, overly administrative, and slow.

Clinical Trials Implementation Committee Report

**Section 4**

**VII. Simplification of Trials:** Making clinical experiments as simple as possible consistent with their essential objectives

<b>Armitage Recommendation</b>	<b>Implementation Committee Response</b>
16. All Groups and cancer centers should use the same protocol guidelines so that each critical element in a format is the same across protocols. This will allow clinical research associates, who deal with the protocols on a daily basis, to move easily and efficiently from protocol to protocol, regardless of the group of origin.	Systems for Electronic Protocol Development are being collaboratively developed as part of the informatics initiative. The early development stages of this system are described in attachment 11)

Long Range Planning Committee Report

**Picturing the CII and Its New Model of the Clinical Trial Process**

To make our vision of the CII more "real", we developed a model of what clinical research will look like in 2004. ... The entire drug development process is greatly enhanced by eliminating redundancy, most of the paper and expediting each step. Trials are authored which focus on the science of the trial, not the text of the protocol document. They are authored collaboratively by appropriate members of the community and approved within 60 days

**VII. Expressed goals/ concerns related to disseminating research findings, clinical trial information**

Armitage Report

**Clinical Trials in a Changing Environment**

This report addresses the question of whether the cancer clinical trials system can respond to the exponential increase in new therapeutics and new technology in a changing fiscal and health care environment.

**Enhanced Communications**

**To be able to create and prioritize the best new ideas in cancer treatment and prevention, the NCI-funded cooperative groups and cancer centers should be provided with the means to access all relevant electronic databases, and should be primary participants in development and testing of the new NCI informatics system.** A single informatics system for the NCI, all cancer centers, and all cooperative groups is important to the success of the clinical trials program.

### **Recruitment of Participants in Clinical Trials**

Without clinical research, recent discoveries in molecular genetics will not be translated into effective interventions for people with cancer, new chemotherapeutics cannot be safely offered to patient populations, and new prevention strategies cannot be tested for their ability to lower cancer incidence.

## Clinical Trials Implementation Committee Report

### **Section 1**

**8. Information Dissemination:** Innovative tools to provide relevant information and educational materials about clinical trials to all who need it and to link with excellent databases of other organizations

## MMHCC Pathology Committee Report Mouse from Models of Human Cancers Consortium (1/19-21/2000)

### **The recommendations of the Pathology Committee:**

5. The discussions of the MMHCC Pathology Panels should be rapidly disseminated throughout the scientific community so the necessary degree of experience can be developed.

## **VIII. Expressed goals/ concerns related to improving the general science and support of clinical trials**

### Armitage Report

### **Clinical Trials and the Community Clinical Oncology Program**

If resources could be identified, the development of a national data base formed by identifying representative cancer patients not participating in clinical trials and monitoring them from diagnosis would provide a method to judge the impact of the cancer clinical trials program on oncology practice in the United States.

## EAB Subcommittee on Gender/Minority Tracking Report

### Concerns

1. Investigators do not routinely provide all data required for the NIH Population Tracking Database
2. Tracking worksheets do not allow for capturing demographic information for certain types of investigations and may therefore not adequately represent gender and minority accrual.
3. Not all NCI programs have computerized database for their active portfolios and gender/ minority data are not centrally collected
4. Investigators are not required to provide gender/minority accrual for interim or phase-put support.

### **Excerpts from NCI Documents Enacting Improvements in the Clinical Trial Program**

This section presents excerpts from two NCI documents detailing specific actions the NCI has undertaken to address some of the needs for improving the clinical trial program.

#### Interagency Agreement Between the Department of Defense and National Cancer Institute for Partnership in Clinical Trials for Cancer

##### **SCOPE:**

1. All DoD MTFs providing oncology services will be allowed to apply for participation in NCI protocols for both adult and pediatric cancers according to the usual NCI Cooperative Group or other clinical trials participation review process.
2. Any TRICARE/CHAMPUS authorized provider providing oncology services will be allowed to apply for participation in NCI protocols in both adult and pediatric cancers according to the usual NCI Cooperative Group or other clinical trials participation review process.

“Document Development and Management Streamlining Plans” Memo from CTEP PIO Head to Associate Director CTEP. August 31, 1998

##### Objective

To streamline the protocol development and review process from conception to protocol activation by reducing the administrative burden and by providing investigators electronic tools to facilitate document development. The NCI’s goal is that in 2001 the average protocol will require less than 250 days to develop.

##### Global issues

- Standards development – Common language and definitions must be developed to provide a foundation for the enterprise database.

## **Further Knowledge Acquisition**

The next steps in Knowledge Acquisition for this project include:

- Validating the information in this report
- Developing a more complete listing of NCI's IT activities and relevant oversight committee documents
- Ascertaining how NCI managers want to use the information