

Attachment 4B. Consultations NCI Advisory Boards and Organizations Outside NCI regarding the Clinical Trials Reporting Program (CTRP) Database:

Organizations Outside NCI

1. Consultations via the NCI's Cancer Biomedical Informatics Grid (caBIG®) Program

In an effort to encourage broad community engagement in the development of the CTRP Database, this project has been coordinated with the National Cancer Institute's cancer Biomedical Informatics Grid (caBIG®) program. As listed below, NCI has made numerous presentations during caBIG face-to-face meetings and teleconference calls, all of which are open to the public and in which the cancer research community actively participates. Moreover, the caBIG® Clinical Trials Management Systems (CTMS) Workspace has been regularly discussing and planning the development of this electronic infrastructure resource since shortly after the NCI Clinical Trials Working Group (CTWG) report recommended the establishment of the CTRP Database in June 2005 as one of four strategic informatics initiatives. The caBIG® CTMS Workspace Steering Committee was established specifically to facilitate strategic feedback and guidance from the biomedical research and informatics communities for the deployment of the CTWG informatics initiatives, including the CTRP Database. This committee is made up of members of the cancer research community, divided approximately equally into "trialists" (e.g., investigators, statisticians, clinical trials office directors) and "informaticists". The CTMS Workspace Steering Committee includes members of the NCI Cancer Center Community, the NCI Cooperative Groups and two patient advocate representatives. NCI and FDA representatives also attend the meeting as federal observers.

The CTMS Workspace Steering Committee meets face-to-face three times yearly; NCI staff members deliver a presentation on the CTRP Database and solicit feedback at each meeting. Moreover, NCI recently established the CTRP Implementation Subcommittee of the CTMS Workspace Steering Committee, which meets regularly by teleconference between quarterly Steering Committee meetings. These meetings will allow in-depth discussions of the design, implementation and progress of the CTRP Database.

Current members of the caBIG® CTMS Workspace Steering Committee include:

- Jan C. Buckner, M.D., Chair, Division of Medical Oncology, and Professor of Oncology, Mayo Clinic College of Medicine, and Chair, North Central Cancer Treatment Group (Co-Chair)

- Sorena Nadaf, M.S., M.M.I., Director, Translational Informatics, and Chief Information Officer, Helen Diller Family Comprehensive Cancer Center, University of California, San Francisco (Co-Chair)
- Robert P. Annechiarico, Director of Cancer Center Information Systems, Duke Comprehensive Cancer Center
- James N. Atkins, M.D., Principal Investigator, Southeast Cancer Control Consortium Community Clinical Oncology Program
- Rebecca J. Benner, Ph.D., Associate Director, Oncology Statistics, Pfizer, Inc.
- Powel H. Brown, M.D., Ph.D., Associate Professor of Medicine, and Director, Cancer Prevention Section, Breast Care Center, Baylor College of Medicine
- Christopher Chute, M.D., Dr.P.H., Professor of Medical Informatics, Associate Professor of Epidemiology and Chair, Biomedical Informatics, Mayo Clinic
- Walter M. Cronin, M.P.H., Executive Director, National Surgical Adjuvant Breast and Bowel Project
- Sharon A. Elcombe, M.A., Systems Coordinator, Mayo Clinic Cancer Center and North Central Cancer Treatment Group
- Gwen Fyfe, M.D., Vice President, Hematology and Oncology, Genentech, Inc.
- Robert J. Gray, Ph.D., Professor of Biostatistics, Harvard School of Public Health, and Group Statistician, Eastern Cooperative Oncology Group
- Collette M. Houston, Director, Clinical Research Operations, Memorial Sloan-Kettering Cancer Center
- Charles S. Hurmiz, Director, Department of Clinical Research Informatics, St. Jude Children's Research Hospital
- Charles J. Jaffe, M.D., Ph.D., Senior Global Strategist, Digital Health Group, Intel Americas, Inc., and Chief Executive Officer, Health Level Seven, Inc.
- Kimberly F. Johnson, Director of Information Systems, Cancer and Leukemia Group B
- Roy Jones, M.D., Ph.D., Professor of Medicine, University of Texas M.D. Anderson Cancer Center

- Philip W. Kantoff, M.D., Professor, Department of Medicine, Harvard Medical School, Director, Lank Center for Genitourinary Oncology, Dana-Farber Cancer Institute, and Associate Physician, Medicine, Brigham And Women's Hospital
- Warren A. Kibbe, Ph.D., Research Associate Professor, Director of Bioinformatics, Center for Genetic Medicine, Director of Bioinformatics, Robert H. Lurie Comprehensive Cancer Center, Associate Director of the Northwestern University Biomedical Informatics Center (NUBIC), Feinberg School of Medicine, Northwestern University
- Rebecca D. Kush, Ph.D., President, Clinical Data Interchange Standards Consortium
- Kevin Lewis, M.B.A., Principal, Business Technologies Group, PRTM Management Consultants, Inc., and Board Member, Colon Cancer Alliance (patient advocate)
- Raymond S. Lord, M.D., Principal Investigator, West Michigan Community Clinical Oncology Program
- Kristin Padavic-Shaller, R.N., M.S.N., Clinical Research Coordinator, Fox Chase Cancer Center
- Electra D. Paskett, Ph.D., Associate Director for Population Science, and Marion N. Rowley Professor of Cancer Research, Ohio State University Comprehensive Cancer Center
- Diane Paul, Consumer Advocates in Research and Related Activities (patient advocate)
- Nicholas J. Petrelli, M.D., Medical Director, Helen F. Graham Cancer Center, Christiana Care Health System
- Daniel J. Sargent, Ph.D., Professor of Biostatistics and Oncology, and Director of Cancer Center Statistics, Mayo Clinic College of Medicine
- Mitchell D. Schnall, M.D., Ph.D., Matthew J. Wilson Professor of Research Radiology, and Associate Chair of Research, Department of Radiology, University of Pennsylvania
- Ida Sim, M.D., Ph.D., Associate Professor, Division of General Internal Medicine, Director, Center for Clinical and Translational Informatics, and Graduate Group Member, Program in Biological and Medical Informatics, University of California, San Francisco
- Donald L. Trump, M.D., President and CEO, Roswell Park Cancer Institute
- Brenda K. Young, Senior Director, Clinical Operations, ACR Image Metrix, Inc., and Senior Director of Clinical Trials Informatics, American College of Radiology

Current federal observers who participate in the caBIG® CTMS Workspace Steering Committee include:

- Jeffrey S. Abrams, M.D., Associate Director, Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute
- Frank M. Balis, M.D., Head, Pharmacology and Experimental Therapeutics Section, Senior Investigator, and Clinical Director, Center for Cancer Research, National Cancer Institute
- James H. Doroshow, M.D., Director, Division of Cancer Treatment and Diagnosis, National Cancer Institute
- Leslie G. Ford, M.D., Associate Director, Division of Cancer Prevention, National Cancer Institute
- Lakshmi M. Grama, M.A., M.L.S., Chief, International Cancer Research Databank Branch, Office of Communication and Education, National Cancer Institute
- Armando Oliva, M.D., CAPT, U.S. Public Health Service, and Deputy Director for Bioinformatics, U.S. Food and Drug Administration
- Sheila A. Prindiville, M.D., M.P.H., Director, Coordinating Center for Clinical Trials, National Cancer Institute
- Dianne Reeves, R.N., M.S.N, Associate Director for Biomedical Data Standards, Center for Biomedical Informatics and Information Technology, National Cancer Institute
- Peggy Tucker, M.D., Director, Human Genetics Program, and Director, Human Genetics Program, and Chief, Genetic Epidemiology Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute
- Linda K. Weiss, Ph.D., Chief, Cancer Centers Branch, National Cancer Institute
- Jo Anne Zujewski, M.D., Head, Breast Cancer Therapeutics, Clinical Investigation Branch, Cancer Therapy Evaluation Program, National Cancer Institute

NCI staff members have made at least 22 presentations and solicited feedback concerning the CTRP Database over the last 3 years at face-to-face meetings and teleconferences of various groups participating in the caBIG initiative, as listed below:

- **caBIG Annual Meeting:** April 2006, February 2007, June 2008
- **caBIG CTMS Workspace Meetings:** December 2006, May 2007, November 2007, April 2008, September 2008, March 2009
- **caBIG Data Sharing and Intellectual Capital Workspace Meeting:** May 2007 and January 2008
- **caBIG CTMS Workspace/Special Interest Group (SIG) Teleconferences:** September 2007, May 2008, July 2008, December 2008, January 2009
- **caBIG CTMS Workspace Steering Committee Meetings:** March 2007, August 2007, December 2007, May 2008, September 2008, December 2008, April 2009

2. Other venues for feedback and comment

NCI has regularly briefed and solicited feedback from the NCI Cancer Center Directors and other NCI grantee groups as well as other members of the cancer research community regarding the CTRP Database. Below is a sampling of groups to which presentations have been made over the last three years:

- **HMO Cancer Research Network (CRN) Annual Conference:** May 2006. The CRN, a program funded by NCI, consists of the research programs, enrolled populations, and data systems of 14 health maintenance organizations nationwide.
- **Onsemble Oncore User Group Conference:** July 2006. A consortium of academic medical centers that using a particular commercial clinical data management software system to perform their day to day tasks. Members include study coordinators, data managers, and financial coordinators. In addition, many individuals at NCI-funded cancer centers like clinical investigators and cancer center administrators rely on the information available through this product for their clinical research operations.
- **Cancer Center Administrators' Forum Annual Meeting:** March 2008, March 2009. The Cancer Administrators Forum is the professional association for chief administrative officers for all cancer centers that receive NCI funding.

- **National Cancer Institute Cancer Center Directors' Retreat:** May 2008. The NCI Cancer Centers Program supports 63 NCI-designated cancer centers nationwide that are actively engaged in trans-disciplinary research to reduce cancer incidence, morbidity, and mortality. The NCI-designated Cancer Centers are a major source of discovery of the nature of cancer and of the development of more effective approaches to cancer prevention, diagnosis, and therapy. They also deliver medical advances to patients and their families, educate health-care professionals and the public, and reach out to underserved populations. They are characterized by strong organizational capabilities, institutional commitment, and trans-disciplinary, cancer-focused science; experienced scientific and administrative leadership, and state-of-the-art cancer research and patient care facilities. NCI-designated Cancer Centers receiving funding for: formal research programs that foster interactions between basic laboratory, clinical, and population scientists; access for investigators to shared services and technologies that are necessary to their research efforts; and other scientific infrastructure.
- **American Association of Cancer Institutes Meeting:** October 2008. The Association of American Cancer Institutes comprises 95 leading cancer research centers in the United States, including the National Cancer Institute-designated centers and academic-based cancer research programs that receive NCI support
- **Cancer and Leukemia Group B (CALGB) Meeting:** November 2008. The Cancer and Leukemia Group B (CALGB) is a national clinical research group sponsored by the NCI, with the Central office headquartered at the University of Chicago and the Statistical Center located at Duke University. The CALGB is a national network of 26 university medical centers, more than 200 community hospitals and more than 3,000 oncology specialists who collaborate in clinical research studies. These studies aim to reduce morbidity and mortality from cancer, relate biological characteristics of cancer to clinical outcomes, and develop new strategies for the early detection and prevention of cancer.