

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

NCI Advisory Boards

NCI staff members have made 22 presentations concerning the CTRP Database to three NCI federal advisory committees, each of which is authorized pursuant to 42 U.S.C. 285a-2(b)(7), section 413(b)(7) of the Public Health Service Act, as amended, and governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

1. Clinical and Translational Research Advisory Committee (CTAC)

NCI staff members have made 7 presentations to the NCI Clinical and Translational Research Advisory Committee (CTAC) concerning the CTRP Database as follows: January 2007, July 2007, November 2007, February 2008, June 2008, December 2008 and March 2009. Minutes for CTAC meetings can be found at <http://deainfo.nci.nih.gov/advisory/ctac/ctacminmenu.htm>.

The CTAC is the NCI advisory committee that reviews and delivers feedback on the plans, progress and timelines for the CTRP Database. The CTAC is charged with overseeing the implementation of all 22 recommendations of the 2005 report of the Clinical Trials Working Group to the National Cancer Advisory Board.

The CTAC consists of 25 members, including the Director, NCI, who chairs the Committee. At least five members must hold concurrent membership on either the National Cancer Advisory Board, Board of Scientific Advisors, Board of Scientific Counselors (Basic Sciences and Clinical Sciences and Epidemiology), or Director's Consumer Liaison Group. CTAC members are required to be authorities knowledgeable in the fields of community oncology, surgical oncology, medical oncology, radiation oncology, patient advocacy, extramural clinical investigation, regulatory agencies, pharmaceutical industry, public health, clinical trials design, management and evaluation, drug development and developmental therapeutics, cancer education, cancer information services, community outreach, vaccine development, cellular oncology, molecular oncology, pediatric oncology, clinical, basic and translational research, cancer center administration, cancer biology and diagnosis, cancer epidemiology, chemotherapy, community outreach, oncology health care providers, pharmacology, pathology, biostatistics, quality of life, pain management, cancer treatment and restorative care, and education of health professionals.

Ex officio members include NCI Deputy Directors, the Director for the Division of Extramural Activities, NCI, the Director for the Division of Cancer Treatment and Diagnosis, an NCI intramural scientist engaged in clinical research, and representatives from the Food and Drug

Administration, Centers for Medicare and Medicaid Services, the Department of Defense and Department of Veterans Affairs.

The CTAC makes recommendations on the NCI-supported national clinical trials enterprise to build a strong scientific infrastructure by bringing together a broadly developed and engaged coalition of stakeholders involved in the clinical trials process. This encompasses oversight of all trials both extramural and intramural. The CTAC provides broad scientific and programmatic advice on the investment of tax payer dollars in clinical trials and supportive science, resulting in enormous potential for more specific cancer treatment, coupled with the complexity of evaluating new, highly specific agents integrating knowledge, insights, and skills of multiple fields into a new kind of cross-disciplinary, scientifically-driven, cooperative research endeavor. In addition, the CTAC makes recommendations regarding the effectiveness of NCI's translational research management and administration program, including needs and opportunities across disease sites, patient populations, translational developmental pathways, and the range of molecular mechanisms responsible for cancer development. The CTAC advises on the appropriate magnitude for dedicated translational research priorities and recommend allocation of translational research operations across organizational units, programs, disease sites, populations, developmental pathways, and molecular mechanisms. The CTAC also ensures that appropriate emphasis is placed on rare cancers, medically underserved populations, and historically lower-resourced pathways to clinical goals.

The goal is to foster an open, collaborative system involving all the critical stakeholders in the prioritization process bringing diverse institutions and individuals together into an integrated and efficient, but innovative and responsive effort, thus moving discoveries to benefit cancer patients.

Meetings of the full Committee are held approximately 3 times within a fiscal year. Meetings are open to the public except as determined otherwise by the Secretary of Health and Human Services (Secretary) in accordance with subsection (c) of section 552b of Title 5 U.S.C.

MEMBERS:

John E. Niederhuber, M.D., Director, National Cancer Institute (Chairperson)

James L. Abbruzzese, M.D., Chairman, Department of Gastrointestinal Medical Oncology, University of Texas M.D. Anderson Cancer Center

Peter C. Adamson, M.D., Professor, Pediatrics and Pharmacology, and Chief, Clinical Pharmacology and Therapeutics, The Children's Hospital of Philadelphia

David S. Alberts, M.D., Director, Arizona Cancer Center

Kirby I. Bland, M.D., Fay Fletcher Kerner Professor and Chairman, Department of Surgery, and Deputy Director, UAB Comprehensive Cancer Center, University of Alabama at Birmingham

Deborah W. Bruner, Ph.D., Independence Professor in Nursing Education, School of Nursing, University of Pennsylvania

Curt Civin, M.D., Associate Dean for Research, Professor of Pediatrics, and Director, Center for Stem Cell Biology and Regenerative Medicine, University of Maryland School of Medicine

Kenneth H. Cowan, M.D., Ph.D., Director, Eppley Cancer Center, University of Nebraska Medical Center

Everett Dodson, Community Health Educator, Lombardi Comprehensive Cancer Center

Stephen S. Grubbs, M.D., Chief of Oncology, Medical Oncology Hematology Consultants, PA

Bruce J. Hillman, M.D., Theodore E. Keats Professor of Radiology, and Professor, Department of Health Evaluation Sciences, University of Virginia School of Medicine

Sandra J. Horning, M.D., Professor of Medicine, Stanford Comprehensive Cancer Center

K. Gabriel Leung, M.S., Executive Vice President, and President, Oncology, OSI Pharmaceuticals

Nancy P. Mendenhall, M.D., Professor, Department of Radiation Oncology, University of Florida Health Science Center

Heidi Nelson, M.D., Fred C. Anderson Professor, Division of Colon and Rectal Surgery, Department of Surgery, Mayo Clinic Foundation

David R. Parkinson, M.D., President and CEO, Nodality, Inc.

Edith A. Perez, M.D., Professor of Medicine, Division of Hematology/Oncology, Mayo Medical School, and Director, Breast Cancer Program, Mayo Clinic Foundation

Timothy R. Rebbeck, Ph.D., Professor, Department of Biostatistics and Epidemiology, University of Pennsylvania School of Medicine

Nancy Roach, Consumer Advocate, C3: Colorectal Cancer Coalition

Carolyn D. Runowicz, M.D., Director, The Carole and Ray Neag Comprehensive Cancer Center, and Northeast Utilities Chair in Experimental Oncology, University of Connecticut Health Center

Daniel J. Sargent, Ph.D., Director, Cancer Center Statistics, and Professor, Division of Biostatistics, Mayo Clinic College of Medicine

Richard L. Schilsky, M.D., Professor of Medicine, and Associate Dean for Clinical Research, Biological Sciences Division, University of Chicago Pritzker School of Medicine

Joel E. Tepper, M.D., Hector MacLean Distinguished Professor of Cancer Research, Department of Radiation Oncology, University of North Carolina Lineberger Comprehensive Cancer Center

James L. Wade, III, M.D., Director of Medical Oncology, Department of Clinical Research, Decatur Memorial Hospital Cancer Care Institute, and President, Cancer Care Specialists

EX OFFICIO MEMBERS:

Anna Barker, Ph.D., Deputy Director, National Cancer Institute

James H. Doroshow, M.D., Director, Division of Cancer Treatment and Diagnosis, National Cancer Institute

Paulette Gray, Ph.D., Director, Division of Extramural Activities, National Cancer Institute
National Institutes of Health

Lee Helman, M.D., Chief, Pediatric Oncology Branch, and Deputy Director, Center for Cancer Research, National Cancer Institute

Sheila A. Prindiville, M.D., M.P.H., Director, Coordinating Center for Clinical Trials, National Cancer Institute (Executive Secretary)

Michael J. Kelley, M.D., F.A.C.P., National Program Director for Oncology Veterans Health Administration, Department of Veterans Affairs

Richard Pazdur, M.D., F.A.C.P., Director, Division of Oncology Drug Products, U.S. Food and Drug Administration

John F. Potter, M.D., Director, United States Military Cancer Institute, Walter Reed Army Medical Center

Alan Rabson, M.D., Deputy Director, National Cancer Institute

2. NCI Board of Scientific Advisors (BSA)

NCI staff members have made 3 presentations to the NCI's Board of Scientific Advisors (BSA) concerning the CTRP Database as follows: March 2007, June 2007, and March 2008. Minutes for BSA meetings can be found at <http://deainfo.nci.nih.gov/advisory/bsaminmenu.htm>

The BSA consists of 35 members, including the Chair appointed by the Director, NCI, from authorities knowledgeable in the fields of laboratory, clinical and biometric research, clinical cancer treatment, cancer etiology, and cancer prevention and control, with emphasis on training and experience in the various disciplines and fields related to scientific areas relevant to carcinogenesis, cancer biology and diagnosis, cancer center administration, medicine, radiological and surgical oncology, cancer chemotherapy, cancer epidemiology, cancer prevention and control, cancer education, cancer information services, community outreach, biological, chemical and physical carcinogenesis, DNA repair and effects, tumor biology and immunology, humoral and cellular immunity, hematopoiesis, cell differentiation and transformation, oncogenes and growth factors, molecular and structural biology and genetic regulation, viral oncology, vaccine development, transplantation, chemotherapy, clinical trial design, management and evaluation, pharmacology, drug development and developmental therapeutics, genetic and immunotherapies, pathology, diagnostic research and cytogenetics, biological response modifiers, imaging, nutrition, survey research, epidemiology, biostatistics, rehabilitation, psychology and behavioral medicine, public health and community oncology, quality of life, pain management, cancer detection and diagnosis, cancer treatment and restorative care, dentistry, nursing, public health, nutrition, education of health professionals, medical oncology, surgery, radiotherapy, gynecologic oncology, pediatric oncology, pathology, and biostatistics.

The BSA advises the Director and Deputy Director for Extramural Science, NCI, and the Director of each NCI Division on a wide variety of matters concerning scientific program policy, and progress and future direction of extramural research programs of each of the Divisions. This includes the evaluation of NCI awarded grants, cooperative agreements and contracts and concept review of those activities which it considers meritorious and consistent with the Institute's programs. The advisory role of the Board is scientific and does not include deliberation on matters of public policy.

Meetings of the full Board are held approximately three times a year. Meetings are open to the public except as determined otherwise by the Secretary of Health and Human Services in accordance with subsection (c) of section 552b of Title 5, U.S.C.

MEMBERS:

Robert C. Young, M.D., Chancellor, Fox Chase Cancer Center, Philadelphia, Pennsylvania
(Chairperson)

Paul M. Allen, Ph.D., Robert L. Kroc Endowed Professor of Pathology Department of Pathology and Immunology, Washington University School of Medicine, St. Louis, Missouri

Christine B. Ambrosone, Ph.D., Professor of Oncology, Chair, Departments of Epidemiology and Cancer Prevention and Control Roswell Park Cancer Institute, Buffalo, New York

Kirby I. Bland, M.D., Fay Fletcher Kerner Professor and Chairman, Department of Surgery, Deputy Director, Comprehensive Cancer Center, University of Alabama at Birmingham, Birmingham, Alabama

Andrea Califano, Ph.D., Director, Center for the Multiscale Analysis of Genetic Networks, Professor of Biomedical Informatics, Dept. of Biomedical Informatics, Institute of Cancer Genetics, Columbia University Medical Center, New York, New York

Michael A. Caligiuri, M.D., CEO and Director, The Comprehensive Cancer Center Ohio State University (OSUCCC), Columbus, Ohio

Curt I. Civin, M.D., Herman & Walter Samuelson Professor of Oncology, Professor of Pediatrics, The Johns Hopkins University School of Medicine, The Sidney Kimmel Comprehensive Cancer Center, Baltimore, Maryland

Susan J. Curry, Ph.D., Professor and Dean, College of Public Health, The University of Iowa, Iowa City, Iowa

William S. Dalton, M.D., Ph.D., Chief Executive Officer and Center Director, H. Lee Moffitt Cancer Center and Research Institute, University of South Florida, Tampa, Florida

Robert B. Diasio, M.D., Director, Mayo Clinic Cancer Center, William J. and Charles H. Mayo Professor
Professor of Pharmacology, Department of Molecular Pharmacology and Experimental Therapeutics, Mayo Clinic, Rochester, Minnesota

Kathleen M. Foley, M.D., Director, Pain and Palliative Care Service, Department of Neurology, Memorial Sloan Kettering Cancer Center, New York, New York

Sanjiv S. Gambhir, M.D., Ph.D., Professor, Department of Radiology and Bio-X Program Director, Molecular Imaging Program, Stanford University, Stanford, California

Todd R. Golub, M.D., Associate Professor, Cancer Program, The Broad Institute of Massachusetts Institute of Technology and Harvard University, Cambridge, Massachusetts

Joe W. Gray, Ph.D., Director, Division of Life Sciences Associate Director, Biosciences, Lawrence Berkeley National Laboratory, Berkeley, California

Leland H. Hartwell, Ph.D., President and Director, Fred Hutchinson Cancer Research Center, Department of Genetics, University of Washington, Seattle, Washington

James R. Heath, Ph.D., Elizabeth W. Gilloon Professor and Professor of Chemistry Division of Chemistry and Chemical Engineering, California Institute of Technology, Pasadena, California

Mary J. Hendrix, Ph.D., President and Scientific Director, Children's Memorial Research Center, Professor of Pediatrics, Feinberg School of Medicine, Northwestern University, Chicago, Illinois

Leroy E. Hood, M.D., Ph.D., President and Founder, Institute for Systems Biology, Seattle, Washington

Marc A. Kastner, Ph.D., Dean, School of Science, Donner Professor of Science, Massachusetts Institute of Technology, Cambridge, Massachusetts

Timothy J. Kinsella, M.D., Vincent K. Smith Chair in Radiation Oncology, Professor, Department of Radiation Oncology, Case Western Reserve University School of Medicine, Cleveland, Ohio

Christopher J. Logothetis, M.D., Chairman and Professor, Department of Genitourinary Medical Oncology, The University of Texas M.D. Anderson Cancer Center, Houston, Texas

Kathleen H. Mooney, Ph.D., F.A.A.N., R.N., Louis S. Peery, M.D., and Janet B. Peery Presidential Endowed Chair in Nursing Research, Professor, University of Utah College of Nursing, Salt Lake City, Utah

James L. Omel, M.D., Education and Advocacy Volunteer, International Myeloma Foundation Volunteer, Multiple Myeloma Research Volunteer, Leukemia, Lymphoma, Myeloma Society, Grand Island, Nebraska

Edith A. Perez, M.D., Professor of Medicine, Division of Hematology/Oncology, Mayo Medical School,
Director, Breast Cancer Program, Mayo Clinic, Jacksonville, Florida

Richard L. Schilsky, M.D., Professor of Medicine, Section of Hematology/Oncology, Biological Sciences Division, University of Chicago, Pritzker School of Medicine, Chicago, Illinois

Robert D. Schreiber, Ph.D., Alumni Endowed Professor of Pathology and Immunology, Department of Pathology and Immunology, Washington University School of Medicine, St. Louis, Missouri

Stuart L. Schreiber, Ph.D., Morris Loeb Professor and Chair, Director, Chemical Biology, Broad Institute of Harvard and MIT Harvard University, Cambridge, Massachusetts

Ellen V. Sigal, Ph.D., Chairperson, Friends of Cancer Research, Arlington, Virginia

Bruce W. Stillman, Ph.D., President and Chief Executive Officer, Cold Spring Harbor Laboratory, Cold Spring Harbor, New York

Victor J. Strecher, Ph.D., MPH, Professor, Department of Health Behavior and Health Education, Cancer Prevention and Control, School of Public Health, University of Michigan, Ann Arbor, Michigan

Louise C. Strong, M.D., Sue and Radcliff Killam Chair, Professor of Cancer Genetics, Department of Cancer Genetics, The University of Texas M. D. Anderson Cancer Center, Houston, Texas
(*pending*)

Jean Y. Wang, Ph.D., Professor, Department of Medicine, Moores School of Medicine, University of California, San Diego, La Jolla, California

Jane C. Weeks, M.D., Professor of Medicine, Chief, Division of Population Sciences, Department of Medical Oncology, Dana-Farber Cancer Institute, Boston, Massachusetts

Irving L. Weissman, M.D., Director, Stanford University Comprehensive Cancer Center, Stanford University, Stanford, California

James K. Willson, M.D., Director, Simmons Comprehensive Cancer Center University of Texas Southwestern Medical Center, Dallas, Texas

3. National Cancer Advisory Board (NCAB)

NCI staff members have made 2 presentations to the National Cancer Advisory Board (NCAB) concerning the CTRP Database as follows: February 2008 and February 2009. Minutes for NCAB meetings can be found at <http://deainfo.nci.nih.gov/advisory/ncabminmenu.htm>

The NCAB consists of: 18 members appointed by the President and 12 nonvoting ex officio members who include the Secretary; the Director of the Office of Science and Technology Policy; the Director of the National Institutes of Health, (NIH); the Chief Medical Director of the

Department of Veterans Affairs; the Director of the National Institute for Occupational Safety and Health; the Director of the National Institute of Environmental Health Sciences; the Secretary of Labor; the Commissioner of the Food and Drug Administration; the Administrator of the Environmental Protection Agency; the Chairman of the Consumer Product Safety Commission; the Assistant Secretary of Defense for Health Affairs; and the Director of the Office of Energy Research of the Department of Energy (or their designees).

Not more than 12 of the appointed members are selected from among the leading representatives of the health and scientific disciplines (including not less than two individuals who are leaders in the fields of public health and the behavioral or social sciences) that are relevant to the activities of the Institute. Not more than six of the appointed members are representatives from the general public, including leaders in fields of public policy, law, health policy, economics and management. Not less than five of the appointed members are individuals knowledgeable in environmental carcinogenesis (including carcinogenesis involving occupational and dietary factors).

The NCAB duties are to advise, assist, consult with, and make recommendations to the Secretary and the Director, National Cancer Institute, with respect to the activities carried out by and through the Institute and policies respecting these activities; the NCAB may recommend for support grants and cooperative agreements, following technical and scientific peer review; and relating to the functions pertaining to the NCI described under sections 405, 406, 413, and 414 of the PHS Act, as amended.

The NCAB may implement procedures for expediting en bloc concurrence of Scientific Review Group recommendations. A member or members may be selected by the Executive Secretary or Chair to provide en bloc concurrence on behalf of the Board. Only those applications that do not require individual consideration shall be included in this expedited process. A report of the en bloc recommendations will be presented at each Board meeting.

Meetings shall be open to the public except as determined otherwise by the Secretary. Notice of all meetings shall be given to the public.

The current membership of the NCAB includes:

MEMBERS

Carolyn D. Runowicz, M.D., Director, The Carole and Ray Neag Comprehensive Cancer Center, and Northeast Utilities Chair in Experimental Oncology, University of Connecticut Health Center (Chairperson)

Anthony Atala, M.D., Director, Wake Forest Institute for Regenerative Medicine
Professor and Chairman, Department of Urology, Wake Forest University School of Medicine,
Winston-Salem, NC

Bruce Allan Chabner, M.D., Clinical Director, Massachusetts General Hospital Cancer Center,
Chief of Hematology/Oncology Massachusetts General Hospital Boston, MA

Victoria L. Champion, D.N.S., Associate Dean for Research, Mary Margaret Walther
Distinguished Professor of Nursing, Center for Research & Scholarship Indiana University School
of Nursing Indianapolis, IN

Donald S. Coffey, Ph.D., The Catherine Iola and J. Smith Michael, Distinguished Professor of
Urology, Professor of Urology/Oncology/Pathology/ Pharmacology and Molecular Science,
Johns Hopkins University School of Medicine, Baltimore, MD

Lloyd K. Everson, M.D., Vice Chairman and Member of the Board of Directors, US Oncology
Incorporated, Houston, TX

Kathryn Giusti, M.B.A., CEO and Founder, Multiple Myeloma Research Foundation, Inc.
Multiple Myeloma Research Consortium Norwalk, CT

William H. Goodwin, Jr., M.B.A., Chairman and President CCA Industries, Inc. Richmond, VA

Waun Ki Hong, M.D., Professor, Head, Division of Cancer Medicine Department of
Thoracic/Head & Neck Medical Oncology, The University of Texas M.D. Anderson Cancer Center
Houston, TX

Robert A. Ingram, Vice Chairman, Pharmaceuticals, GlaxoSmithKline, Research Triangle Park,
NC

Judith S. Kaur, M.D., Medical Director, Native American Programs, Mayo Comprehensive Cancer
Center, Professor of Oncology Department of Medical Oncology Mayo Clinic, Rochester, MN

David H. Koch, M.S., Executive Vice President, Koch Industries, New York, NY

Mary Vaughan Lester, Board of Directors University of California, San Francisco Foundation, Los
Angeles, CA

Diana M. Lopez, Ph.D., Professor, Department of Microbiology and Immunology, University of
Miami Miller School of Medicine, Miami, FL

Daniel D. Von Hoff, M.D., F.A.C.P., Physician in Chief, Senior Investigator, Translational
Genomics Research Institute (TGen), Clinical Professor of Medicine, University of Arizona,

Arizona Cancer Center, Arizona Health Sciences Center, Phoenix, AZ

H. Kim Lyerly, M.D., Director, Duke Comprehensive Cancer Center, George Barth Geller Professor of Cancer Research, Duke University Medical Center, Durham, NC

Karen M. Meneses, Ph.D., Professor and Associate Dean for Research University of Alabama at Birmingham School of Nursing, Birmingham, AL

Jennifer A. Pietenpol, Ph.D., Director, Vanderbilt-Ingram Cancer Center B.F. Byrd, Jr. Professor of Oncology Professor of Biochemistry, Vanderbilt University Medical Center, Nashville, TN

EX OFFICIO MEMBERS

Linda S. Birnbaum, Ph.D., D.A.B.T., A.T.S., Director, National Institute of Environmental Health Sciences and The National Technology Program, National Institutes of Health, Research Triangle Park, NC

Christine Branche, Ph.D., Acting Director, National Institute for Occupational Safety and Health (NIOSH), Washington, DC

Ms. Ellen P. Embrey, Performing the duties of the Assistant Secretary of Defense for Health Affairs, The Pentagon, Washington, DC

Margaret A. Hamburg, M.D., Commissioner, Food and Drug Administration, Silver Spring, MD

John P. Holdren, Ph.D., Science Advisor to the President, Director, Office of Science and Technology Policy, Executive Office of the President, Washington, DC

Lisa Jackson, M.S., Administrator, Environmental Protection Agency, Washington, DC

Raynard S. Kington, M.D., Ph.D., Acting Director, National Institutes of Health, Bethesda, MD

The Honorable Dr. Michael J. Kussman, Under Secretary for Health, Veterans Health Administration Department of Veterans Affairs Washington, DC

Mr. Thomas H. Moore, Acting Chairman and Commissioner Consumer Product Safety Commission, Bethesda, MD

Anna Palmisano, Ph.D., Associate Director, Office of Biological and Environmental Research, Department of Energy Washington, DC

The Honorable Kathleen Sebelius, M.P.A., Secretary, Department of Health and Human Services,

Washington, DC

The Honorable Hilda L. Solis, Secretary, Department of Labor, Washington, DC