An Overview of the NCI and CCR

Elizabeth Ness, RN, MS
Nurse Consultant (Education)
Center for Cancer, NCI
The National Cancer Institute

• Largest component of the NIH
• Largest cancer research organization in world
• >3,000 FTEs
• Director: Harold Varmus, M.D.
NCI Organizational Structure

NIH

NCI

Office of the Director

>20 offices/centers

Office of Communications & Education

Center for Biomedical Informatics & Information Technology (CBIIT).

CCR *

DCB #

DEA #

DCTD #

DCEG *

DCP #

DCCPS #

* Intramural Research Program
# Extramural Research Program
DCTD Programs

- Cancer Diagnosis Program (CDP)
- Cancer Imaging Program (CIP)
- Cancer Therapy Evaluation Program (CTEP)
- Developmental Therapeutics Program (DTP)
- Radiation Research Program (RRP)
- Biometric Research Branch (BRB)
- Office of Cancer Complementary and Alternative Medicine (OCCAM)
NCI Budget

• > $5,000,000,000
• ≈ 81% extramural research activities
• ≈ 15% intramural research activities
Major Milestones

1937: National Cancer Institute Act

1944: PHS Act

1971: National Cancer Act
National Cancer Program

Conducts and supports research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients
NCA Key Provisions

• National Cancer Advisory Board (NCAB)
  • 18 scientific and lay members are appointed by the President to advise NCI on major initiatives against cancer

• President's Cancer Panel
  • 3-member panel of experts, including a consumer, who independently appraise the progress of the national program and submit an annual report directly to the President.

• Granted bypass budget authority
• NCI Director: presidential appointee
NCI Designated Cancer Centers (n = 68)

- Three major areas of research:
  - Basic research
  - Prevention, control, behavioral and population-based
  - Clinical research

- Two types of centers:
  - Cancer Centers (27)
    - Scientific agenda focuses on any one or two areas
  - Comprehensive Cancer Centers (41)
    - Scientific agenda integrates all three areas
Cooperative Group History...

- 1955 Congress awarded $5 million to the NCI to establish the Cancer Chemotherapy National Service Center (CCNSC)

- 1955-1960:
  - Development of over 15 Groups, organized and operated by research grants from NCI
  - Main purpose - test new anticancer agents from the NCI’s investigational agent development program
Cooperative Group History

- 1966: Separated from the drug development program; multidisciplinary studies begun

- 1968: Clinical Investigations Branch created at NCI to administer program & Cancer Clinical Investigations Review Committee was chartered

- 1981 Mechanism of support converted from a grant to cooperative agreement to define the involvement of NCI program staff in the coordination of Group activities
Implementing IOM Recommendations

NCI is implementing a comprehensive approach to transforming its clinical trials system to create a highly integrated network that can address rapid advances in cancer biology based on:

- IOM Recommendations
- Previous reports (Clinical Trials & Operational Efficiency Working Groups- CTWG & OEWG)
- Current stakeholder input
NCI National Clinical Trials Network (NCTN)

• Alliance for Clinical Trials in Oncology
  • Cancer and Acute Leukemia Group B (CALGB) + North Central Cancer Treatment Group (NCCTG) + American College of Surgeons Oncology Group (ACOSOG)

• Eastern Cooperative Oncology Group (ECOG) + American College of Radiology Imaging Network (ACRIN)

• National Surgical Adjuvant Breast & Bowel Project (NSABP) + Radiation Therapy Oncology Group (RTOG) + Gynecologic Oncology Group (GOG)

• Southwest Oncology Group (SWOG)

• Children’s Oncology Group (COG)
NCI Community Oncology Research Program (NCORP)

• Approved by the Board of Scientific Advisors on June 24, 2013
• Creates a network for cancer care delivery research
  • New program expands upon the success of the Community Clinical Oncology Program (CCOP) Network (including its Minority-Based CCOPs)
  • Adds elements of the NCI Community Cancer Centers Program (NCCCP)
NCI and Drug Development...

- 1955: Cancer Chemotherapy National Service Center (CCNSC)
- First federal program to promote drug discovery for cancer
- Developed methodologies and crucial tools for chemotherapeutic development
  - cell lines (NCI-60)
  - animal models
- >400,000 drugs in repository that have gone through screening process
NCI and Drug Development

- ≈ 80,000 compounds screened since 1990 using current screening system
- NCI develops small amount of agent for basic science research and initial clinical trials, then works with a manufacturer
- Mechanisms of collaboration via technology transfer agreements
  - Cooperative Research and Development Agreements (CRADAs)
  - Clinical Trial Agreements (CTAs)
Mission of the CCR

To inform and empower the Nation’s research community by making breakthrough discoveries in basic and clinical research and by developing them into novel therapeutic interventions for adults and children with cancer or HIV infection.
CCR Leadership

• **Director, CCR**
  Robert H. Wiltrout, PhD

• **Scientific Director for Basic Research**
  Robert H. Wiltrout, PhD

• **Scientific Director for Clinical Research**
  Lee Helman, MD

• **Deputy Directors:**
  William L. Dahut, MD
  Ronald E. Gress, MD
  Lee J. Helman, MD
  Glenn Merlino, PhD
  Lawrence E. Samelson, MD
  Jeffrey N. Strathern, PhD
  Mark C. Udey, MD, PhD
Branches focus on pre-clinical and clinical research related to cancer diagnosis, treatment, and prevention.

- Dermatology Branch
  - Mark Udey, M.D., Ph.D.

- Endocrine Oncology Branch
  - Electron Kebebew, M.D., F.A.C.S

- Experimental Immunology Branch
  - Alfred Singer, M.D.

- Experimental Transplantation and Immunology Branch
  - Ronald Gress, M.D.

- Genetics Branch
  - Paul Meltzer, M.D., Ph.D.

- Genitourinary Malignancies Branch
  - James Gulley, M.D., Ph.D.

- HIV and AIDS Malignancy Branch
  - Robert Yarchoan, M.D.

- HIV DRP Host-Virus Interaction Branch
  - Stephen Hughes, Ph.D.

- Lymphoid Malignancies Branch
  - Thomas Waldmann, M.D.

- Neuro-Oncology Branch
  - TBD

- Pediatric Oncology Branch
  - Crystal Mackall, M.D.

- Radiation Biology Branch
  - James Mitchell, Ph.D.

- Radiation Oncology Branch
  - Kevin Camphausen, M.D.

- Surgery Branch
  - Steven Rosenberg, M.D., Ph.D.

- Urologic Oncology Branch
  - W. Marston Linehan, M.D.

- Vaccine Branch
  - Jay Berzofsky, M.D., Ph.D.
Laboratories

Laboratories are composed of investigators studying the molecular origin and growth mechanisms of cancer and AIDS. Experts in fields such as molecular and cell biology, developmental biology, biochemistry, carcinogenesis, and immunology are providing the knowledge base required to understand and treat these and, potentially, other diseases as well.
# Programs

Programs encompass investigators, organized within a specific field of research, who are working together to solve a complex scientific problem.

<table>
<thead>
<tr>
<th>Program</th>
<th>Lead Investigator</th>
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<tbody>
<tr>
<td>Cancer and Inflammation Program</td>
<td>Giorgio Trinchieri, M.D.</td>
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<tr>
<td>HIV Drug Resistance Program</td>
<td>Stephen Hughes, Ph.D.</td>
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<tr>
<td>Molecular Imaging Program</td>
<td>Peter Choyke, M.D., F.A.C.R.</td>
</tr>
<tr>
<td>Mouse Cancer Genetics Program</td>
<td>Lino Tessarollo, Ph.D.</td>
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Office of the Clinical Director
Office of Research Nursing

- Director
  - Team Lead
    - Research Nurses
  - Team Lead
    - Research Nurses
  - Team Lead
    - Research Nurses
  - Team Lead
    - Research Nurses
CCR Protocols
Total = 418
Open to Accrual = 277

66% Open protocols Phase 0-III
71% Total protocols Phase 0-III
Overview of Federal Contract Process

Government sends out a RFP
- Outline the contractual obligations and services provided by contractor to customer
- Define contract deliverables
- Require periodic reports

Contractor/vendor responds to RFP
- Define key staff and staffing levels

Government reviews all RFPs
- Formal, competitive process

Contract awarded
Contractors for CCR

- Harris Corporation
- SAIC/Leidos
- Kelly Services
- Others based on CTAs
NCI/CCR Data Management Contract

- Contract exists between the NCI and Harris Corporation
- Subcontractor (IT): Asclepius Solutions, Inc. (ASI)
Scope of Work…

• Coordinate clinical data management program and services for the CCR clinical program including:
  • data entry
  • data abstraction
  • data verification
  • central registration
  • randomization services

• Quality assurance and quality control for data management processes
...Scope of Work...

- Central registration office (CRO) functions
- Orientation and training especially database utilization and procedures
- Assist with audit/monitoring preparation activities
- Monitoring visit for internal/investigator-sponsor trials
...Scope of Work

• Programming support for the development of the C3D

• Support and maintenance for all legacy (old) databases
Key Staff

• Government:
  • Project Officer: Caryn Steakley

• Contractor:
  • Project Manager: Elena Byrley
  • Manager, CDM Services : Christine Gordon
Current Staffing

Staff Make-up:

• Management
  • Team Leads
• Informatics
• QA
• Central Registration
• Clinical Data Managers
CCR Accomplishments

http://home.ccr.cancer.gov/ccrataaglance/whatweaccomplished.html