Alliance Organizational Structure

Trini Ajazi, MM
Alliance Chief Administrative Officer
Clinical Research Professional Orientation

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NCI-NCTN

• National Cancer Institute (NCI) National Clinical Trials Network (NCTN) is a consolidated, integrated network comprised of organizations that conduct definitive, randomized clinical treatment trials across a broad range of diseases and diverse patient populations

• 4 Adult Network Groups, 1 Canadian and 1 Pediatric Group that sponsor and lead NCTN trials
NCORP

• NCI Community Oncology Research Program (NCORP) – community based program designed to bring clinical trials to individuals in their own communities and contribute to improved patient outcomes and reduction in cancer disparities

• NCORP designs and conducts cancer prevention, control, screening, post surveillance and cancer care delivery clinical trials

• Facilitates access to treatment and imaging trials from NCTN
NCI National Clinical Trials Network Structure

LEGEND
- Centralized Functions:
  - Centralized Institutional Review Board
  - Cancer Trials Support Unit
  - Imaging and Radiation Oncology Core (IROC) Group
  - Common Data Management System Central Hosting
- 30 Lead Academic Participating Sites (LAPS)
- Operations
- Statistics & Data Management
- Tissue Banks
- Member Sites
About the Alliance for Clinical Trials in Oncology

National Clinical Trials Network (NCTN) Group consists of nearly 10,000 cancer specialists at approximately 1000 hospitals, medical centers, and community sites across the United States and Canada.

Vision: to reduce the impact of cancer by uniting a broad community of scientists and clinicians from many disciplines, committed to discovering, validating and disseminating effective strategies for the prevention and treatment of cancer.
Alliance Mission

Alliance achieves its purpose by conducting high quality multidisciplinary cancer control, prevention, and treatment trials that engage a comprehensive research network;

furthering our understanding of the biological basis of the cancer process and its treatment, from discovery, to validation, to clinical practice;

providing a scientific and operational infrastructure for innovative clinical and translational research in academic and community settings
Alliance History

Merger of three Groups

- American College of Surgeons Oncology Group (ACOSOG)
- Cancer and Leukemia Group B (CALGB)
- North Central Cancer Treatment Group (NCCTG)
- Merger initiated in 2011 and completed March 2014 with start of new NCTN grant period
Alliance Network Membership

• Institutions must meet Alliance accrual and performance requirements per Alliance Policies and Procedures

• Members are academic and community sites, including NCI grant funded Lead Academic Participating Sites (LAPS) and NCI Community Oncology Research Program (NCORP) sites

• Most studies are available to all NCTN member sites via an open menu
The primary governance body of the Alliance is the Board of Directors, which represents the group’s institutional members.

The Alliance is also supported by five program directors, each responsible for a specific program integrating discipline-related science and operational functions across all disease committees.

The Alliance is led by the group chair with assistance from the group vice chair.

The Executive Committee represents the Board of Directors and assists the group chair in planning and coordinating group activities.
Scientific Modality/Disciplines

Surgical Oncology, Research Program, Transplant, Radiation Oncology, Pathology, Imaging, Oncology Nursing, Clinical Research Professionals, Biostatistics, Bioinformatics, Pharmacology, Pharmacogenomics, Patient Advocates, Health Outcomes, Symptom Intervention, Experimental Therapeutics, Community Oncology, Research Ethics, Laboratory Medicine, Cancer Prevention, Cancer Care Delivery, Young Investigators, Pharmacy

Administrative Committees:
Board of Directors, Executive Committee
Constitution and Bylaws, Membership, Institutional Performance Evaluation, Conflict of Interest, Audit, Publications, Data and Safety Monitoring Board
Alliance Leadership

• Group Chair: Monica Bertagnolli, MD, Dana-Farber/Brigham Women’s Hospital Cancer Center

• Group Vice Chair: Suzanne George, MD, Dana–Farber Cancer Institute

• Group Statistician/Director SDMP: Sumithra Mandrekar, PhD, Mayo Clinic

• Director, Central Protocol Operations Program: Gini Fleming, MD, University of Chicago

• Director, Cancer Control Program: Jan Buckner, MD, Mayo Clinic

• Director, Translational Research Program, Fraser Symmans, MD, MD Anderson Cancer Center

• Director American College of Surgeons Clinical Research Program: Kelly Hunt, MD, MD Anderson Cancer Center
Board of Directors

● Comprised of 50 Alliance Principal Investigators or institutional representative

● Responsible for final approval of overall policy for the Alliance, election of Group Chair, approval of institutional membership.

● Executive Committee reports to the Board of Directors
Executive Committee

- Led by Group Chair and Group Vice Chair
- Members include the 5 program directors/co-principal investigators and 4 academic BOD representatives and 4 community BOD representatives
- Recommends to the Board of Directors overall Alliance policy, direction, priorities, and activities
- Approves committee chair and vice chair appointments
Office of the Group Chair

Operations Units (located at BWH and UChicago)
- Group Administration
- Finance
- Membership Services and Communications
- Regulatory Compliance and Quality Assurance

Scientific Committees
- Breast, Gastrointestinal, Genitourinary, Leukemia, Lymphoma, Myeloma, Neuro-oncology, Respiratory, Transplant
- Patient Advocates, Clinical Research Professionals, Experimental Therapeutics, Oncology Nursing, Radiation Oncology

Administrative Committees
- Audit, Patient Communications, Conflict of Interest, Constitution, DSMB, Ethics
- Young Investigators, Institutional Performance Evaluation, Membership, Pharmacy, Publications

Group Chair and Principal Investigator: Monica M. Bertagnolli, MD - Dana-Farber/Brigham and Women’s Cancer Center

Group Vice Chair: Suzanne George- Dana Farber Cancer Institute
Statistics and Data Management

Operations Units (located at Mayo and Duke)
• Data Management
• Systems Management
• Information Systems
• Statistics

Scientific Committees
• Biostatistics
• Bioinformatics

Group Statistician and Principal Investigator: Sumithra Mandrekar, PhD - Mayo Clinic
Operations Manager: Cari Cummins – Mayo Clinic
Central Protocol Operations

Operations Units (located at UChicago)

- Protocol Office (Protocol Development and Management)
- Pharmaceutical Affairs

Scientific Committees

- Study Concept Review

Principal Investigator and Director: Gini F. Fleming, MD - University of Chicago
Director of Protocol Operations: Michael Kelly, MA, University of Chicago
Translational Research Program

Operations Units
(located at MS Anderson, Uchicago, Wash U)
- Integrated Biorepositories
- Translational Research Operations

Scientific Committees
- Leukemia Correlative Sciences, Solid Tumor Correlative Science, Imaging, Pharmacogenomic & Population Pharmacology, Pathology, Sequencing

Administrative Committees
- Karotype Review, Biorepositories

Principal Investigator and Director: W. Fraser Symmans, MD, MD Anderson Cancer Center
Director Biorepositories: Mark Watson, MD, Washington University
Director Translational Research Operations: Yujia Wen, PhD, University of Chicago
Cancer Control Program

Operations Units (located at Mayo)
- NCORP Research Base

Scientific Committees
- Cancer in the Elderly, Health Disparities, Health Outcomes, Prevention, Symptom Intervention
- Community Oncology (Administrative)

Principal Investigator and Director: Jan C. Buckner, MD - Mayo Clinic
Program Manager: Jacqueline Lafky, MS – Mayo Clinic
ACoS Clinical Research Program

Operations Units (located at MD Anderson/ACS Chicago)
- Commission on Cancer
- National Cancer Database
- Program Management

Scientific Committees
- Cancer Care Standards Development
- Cancer Care Delivery Research
- Dissemination and Implementation

Administrative Committees
- Education

Principal Investigator and Director: Kelly Hunt, MD, MD Anderson Cancer Center
Program Manager: Amanda Francescatti, MS, American College of Surgeons
Alliance for Clinical Trials in Oncology Foundation

Not-for-Profit Corporation created to enhance and expand the ability of Alliance members* to conduct cancer clinical research

• 501(c)3
• Governance and operations structure separate from the Alliance

Alliance Foundation Trials, LLC (AFT)

• LLC (sole member = Foundation) created to conduct cancer clinical research involving partners other than the National Cancer Institute
Study Design by Scientific and

Study Operations

ALLIANCE NCTN/NCORP

ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

ALLIANCE FOUNDATION TRIALS, LLC
Org Charts
Central Protocol Operations Program

Principal Investigator/Director
Gini Fleming, MD

Executive Officers
Linda Sluman, MD
Selina Chow, MD
Priya Kumthekar, MD

Pharmaceutical Affairs Manager
Ligi Matthews, PharmD

Director Translational Research Operations
Yujia Wen, PhD

Director Protocol Operations
Michael Kelly, MA

Protocol Information Specialist

Clinical Trial Managers

Protocol Coordinators

Senior Protocol Coordinators
Figure A.2. Alliance NCORP Research Base Scientific and Administrative Organization

Board of Directors

Alliance Executive Committee

Group Chair

Cancer Control Program Director & Deputy Director (Multiple PIs)

Prevention
Risk Assessment and Screening
Symptom Intervention
Survillance & Survivorship
Post-treatment
CCDR

Health Outcomes
Health Disparities
Cancer in the Elderly
Community Oncology
Alliance/American College of Surgeons Clinical Research Program Committee Structure
Alliance/American College of Surgeons Clinical Research Program Staff Structure

- Program Director, Clinical Research Program
- Manager, Clinical Research Program
- Developer
- Project Manager

A Collaboration between American College of Surgeons and the Alliance