



# Alliance Organizational Structure

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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

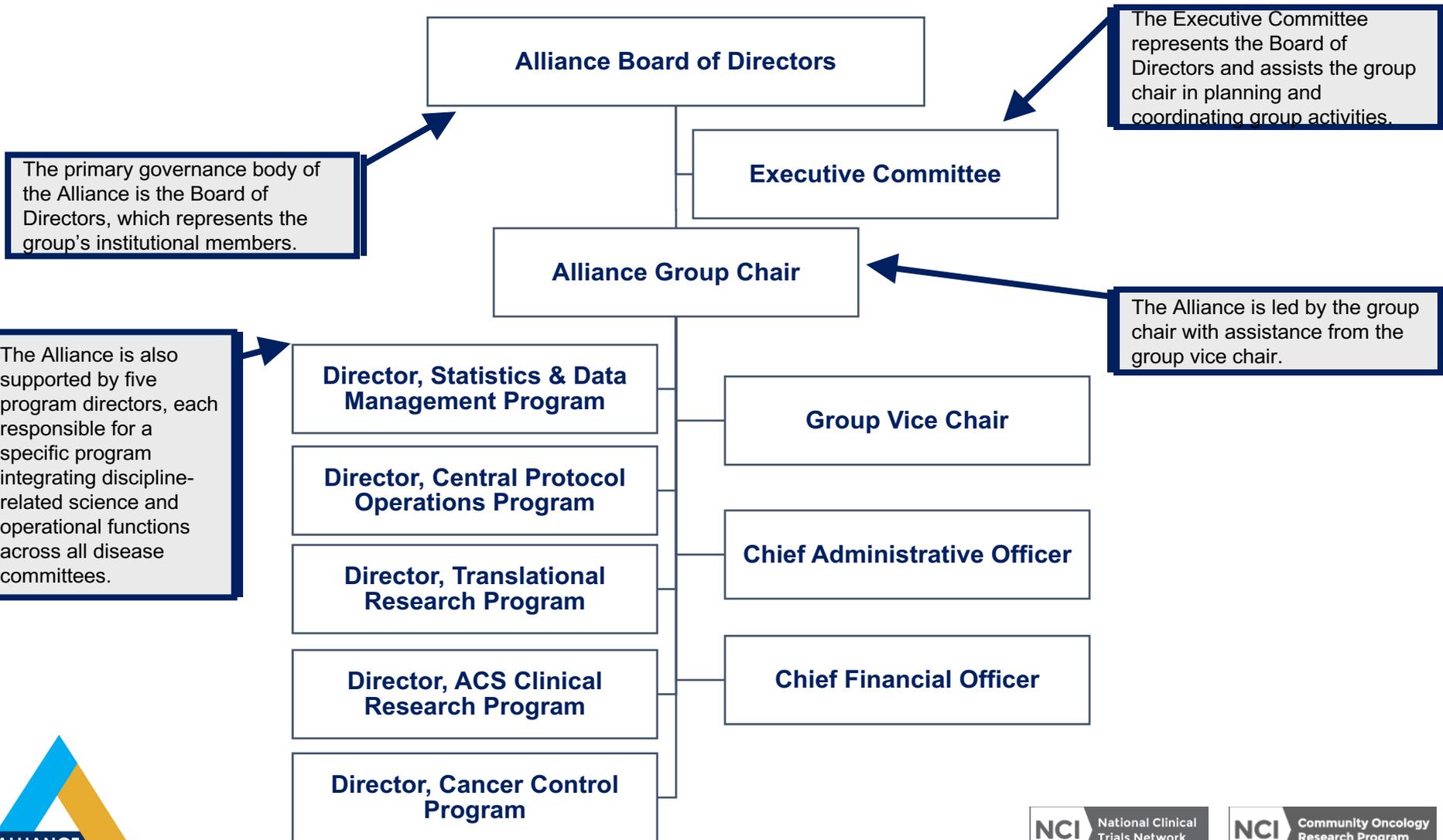
## Merger of three Groups

- 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

# Alliance: Overview of Governance and Program Structure





Breast	Gastro-intestinal	Genito-urinary	Respiratory	Neuro-Oncology	Leukemia	Lymphoma	Myeloma
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### 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. Bertagnoli, 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 Biorespositories:** 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

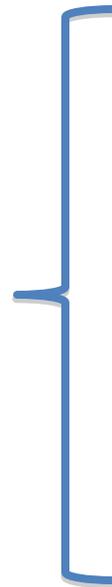
## **Alliance Foundation Trials, LLC (AFT)**

- LLC (sole member = Foundation) created to conduct cancer clinical research involving partners other than the National Cancer Institute

Study Design by  
Scientific and

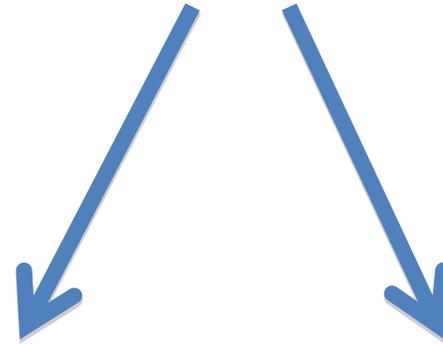


Study  
Operations



ALLIANCE  
NCTN/NCORP

ALLIANCE  
FOUNDATION TRIALS, LLC

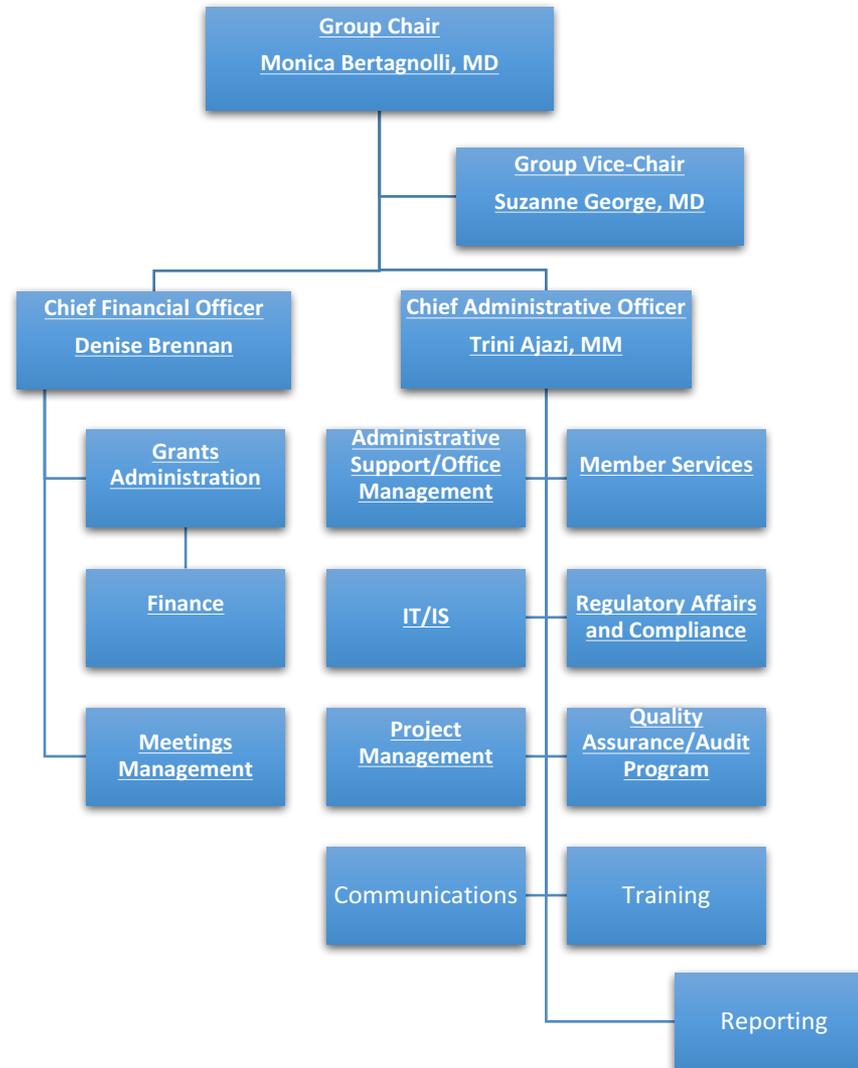


ALLIANCE  
FOUNDATION TRIALS, LLC

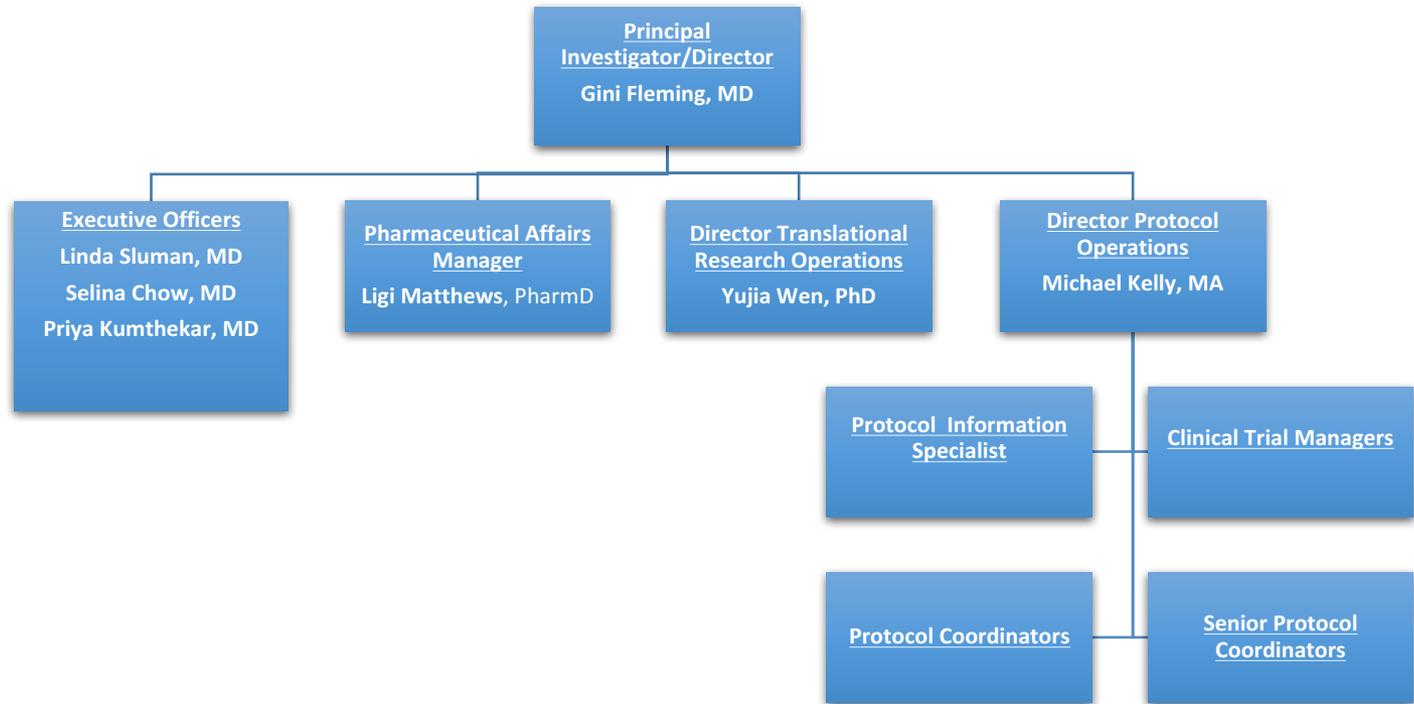


# Org Charts

# Office of the Group Chair

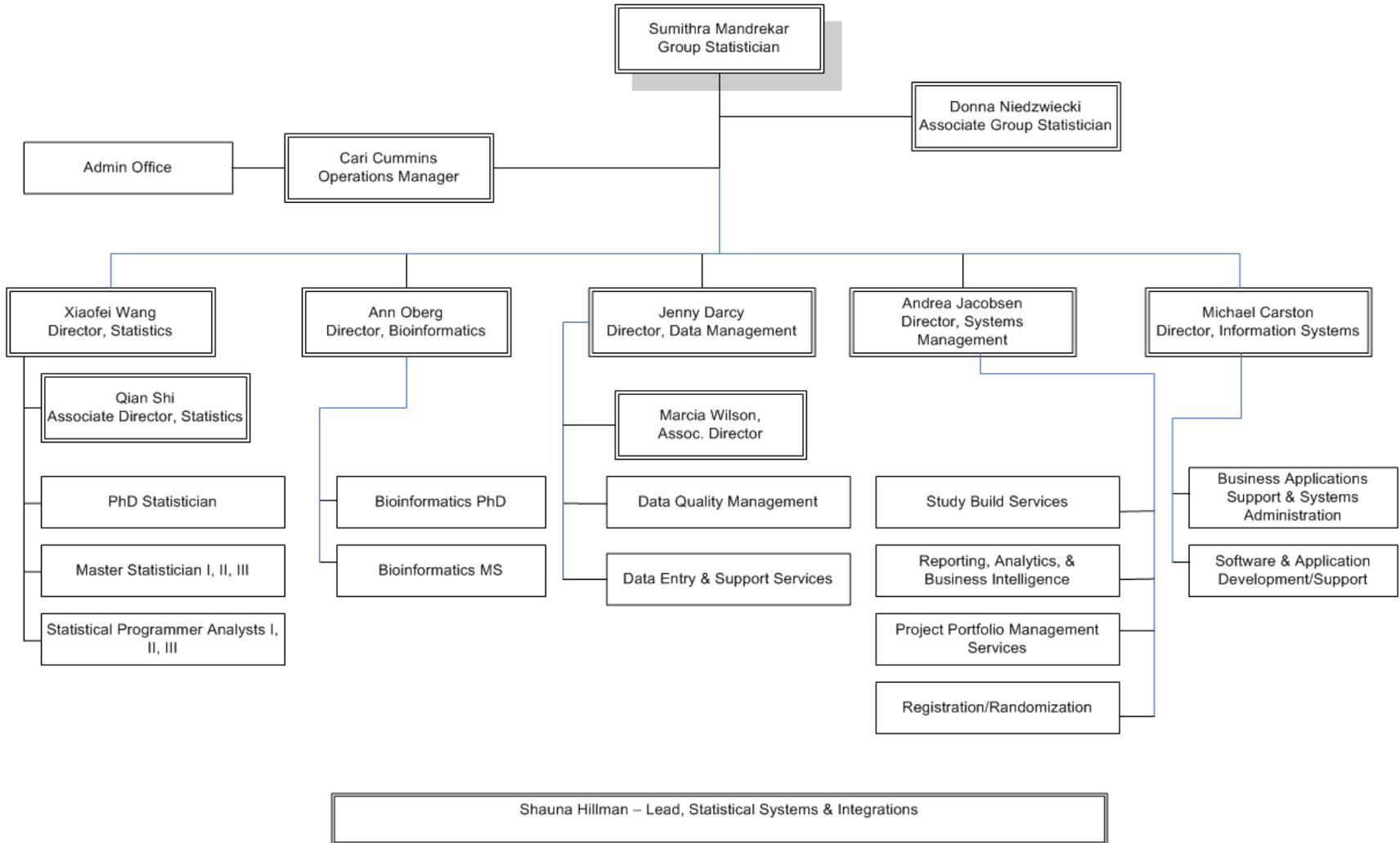


# Central Protocol Operations Program

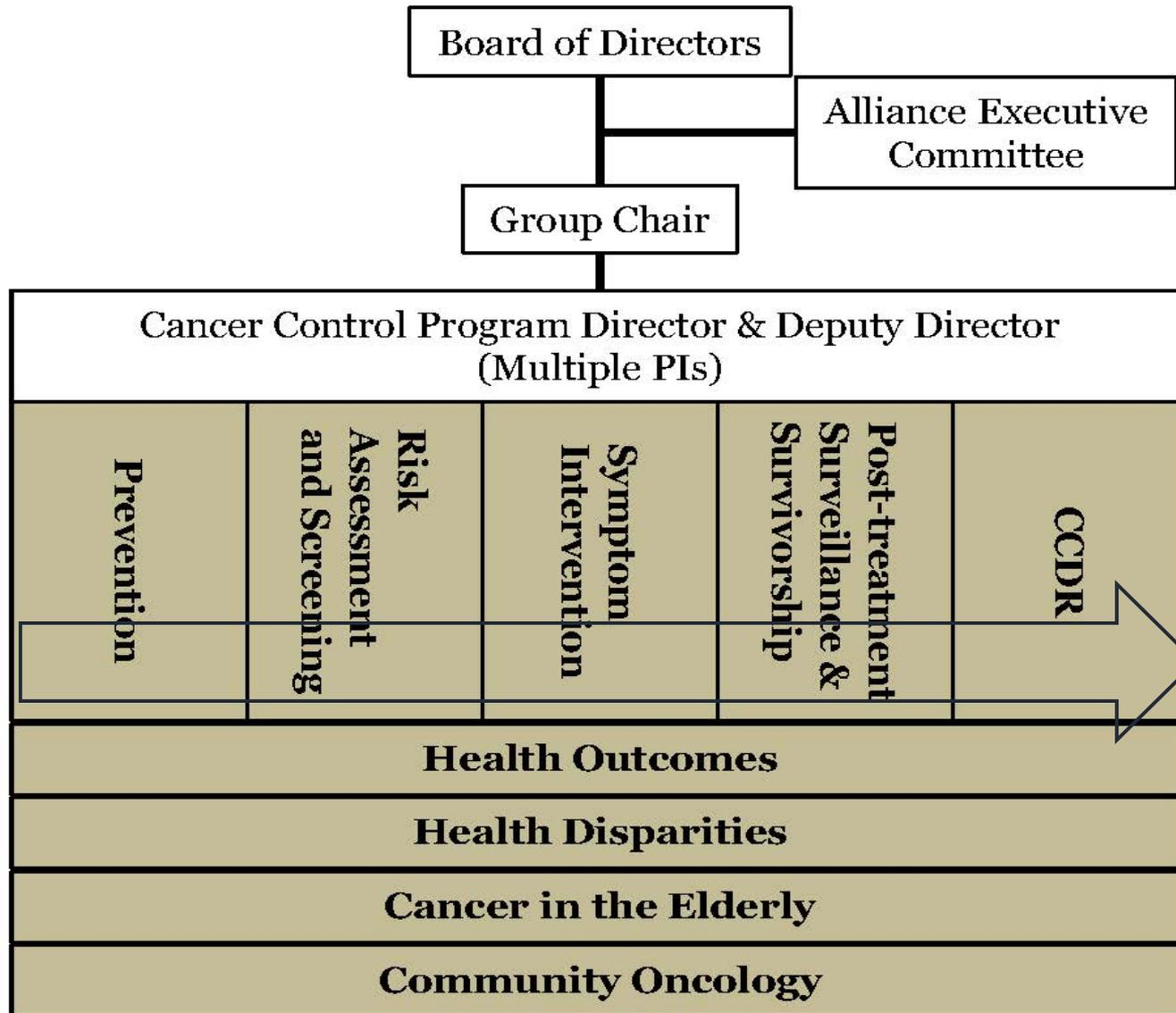


# Alliance Statistics and Data Center (Functional)

April 2017



**Figure A.2. Alliance NCORP Research Base Scientific and Administrative Organization**



# Translational Research Program (TRP)

TRP Scientific Advisory Board

Biorepository  
Systems

TRP  
Administrative  
Core

Molecular Reference  
Laboratories

Tissue Collection

Tissue Storage

Specimen Tracking

Tissue Processing

Information  
Technology

Sequencing  
Committee

Pathology  
Committee

Biorepository  
Committee

TRP  
Executive  
Committee

Imaging  
Committee

Karyotype  
Review

IHC/FISH/PCR

Microarray

Serum Proteomics

Pharmacokinetics

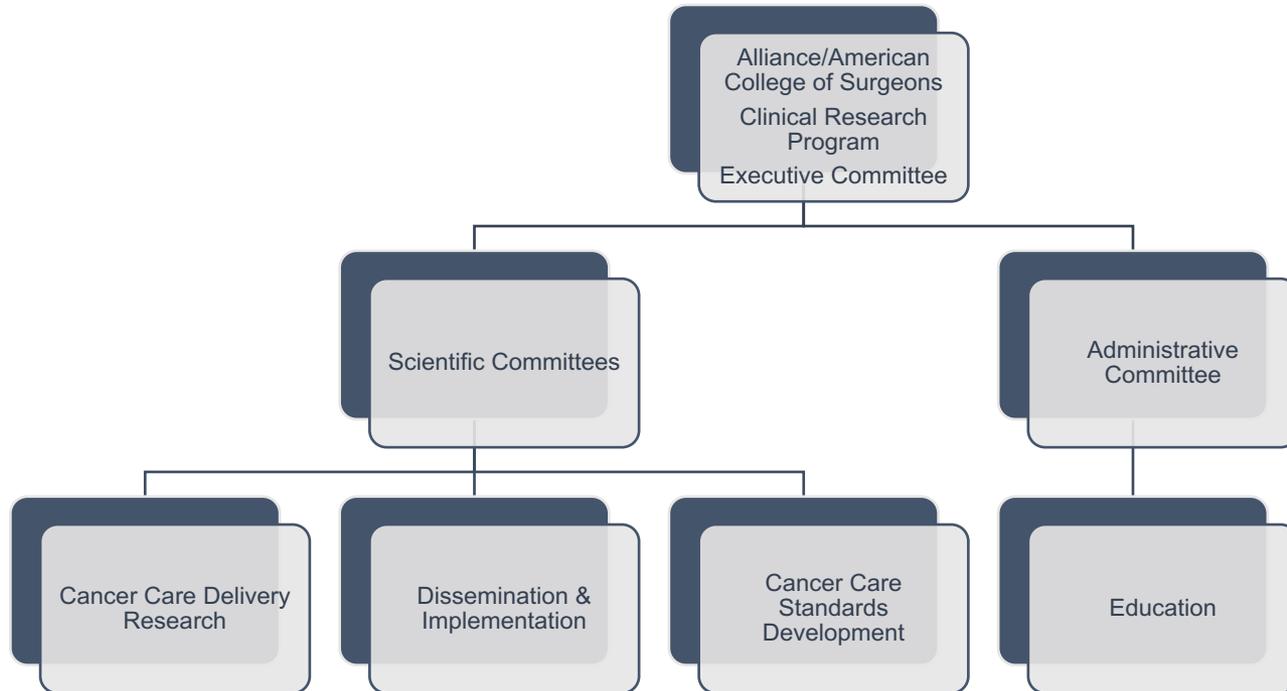
Pharmacogenomics

Sequencing

Pharmacogenomics  
and Population  
Pharmacology

Leukemia Correlative  
Science Committee

# Alliance/American College of Surgeons Clinical Research Program Committee Structure

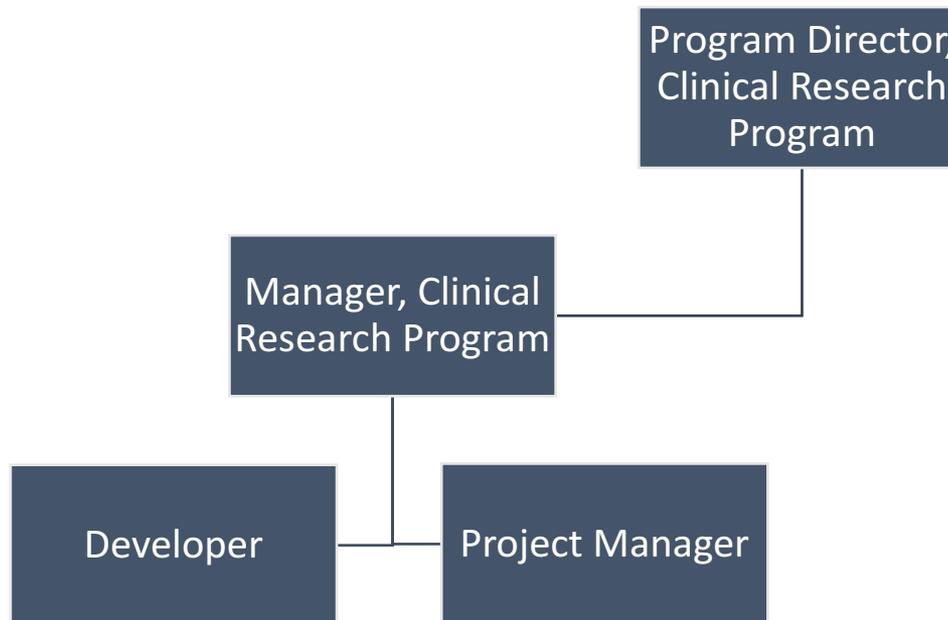


**CLINICAL RESEARCH PROGRAM**

A Collaboration between American College of Surgeons and the Alliance



# Alliance/American College of Surgeons Clinical Research Program Staff Structure



A Collaboration between  
American College of Surgeons  
and the Alliance



# AFT Operations Structure

