CALGB-NCCTG-ACOSOG Statistical and Data Center Integration

Director: Daniel J. Sargent, PhD
Location: Mayo Clinic, Rochester, MN

Cooperative Group Mission

- Provide a scientific and operational infrastructure for innovative clinical and translational research
- Conduct definitive clinical trials that improve patient care
- Engage the widest possible clinical research network so that results are applicable to the broad US health care setting
- Provide a mechanism for translational research that encompasses the spectrum from discovery to validation

Practice-Changing Study Conclusions

Additional hypothesis-generating study data:
whole genome sequencing, pharmacogenomics, QOL, economics, etc.

Data Analysis:
Study Statistician
Study Chairs

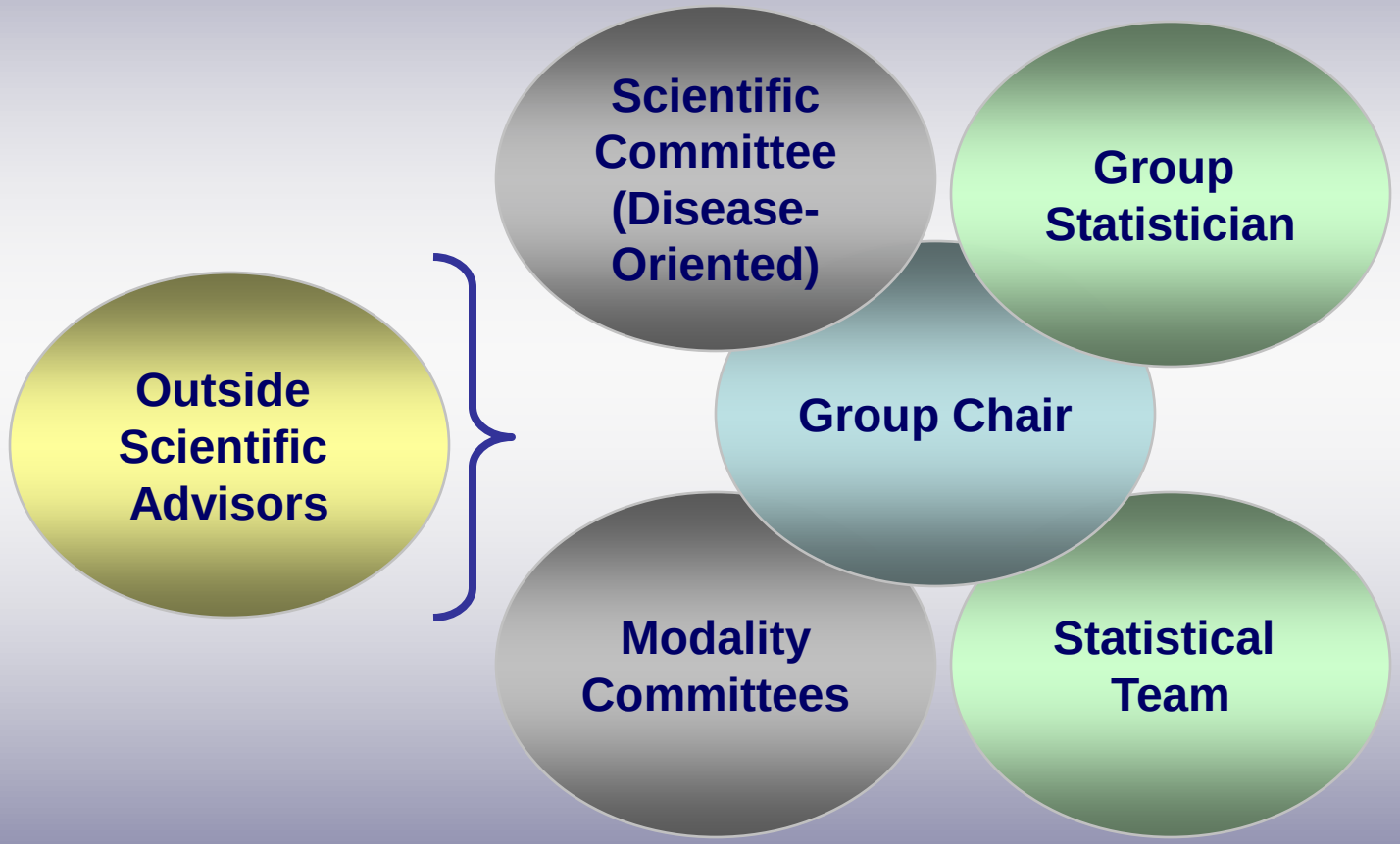
Accrual, Data and Biospecimen Acquisition:
Group/CTSU

Protocol Approval:
Group Review Committe
CTEP-Steering Committe

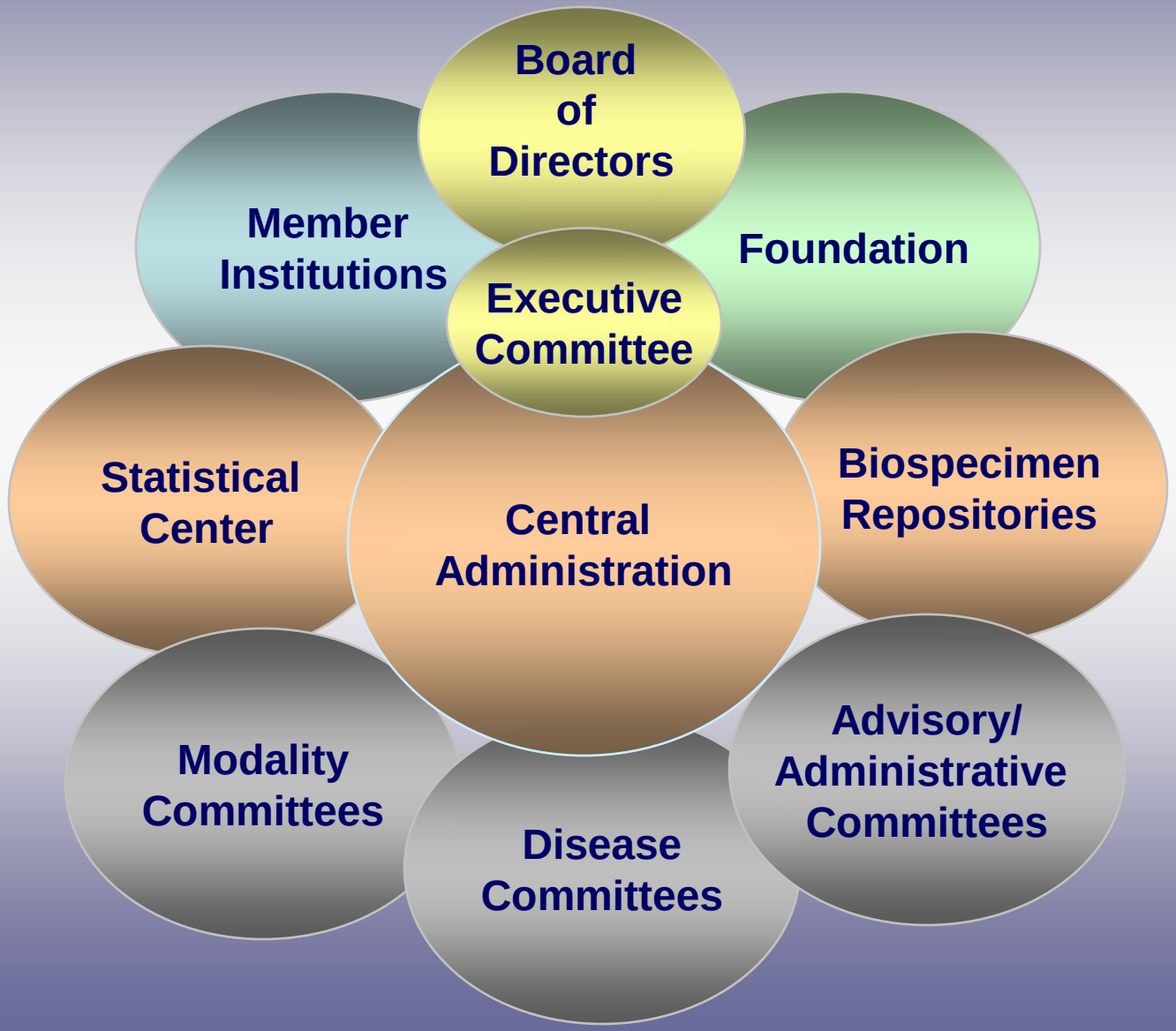
Study Design:
Disease & Modality Committees

Increasing emphasis on:
Biomarker driven trials,
Adaptive trial design,
NCI-industry collaborations

Group Scientific Team



Group Operational Team



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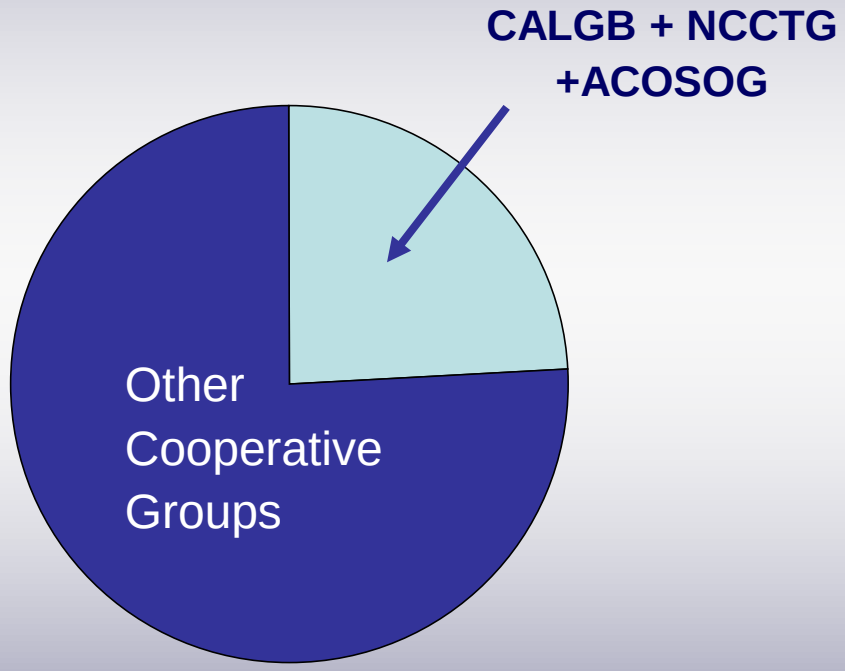
Goal: Better Studies Faster

- Voluntary integration of operational aspects of Group statistics and data management centers to achieve:
  - increased efficiency
  - greater ability to direct resources toward science rather than infrastructure
  - enhanced capability of groups to lead cutting edge research (e.g. biomarker driven trials; adaptive trial designs)
  - increased depth and breadth of statistical talent available to group scientific committees
- Potential benefit in providing infrastructure for inter-group scientific collaboration

2009 Study Accrual



Background

- Summer, 2009 (IOM committee just convening)
  - M. Bertagnolli and J. Buckner discuss potential synergy between CALGB & NCCTG SDCs
  - ACOSOG & NCCTG SDCs in process of formally merging
- April, 2010: CALGB Search Committee recommends Dan Sargent as CALGB Group Statistician
- Requirements for successful recruitment:
  - Transfer of Statistical Center U10 grant to Mayo
  - Negotiation of arrangement with NCCTG & ACOSOG
- IOM Report released the following week

Background

- May, 2010: CALGB begins discussions with NCI concerning SDC leadership transition
- Formal proposal submitted by Dan Sargent, including budget for funding integration in a manner that would not disrupt current Group operations
- June, 2010: CALGB Board of Directors approves appointment of Dan Sargent as Group Statistician
- July, 2010: Notification of NCI supplemental funding for SDC integration

Background

- Ongoing:
  - Implementation of plan for relocation of CALGB SDC leadership to Mayo Clinic
  - Discussions between CALGB, NCCTG and ACOSOG concerning optimal governance and management of an integrated SDC
  - Key goals: Best science, faster; Retain existing strengths and group loyalty at each institution

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Cooperative Group SDC Requirements: 2010 and Beyond

- Personalized medicine: must integrate science (biomarkers) into trials
- Multitude of agents: must be innovative and rapidly assess success
- Efficient: process, systems cannot delay science
- Talent: no one institution has sufficient expertise

Key Functions of a Statistics and Data Center

- Scientific
  - Design of Group protocols
  - Lead selected clinical projects
  - Methods research
  - Requires deep disease-specific integration
- Operations
  - Manage vast data engine
  - Essential for successful group research
  - High quality
  - Timely
  - Efficient

ACOSOG/NCCTG SDC:
Already competed

- Statistical: Sharing of faculty & expertise
- Common systems
  - Remote Data Capture
  - Registration/Randomization
  - Data Quality Review
  - Membership/Committee structure
- Shared:
  - SOPs
  - Supervisory structure

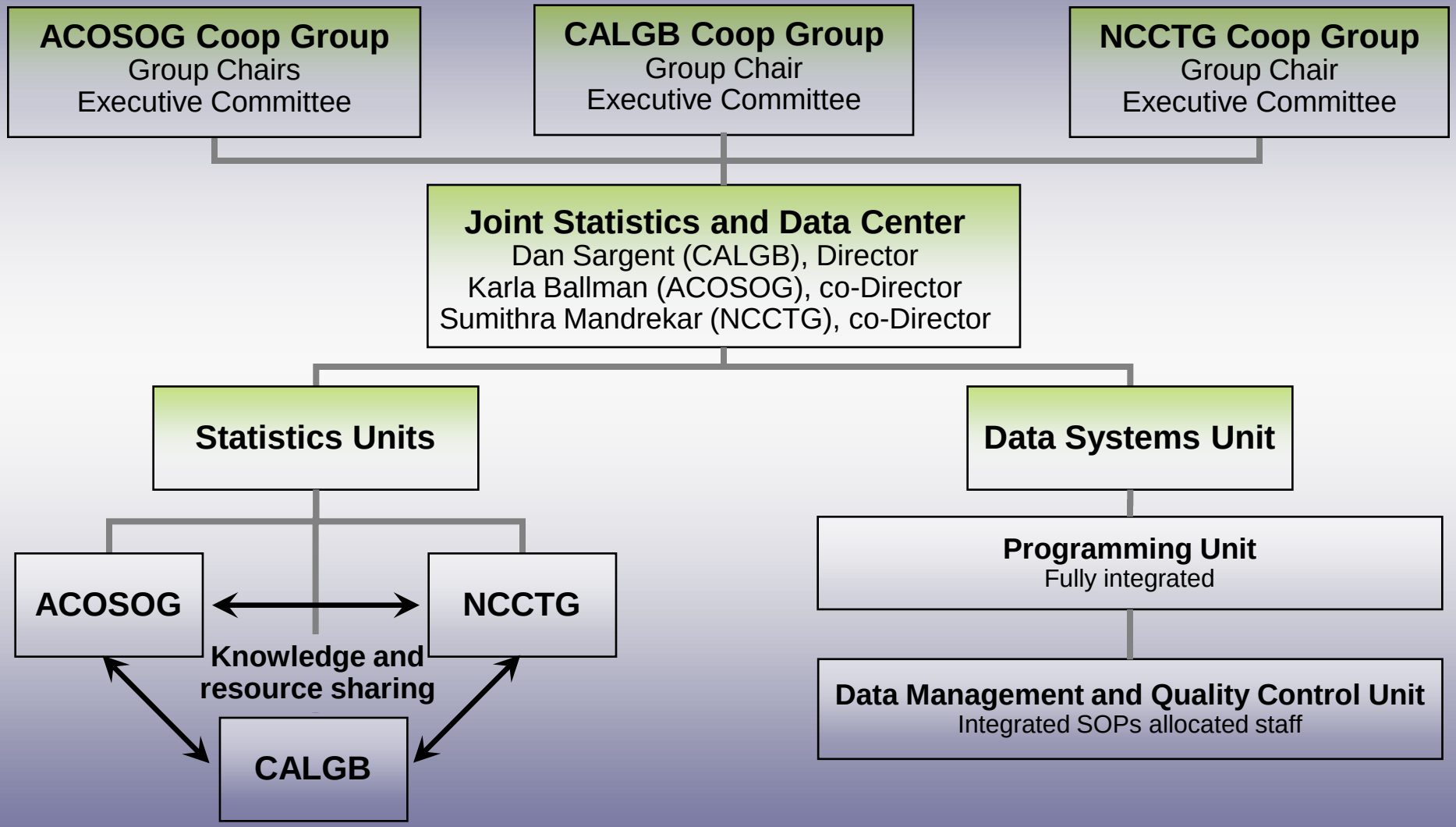
Goals for Joint SDC

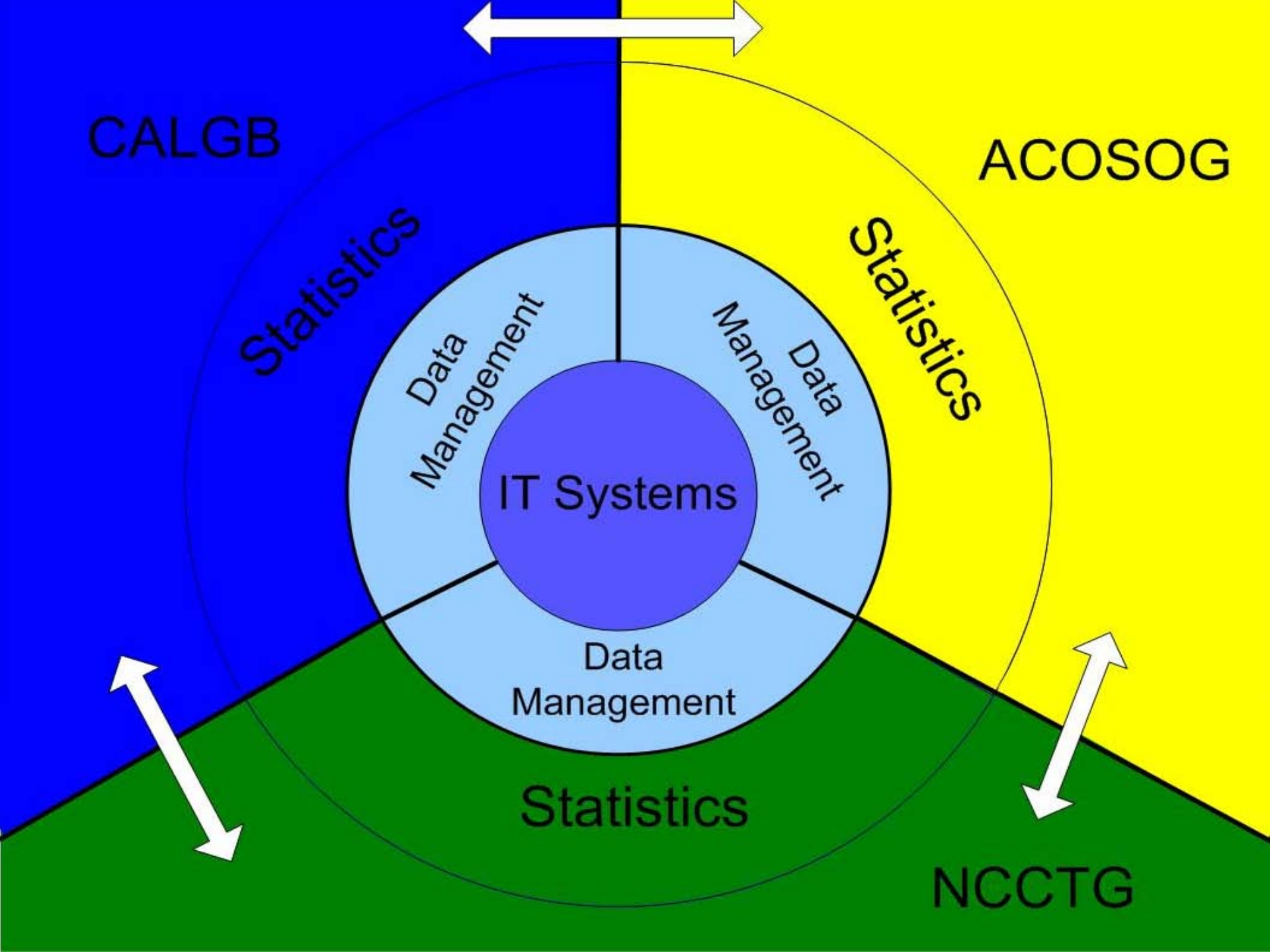
- Hire, train, retain dedicated faculty with passion and skill for innovation in statistical, translational and clinical research
- Deeply integrate statistical center staff into ongoing group research activities at all levels
- Develop and continually improve IT and human systems and processes to maximize efficiency and timeliness

Joint SDC Operational Benefits

- Share best practices
- Leverage group resources
  - IT
  - Administration
- Single process for adapting to changing standards
- Elimination of redundant systems
- Sharing staff as needs fluctuate

Joint SDC Organization




CALGB
ACOSOG
NCCTG
Statistics
Statistics
Statistics
Data Management
Data Management
Data Management
IT Systems

Joint SDC Functional Organization

- Statistics
  - Retain existing statistical faculty at both Mayo & Duke
  - Group and Committee Specific assignments
  - Share SOPs, systems, knowledge
- IT
  - Fully integrated using primarily MCCC systems
- Data Management
  - Distributed personnel (Duke and Mayo)
  - Identical SOPs, systems

Goal: Facilitate Group Science

- Gains from efficiency
  - More time for statistical activities
  - Science not delayed by systems
- Increase use of novel designs
  - Almost real-time, higher quality data for adaptive designs
  - Ability to rapidly assess outcomes

Sharing Best Practices

- NCCTG → CALGB/ACOSOG
  - Site/staff administration
  - NCCTG implemented new system Nov, 2009
- ACOSOG → NCCTG/CALGB
  - Regulatory support, credentialing
  - ACOSOG piloted leveraging CTSU system, CALGB/NCCTG to follow
- CALGB → NCCTG
  - Per patient case payment application (PCPA) and specimen tracking system (STS)
  - CALGB implemented, NCCTG need

Ongoing Priorities

- Support existing staff
- Gain mutual understanding
  - Multiple trips of Mayo personnel to Duke, and Duke personnel to Mayo
- Define & initiate systems integrations
  - What exists?
  - Where is there overlap?
  - What is best strategy to deal with overlap?

Joint SDC: Take home messages

- Emphasis on statistician leadership and innovation: statistical, clinical, collaborative
- Collaboration will allow deeper integration into clinical disease committees
- Efficiency of systems critical to new science
  - Focus limited resources on highest scientific needs

Summary

- An integrated SDC provides greater expertise with greater efficiency
- Voluntary collaborations between cooperative groups are possible and are most likely to succeed
- Each group contributes in a different manner, and it is an advantage to encourage these distinctive contributions that provide a broad platform for innovation

Discussion