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

Data Analysis:
- Study Statistician
- Study Chairs

Accrual, Data and Biospecimen Acquisition:
- Group/CTSU

Protocol Approval:
- Group Review Committee
- CTEP-Steering Committee

Study Design:
- Disease & Modality Committees

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

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

- Group Chair
- Scientific Committee (Disease-Oriented)
- Group Statistician
- Modality Committees
- Statistical Team
- Outside Scientific Advisors
CALGB-NCCTG-ACOSOG
Statistical and Data Center Integration
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

CALGB + NCCTG + ACOSOG

Other Cooperative Groups
• 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
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
• 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
CALGB-NCCTG-ACOSOG
Statistical and Data Center

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

ACOSOG Coop Group
Group Chairs
Executive Committee

CALGB Coop Group
Group Chair
Executive Committee

NCCTG Coop Group
Group Chair
Executive Committee

Joint Statistics and Data Center
Dan Sargent (CALGB), Director
Karla Ballman (ACOSOG), co-Director
Sumithra Mandrekar (NCCTG), co-Director

Statistics Units

Data Systems Unit
Programming Unit
Fully integrated

Data Management and Quality Control Unit
Integrated SOPs allocated staff

ACOSOG
Knowledge and resource sharing
NCCTG
CALGB
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
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

Goal: Facilitate Group Science
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?
• 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
• 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