

Group Statisticians' Perspective

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Outline

► Overall vision

- Cross-Group issues
- Statistical centers
- Biostatistics is an essential component of Group science
- Complexity of Group science requires independent, academically-based statistical leadership

► Areas of progress

► Issues for transition

Vision – Cross-Group Issues

- ▶ **Need a cooperative group system that**
 - **Efficiently facilitates participation in studies led by any Group**
 - **Avoids duplicative activities within different groups**
 - **Facilitates combining information across studies and Groups**
 - **Facilitates conducting studies to develop and evaluate molecular and imaging markers for treatment selection, management, and monitoring**

Vision – Cross-Group Issues

► Need

- Common information systems
 - Electronic data capture, patient enrollment, credentialing, sample tracking, ...
- Standardization of data collection / management
 - Data collection modules
 - Data management processes
 - Data submission schedules
 - Site performance monitoring
- Standardization of administrative requirements

Common Information Systems

- ▶ **Current system is competitive**
 - Each group develops systems on its own
 - Innovation is rewarded
 - 10 independent systems to perform similar work is inefficient
 - Greatly complicates cross-group participation
- ▶ **Group resources inadequate to develop and maintain increasingly complex systems**
- ▶ **Utilizing common solutions is crucial for efficiency**

Vision – Structure of Statistical Centers

- ▶ Groups should have statistical centers that combine biostatistics and data management under a separate grant, as is currently the case for many Groups
 - Biostatistics is an essential component of Group science
 - Complexity of Group science requires independent, academically-based statistical leadership
 - Data management needs to be operationally and financially under biostatistics
 - Need not be physically combined

Vision – Structure of Statistical Centers

- ▶ **Group science needs to be integrated with biostatistical leadership**
 - **Efficiency and quality of statistical support require that statisticians thoroughly understand the science**
 - **Ongoing collaboration on multiple projects within a specific area**
 - **Group studies involve much more than analysis of primary clinical endpoints**
 - **Complex lab correlatives and other ancillary projects**

Vision – Structure of Statistical Centers

- ▶ **Data management needs to be integrated with biostatistics**
 - Data collection and processing / review need to focus on key data for study objectives and anticipated ancillary projects
 - Needs to be substantial interaction between statistical analysts, data managers and study chairs throughout the life of a study to ensure data will be appropriate
 - Prioritization of data management needs to be based on necessary (sometimes confidential) statistical analyses (i.e. interim analyses for DSMB)

Vision – Structure of Statistical Centers

- ▶ Statistical centers should be semi-independent with a separate grant
 - Attract leadership from top academic centers
 - Stable support / institutional cost sharing
 - Ensuring proper conduct of research / keeping the system honest

Progress – Patient Enrollment

- ▶ Cross-group registrations used to require phone calls
- ▶ SWOG and ECOG cross-registration system
 - Each Group's members use their own Group's web registration front end to enroll patients on the other Group's studies
- ▶ Oncology Patient Enrollment Network (OPEN)
 - New common front end for enrollment on all Group studies (developed at CTSU)
- ▶ Regulatory Support System (also CTSU)

Progress – Remote Data Entry

- ▶ In Sep 2005, Groups met to consider developing common RDE front end
- ▶ Groups collaborated on developing system requirements
- ▶ Focus shifted to evaluating commercial RDE systems jointly with NCI
- ▶ Medidata Rave recommended as the preferred system (Fall 2007)

Progress – Remote Data Entry

- ▶ After a long, difficult procurement, NCI now making Medidata licenses available
 - NCI funding costs for Medidata hosting during an initial implementation period
- ▶ All Groups now engaged in collaborative work on implementation issues (configuration, study build, validation, user administration, data quality / expectancy / delinquency, data elements / library, study conduct and workflow)
- ▶ Expect to have studies open in late 2011

Progress – Data Standardization

- ▶ Long history of Group efforts
- ▶ Data collection is expensive
 - Tailor data collection to the objectives and purpose of the study
- ▶ Standardized CRF project (through caBIG)
 - Define modules for different types of data
 - Modules used if the data are relevant
 - If a module is used
 - Module's mandatory items must be collected
 - Select which optional items to include

Transition – Statistical Centers for Merged Groups

- ▶ Statisticians need not all be in one location
 - Eg COG
- ▶ Data management need not be all in one office
 - With all electronic data, workers can be anywhere
 - Need not be physically integrated with biostatistics
 - Good communication is critical
- ▶ Will need to maintain legacy studies in legacy systems for years

Transition – Statistical Centers for Merged Groups

- ▶ Combined statistical centers likely to continue with the same personnel in the same locations
- ▶ May have co-Group Statisticians & multiple PIs
- ▶ Efficiency gains will result from adopting common systems and standards across groups, not from merging statistical and data management operations

Summary

- ▶ Efficiency improvements through greater standardization and greater use of common information systems
- ▶ Statistical centers combining biostatistics and data management under a separate grant
 - Biostatistics is an essential component of Group science
 - Complexity of Group science requires independent, academically-based statistical leadership
 - Data management is integral to biostatistics

