

Report of Breakout Sessions and Discussion:

Data Management

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Session Observations

- ▶ Absence of clear definitions limits the value of the survey and the session
- ▶ Participants were concerned that the findings would be utilized to mandate requirements for future NIH RFAs and RFPs
- ▶ No evidence base exists for data management operations. In lieu of evidence, we can't call things Best Practices.
- ▶ Average of 30% non-respondents to session questions



Outline for Session

- ▶ Topics discussed in the breakout session
 - Data Center placement
 - Management and Oversight of DC
 - Policies and Procedures
 - Methods used to Transfer Data
 - Data Standards
- ▶ Overriding comments and concerns
- ▶ Material for further study



Who participated in the DM breakout session?

- ▶ Of ~ 90 attendees:
 - Average of 52 persons responded to the pooling questions (range 41-72)
 - 73% declared they were associated with a CRN



Is Centralization a Best Practice?

- ▶ 83% - Yes
- ▶ What about Global and International trials – 67% yes
– 88% would implement

Session Comments

- ▶ Centralization improves Data Quality
- ▶ Industry sponsors tend to maintain data ownership
- ▶ Curating the data should be done at sites, storage at intermediary, analysis done centrally
- ▶ If you integrate poor quality data at a central center, it is still poor quality
- ▶ Data quality begins at the site



Management and Oversight

- ▶ 88% - Best Practice to have individual responsible for Data Management
 - 100% would implement
- ▶ 59% - Standing Data Committee is a Best Practice
 - 71% would implement

Session Comments

- ▶ Fearful of RFA/RFP's mandating a position or a percent - takes away room to creatively distinguish themselves
- ▶ A data manager without a data center is no good. If you have a data center, you generally have a Data Manager.
- ▶ If you have a competent data center, you don't need a standing committee
- ▶ Committee assures that goals for multiple stakeholders are met



Policies and Procedures

- ▶ 89% - yes, Documenting is necessary for Data Quality
 - 100% would implement
- ▶ Whether written by the CRN or Data center, SOPs need to exist and be specific to the studies conducted

Session Comments

- ▶ Majority feel documenting is a Best Practice to ensure data quality and integrity
- ▶ Documenting is highly desirable
 - Drawbacks are that it adds burden
- ▶ Implementers of SOPs have to have input - it only succeeds if you have the whole CRN involved in writing and maintaining them



Electronic Data Capture (EDC)

- ▶ 76% yes – Use of EDC is a Best Practice
- ▶ 88% - Would use EDC, if no barriers,
- ▶ 48% - yes, EDC increases/decrease cost
- ▶ 10% - EDC increases total time from final protocol to data lock
- ▶ 90% - EDC decreases total time from final protocol to database lock

Session Comments

- ▶ Need studies of cost and effectiveness of EDC
- ▶ Need studies on impact of EDC on data quality



Measuring site performance

- ▶ 98% - yes, Measuring site performance is a Best Practice
 - 100% would implement

Session Comments

- ▶ Most applicable for those sites having trouble
- ▶ Acceptance criterion and procedures to address sites performing “below the mark”, are more useful



Data Standards

- ▶ 81% - yes, developing standards specifically for your CRN is a Best Practice
- ▶ 78% - yes, using nationally recognized standards from an ANSI-accredited source is a Best Practice
 - 84% would implement nationally recognized standards

Session Comments

- ▶ Local standards are good where nationally recognized standards don't exist
- ▶ National standards should be used when they exist



In closing...

- ▶ Session participants identified
 - Future research topics for data management
 - Unresolved issues, e.g., data standards
 - Challenges in incorporating evolving data management technology into network operations

Many thanks to participants for their valuable input!

