

Essential systems, procedures and tools for supporting a multi-site, multi-protocol research network

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Topics

- Overview
- Communication
- Data Entry and Data Management
- Training
- Site Visits
- Analysis Request and Manuscript Production

Overview

- Scope:
 - Coordinating Center for a large 17 region Clinical Trials Network conducting multiple protocols across multiple sites
- Tools (procedures and systems):
 - Clear communication
 - Rapid system development
 - Standardized training
 - High quality data
 - Timely production of manuscripts
- Insights:
 - Successful approaches
 - Lessons learned

Communication

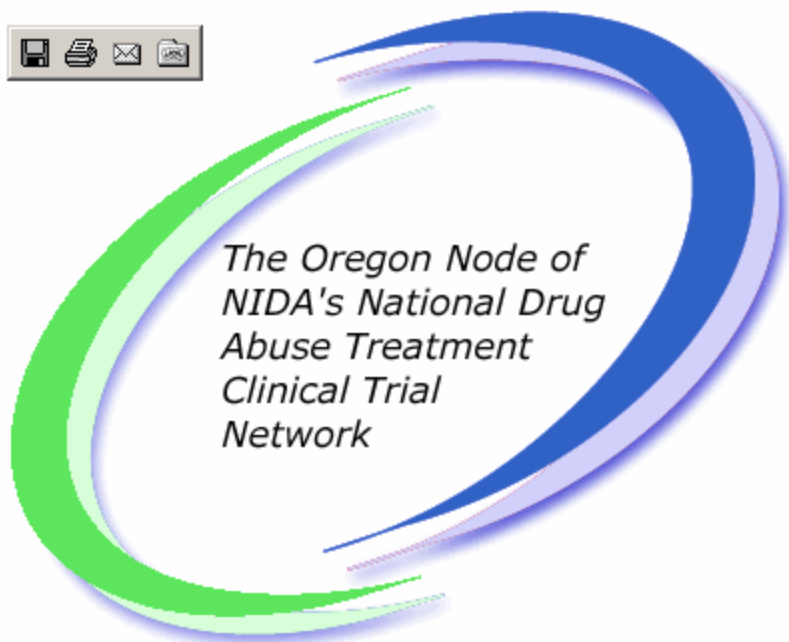
- Project Management Website
 - Staff and organization tracking
 - Group tracking
 - Calendar
 - Document posting
 - Protocol tracking
- The “Personal Touch”

**OR
Node**

- NIDA
 - Nodes
 - Organizations
 - Groups
 - Staff
 - Protocols
 - Data Entry
 - Calendar
-
- My Information
-
- Search
 - Upload Docs
 - Manage Docs
 - Manage Users
 - Site Admin Groups

March 2007

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*The Oregon Node of
NIDA's National Drug
Abuse Treatment
Clinical Trial
Network*



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ornode@kpchr.org

Communication – Successful Approaches

- Project Management Website
 - Central location for all contact information
 - Organization of website needs to be flexible
 - All protocol information organized in one place
- “Personal Touch”
 - Staff at the sites need to know who to call at the DCC and that the DCC is there to answer questions

Communication – Lessons Learned

- Project Management Website
 - Difficult to get network members to access the website
 - Important to keep the website up to date – need adequate staff time
- “Personal Touch”
 - Do not underestimate the time it takes to support the staff at the sites implementing the protocols

Data Entry & Data Management

- Secure web-based data system includes:
 - Participant registration
 - Protocol event tracking
 - Data entry
 - Data Management
 - Data Queries
 - Reports
 - Randomization

Data Entry & Data Management – Successful Approaches

- Protocol event tracking
 - Participant-specific calendar tracks acceptable date windows and forms to be collected; also produces a visit checklist to aid in preparation and completion of visit
 - Study Coordinators at the sites found this feature very helpful for tracking exactly what is happening with each participant at any given time
- Data Management
 - Data checking done on multiple levels (at time of entry and on the back end)

Participant ID: 1001

[Icon Legend](#)



	Baseline	Workshop			Follow-Up 1	Follow-Up 2	Follow-Up 3
		Session 1	Session 2	Session 3			
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Data Entry & Data Management – Successful Approaches

- Reports
 - Done in a timely manner so sites can be in touch with their data
 - Appropriate staff have access to the reports
- Randomization
 - Available on a 24/7 basis.
 - Important to have a back up system

Data Entry & Data Management – Lessons Learned

- Data quality and appropriate use of resources
- Timeliness of posting the trial monitoring reports
- “Live” vs. “static” reports

Training

- Adequate training is critical to successful implementation of a protocol
 - Good Clinical Practices
 - Forms Administration
 - Data Entry
 - Data Management
 - Intervention and/or clinical measurements

Training – Successful Approaches

- Opportunities for trainees to have “practice time”
 - Creation of hands-on packets for forms administration, data entry and data management
 - Exams to confirm understanding of training
- Relationship building
 - Often first opportunity to meet key staff
 - Understanding of any site specific issues
 - Sites know who to call when they have problems

Training – Successful Approaches

- Recertification and training additional staff
 - Provide certified trainees with tools/documentation to train site staff back at their shop
 - Plan for a recertification process
 - Timing depends on study length
 - Recertification of all current staff to ensure continued protocol adherence
 - Recertification of staff who may be having problems at any time during the protocol

Training – Lessons Learned

- Adequate training time is critical
- Appropriate staff need to attend the training
- Process needed for trainees who do not pass the certification process

Site Visits

- Site Visits are another important method used to ensure protocol adherence and high data quality
 - Review of regulatory documentation
 - Review of participant research charts
 - Walkthrough of the site and their processes
 - Support on site specific issues
 - Cross-site trends
- Expectations and accountability

Site Visits – Successful Approaches

- Important to balance the resources needed at both the CC and the sites to conduct site visits
 - Number of visits dependent on type of study, length of study, problems at the sites
- Review of participant research chart early in the data collection process to correct simple misunderstandings
- Support vs intimidation

Site Visits – Lessons Learned

- Timely feedback to the sites is very important
 - Debriefing session with Study Coordination and PI at the end of the visit
 - Site Visit report sent to site within 2 weeks of visit
- Standardization of visits
 - Use of standardized monitoring checklist to ensure that all sites are being reviewed in the same manner
 - Ideal to have the same site visit team

Analysis Request and Manuscript Production

- Important to have a process for managing multiple data requests from multiple investigators
 - Tracking system to manage process from manuscript approval, data requests and production of the paper
 - Includes voting process for publication committee members
 - Standardized data request form used by investigators
 - Clear documentation on all datasets are provided to investigators by CC

Analysis Request and Manuscript Production – Successful Approaches

- Tracking system to manage all aspects of the paper production
 - CC website as the communication tool (data request forms, dataset documentation, etc.)
 - Paper Status reports are posted to the website in a timely manner
 - Reports are used on trial wide committee calls to keep paper production process moving

Analysis Request and Manuscript Production – Lessons Learned

- Keep the request process simple
 - Minimize confusion and resources
 - Enter data request forms directly into the system
- Communication is key
 - Analyst needs to contact the requestor to confirm the request
 - Establish a working relationship
 - Minimize misunderstandings of data request

Summary

- Strong communication provides the building blocks for high data quality and overall project success
 - Establishing a strong connection in the beginning (Training/Site Visits)
 - Providing tools to enable good communication (Project Website/Data management Systems/Site Visits/Analysis and Manuscript Production)
 - Supporting the sites with a professional and friendly communication style (“personal-touch”)