Research/Regulatory Support Services

Workgroup participants:

Karen Hartman, Operations Manager, Office of Research Regulatory Support
Cheryl Nelson, Associate Director - Administration, Mayo Clinic Center for Translational Science Activities (CTSA); Administrator, Research Operations
Stacey Scirocco, Associate Director YCCI, Operations manager, Office of Research Services
Theresa Katz, Coordinator, Office of Research Services, YCCI Administration

Ad Hoc Members:
Michael Lin, IT Unit Head, CTSA Informatics
Joe Wick, Sr Analyst/Programmer, CTSA Informatics
Robert Pawluk, Sr Analyst/Programmer, CTSA Informatics
Thomas Johnson, Information Services Technical Specialist, CTSA Informatics
Charles Lu, Assoc Dir Technology & Systems Dev, Ctr for Medical Informatics
Frederic De Pourcq, Assistant Director, YCCI
Purpose/Objectives

- Identify opportunities to share practices for improvement of each other’s research/regulatory support services
- Evaluate and assess for feasibility; Develop implementation strategy and execute
- Development of collaboration model(s) and lessons learned for dissemination to the CTSA consortium
Projected Impact:

• Increased support/services for CTSA faculty with barriers minimized
• Increased support to regulatory/reporting burden
• Achievement of overall cost savings through sharing of practices/services/support models
• CTSA consort. learning from our experiences (collaboration model, lessons learned, and IT transfer experience)
Sub-project A: Centralized Coordination for FDA audits

Mayo resources: Tools, checklists and process flow for support during FDA audits

- Mayo knowledge shared to Yale
- Yale Assessment complete

- Status: Yale service organization in development, awaiting new hire
Sub-project B: Support for Study Files Management

Mayo checklists and templates for support to study teams:

- Mayo knowledge shared to Yale
- Yale Assessment complete- will implement

Status: Yale determining how best to disseminate resources for optimal benefit; currently available as tools on the web
Sub-project C: Research Assistant/Nursing Pool for Investigators

YCCI nurse/coordinator pool:

- Yale knowledge shared to Mayo
- Mayo Assessment complete

- Status: Mayo determined this was not feasible to implement
Sub-project D: Exploration of Informatics Solutions

Mayo:
1. IND/IDE Tracking System
2. Grant and Publications Tracking and Reporting
3. Clinicaltrials.gov registration facilitation

☑ Mayo systems presented to Yale
☑ Yale Assessment Complete

☑ Status: Working to transfer modified Grants & Publications system to Yale; Transfer Team in place; Yale working to correct a local issue
Sub-project E: Facilitation of Clinicaltrials.gov reporting requirements

Mayo and Yale to work together to identify solutions in support of studies

- Developing team to evaluate effective practices for providing support; 1st meeting in March
- Goal: share ideas and jointly develop potential solutions or models; share with consortium
Project Strategy/Timeline

• Presentation/sharing of information, e.g., support model/service/solution- **COMPLETE**

• In depth assessment of feasibility of adoption of support model/service/solution- **COMPLETE**
  • Includes evaluation of cost efficiencies

• Development of implementation strategy and timeline- **IN PROGRESS**
Project Deliverables

Locally:

• **Access** to the resources of another research service center; **Information**, lessons learned, etc.
  • Access to the skill set of another institution

• FDA audit **Service Model** including **Tools & Checklists** for investigators and studies

• Study files management checklists and **Templates**

• Potential clinicaltrials.gov reporting **Solutions**
Project Deliverables

Nationally:

• REPORT on collaboration model incl. guidance and lessons learned to consortium

• Piloting of Informatics tool transfer
  • POTENTIAL SHARING with other CTSA’s

• SUGGESTIONS for clinicaltrials.gov reporting models
Lessons Learned

• Development of lessons learned guidance to accompany collaboration/practice improvement sharing model, including:
  • Cost savings/cost avoidance lessons
  • Did the collaboration results challenge the assumptions made about sharing practices?
  • Implementation lessons (budgetary, organizationally, etc.)
Lessons Learned (to date)

- Site transferring tools/processes gains feedback and ideas for improvement.
- Site receiving tools/processes saves time with original creation, but needs to plan for modifications specific to site use, wording, audience, etc.
- Informatics systems may not be easily transferred (assessment is key).