Sharing Resources for Regulatory Services and Support
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BACKGROUND
A team was formed to identify opportunities to share practices for improvement of each other’s research and/or regulatory support services.

PROJECT WORK PLAN
• Identify opportunities
• Evaluate and assess for feasibility
• Develop implementation strategy and lessons learned to share

PROJECTED IMPACT
• Maximize resources and increase support for investigators and study teams
• Decrease regulatory burdens for investigators and study teams by providing regulatory assistance
• Sharing of effective practices, services and support models at a cost savings
• Dissemination of knowledge and "lessons learned" from our experiences to CTSA consortium members

PROJECT CONCENTRATION AREAS
• Centralized Coordination for FDA Audits
• Support for Study File Management
• Research Assistant/Nursing Pool for Investigators
• Facilitation of ClinicalTrials.gov results reporting

LESSONS LEARNED
• Site transferring processes gains feedback and suggestions for improvement from receiving site
• Informational systems may not be easily transferred. A thorough assessment prior to decision must be conducted
• Receiving site needs to anticipate need for modifications specific to site use, including wording, intended audience, systems, etc.
• Other projects and information were identified for future sharing as the project progressed and relationships continued to develop
• Discussions resulted in discovery of previously unknown resources at one’s own institution

METHODS
• The project team met to identify key components under each subproject and scheduled telephone and face-to-face meetings.
• Mayo Clinic knowledge transferred to Yale on centralized FDA audit coordination, support for study file management and exploration of informatics solutions. Yale knowledge transferred to Mayo Clinic on research assistant/nursing pool and start-up service.
• The team reviewed information, assessed the utility of having the service at the home institution and the ability to implement (if yes, set up for transfer. If no, documented why and identified if other resources could be used instead.)
• Receiving team evaluated the offered service so that the home institution could benefit from external feedback and incorporate as appropriate.
• Both institutions are working in parallel on clinical trials registration and results reporting.

NEXT STEPS
• Cost comparison evaluation
  • Cost comparison (between creating center and adopting center)
  • Identify costs avoided and unanticipated costs incurred
• Further Evaluation
  • Survey Yale coordinator staff to evaluate benefits of study file management tools and FDA audit assistance
  • Evaluate publications tracking database at APR year mid-point
• Further identification of how to adapt inter-institutional sharing for other centers
• Continued meetings for clinical trials results reporting facilitation project
  • Describe current processes of support
  • Identify possible solutions for investigator assistance
  • Exploration of any new processes or systems to be used for reporting

Use of Mayo-Originate tools for Yale Education: Mayo FDA Audit Preparation documents were utilized in several education venues. They received rave reviews and more requests to present the information. These required little or no effort to adapt/adapt.