Administrative Supplement Progress Report

NCRR ARRA funded Administrative Supplement for CTSA Consortium Strategic Goals

Linked supplement with the Mayo Clinic CTSA

Overview: This linked collaborative project between the Mayo Clinic Center for Translational Science Activities (Mayo Clinic CTSA) and the Yale Center for Clinical Investigation (YCCI) explores opportunities to exchange best practices, administrative and regulatory support models, and related infrastructure supporting clinical research to minimize barriers to the initiation of research and provide timely access to exceptional support resources for our investigative faculty. The Specific Aims proposed are:

Specific Aim 1: To explore and assess the feasibility of exporting Yale knowledge, expertise and support models in support of clinical research management and study initiation activities for Mayo-based clinical and translational research.

Specific Aim 2: To explore and assess the feasibility of importing Mayo knowledge, expertise and support models in support of clinical research management and study initiation activities for Yale-based clinical and translational research.

Specific Aim 3: To evaluate the efficiency and effectiveness of leveraging resources across CTSA institutions, including ascertaining barriers and identifying potential solutions to resource sharing at the national level, share lessons learned/best practices, and disseminate the collaboration model(s) to the entire network.

Major Accomplishments: This new form of “translation” has been an major success. Most notable for Yale is the adopting and adapting of the Mayo Clinical Office of Diversity in Clinical Research Cultural Advisors program: Designed to reach Minnesota’s Somalia and Hmong (Asian ethnic group) populations re-designed to reach Connecticut’s Hispanic and African American populations. The program modification have been shared back with Mayo for adoption consideration.

Joint Accomplishments: Project oversight is accomplished through an Oversight Group which continues to meet on a monthly basis via conference call. The group ensures progress on agreed milestones and deliverables, coordinates face-to-face meetings, addresses barriers and communicates with CTSA leadership. Since the last update, project teams met face-to-face on the following dates:

- May 5, 2011, meeting at Mayo Clinic.
- June 20-21, 2011, Washington, DC. YCCI and Mayo personnel gave four poster presentations:
  - Leveraging Mayo Action Project (Project 1), Diversity and Patient Recruitment Strategies (Project 4), Office of Regulatory Support/Service Center (Project 5), IRB Process Mapping (Project 6); and two oral presentations: Using Value Stream Mapping/Lean Six Sigma to Improve Processes (Project 6) and the overall YCCI/Mayo Clinic collaborative project/model at the NCRR-sponsored Clinical Research Management Workshop.
- November 15, 2011 at YCCI. – Development of dissemination plans
- April 5, 2012 at YCCI. – Implementation and completion of dissemination plans
- June 7, 2012 at YCCI (planned).

Substantial progress has been made in the second year of this supplement. In general, all remaining projects are pursuing implementation and evaluation strategies as reported below. See Table 1 for a summary of progress and accomplishments to date across all specific aims.

Specific Aim 1 Progress Update
- Knowledge overview and transfer completed; project assessments completed; benchmarking completed; internal administrative and/or legal reviews completed; and project adoption determinations completed for all projects.

Specific Aim 2 Progress Update
- Program implementation strategies have been developed for all projects and are being implemented.
- Implementation lessons learned and evaluation plans are complete.
Specific Aim 3 Progress Update

- The current focus for all projects is on dissemination to the broader CTSA community. Dissemination plans have been developed that include journal articles, poster presentations, conference presentations, training (slide presentation template) sharing and special web pages at both institutions dedicated to this supplement.

### Table 1: Summary of Progress and C. Accomplishments

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<thead>
<tr>
<th>Project List and Knowledge Expert</th>
<th>Aim #1</th>
<th>Aim #2</th>
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<td>Knowledge overview shared</td>
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<td>Knowledge transfer complete</td>
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<td>Evaluation Plan Developed</td>
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<td>Dissemination strategy developed</td>
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**Project Descriptions:**

**Project 1: Leveraging the Mayo ACTION Project**
This project focuses on sharing information, practices and tools developed by Mayo Clinic as part of an in-depth assessment/process improvement of business processes associated with clinical protocol development through protocol activation.

**Project 3: Education Protocols**
The overall goal of this project is to improve educational and training opportunities and competency for clinical research staff by establishing best education practices, identifying learning needs, developing processes to share content, and evaluating the ability to implement at each institution.
Project 4: Diversity and Patient Recruitment Strategies
The goal of this project is to identify and share practices and strategies for effective diversity and patient recruitment.

Project 5: Office of Regulatory Support/Service Center
This project’s aim is to enhance the research regulatory support services available to clinical and translational research. Next steps for all elements of this project are to (i) develop lessons learned and (ii) assess broader application and dissemination strategies for the consortium.

Project 6: IRB Collaboration
Project aims to identify and establish best practices associated with the IRB review process.

Out-of-Scope (Additional) Project
Project aims to improve a certain opportunity of Yale’s choice with Mayo process improvement expertise. If the process meets the expectations, consider another opportunity for improvement and observe the process, map the current state and compute the process performance metrics and collect data to determine if the process meets the customer expectations (or requirements):

- If the process does not meet the requirements, map the future state.
- Determine the transition plan and Kaizens.
- Implement solutions while monitoring the data.
- Once the process is improved, transition the project.

Challenges:
- Time pressures occasioned by the pending submission of respective CTSA competitive renewals was effectively managed via a coordinated project management approach note above.
- Internal legal review of agreements and related documents led to substantive delays.

Plans for the next funding period, milestones, and timelines: In general, all projects continue to make excellent progress.

Plans for balance of project period
- Complete evaluation template and conduct evaluations of all projects.
- Complete dissemination strategies and communicate findings to consortium, which may include travel to key function committee meetings.
- Pursue feasibility of an additional out-of-scope quality initiative project based on results from the initial one.
- Develop and design websites at each institution (and linked to one another) dedicated to the supplement collaboration that shares:
  - Application information
  - Mission statement
  - History of project
  - Workgroup members
  - Workgroup products
  - Collaboration agreement
  - Presentations
  - Posters
  - Useful forms, tools and other deliverables
  - Progress reports
  - Published articles with links