The Clinical and Translational Science Awards (CTSAs) Are Transforming the Way Academic Medical Institutions Approach Translational Research: The University of Michigan Experience

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Introduction

In 2006, the National Institutes of Health (NIH), guided by the leadership of Elias Zerhouni, launched the Clinical and Translational Science Award (CTSA) program to jump-start transformative change in the nation's research agenda to emphasize translating discovery from the bench to implementation in the community.[1–5] Much of the funding for the CTSAs was garnered by rolling NIH funding of General Clinical Research Centers and educational K and T awards. Successful applicants were then asked to utilize these funds to (as stated in the Request for Applications) "transform the local, regional and national environments for clinical and translational science and to increase the safety, efficiency and speed of clinical and translational research."[4] Each of the 60 CTSA institutions has approached addressing this transformation in slightly different ways; however, it has become clear over the last 5 years that substantive changes, as a result of CTSA funding at academic institutions, are transforming medical research and the infrastructure that supports it.

Each of the CTSA's is required to address specific key functions to advance the consortium goals. These required key functions are (1) expertise in Biomedical Informatics, (2) a program in Research Education, Training, and Career Development, (3) a program in Community Engagement and Research, (4) an Evaluation component, (5) Pilot Projects in Translational and Clinical Studies, and (6) a Regulatory Knowledge and Support component. Optional CTSA key functions include (1) support of the Development of Novel Clinical and Translational Methodologies, (2) components or cores to support Research Design, Epidemiology, Biostatistics, and Clinical Research Ethics, (3) Clinical Research Resources and Facilities, and (4) components or cores that develop Translational Technologies and Resources. It is also encouraged for institutions to support research in Child Health.

Addressing these key functions at the University of Michigan, for example, has led to transformational change in the structure and culture of the institution.

Identifying barriers to translational research

After receiving a CTSA award in 2007, the University of Michigan (U-M) conducted a strategic assessment of the translational research enterprise through over 100 extensive interviews of faculty and staff providing the infrastructure for translational research, as well as the investigators conducting that research. The institution then conducted a survey of research team members involved in human subject research to identify and describe the current challenges facing translational research—specifically, the administrative processes associated with its planning and execution. In addition to identifying the issues, the team rated the technical and cultural/political levels of difficulty in implementing the solutions, as well as the corresponding impact each solution would potentially bring. These were then graphically mapped on a three-dimensional bubble chart (Figure 1). This stratification assisted in the planning, design, and prioritization of solutions, offering insights that guide the refinement efforts of a clinical research enterprise's organization, business, and information technology (IT) processes.

Recommended solutions being addressed by the CTSA

Eight areas were identified as solution categories. The topics include organizational, procedural, financial, structural, educational, technological, and cultural elements.

1. *Transform and expedite study and contract approval process.* The contract approval process, especially in regard to industry protocols, was recognized by the faculty as their number one area of discontent. The approval process was not clear to research team members and varied widely by unit and department as well as by type of sponsor. Educational and process improvement opportunities were identified. To address these issues, U-M has set a goal to expedite study approval process so that the contract and regulatory processes are executed within 60 days from submission for all studies and 45 days for industry-sponsored studies. The primary strategy to accomplish this aggressive goal was to create a team consisting of members of the units involved and to reengineer processes and conduct a demonstration project for feasibility within 1 year. Secondary strategies included increasing the transparency of contracting within the system to allow better tracking of proposals by the faculty and study teams, publishing desirable contract terms on a website for faculty and staff to use as protocols are developed, and to create an interactive, web-based research road map to guide faculty and staff through the necessary administrative steps to conduct translational research.[6]
2. *Establish a clinical research support unit with best practice tools.* The current translational research enterprise consists of multiple units with redundant functions of varying quality.

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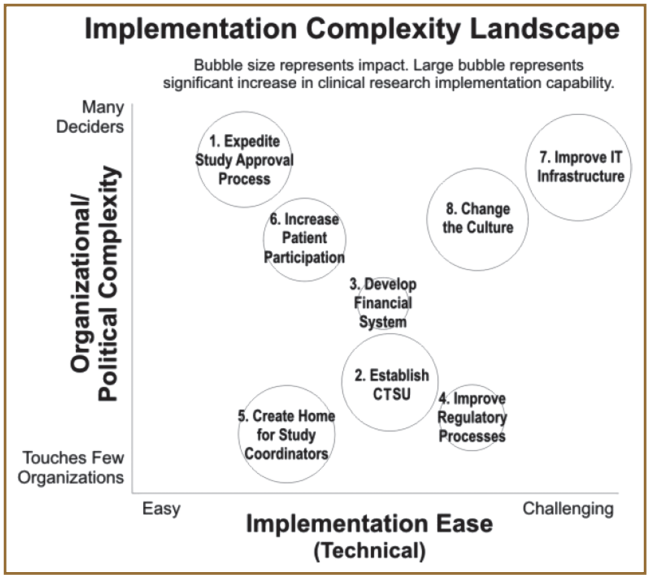

Figure 1. Bubble chart of implementation complexity. The chart orders tasks by level of execution difficulty—both technical and fiscal execution difficulty—as well as organizational and cultural complexity. The bubble size represents impact such that the bigger the bubble, the bigger the impact the change will have on improving translational research. For instance, enhancing study coordinator programs is relatively easy both technically and from an institutional buy-in perspective and was judged to provide a relatively large impact. Creating integrated informational technology systems involves significant investment, is more technically complex, requiring buy-in from multiple parties within the institution but is pivotal for achieving the goal of doing more effective translational research. The visual mapping provides context and definition to the challenge of enhancing the efficiency and effectiveness of translational research not only at the University of Michigan but all of the CTSAs. IT = Information Technology, CTSU = Clinical Trials Support Unit.

The primary strategy was to create a leveraging of the resources of the CTSA to develop a franchisable model built on best practice modules that could then be easily adopted by other units throughout the university.

3. *Develop a customer friendly, transparent financial system that spans clinical trial budget creation to account reconciliation and study close out.* The lack of transparent and integrated financial systems to track costs and other financial aspects of clinical research including budgeting and billing remains a challenge for study team members. The University of Michigan Office of Research has created the Calendar Review and Analysis Office (CRAO) to assist researchers with this process and is currently implementing a clinical study budget tool, eThority, to create standard billing calenders and processes across the organization. CRAO will also champion the evaluation of financial feasibility prior to proposal initiation; provide more assistance to PIs and research team members with study budgets, through increased training on best practices, budget negotiators, and standardized internal budget; and generate a new reconciliation report that will make study account statements more easily understood by research teams.
4. *Improve regulatory approval process and reduce Institutional Review Board (IRB) turn-around time.* Significant gains have been made, resulting in a 40% improvement in IRB cycle time. Study teams will be advantaged by continuous improvements to the process. Embedded within the goal to expedite study approval is the goal to reduce IRB turnaround time (TAT) to 21 days for full convened board approval, including ancillary committees, and reduce no more than minimal risk studies to 5 days TAT. U-M is investigating strategies for greater IRB board participation of faculty, instituting another IRB board specifically for industry-based studies, as well as dedicating a board to minimal risk studies. The CTSA is also identifying various research teams to extract best practices. The CTSA has created an IND/IDE consultation and support team for researchers that have already helped over 100 investigators with IND/IDE applications.
5. *Create a home for study coordinators to promote education and sharing of best practices.* A strong research team, anchored by a solid study coordinator, is critical to clinical research success. Study coordinator turnover was noted to be 18% a year. Of all study coordinators, 75% have been at U-M less than 3 years, compared to 44% of the rest of U-M staff and 56% of study coordinators nationally. Study coordinators noted that there was no coherent program or "home" for them within the system. Several strategies have been developed and are being enacted to address this problem. The CTSA created a virtual, web-based site for study coordinator support that will eventually include standardized resources such as workflow steps, templates, forms, and answers to common questions. A monthly study coordinator forum has been enacted to share challenges and best practices. Human resources has been engaged to develop uniform study coordinator job descriptions and to mentor the coordinators to develop a meaningful career path.
6. *Increase patient participation (enrollment) in research.* The institution has set an ambitious goal to double patient participation in research in 5 years, while decreasing the number of studies that do not enroll a subject to 5%. A primary strategy to accomplish this was the creation of a web-based participant registry (UMclinicalstudies.org) to help match interested patients and volunteers with open studies. Currently, over 7,000 participants are registered. U-M is also investing in an electronic medical record system that better enables queries and "flags" potentially eligible patients. Further investigation by a study team is necessary to determine the underlying reasons for poor accrual to studies, whether due to missed competitive enrollment periods, rare disease studies that inherently will be challenged to accrue, registry studies with open enrollment, lack of ability to find enough patients within the patient population, or unwillingness to ask patients to participate. Understanding and addressing the underlying issues provides an opportunity for the CTSA to improve the quality, and potentially reduce "waste," in the proposal and regulatory systems.
7. *Achieve efficiencies through integration of multiple, fragmented IT systems.* More than 30 IT systems, as well as paper records, were identified that are currently utilized by investigators to perform clinical and translational research. Moreover, multiple IT service providers exist across the institution with poorly defined roles, responsibilities, and accountability. Alignment of key IT systems and personnel that support clinical and translational research is imperative. The CTSA is playing a central role in developing and leading a cohesive strategy that integrates IT for researchers' benefits. For example, the institution is investing in a system-wide approach to develop an overall architecture that will create a clinical data repository.
8. *Evolve the culture of U-M to be more supportive and enthusiastic of clinical research.* Like many academic institutions, the University of Michigan has struggled to value clinical research

to the same extent as the basic sciences. In interviews and surveys, many faculty noted that choosing a career in clinical research can be seen as "falling between the cracks" or not as respected as a career in basic research. While improving infrastructure demonstrates value to these researchers, it is not enough. The CTSA has advocated to create a working group to make recommendations to University leadership to increase recognition for excellence in clinical research, to refine promotion and incentive criteria to value scholarly clinical activity and emphasize collaboration and innovation across all disciplines (team science). Furthermore, a plan is being developed to expand training programs to support training of those who want to become clinical and translational researchers, beyond the few slots that the CTSA (K and T programs) can currently support.

Conclusion

The mission of the CTSA to enhance an investigator's ability to conduct translational research at the University of Michigan has resulted in concrete organizational plans and investments to improve infrastructure of translational research and increase the satisfaction of participants, faculty, and staff who are engaged in these activities.[7] Similar changes are occurring at CTSA institutions all over the country, validating the vision of Dr. Zerhouni and the investment in these vehicles of change by the NIH.

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