Partnership between CTSI and Business Schools Can Promote Best Practices for Core Facilities and Resources

Lilith Reeves, M.S., M.T. (A.S.C.P.) S.H.[1], Linda M. Dunn-Jensen, M.S., Ph.D.[2], Timothy T. Baldwin, M.B.A., Ph.D.[2], Mohan V. Tatikonda, M.S., M.B.A., Ph.D.[2], and Kenneth Cornetta, M.D.[1]

Abstract

Biomedical research enterprises require a large number of core facilities and resources to supply the infrastructure necessary for translational research. Maintaining the financial viability and promoting efficiency in an academic environment can be particularly challenging for medical schools and universities. The Indiana Clinical and Translational Sciences Institute sought to improve core and service programs through a partnership with the Indiana University Kelley School of Business. The program paired teams of Masters of Business Administration students with cores and programs that self-identified the need for assistance in project management, financial management, marketing, or resource efficiency. The projects were developed by CTSI project managers and business school faculty using service-learning principles to ensure learning for students who also received course credit for their participation. With three years of experience, the program demonstrates a successful partnership that improves clinical research infrastructure by promoting business best practices and providing a valued learning experience for business students. Clin Trans Sci 2013; Volume 6: 297–302

Keywords: core facilities, service-learning, graduate business education, life science industry, clinical and translational research, interdisciplinary project management

Introduction

Biomedical investigators have relied on increasingly sophisticated tools to conduct their research. Examples include high-end instrumentation for genomic and protein analysis, multimillion dollar imaging equipment, and access to sophisticated small and large animal models. The data generated also requires access to skilled statisticians, informaticians, and robust computing resources. Rapid and cost-effective realization of the projects to medical practice or intellectual property demands well-coordinated translational support services. To provide these critical research tools, academic institutions have created core service units that promote multiuser access to research infrastructure.[1] Core service units can be created *de novo* by the institution or evolve as an extension of a research program started by a single investigator. In both instances, the core director is often selected for their scientific accomplishments and expertise with the technology.

How core service units are funded vary highly from academic institution to institution, but rely on a combination of user fees charged to the investigator, institutional support, and extramural funding. The latter can be an extremely important source of revenue, with the National Institutes of Health (NIH) estimating that $900 million per year is provided to operate and use core facilities.[2] The large expenditures required to maintain and upgrade cores has also led to the pursuit of commercial work to supplement revenue since facility capacity is often not met by performing academic projects alone. What have evolved are core service units with large overhead, workflow challenges, complex financial structures, and a need to market their services to academic and commercial customers. While these issues are well known to the business community, they are not familiar to most scientists operating core service units.[3] With increasing financial pressures faced by most academic and federally funded organizations,[4] academic research institutions are being forced to change their workplace practices to incorporate an emphasis of implementing business-oriented practices. While many universities see the need to implement business practices within their cores, they may lack the internal resources or skills and/or

a budget to hire external business consultants. In other words, academic research institutions need business assistance; they must be creative in finding this talent.

In parallel, business schools seek opportunities for students to engage in real-world business projects, particularly those involving clinical research, health care delivery and other aspects of life sciences.[5-7] One approach business schools have been using to ensure that students have opportunities to gain real-world experience is through service learning projects. Service learning is designed to promote academic learning through student service in the community. Much of service-learning has been focused on civic engagements.[8,9] More recently, there has been a growing focus on governmental partnerships or federally funded organizations. Thus, these organizations acquire cost-effective business assistance and business students get access to meaningful and impactful projects: A win–win for all.[10] But to be successful, these multidisciplinary team members need an understanding of the process and potential pitfalls to create these winning partnerships.[11] Partnering a business school with academic research institutions has unique opportunities and challenges.

This paper provides a framework for developing and administrating a partnership between a federally funded research program and a graduate business school. Our aim is to contribute to a growing number of research that highlights the needs of integration of business practices into the translation of science[12-14] and the dissemination of best practices.[15] We offer a "how-to" successfully implement a partnership between faculty from an academic medical research institute, business school faculty, and MBA students by presenting the best practices we have developed over three years.

Methods

Establishing a business assistance and knowledge transfer partnership

The Indiana Clinical and Translational Sciences Institute (I-CTSI) with its home in the Indiana University (IU) School

of Medicine was founded to promote life science research throughout the translational science spectrum. The I-CTSI is a statewide program that includes the three major biomedical research universities in the State; Indiana University, Purdue University and the University of Notre Dame. In the earliest of planning stages for the I-CTSI it was recognized that the Indiana University Kelley School of Business could serve as a mutually beneficial partner.

One program within the I-CTSI is the Translational Technology Resources Program (TTR) with a goal of promoting the use of novel technology including core laboratories and service programs, the majority working through a cost-recovery charge-back model. The TTR works with more than 60 core laboratories and service program across all I-CTSI institutions. In a survey taken by the TTR program, I-CTSI Core Laboratory Directors expressed a lack of confidence in their ability to develop a valid business plan along with their recognition that this is critical to the success of any research core or program. Upon discussion between I-CTSI TTR and the IU Kelley School of Business representatives, it was determined that collaborating to connect a team of MBA students to partner with core directors would provide the business assistance requested by the core directors and serve as real-world experience for the students.
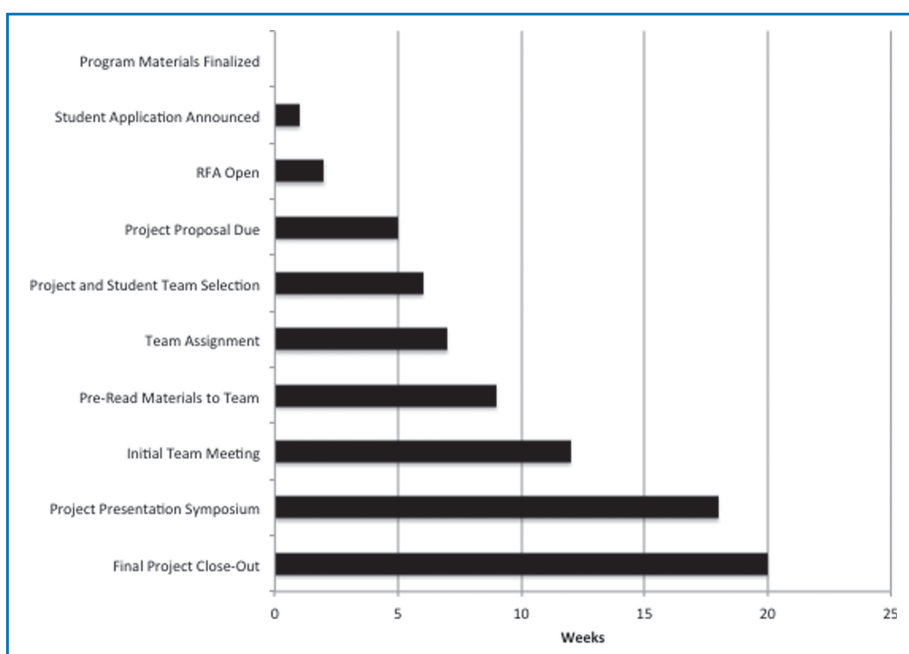

Figure 1. Logistical and operational best practice sequence of the core business management assistance program.

Developing logistical and operational best practices

Program objectives

For the I-CTSI, the goal of the Partnership is optimization of translational research by promoting cost-effective operations and higher quality core services within its member institutions. As the MBA student participation is part of their formal course work, it is also important to define their learning objectives. Therefore, projects appropriate for the partnership are required to provide the students with an opportunity to: (1) work on a cross-functional consulting team, (2) apply skills acquired and honed during business school to develop well-reasoned recommendations, (3) explore the health care and life sciences industry, (4) learn about the NIH focus for transforming research, and (5) allow the students to share the details of their experience with potential employers.

Program design

Anticipating the program would have significant interest from core facilities and students, a formal application selection process was developed. We began with defining the scope of work, establishing written guidelines and application materials, and then developed a strategy for recruitment of students and core facilities. The initial challenge is to balance the business management needs of the core facilities with the expertise of the MBA students. Four categories of projects were established: project management, marketing, financial management, and resource efficiency management. The partnership program was then modeled after the process

of developing internal grant competitions and included the following: Project timeline, Guideline for Applicants, application forms, and guide for review and project selection. Development of these documents provides an organized process to ensure that we are addressing critical issues prior to accepting applications from core facilities, permits students to better understand the course goals, and fosters consistent review and selection of applications.

The project timeline document for our first round of applications was developed by identifying the dates for the academic coursework to which the student credit is connected and working back from that date (*Figure 1*). The figure includes critical milestones and the anticipated time period to accomplish each component of the program.

The recruitment phase

The purpose of the recruitment phase is to generate interest in the I-CTSI community and among MBA students. The I-CTSI-TTR personnel initiate email and direct discussions with the I-CTSI core and program leaders about the opportunity to gain business management support and advertise the opportunity on the I-CTSI website. The I-CTSI-TTR manager encourage pre-application meetings with core personnel to assist in project development and the application process. In parallel, business school faculty activities include a call to the MBA students to work on health care and life science consulting projects.

Competition materials

The policy that governs the program is defined in the Guidelines for Applicants. This document contains the essential components of the program including a general description, goals, eligibility, responsibilities of core directors and students, and contact information. To assist core directors unfamiliar with business practices in preparing an appropriate project, the Guidelines have a written definition of the four types of assistance available (project management, marketing, financial management, and resource

efficiency management). In staying with the inclusive mandate of the I-CTSI, the proposal is open to all cores and programs that support translational research infrastructure within any of the I-CTSI affiliated academic institutions. A critical component of the Guidelines is the "Responsibilities" section designed to alert core applicants to the importance of their commitment to the MBA students. Failure of Core Directors to actively participate can jeopardize the students' successful completion of their coursework. Responsibilities for students are also outlined and include presentation of their work at an I-CTSI symposium.

The core applications

The program Application form follows the points highlighted in the Guidelines and is designed to assist applicants in capturing the essential information for project review, selection, and student matching. Applicants must provide an overview of their organization to include a brief history, focus, goal statement, and organization structure of the unit. The key component of the application is the description of the problem, what specific assistance is requested, and why resolution of the problem is important to the core. Since I-CTSI personnel are being utilized to manage the project, applicants must describe how services to I-CTSI investigators will be improved by successful completion of the project. To reinforce the commitment of the applicant, we require a brief statement of resources that the core will make available to the project including commitment of core personnel time and effort to complete the project. The applicant must clarify in advance if confidentiality or intellectual property considerations apply to the project. The I-CTSI personnel are available to assist core directors in completing the application, and discussion prior to submission is encouraged. The deadline for receipt of application is advertised on the I-CTSI website and in an I-CTSI newsletter sent to all core and service program directors. The application forms and Guidelines for Applicants are all available on the grant section of the I-CTSI website; applications are submitted electronically through the website.

Student selection: School of business focused activities

Once the students have submitted their applications, the student selection process begins. To ensure success for both the student and the project, the Business School professor reviews the student's application along with their resume.

Generally, students are selected by the Business School professor based on their year in the program (preference given to the 2nd year MBAs), prior work experience, career goals, and discussions with faculty and MBA program staff regarding potential for client management skills. Participants from the Bloomington campus are selected from approximately 25 students in the Life Science Plus Group who have previously committed to two life science courses and four life science experiential activities. The selection process also considers the MBA student's area of concentration (ex. marketing, finance, consulting, or supply chain management), which is used in pairing student strengths with the expertise needed for the project. Participants from the Indianapolis campus are selected through competitive admission based on their interest in supply chain and operations management, proven initiative and professionalism, and success in prior coursework. The small annual program cap of 20 students permits a low student/faculty ratio and assures more generous Business faculty time for consultation with each project team and client. Admitted students are then matched by the Business

professor to specific projects based on student interests (e.g., some seek pharmaceutical-grade laboratory experiences), complementary and cross-functional student team skills to best meet project requirements (e.g., team composition may include students, respectively, experienced in financial analysis, process analysis, and information technology), and schedule practicalities regarding student course and work schedules.

Project selection and student matching: Project management focused activities

To facilitate review, a reviewer guide and assessment form is developed to define reviewer responsibilities and the criteria for selection. After the application deadline has passed, the I-CTSI project manager performs an initial administrative review of all applications to ensure they are for support of cores and projects that fit with the I-CTSI mission. Next in the selection process, the review team from the School of Business evaluates the scope of the projects and eliminates any projects that fail to meet the learning outcomes for the course. Finally, the School of Business and I-CTSI faculty meet to prioritize the eligible projects using the criteria defined in the Guidelines for Applicants; specifically projects that will (1) provide a high-quality service learning for the MBA students; (2) lead to improvements in organizational efficiency, speed of service, and/or quality; and (3) has the potential to be extrapolated and benefit other Cores, Resources or Projects.

Results

Partnership experience

In our partnership, the inaugural year of 2009 teamed 3 student groups with technology cores. Initially students from IU's full-time MBA program (based in Bloomington, IN, USA) participated. The positive feedback from students and core directors led to an expansion of the program to include MBA students from IU's part-time MBA program (based in Indianapolis, IN, USA). A total of 22 projects have been completed (*Figure 2*). While the
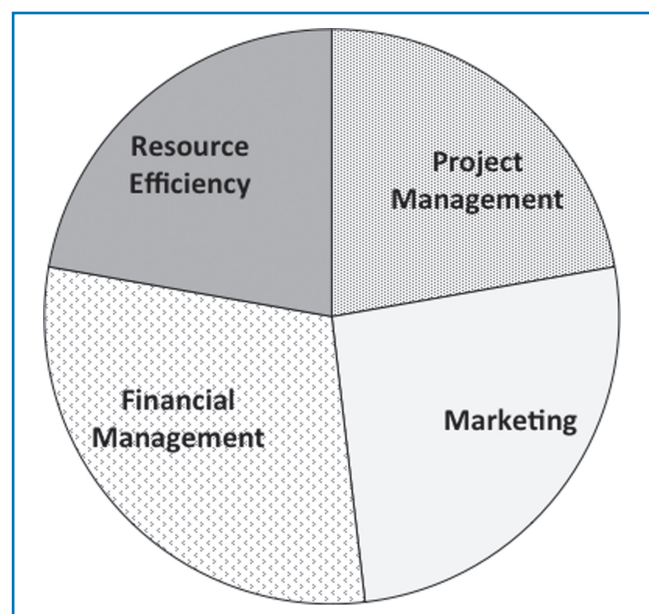
Figure 2. Assistance requests from 22 core and service facilities enrolled in the core business management assistance program.

I-CTSI Core	Service	Project Deliverable
Clinical Discovery Laboratory	Veterinary clinical trial support	Project management
Clinical Pharmacology Analytical Core	Preclinical and clinical pharmacokinetic analysis	Project management, resource efficiency
Clinical Pharmacology Program	Pipeline development of novel drugs	Project management
CRC	Inpatient and outpatient clinical trial center	Financial management
CRC	Inpatient and outpatient clinical trial center	Resource efficiency
CRC	Inpatient and outpatient clinical trial center	Marketing
Indiana BioBank	Collection of human biospecimens	Marketing
Indiana center for biologic microscopy	Confocal and live cell imaging	Marketing
Indiana center for biologic microscopy	Confocal and live cell imaging	Financial management
Indiana CTSI biorepository	Storage of human biospecimens	Financial management
IU core administration	Core laboratory oversight	Resource efficiency
IU core administration	Core laboratory oversight	Marketing, resource efficiency
Indiana Institute of Personalized Medicine	Improve patient therapy by provided genetic data for personalized drug therapies	Project management, marketing
IU Vector Production Facility	GMP production facility for clinical gene therapy vectors	Financial management
IU Vector Production Facility	GMP production facility for clinical gene therapy vectors	Resource efficiency, project management
In Vivo Therapeutics Core	Murine xenograph of human tissue for testing drug and cell therapies	Project management, financial management
METAcyt Biochemical Center	Proteomics	Financial management
National Gene Vector Biorepository	NIH funded gene therapy resource program	Resource efficiency
Ossabaw Swine Resource	Porcine model of diabetes and heart disease	Marketing
ResNet recruitment resource	Research subject recruitment through multi-provider network	Financial management
Susan G. Komen Tissue Bank	Repository of normal and cancerous breast tissue	Marketing
University of Notre Dame Core Administration	Core laboratory oversight	Financial management

Table 1. Summary of Business Management Assistance Projects 2009–2012.

majority of projects involved core facilities and service programs at the IU School of Medicine in Indianapolis, projects were also performed at Purdue University and the University of Notre Dame. As shown in *Figure 2*, the projects encompassed all four categories of assistance with relative equal distribution among project management, marketing, financial management, and resource efficiency management. Projects involved a wide range of cores and services programs and included animal research cores, proteomics cores, imaging facilities, national biobanking programs, and research administration programs (*Table 1*).

One of the critical roles to getting the projects started successfully has been the guidance by the I-CTSI TTR & the School of Business project managers. The I-CTSI TTR project manager coaches core directors and personnel to gather pertinent information to send to the students while also offering suggestions on how best to work with the student teams. The School of Business project manager meets with the students to review the learning objectives along with guidance on how best to work with their I-CTSI partners. This gives both the core directors and the students a foundation to move forward on the projects.

A key component to success is engagement between the students and the I-CTSI project teams as soon as the teams have been assigned. The goal of the initial meeting is introduction and a high level overview of the project and is often held via teleconference. The I-CTSI project manager communicates with core personnel within the first week of team assignment to: (1) ensure that communication had been initiated successfully; (2) core background information having been provided to the student; and (3) that students demonstrate an understanding of the project needs and scope.

Each team assigns one student to serve as the project leader. It is the responsibility of the student leader to coordinate the project plan, deliverables, and meeting times with the core director. One imperative to the success of the teams is that project meetings need to be scheduled a few weeks in advance. This mindset of scheduling meetings in advance was a change for some of the students. Academic life has its own rhythm and norms that at times collided with the more pressured schedules of the core teams. However, once this challenge became evident this learning has been documented as "Practices to be Considered" with the student teams for future projects.

Because student and cores may be based at different I-CTSI institutions that are over an hour apart, several different types of technology were used to facilitate the meetings, such as Skype, teleconference, and video conferencing to supplement face-to-face meetings. While the project managers conducted

regularly scheduled project reviews with the teams, the day-to-day management of the projects was student-directed. While each team is given leeway to develop communication options best suited to the project at hand, a minimum of three face-to-face meetings were required including a mid-point check-in that included the School of Business professor, an end of the project meeting with core personnel to finalize deliverables, and participation in a project presentation and poster session to the I-CTSI scientific community.

The partnership has led to tangible benefits for CTSI programs and cores. For example, the Clinical Research Center (CRC) was exploring a public-private partnership to support Phase I pharmaceutical studies. The MBA students performed a gap analysis and identified Standard Operating Procedures and laboratory infrastructure needed to meet the new level of service. The recommendations were implemented and the CRC successfully completed an external industry audit. Two additional projects were recently highlighted in the Indiana CTSI newsletter.[16] MBA students and the Indiana Institute of Personalized Medicine collaborated in the development of the Personalized Medicine Clinic. The students performed mapping and capacity analysis of the laboratories (including next generation sequencing data), mapping of information flows between clinics, laboratories, and a cost simulation model. The clinic is now in the implementation phase with a second MBA team assigned to continue the collaboration by providing project management and financial management guidance. A second example highlights a collaboration of MBA students with a core laboratory. The Indiana University Vector Production facility operates a manufacturing facility that generated gene therapy viral vectors for Phase I/II clinical trials. The core needed financial assistance in assessing costs of this highly complex activity and generating estimates in a manner that met NIH regulatory requirements.[17] MBA students developed an Excel-based costing tool that easily adapts to different batch sizes. A unique component of the tool is the ability to provide data on different financial models for allocating facility and personnel costs; providing the user with alternatives that best fit the specific environment of the core. The tool is being made publically available through the NHLBI National Gene Vector Biorepository program and is described in a recently accepted manuscript.[18]

Service learning experience
In carrying through the projects, the students apply theories and frameworks learned in their business school coursework, for example, financial scenario and net present value analysis, market promotion and diffusion models, and structured process improvement methods including six sigma and lean operations techniques. The students also conduct qualitative and/or quantitative data analysis, depending on the needs of the project, and provide to the sponsor data-based analysis, findings, and business guidance.

The students have several deliverables during their projects. The students deliver a detailed presentation in which they reviewed their recommendations for their client along with any work product that might have been produced on the client's behalf (e.g., marketing brochure). In addition, the projects were presented in an open symposium in which the teams presented both an executive summary and a poster session. Sharing findings and recommendations in poster sessions and open symposium is not typically part of MBA training and serves to improve the student skill set while informing the CTSI community.

Knowledge transfer between both groups is an important aspect of the partnership. A primary learning goal for students is an experience that will increase their knowledge about how business processes function in the health care and life science industry. However, for this partnership to be truly successful, it was also important for the I-CTSI project teams to increase their business literacy. To gather reflections from the students and the I-CTSI project leads we solicited feedback from them via a survey. When asked the reason for participating in the course, over half of the students expressed interest in participating as a means to build skills. Others expressed an interest in gaining some practical "real-world" experience in the field. Students also wrote about creating a positive impact for the clients. When asked to reflect on their learnings, the majority of students believed that they had walked away with a better understanding of the business of life science and the ability to apply their classroom business skills into real-world business settings. For example, one student reflected, "I did learn about changes in funding to research centers as well as had the opportunity to apply what we learned in the Strategic Cost Control and Analysis course to this project." On the other hand, some students did not quite capture the learnings they were expecting. For example, one student responded, "I did learn a lot of new information but my project did not require a large amount of analysis." Thus, continued refinement of matching projects based on student's expectations, skill set, and project deliverables was considered a goal for improvement in subsequent project selection. We also surveyed the I-CTSI partners who provided very positive feedback on the collaboration. An area of improvement noted in year one of the program, was the length of the program. The initial program offered an intense 7-week program but a number of cores expressed a strong desire to have projects last 14–16 weeks. Based on this feedback, the IU Bloomington based teams provide a 7-week assistance program while the Indianapolis teams offer semester-long assistance.

Discussion
In reflecting on this partnership, a number of key lessons learned should be highlighted. First, it is important to use a learning framework to give structure to the instructor and the students in order to ensure that the projects are not perceived or undertaken as consulting projects without learning. In our partnership, we model the interaction with the students around the service learning framework. Second, it is important to draw on the expertise of the I-CTSI program manager and to assist core directors in developing projects that can be accomplished in the time constraints of the program. It is also critical that the business school faculty review proposals for educational value and feasibility. Third, identifying the project management, marketing, financial management, and/or resource efficiency management aspects of the proposal facilitates selection of student with complementary skills and in an area compatible with their future career path. A fourth lesson learned was the experience gained by both scientists and business participants as they tackled problems using different but often complementary means of problem solving and analysis. Finally, as students begin their initial analysis of the project at hand they uncover issues that occasionally changed the scope or direction of a proposal. Therefore, the willingness to learn and demonstrate flexibility within the project management partnership is a key to success.

While the projects are student-led, the Business School faculty involvement through weekly or biweekly advising sessions is

important in refinement of final deliverables. Much of this is "off line" from the core directors. As a result of their supervision of student teams, Business School faculty are indirectly providing free business consultation to core directors which is highly valuable and an innovative way to improve research infrastructure while providing service-learning opportunities to business students.

As we continue to refine our I-CTSI-School of Business partnership, there are two proposed areas of development for future work. One is a new Project Implementation Program that will provide an opportunity for students to work with cores on implementing plans developed by the previous student group. The second area in our knowledge sharing activities will address a need for the broader I-CTSI community to learn about business topics such as "How to Create a Marketing Plan," "Putting Together a Business Plan," or "Steps in Process Improvement." Our goal in addressing this need is to offer presentations in an open symposium addressing these topics.

Conclusion

The I-CTSI-School of Business partnership has been an engaging, informative, and rewarding opportunity for all members of this interdisciplinary team. The opportunity to work on impactful projects along with gaining and sharing knowledge for both the immediate members of the project teams and the larger Indiana I-CTSI community gives support to the notion that the pedagogy of service learning projects can be modeled with success to transfer the business of life science.

Acknowledgment

Disclosures

K.C. is founder of Rimedion Inc. that seeks to develop gene therapy applications. He is not employed by the company and there is no conflict of interest with the work presented in this manuscript.

References

1. Angeletti RH, Bonewald NF, De Jongh K, Niece R, Rush J, Stults J. Research technologies: fulfilling the promise. *FASEB J*. 1999; 13: 595–601.

2. Farber GK, Weiss L. Core facilities: maximizing the return on investment. *Sci Translat Med*. 2011; 3: 1–3.

3. Haley R. A framework for managing core facilities within the research enterprise. *J Biomol Tech*. 2009; 20: 226–230.

4. Alexander J. Adaptive strategies of nonprofit human services organizations in an era of devolution and new public management. *Nonprofit Manage Leadership*. 2000; 10: 287–303.

5. Brower HH. Sustainable development through service learning: a pedagogical framework and case example in a third world context. *Acad Manage Learn Educat*. 2011; 10: 58–76.

6. Deeley SJ. Service-learning: thinking outside the box. *Active Learn High Educat*. 2010; 11: 43–53.

7. Flannery BL, Pragman CH. Service-learning and integrated course redesign: principles of management and the campus kitchen metaproject. *Acad Manage Learn Educat*. 2010; 34: 11–38.

8. Bringle RG, Hatcher JA. Implementing service learning in higher education. *J Higher Educat*. 1996; 67: 221–239.

9. Koliba CJ. Moral language and networks of engagement: service learning and civic education. *Am Behav Scientist*. 2000; 43: 825–838.

10. Kenworthy AL. Service-learning and negotiation: an educational "win–win." *J Manage Educat*. 2010; 34: 62–87.

11. Hansen K. A practical guide for designing a course with a service-learning component in higher education. *J Faculty Development*. 2012; 26: 29–36.

12. Calhoun WJ, Wooten K, Bhavnani S, Anderson KE, Freeman J, Brasier AR. The CTSI as an exemplar framework for developing mulitdisciplinary translational teams. *Clin Translat Sci*. 2013; 6: 60–71.

13. Disis ML, Schwartz HD, Ramsey BW. Wouldn't we all like to be a little more LEAN? *Clin Translat Sci*. 2010; 3: 207–209.

14. Falk-Krzesinski HJ, Borner K, Contractor N, Fiore SM, Hall KL, Keyton J, Spring B, Stokols D, Trochim W, Uzzi B. Advancing the science of team science. *Clin Translat Sci*. 2010; 3: 263–266.

15. Larkin ME, Griffith CA, Pitler L, Donahue L, Sbrolla A. Building communities of practice: the research nurse round table. *Clin Translat Sci*. 2012; 5: 428–431.

16. Indiana CTSI. MBA students offer business insight to Indiana CTSI. 2013. Available from: http://www.indianactsi.org/news/ksobctsi2012. Accessed January 29, 2013.

17. U.S. Office of Management and Budget. Circular A-21 Title 2: Grants and Agreements. PART 220—Cost Principles for Educational Institutions. Available from: http://ecfr.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title02/2cfr220_main_02.tpl. Accessed January 29, 2013.

18. Boeke A, Doumas P, Reeves L, McClurg K, Bischof D, Sego L, Auberry A, Tatikonda M, Cornetta K. Vector production in an academic environment: a tool to assess production costs human gene therapy methods. 2013; 24: 49–57.