

**Informal Summary of Interactions
between Clinical and Translational Science Award (CTSA) Institutions and
Schools of Business**

(Submitted by CTSA PIs, June 2008)

Table of Contents

<u>Institution</u>	<u>Page</u>
Columbia University	2
Duke University	2
Harvard University	3
Indiana University	4
Northwestern University	5
Oregon Health and Science University	5
Stanford University	8
University of Alabama at Birmingham	8
University of California, Davis	8
University of Chicago	9
University of Michigan	10
University of Pennsylvania	11
University of Pittsburgh	11
University of Washington	12
Vanderbilt University	14

Institution: Columbia University

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Prof. Nachum Sicherman, professor, Columbia School of Business, has become interested in the factors that will determine interest and ability of community physicians to participate in a National Institutes of Health (NIH)-sponsored clinical research network. Columbia University's School of Business health policy economists believe that a major factor affecting the compensation required to induce community physicians to participate in clinical research is his/her "opportunity cost" of time. This might include direct loss of income associated with trial-related activity, as well as the minimum amount of money (or other compensation) required to induce a person to perform a task rather than do something else. A survey has been proposed to find out what monetary and non-monetary incentives motivate physicians to participate in clinical trials research. Factors that may affect these incentives and how they vary among physicians also need to be investigated. Using family practices and internal medicine practices as our initial survey targets, the hope is to access information that will further elucidate the role of electronic health records (EHR) in research. The program also wishes to conduct additional pilot studies to evaluate our survey questions, and has planned focus group discussions of survey participants to further inform the analysis.

Concerning organizational issues, Prof. Sicherman thinks the best people for such a task (combined with economists) are OR (Operational Research) experts. At Columbia, the formal name of that group is "Decision Risk and Operation." Columbia has one of the strongest OR groups in the country and one of the faculty (Linda Green) has carried out extensive work in the health care area. When the project was described to the Dean of the Business School (Prof. Paul Glasserman), who is also a leader in the field, he thought that several of his faculty would be able and willing to work on organizational issues.

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The Duke CTSA has an active collaboration with the Health Sector Management Program at the Fuqua School of Business, which was built into the CTSA application from its initiation. . Kevin Schulman is both the associate director of the Duke Clinical Research Institute and director of the Health Sector Management Program in the Business School. The Duke HSM program is the largest such program in the United States. The business school has interests in both health care and entrepreneurship, and the CTSA has collaborated with faculty at Fuqua as it has moved forward in the following areas:

- Business plan development: The CTSA has borrowed a structure from the business and engineering schools for opportunity assessment and business plan development. This approach has also been used as an educational experience and draws students from across the University into this process. It is led by Ana Valverde MBA, a Fuqua graduate who is both a CTSA administrator and a member of the School of Medicine faculty.
- Educational programs: The CTSA has cross-listed courses in biotechnology and medical device innovation from the business school with its Clinical Research Training Program. CTSA faculty has also been allowed to take these courses as time permits.
- Development of case studies: The CTSA has begun to develop a library of case studies on translation from a business perspective and has created a new faculty slot to support this effort. The hope is to develop a research agenda in the science of translation through this effort.
- The Duke CTSA is working with the Fuqua on a strategy for international clinical and translational research that will include Duke's medical school in Singapore and significant joint efforts in India and China.

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The Harvard Clinical and Translational Science Center (CTSC) is developing a program called *Linkages*, intended to forge new alliances and promote and facilitate ongoing relationships between the CTSC/Medical School and other Harvard schools, industry, and over time, CTSCs. To this end, *Linkages* Director Dr. Guinan attended a one-day symposium entitled "Science-Based Business and the Business of Science," hosted in March by the Harvard Business School. A collaborative application for a sponsored Radcliffe Institute Advanced Seminar grew out of that interaction. In addition, the Business School proposed that the *Linkages* Director attend a week-long executive leadership course in "Management of Science-Based Business," which Dr. Guinan just completed. Not only was it instructive, but that interaction has produced numerous ideas for initiatives that are currently in development. These range from an educational program for the Harvard Board of Overseers on Intellectual Property and Patents to developing a strategic plan for an integrated, Harvard-wide multi-investigator/laboratory response to industry trial solicitations. An ongoing meeting schedule has been established between the *Linkages* program, CTSC leadership, and relevant Business School faculty. The impression is that there is a great deal to learn and that there are interesting paradigms for management of complex, scientifically based enterprises that can be adopted with guidance and collaboration from colleagues on the business faculties at CTSC-holding institutions. The CTSC would be very interested in participating in any ongoing dialogues or ventures in this area. A relevant quote from John Holt: "True intelligence is not what we know but how we behave when we don't know what to do."

Institution: Indiana University

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The Indiana Clinical and Translational Science Institute (CTSI) has forged a strong relationship with two business schools as its partners—the Kelley School of Business at Indiana University (IU) and the Krannert School of Management at Purdue. The CTSI is in the process of developing additional collaborations with Notre Dame University, including with its school of business. The schools of business will assist in the following activities.

Operational assistance: The CTSI has a faculty participant from the Kelley school of business, Dr. Davidson, who will be part of its management team. **Lawrence Davidson, Ph.D.**, Professor of Business Economics and Public Policy, liaison with the Kelley School of Business, IU Bloomington, Healthcare and Life Sciences Initiative, will assist in engaging the many state and business life sciences initiatives in Indiana with the goals of the CTSI. He will help with implementation of the CTSI programs with a clear definition of deliverables, cost-effectiveness analyses, and other means of optimizing the performance of the different programs. He will also guide the CTSI in issues of commercialization, entrepreneurial activities, and development of start-up companies. He will devote 2.5 academic months to these activities.

Intellectual Property Development: Kelley School of Business at IU and the Krannert School of Management at Purdue will be providing critical support to the evaluation of operational procedures as well as intellectual property issues. The decision to file for patent protection on an invention disclosure requires clear definition of ownership of the invention and an investment in the costs of filing. The CTSI will create new, formal interactions among these processes in these universities and the CTSI community partners or industry partners to establish a set of guidelines and practices to guarantee that technology transfer and commercialization processes proceed smoothly to fruition. CTSI-prescribed connections will be used to expedite the process of intellectual property negotiations between the universities and industry partners that collaborate on taking clinical and translation projects to the market. The three business schools and their strong ties with the CTSI and its community partners should allow more robust and efficient commercialization and technology transfer mechanisms to emerge.

Marketing and Satisfaction Surveys: The marketing and user targeting strategies developed in business schools will also be brought to enhance the activities of the Indiana CTSI. **Dena Cox, Ph.D., and Anthony Cox, Ph.D.**, Professors of Marketing at the IU Kelley School of Business at Indiana University–Purdue University Indianapolis (IUPUI), will assist in developing strategies to communicate the CTSI mission to a wide range of stakeholders in the state of Indiana and will participate in development and analysis of survey tools used in the Bioethics Program and in the Tracking and Evaluation Program. They also will assist with focus groups that assess satisfaction with activities of the CTSI.

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Northwestern University Clinical and Translational Sciences Institute (NUCATS) has reasonably strong interaction with the Kellogg School of Business. They are working with NUCATS on team science initiatives and an effort to provide market analysis of newly developed medical technologies.

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The Oregon Clinical and Translational Research Institute (OCTRI) has formed a robust partnership with Oregon Health and Science University's (OHSU) Division of Management, a unit within the OHSU School of Medicine. This interaction has four primary components: (1) an education and training program focused on promoting commercialization of OCTRI-developed science and technology; (2) academic leadership education offerings created for OCTRI's Human Investigations Program; (3) application of modern management concepts within OCTRI itself; and (4) enhancement of interactions between OCTRI and the regional bioscience industry.

Public-Private Partnership Education and Training Programs

The goals of the education and training programs are to introduce OCTRI researchers to the notion that commercialization (in whatever form) is a legitimate translational pathway and to provide education and training that enables commercialization as a translational path for OCTRI researchers.

The first goal is addressed by the *Marketplace for Ideas* program, which is designed to expose researchers to the prospect of a commercialization pathway for their research by providing university role models and resources for commercialization as well as by creating a forum for researchers to network and build connections. Researchers who are particularly interested in entrepreneurship are invited to participate in the *Entrepreneurship Academy/Lab2Market* program. This is a one-week intensive experience in which researchers are introduced to the fundamentals of translating their research into commercial ventures. It is offered by OCTRI and OHSU's Division of Management in collaboration with Portland State University's School of Business Administration, based on a curriculum originally developed at University of California Davis. It will be offered annually (the next time in August 2008), with quarterly follow-up meetings to reinforce learning and to provide a support network for the bio-entrepreneurs, including introductions within the Oregon Entrepreneurs Network.

The second goal (i.e., enabling commercialization through education) is addressed through the Division of Management's Certificate and M.S. in Management programs. The Bioscience Industry track in the Certificate/M.S. program consists of five bioscience industry-specific courses: *Global Environment of the Bioscience Industry*; *Managing the Medical Product Lifecycle*, *Organizational Models, Strategies, and Financing in Bioscience*; *National and International Regulatory, Legal and Ethical Environment*; and *Intellectual Property Management in the Bioscience Industry*. Another option in the Certificate/M.S. program is a focus on innovation, commercialization, and entrepreneurship, involving such courses as *Managing Innovation and Creativity*, *Commercialization Practicum*, *Business Plan Development Capstone*, etc. Both the bioscience industry and entrepreneurship programs are under the direction of Professor Jack Raiton [raitonj@ohsu.edu].

The Division of Management has been involved in the discussion of public-private partnership issues as part of the West Coast CTSA Consortium. At the June meeting of the Consortium in Davis, Jim Huntzicker was a prominent participant and is taking a leading role in organizing discussions among the west coast CTSA institutions about joint educational programs in commercialization. Moreover, the *Entrepreneurship Academy* occurring in Portland (August 2008) will be attended by faculty involved in the University of Washington CTSA, and represents an opportunity for Oregon and Washington to partner in that area.

Academic Leadership Education Programs

Division of Management faculty members Dr. Niki Steckler, Jeff Oltmann, and Jesse Reeder have created and taught the following "Academic Leadership" courses within OCTRI's postdoctoral Human Investigations Program: *Understanding and Managing Academic Organizations*, *Influence and Communication Skills for Leading Research Teams*, and *Best Practices in Project Management*. OCTRI staff members have participated in professional development workshops offered by these faculty on topics including *Leading with Conscious Influence* and *Foundations and Best Practices in Project Management*.

Related education programs offered by the Division of Management include the M.S. in Management/Healthcare Management track and an MBA in Healthcare Management to be offered in collaboration with Portland State University's School of Business Administration beginning September 2008.

OCTRI Management

Faculty members of the Division of Management have made particular contributions to OCTRI management. Professor Niki Steckler coaches, facilitates, and consults with key leaders within OCTRI on effective group process, enhanced cross-unit communication, performance feedback, mentoring, and leadership development. She has played a key role in helping to build cohesion among the program directors during the start-up phase of OCTRI.

Adjunct Professor Mike Neal, a retired Intel executive with expertise in operations and quality improvement, conducted a 12-week workshop to support OCTRI managers in the application of process improvement methods to multiple areas of OCTRI's operations. These sessions were designed to acquaint OCTRI staff with the fundamentals and practice of process improvement through a series of classroom sessions coupled with mentored project work. Classroom sessions

focused on learning the fundamentals of lean process improvement and Six Sigma problem solving. In parallel, participants worked through the stages of their improvement projects, from project definition through implementing the changes, under the direction of the project coach. These process improvement projects included, among others, biomedical informatics change requests, nursing scheduling, bionutrition outpatient meals, nursing patient set-up, etc.

More recently Mike Neal has launched a series of workshops and interactions with program directors to assess the current state of OCTRI programs against stated goals and to define changes and improvements to maintain effective execution. The focus of the work will be to integrate these activities into the daily work of the organization. Through a series of workshops and mentored project work, OCTRI managers will become familiar with the concepts and tools in the Baldrige Assessment program to measure progress, develop strategy maps and associated balanced scorecards to define and track key initiatives, and *hoshin* planning to integrate multi-layered short and long term plans throughout the organization.

Industry Relations

Jim Huntzicker and Jack Raiton from the Division of Management are part of a collaborative group at OHSU that brings together OCTRI, the Division of Management, Technology and Research Collaboration (tech transfer), and the OHSU VP Commercialization. The group is broadly dedicated to industry partnerships and commercialization, and OCTRI's role is to promote/support the clinical and translational elements of those partnerships. In that group the Division of Management plays a key role in partnering with industry and creating educational opportunities to promote greater involvement of faculty in the commercialization process.

The joint OCTRI/Division of Management *Bioscience Industry Seminar Series* was created to bring together academic bioscience researchers with bioscience industry professionals. Examples of recent seminars include:

- *Rethinking the Wall Street Directed Approach to Drug Development—Why Scientists Must Influence the Decision Making Process* (Bernard Fox, Providence Medical Center).
 - *Biopharmaceutical Drug Development—Putting the Pieces Together* (Andrew Goldstein, Artielle ImmunoTherapeutics).
 - *Observing Primary Care Physicians at Work—Informing Technology Development to Improve Healthcare* (Nancy Vuckovic, Intel).
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The grant application for the Stanford Center for Clinical and Translational Education and Research includes plans for interaction with the Stanford Graduate School of Business in the areas of education, training, career and leadership development, and program evaluation. In addition, they propose to create a “Clinical and Translational Medicine Incubator” that will schedule seminars, foster communication between individuals interested in clinical trial research, and encourage the creation of multidisciplinary teams of researchers.

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Dean Klock brings both academic and business experience to his new position. He joined UAB from the College of Business Administration at California State Polytechnic University – Pomona where he served as Dean. Prior to that appointment, he served chairman and CEO of CompBenefits Corp., a health care benefits provider that he and his wife founded in 1991. In his 11 years at the helm, Dean Klock transformed CompBenefits into a publicly traded company with 800 employees with more than \$300 million in revenue.

We have discussed multiple potential points of interaction between the UAB Center for Clinical and Translational Science (CCTS) and the School of Business. These include:

- focus on process evaluation and systems management
 - build case studies re: translational research to use in cultivating community engagement and investment in the CCTS
 - develop models for effective team science
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Institution: University of California, Davis

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The UC Davis Clinical and Translational Science Center (CTSC) is making progress in developing an entrepreneurial spirit among faculty. Recently, the CTSC hosted a special seminar with Dr. Andrew Hargadon, Director of Technology Management Programs and the UC Davis Center for

Entrepreneurship to discuss entrepreneurship and intellectual property at UC Davis, exploring the inextricable link between research and inventions. Topics included:

- Dynamics of the commercialization process of new inventions.
- Moving along the path of research to market.
- Purpose of intellectual property in the commercialization process.
- When is an idea worth protecting and why?
- Options for faculty, students, and staff in commercializing their research.
- Resources available to navigate the journey from research to commercialization.

This theme was expanded as the School of Medicine hosted a business development intensive program with an emphasis on biotechnology led by Dr. Hargadon. The one-week program targeted School of Medicine faculty and trainees, including those participating in CTSC training programs, Ph.D. students, and postdoctoral fellows interested in commercializing their research and exploring business development opportunities before heading into a career in industry or taking the first steps toward launching a new venture. Participants learned:

- Dynamics of innovation and entrepreneurship.
- Innovation strategies and work practices.
- Evaluating technology/market opportunities.
- Pursuing IP patenting and licensing strategies.
- Building the team.
- Modeling finance and investment strategies.
- Rapid prototyping and testing strategies.

The School of Medicine faculty has been extremely enthusiastic about this program and a future program on “Health and Wellness Entrepreneurship” is planned in the fall in cooperation with the UC Davis campus-wide, translational Foods for Health Initiative. Several investigators have already expressed an interest in participating in the forum.

To capitalize further on this momentum, the CTSC has partnered with the UC Davis Center for Biophotonics to provide a new technologies showcase to highlight novel concepts and further spark the entrepreneurial spirit at UC Davis.

Institution: University of Chicago

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Here is a list of some colleagues there, who interact mostly with Dr. Meltzer’s Center for Health and the Social Sciences, which interfaces closely with the CTSA:

Kevin Murphy and Bob Topel: Value of research
Ron Burt: Social network analysis and management
John Birge: Decision sciences
George Wu: Psychology of decision making

There are also related interactions with faculty in the Department of Economics or in the Harris School of Public Policy:

Tomas Philipson and Wes Yin: Pharmaceutical innovation and its determinants

Institution: University of Michigan

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The University of Michigan has been extremely involved in “lean thinking” exercises. About 20 people from the Michigan Institute for Clinical & Health Research (MICHHR; the institute that houses the CTSA) spent three entire days meeting as a group (and countless hours in between) dealing with its processes from when it first meets with an investigator for any type of help to when the investigator gets a grant or has a project successfully submitted. As expected, the exercise pointed out many inefficiencies in these processes that are now being corrected.

If this would be of interest in any type of national forum, staff who led this exercise (Dorene Markel or Ana Austin) would be happy to present these experiences, and the person who facilitated this group (who apparently is very well known in lean thinking circles—Toyota has its large R & D facility just outside Ann Arbor so there is a lean “Institute” here) might be persuaded to participate. At Michigan, Bill Lovejoy, a Professor in the Ross Business School, in charge of the evaluation program, is internationally known for improving the efficiency of organizations by defining metrics, goals, etc., and helped do this for each CTSA program at Michigan as well as for the entire institute. His suggestion, which the CTSA will heed, is to use other business school colleagues who are involved in “organizational psychology” to help with further aspects of publicizing the CTSA and improving a sense of cohesion amongst the units and programs. Most of the in medical school leadership have taken short courses at the business school as part of their leadership development program, so they know these other faculty and will use them as consultants in the future. A number of lean thinking exercises have also been performed within the institute, but because it turns out this isn’t formally linked to the business school, the health system has adopted these practices system-wide and provides these consultants free of charge.

Institution: University of Pennsylvania

PI: Garret FitzGerald, M.D.

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Terry Fadem has joint appointments in the School of Medicine (SOM) and the Wharton School. The core has assembled representatives of many relevant entities—Wharton's Mack Center; the technology transfer offices of Penn, the Children's Hospital of Philadelphia, and the Wistar Institute; the SOM industry liaison; the Science Center (a free standing incubator); etc. to:

- Introduce themselves and their capacities.
 - Develop integrated strategies of education and process.
 - Hold workshops.
 - Streamline processes.
 - Survey the population as to their needs.
 - Initiate placements of business students in scientific environments.
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Institution: University of Pittsburgh

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The University of Pittsburgh CTSI has been working closely with the University of Pittsburgh Katz Graduate School of Business as part of an initiative to develop an online research community. Here is a brief summary of these collaborative effort:

- Project collaboration on expertise locating systems:
 - Design and development of the Digital|Vita system, an application designed to facilitate the process of establishing scientific collaboration through comprehensive scientist profiles and a social network.
 - Redesign of the University of Pittsburgh's Faculty Research Interests Project, a comprehensive index of faculty research interests and publications.
- Published one conference presentation and one peer-reviewed journal paper:
 - Schleyer T, Spallek H, Butler B, Kelleher C, Johnson S. Online communities for translational research, AMIA Spring Congress (2006).
 - Schleyer T, Spallek H, Butler BS, Subramanian S, Weiss D, Poythress ML, Rattanathikun P, Mueller G. Facebook for scientists: Requirements and services for optimizing how scientific collaborations are established, *Journal of Medical Internet Research* (in print).

- Development of an implementation and evaluation plan for expertise-locating systems at the University of Pittsburgh, as well as partial implementation of that plan by two successive teams of MBA students (fall '07 and spring '08).
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Institution: University of Washington

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The Seattle Institute of Translational Health Sciences (ITHS) Development of Novel and Clinical Translational Methodologies Core has formed four types of collaborations with the University of Washington (UW) School of Business: A summer fellowship program, a summer internship program, an "Invention to Startup" speaker series and an "Entrepreneurial Law Clinic."

The ITHS formed a partnership with the Wallace H. Coulter Foundation program in the bioengineering department <http://depts.washington.edu/bioe/coulter/index.html> in collaboration with the Center for Innovation and Entrepreneurship (CIE), in the School of Business <http://foster.washington.edu/cie/>.

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Three summer fellowships were awarded for 2008 to second-year MBA students who were matched with translational research programs at the UW and the Fred Hutchinson Cancer Research Center (FHCRC). This process was facilitated by the technology transfer offices at UW and FHCRC. ITHS funded two MBA fellowships and the Coulter program funded two (one for a bioengineering student and the other for an MBA student). The three summer fellowship programs are listed below:

ITHS-COULTER TRANSLATIONAL RESEARCH FELLOWSHIP: The Wallace H. Coulter Foundation (WHCF) Translational Partnership program has joined forces with the Institute for Translational Health Sciences (ITHS) to create summer fellowships for an MBA student to evaluate medical technology opportunities for commercialization and significant clinical impact. The WHCF translational partnership produces mature technology opportunities, especially suitable for start-up

creation based upon the advanced status of technical proof of principal, intellectual property assessment, business model, and commercialization strategy.

Early diagnosis and prevention of esophageal cancer

Inventors: Xingde Li, Bioengineering, and Joo Ha Hwang;

Gastroenterology Technology Manager: Jim Roberts;

UW technology transfer MBA student: Cortilia Lin.

A novel imaging instrument based on optical coherence tomography (OCT), which uses light to penetrate the inner tissue of the esophagus and produce a high-resolution, 3D image. The system has been confirmed to detect lesions in excised human esophagus from patients with esophageal erosion—a major predictive state for esophageal cancer.

Pressurized olfactory drug delivery system for CNS delivery

Inventor: Rodney J. Ho, Professor, School of Pharmacy;

Technology Manager: Bolong Cao;

UW technology transfer MBA student: Michael Hite.

A novel pressurized olfactory drug delivery (PODD) device that exploits the unique, highly permeable property of olfactory epithelium (nose-to-brain barrier) to deliver neurologically active, analgesic, and cancer drugs directly to the brain.

Method to prioritize patients for enrollment into clinical trials based on in vivo efficacy screening

Inventor: James M. Olson, M.D., Ph.D., Fred Hutchinson Cancer Research Institute;

Technology Manager: Ulrich Mueller, VP Industry Relations;

Technology transfer MBA student: Maria Guerrero.

A method to prioritize patients for enrollment into clinical trials based on whether or not their cancer cells respond to the anti-cancer agent when directly exposed to the drug would prevent patients from being exposed to drugs that will cause toxicity without potential for benefit and would reduce the cost of human clinical trials by hundreds of millions of dollars per year. To address this need, we have developed a device and method for direct comparison of candidate drugs in the tumors of individual patients prior to surgical resection of the tumor.

The 2008 MBA summer intern will create a business plan for the General Clinical Research Center (GCRC) to make it profitable and to decrease dependence on the grant. The scope of work will include:

- Scoping out for-profit cancer treatment units (CTUs) and performing a comparative analysis.
- Defining new lines of business.
- Defining potential revenue streams.
- Reviewing cost structure.
- Performing a customer analysis, etc.

In 2007, the School of Business and the Applied Physics Lab set up a seminar series titled “From Invention to Start up” <http://www.inventiontostartup.washington.edu/>.

In 2008, the School of Business Center for Innovation and Entrepreneurship developed a “road show” program. They currently arrange customized presentations for individual departments.

The Entrepreneurial Law Clinic, <http://www.law.washington.edu/clinics/entrepreneurial/>.

“Entrepreneurial Law Clinic Accepting Client Applications for 08-09 Academic Year,” posted on the ITHS Web site at <http://iths.org/ITHSELCAApplication.doc>.

“The Entrepreneurial Law Clinic (ELC) at the UW Law School is now accepting applications from prospective life sciences clients for the coming academic year. ELC helps you analyze your technology’s potential for commercialization, develop a business plan and legal/regulatory strategy, and protect your intellectual property. During an initial five to ten week process, you will be matched with a team of life sciences oriented law students, business students, attorneys and successful entrepreneurs who will provide you with confidential written findings and recommendations about your technology. Further services may be available based on the findings of the initial report. ELC works in conjunction with the Foster School of Business, UW TechTransfer, and ITHS to deliver these services for free to the community.”

Institution: Vanderbilt University

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Vanderbilt’s business school (Owen Graduate School of Management) has been formally engaged in the CTSA. Dean Jim Bradford is a member of our Internal Advisory Board. He has been most helpful in making recommendations to the program related to the formation of highly visible target objectives, proposed achievement dates, and the role of the internal board. CTSA representatives are meeting with him one-to-one next month to further discuss his recommendations and explore other potential partnerships. (Vanderbilt’s business school may be somewhat unique in that it has a health care MBA.) As new collaborations are formed with Owen, which are expected, the CTSA will share those with the consortium.

Dr. David Dilts, with training in both engineering and business management and extensive experience in modernizing systems in the automobile industry is a consultant to the Vanderbilt CTSA. He has led exhaustive studies of processes involved in initiating cancer trials both at the local and national levels. For example, in studies conducted four to five years ago, he was able to show in exquisite detail the substantial impediments within Vanderbilt to the efficient launch of clinical trials. This information was used to substantially streamline our processes and that work continues. More recently, he was invited to study processes in the National Cancer Institute’s Eastern Cooperative Oncology Group (ECOG). He studied 28 phase III studies activated between January 2000 and July 2006 and was able to show that more than 481 distinct processes were required for study activation: 420 working steps, 61 major decision points, 26 processing loops, and 13 stopping points. Median calendar days to activate a trial was 783 days (range, 285–1,542 days) from executive approval and

808 days (range, 435–1,604 days) from initial conception of the study. His data showed that although much of the attention to perceived delays in trial initiation has been focused on institutional processes, research needs to be directed toward streamlining both internal and external groups and processes if real progress is to be made (Dits et al. *Clinical Cancer Research*. 2008 Jun 1;14(11):3427-33).
