Abstract

Since its inception – four years ago as the Biomedical Engineering Institute – the Florida International University (FIU) Department of Biomedical Engineering (BME) has adopted a broad definition of its role as part of South Florida’s largest academic institution. In addition to the mission of excellence in research and teaching, BME aimed at becoming an engine of biomedical innovation and a driver of regional economic growth. To achieve these goals, BME has developed an integrative approach to biomedical innovation that positioned BME at the center of a closed biomedical innovation loop. In that loop, BME faculty, students, and alumni are integrated at the three phases of biomedical innovation and commercialization: the ideation/innovation/research stage, at the development/realization step (via partnership with industry), and at the clinical implementation phase (through partnership with clinical organization). This approach propelled biomedical entrepreneurship to the forefront of the academic discussion at FIU, and created new opportunities for its faculty, students, and alumni.

At the core of FIU’s Biomedical Engineering Partnership Program is the understanding that a successful biomedical innovation and commercialization process is dependent upon the integration of three equally significant components: academia, industry, and clinical medicine. In such a partnership academia provides the innovation or, specifically, the newly created intellectual property; industry provides the development and commercialization know-how; and clinical medicine provides access to and feedback from the customer/end user. This arrangement places BME at a leadership position where it serves as a process facilitator and integrator. BME is, thus, actively creating entrepreneurial opportunities and identifying opportunities for its faculty and students to participate in the academic, industrial, or clinical settings. Moreover, the program creates a framework that allows partners a look into the biomedical engineering academic program and to participate in formulating their prospective employees’ professional preparation.

This paper will present the Biomedical Engineering Partnership Program as a case study for a university-lead partnership between academia, industry, and clinical medicine. It will discuss program structure, mechanics, and other issues arising from this unique partnership. It will also describe innovative joint programs that made the partnership successful: corporate and entrepreneurship options for Senior Design Project, business plan competition, and the two-phase Collaborative Technology Innovation Program (CTIP).
Introduction

FIU - Miami's public research university – is South Florida’s largest academic institution and one of America's most dynamic institutions of higher learning. Since opening in 1972, FIU has achieved many benchmarks of excellence that have taken other universities more than a century to reach. The University has a nationally renowned faculty known for their outstanding teaching and cutting-edge research; students from throughout the U.S. and more than 130 foreign countries; and its alumni have risen to prominence in every field and are a testament to the University's academic excellence. The University has 34,000 students, 1,000 full-time faculty, and 105,000 alumni - placing it among the nation's 30 largest colleges and universities - and offers more than 190 baccalaureate, master's and doctoral degree programs in 19 colleges and schools. FIU’s sponsored research funding from external sources was $75.5 million in 2002-03 and over 50% and approximately 15% of its student population is Hispanic and African American respectively.

The Florida International University College of Engineering was established in 1984 and is now South Florida's leading engineering educational resource. The College has approximately 1,600 enrolled students and 80 world-class faculty members. It is the top producer of Hispanic engineers in the country, and is ranked 18th in American universities in production of African American engineers. The College is made up of six departments- Biomedical Engineering, Civil and Environmental Engineering, Electrical and Computer Engineering, Industrial and Systems Engineering, Mechanical and Materials Engineering, and Construction Management and offers seven bachelor degree programs, 13 master degree programs, and four Ph.D. programs.

FIU resides in one of the densest regions of biomedical industry within the US. A balanced mixture of large and small (entrepreneurial) companies constitute a medical device and pharmaceutical industry base that already ranks high in the nation in terms of employment and number of firms. This industry also benefits from a rich local environment for clinical trials due to the large number of clinical establishments dedicated to research, the high physician to population ratio, and the diverse patient pool. Miami-Dade County ranks 10th in medical devices employment and 13th in pharmaceutical employment with 3996 and 1583 employees, respectively.1 South Florida is home of the leading manufacturer of generic drugs (IVAX), and contains major divisions of four of the world’s largest medical devices companies (Johnson & Johnson (Cordis), Boston Scientific, and Beckman Coulter). Many former employees of these businesses as well as founders of the small companies that are now divisions of the large corporations also provide a rich selection of local entrepreneurs. The Beacon Council serves as the economic development arm of Miami-Dade County, and as such is leading the effort to sustain and grow the local biomedical industry, one of its two technology-based target markets (the other being telecommunications).

Venture capital interest in biomedical technology is at an all-time high. Money raised in the US for funds dealing with biotechnology, medical devices and health care technology rose 320% in 2001, to $4.2 billion from $1 billion in 2000.2 Due to its current strength in South Florida and future potential growth, the biomedical industry is the number one priority for the local economic development group (The Beacon Council). For the same reason, biomedical engineering is the number one priority for the College of Engineering.
Furthermore, Fort Lauderdale and Miami are ranked 4th and 8th respectively by Entrepreneur Magazine among the best cities for entrepreneurs and Florida is ranked the 11th largest biotechnology center in the nation; the quality of Florida’s hospitals is ranked second in the nation by the Sixth annual HealthGrades Hospital Quality in America study and, in terms of workforce development, Florida is ranked 1st in the nation by the Agency for Workforce Innovation in total employment growth for the year ending July 2003.

The above economic parameters were anticipated by FIU that, in the fall of 1997, dedicated more than $300,000 of recurring annual funds to establish a Cardiovascular Engineering Center (CVEC) in the College of Engineering. The Center was chartered with the mission to significantly increase the speed and effectiveness of cardiovascular technology transfer to commercialization and clinical implementation. In 1999, the Biomedical Engineering Institute (BMEI) was created to house the newly created biomedical engineering academic program and biomedical engineering research activity. Since then BMEI has become one of the fastest growing programs at FIU. A Master of Science (MS) and innovative combined Bachelor of Science (BS)/MS programs - BS in Electrical Engineering (EE) or Mechanical Engineering (ME) combined with MS in Biomedical Engineering – was started in 1999. A BS program in biomedical engineering was launched in the Fall of 2002 and, in the Fall of 2003, the Department of Biomedical Engineering (BME) became the academic unit housing the biomedical engineering research and academic programs in lieu of the BMEI and a combined BS/MS (Both BS and MS in biomedical engineering) were opened. The Ph.D. program is scheduled to open in the Fall of 2004. External funding in the form of a $1 million grant from The Whitaker Foundation and a $5 million endowment from the Wallace H. Coulter Foundation (and additional $5 million in endowment match from the State of Florida) have allowed for this rapid growth. Currently, six faculty have their full appointment in the Department of Biomedical Engineering and six additional faculty have joint, secondary, or research appointments in the Department. This faculty is active in research and technology development in five major biomedical areas: biomechanics, biomaterials, and medical devices; bioinstrumentation and bioimaging/biosignal processing; drug delivery and tissue engineering; medical physics and nuclear medicine; and bionanotechnology and systems biology. This faculty - seven of which are new Assistant Professors within the last three years and only one a full professor - secured over $5 million in external research grants and six invention disclosures over the past five years. FIU is now searching for two additional senior biomedical engineering faculty for positions endowed by the Coulter Foundation grant.

**Early Setting**

Partnership with industry and with clinical organizations has been a cornerstone in the development of BME from its infancy stages. Local biomedical business leaders and key members of the clinical community relevant to the research performed at that time by faculty affiliated with the biomedical-related activity were occasionally requested to provide input about research foci, educational initiatives, and funding issues. This input was delivered in ad-hoc team meetings and occasional one-on-one meetings between faculty and their industry and clinical counterparts.
Driven by the understanding that a successful technology transfer effort in the biomedical engineering field requires participation of all three stakeholders – academia, clinicians/clinical organizations, and industry - the first attempt to formalize a partnership program between faculty with common research interest in biomedical engineering and their industry and clinical counterparts occurred under the hospice of CVEC. An incorporation of a dedicated industry liaison, reporting to the director of CVEC, into the structure of the Center preceded this initiative. The liaison allowed CVEC to develop and implement marketing and operational plans for the proposed partnership program and maintain and build its network through regular communication and through a buildup of its marketing tools. The program, named the Industry Affiliate Program (IAP), focused on becoming a major development vehicle that supports CVEC research. The inaugural meeting of the Cardiovascular Engineering Advisory Board, comprised of representatives of paying IAP member organizations, was held on September 2000.

In its first meeting, the Cardiovascular Engineering Advisory Board - comprised of representatives of CVEC IAP members of the Partner and Executive Partner levels and a representative of CVEC and sitting as a Board of Directors for the IAP - adopted the Program’s By-laws. The following are key excerpts from CVEC IAP By-laws:

CVEC IAP MISSION: CVEC IAP is committed to becoming the major support program of FIU’s Cardiovascular Engineering Center for advancing biomedical engineering research and education in Florida International University; for serving the joint interests of the biomedical industry and FIU and for promoting CVEC to a nationally recognized cardiovascular engineering research center.

CVEC IAP PURPOSE: To raise funds in support of CVEC’s vision and mission; to receive gifts in promotion of CVEC’s purposes and goals; to disburse resources to for the purpose of advancing CVEC’s mission and objectives; to expend funds to foster and promote industry-academia cooperation and collaboration; and to support the Cardiovascular Engineering Center, its prosperity and its growth.

At that point CVEC IAP Advisory Board elected, besides donating their own organizations’ gifts and their time to the program, not to take an active role in the fund-raising activity of the program. Instead, it identified to itself the following roles: serve as a source of collective wisdom, advice and support for CVEC; serve in an advisory capacity to the Director of CVEC; continually appraise CVEC activities, programs and initiatives; offer ideas and suggestions to the Director of CVEC; and approve the budget of CVEC IAP.

The Board agreed that pledges are to be made, as a minimum, for a period of three (3) years and are continued on a yearly basis thereafter and that cash contributions only will be considered for the purpose of IAP membership. It also adopted a three-tier membership structure: CVEC Sponsor ($5,000 per year), CVEC Partner: ($15,000 per year), and CVEC Executive Partner: ($25,000 per year).

Under the program structure presented above, CVEC IAP faced increasing difficulties at maintaining its member participation and membership growth that were critical for the effectiveness of the program. At that point, with FIU’s biomedical technology portfolio and biomedical research programs in their infancy stages, many IAP prospective industry members...
found it difficult to justify the CVEC IAP membership levels. For young entrepreneurial biomedical companies the CVEC IAP membership cost was, in many cases, prohibitive. Furthermore, after randomly surveying several companies in the area, the interest of most them was more in the stream of prospective FIU BME engineers that could be locally recruited into their companies. They, thus, had immediate interest at shaping up the academic program that yielded these engineers rather than investing in early stage research that may result in technological breakthroughs in the more distant future. For clinical - not-for-profit - organizations, participation in a partnership program based on cash donations was not feasible thus clinical member participation was none-existent and impossible to improve upon.

The current Biomedical Engineering Partnership Program implemented lessons learned through the CVEC IAP; deploying it at the Biomedical Engineering Institute level and targeting high membership and broad member participation. The new program labeled itself as an inclusive program aiming to significantly improve the interaction between its academic, industry, and clinical components and fostering joint activities and programs. The Biomedical Engineering Partnership Program built itself as an equilateral triangle of its clinical, academic, and industry components thus allowing for each of the members to leverage each others expertise and know-how for its own improvement and advancement. Such an arrangement has also opened an opportunity for the Program to have a cumulative effect on the economic dynamics and vitality of South Florida.

The Biomedical Engineering Partnership Program

FIU’s Biomedical Engineering Partnership Program was formally initiated in June of 2001. It is a joint enterprise of FIU, clinical research establishments, and biomedical companies. Its mission is to foster excellence in biomedical education and training; support biomedical innovation, invention, and discovery; cultivate biomedical research and development; and promote biomedical engineering entrepreneurship in South Florida. The objectives of this proposed Partnership for Innovation (has this NSF program been described yet?) program is to implement a set of specific activities that will enable the Partnership Program to realize its mission, and to provide the requisite support structure for assurance of success. The Program Advisory Board adopted new by-laws in September 2001 that conveys the increased interest in improving inclusiveness and joint activities, focus on both educational and research interests, and inclusion of overarching regional objectives. The vision, mission and purpose of the new program accurately depict the shift in its focus:

VISION: The Partnership Program will be recognized in the country as the premier catalyst for excellence in biomedical engineering education, innovation, and entrepreneurship.

Mission: The Partnership Program is a joint enterprise of FIU, healthcare providers, and biomedical companies. It fosters excellence in biomedical education and training; supports biomedical innovation, invention, and discovery; cultivates biomedical research and development; and promotes biomedical engineering entrepreneurship in South Florida.

PURPOSE: to provide advice and guidance for the overall direction of research and education at the Department of Biomedical Engineering (BME); to contribute to and participate in the training of the next-generation biomedical engineers, scientists, and researchers; to
foster cooperation and collaboration between industry, clinical-medicine and academia; to promote education, research and development leading to innovation, invention, and discovery in the delivery of medicine; to secure funds in support of its mission; and to support its members, their prosperity and growth.

The result of these programmatic changes was a vastly increased membership and significantly improved member participation. Current member organizations include Beckman-Coulter, Bolton Medical, Boston scientific, and Cordis, a Johnson & Johnson Company as large industry organizations; Bioheart, IDEXX, Innovia, Millennium Scientific, Rochal Industries, Scion Cardiovascular, VasCon, and Viragen as small/startup type organizations; Baptist Health Systems of South Florida, Mercy Hospital, Miami Cardiac & Vascular Institute, Miami Children’s Hospital, and Mount Sinai Medical Center as clinical partners; Avisena and Langley Group as healthcare management and investment firms respectively; and Nova Southeastern University as an academic member.

**Operational Innovations**

**Program Administration**

The program is managed by the industry liaison that uses the help of a part time student assistant to operate the program. Clerical support is provided primarily by the student assistant. Funds are monitored via the regular accounting system of the university with interface between the program manager and the university via the accountant of BME. In kind donations are monitored by the Partnership Program in a separate system. Cash value of in-kind gifts is processed through the regular accounting system. While administrative overhead is fully carried by the university the program provides enough funds to support its direct costs.

**Advisory Board and Executive Committee**

The Biomedical Engineering Advisory Board is composed of volunteers that represent Partnership Program members. Each Partnership Program member appoints representatives to the Advisory Board. If more than one representative is appointed by a member only one serves as a voting member. The Advisory Board is chaired by the Chair of BME; it meets twice annually, in the Fall and in the Spring, and is regularly invited to FIU, College of Engineering and BME events and ceremonies. Board meetings are hosted by the partnering organizations in rotation.

The Biomedical Engineering Advisory Board is a source of collective wisdom, advice and support for BME; serves in an advisory capacity to the Chair of BME; continually appraise BME activities, programs and initiatives; offers ideas and suggestions to the Chair of BME; approves the budget of The Partnership Program.

The Executive Committee is comprised of three volunteers from within the Advisory Board. The volunteers represent, each, one of the sectors represented on the Board: large companies, small companies, and clinical organizations. The Executive Committee are voted into the committee by the Board. It is chaired by one of the committee members who is also voted to that position by
the Board. The Executive Committee serves as liaison between the Department and the Board and acts as a decision-making body for the Board between meetings. The Executive Committee decisions are ratified by the Board in its following meeting.

The Partnership Program attempts to strike a fine balance with its advisory board; it attempts to appeal to senior managers that, on one hand, are looking for the hands-on/active personal participation while, on the other hand, could commit the time, bring organizational commitment, and lead change throughout large areas of their organizations. All the members of the Advisory Board are senior managers - usually Presidents, CEO’s, COO’s, VP’s or Directors with responsibility and authority in research, development, clinical, or engineering – with genuine enthusiasm about the partnership program and personal interest in its success. Clinical organizations may appoint the VP of Research or the Medical Director while a faculty with administrative responsibilities may be appointed by an academic organization.

Program Sponsorship

To address the specific issue of membership fees, the Biomedical Advisory Board has created a taskforce. The taskforce of five included Advisory Board members representing FIU, small and large industry partners, and the clinical organizations: Hamid Shahrestani of Boston Scientific, Chair, Bill Abraham of Mount Sinai, Topaz Kirlew of Bioheart, Mark Pomeranz of Cordis, and Ofer Amit of BME (ex officio). It created an innovative plan that addresses the needs of small and large industry partners as well as the unique circumstances of clinical partners. The plan provides incentives for activities that support the mission of the program as well as opportunities for and recognition of cash contributions. The plan was presented by the taskforce to and adopted by the Advisory Board in its sixth meeting on September 9th, 2003.

At the root of this plan is an equivalency table that translates members’ contributions to the program - in the context of their sector’s economic and other circumstances – into points that allow for unbiased accounting:
A standing committee was created by the taskforce and approved by the Board to monitor the implementation of the sponsorship program.

**Programmatic Innovations**

**Mentoring and Internship Program**

A second taskforce – comprised of Ray Diaz of Scion CV, Chair; Mark Pomeranz of Cordis, Alan Carsrud of FIU’s Global Entrepreneurship Center, and Ofer Amit of BME (ex officio) - structured a program that provides undergraduate students of the Department of Biomedical Engineering with unique corporate or entrepreneurial experience that will enhance their professional skills and ease their transition from an academic to a professional environment. The mentoring and internship program provides the member organizations with junior engineer-level talent that could produce projects for the organization. In addition, the program creates a flow of local engineering talent through the organization that is available, in most cases, to be hired upon graduation. Program activity complies with the requirements of the Accreditation Board for Engineering and Technology (ABET) for senior design projects.

The Biomedical Engineering Mentoring and Internship program is offered to seniors majoring in Biomedical Engineering. The program is comprised of a three-semester sequence that begins during the latter half of the Spring Semester of the Junior year or the Summer Semester of the Senior year. Seniors that do not participate in the program do an in-house senior design project.

The program offers two tracks: an entrepreneurial track and a corporate track. In the entrepreneurial track student entrepreneur(s) recruit prospective team members for the duration of the project and lead the development of their own biomedical technology-based business plan. The team contacts and recruits a mentor to provide guidance in developing their business plan. Student’s Academic Advisor and the Mentor define the scope of the project, which culminates in a submission into FIU’s Business Plan competition. In the corporate track the student-interns operate as a team of junior engineers and immerse themselves into the sponsoring organization’s environment. Students are first interviewed and are then “hired” (or rejected) by the sponsoring organization that will assemble the team. The team is mentored and supervised by an individual assigned by the sponsoring organization for the duration of the project. Project selection and assignments are commensurate with FIU requirements for such activity and must be approved by student’s Academic Advisor.

In semester I students declare their intention to become part of the program to their academic advisors. Under the entrepreneurial track the project leader(s) recruits a mentor and team members and holds the first team meeting with the mentor. Students take entrepreneurship classes and participate in entrepreneurship-related/team-building/creativity activities. Under the corporate track students are interviewed and are “hired” by the sponsoring organization; first Team meeting is held with Internship Supervisor and students participate in summer team-building/problem-solving/creativity activities.
In semester II students enroll in BME 4090, Design Project Organization Course (1 credit). In the entrepreneurial track the team develops initial concept(s), generates a business plan outline, and obtains academic advisor approval on the proposed project. In the corporate track the team completes preliminary concept work; presents a proposal and obtains approval to proceed with the project from the academic advisor and internship supervisor.

In semester III students enroll in BME 4xxx, Senior Design Project Course (3 credits). Under the entrepreneurial track the team generates a final business plan and Business Plan and enters FIU’s Business Plan Competition. In the corporate track the team completes project per the approved proposal and enters FIU’s Engineering Project Expo.

Grades, where applicable, are assigned by the FIU faculty, with input from Internship Supervisor, upon completion of the project.

Collaborative Technology Innovation Program (CTIP)

The Collaborative Technology Innovation Program (CTIP) is a two-phase program aimed at seeding projects that hold the potential for discovery, innovation, and invention and that present an opportunity for commercialization or additional funding. CTIP is open to all members of the Biomedical Engineering Partnership Program. Projects are equally sponsored by FIU and the partnering organizations and seek to uniquely leverage the knowledge and expertise of faculty and students at FIU, biomedical companies, and clinical organizations.

CTIP Phase I projects are supported, at FIU’s end, by a grant from the Wallace H. Coulter Foundation. CTIP Phase I is designed to annually seed five year-long projects. From a special gift from the Wallace H. Coulter Foundation, the Department of Biomedical Engineering is providing each of the projects with $10,000. Each of the partnering organizations provides its corresponding project with a minimum of $10,000.

CTIP Phase II projects are supported by a grant from the National Science Foundation (NSF) Partnership for Innovation program. Upon completion of phase I, each of the CTIP Phase I participants is invited to apply to Phase II. CTIP Phase II is intended to provide one phase I project with an opportunity for further development and augmentation. On a yearly basis and for a period of one year, FIU provides one project team with $50,000. As a minimum, the partnering organization provides additional $50,000 in support.

For a proposal to be eligible to be submitted to the CTIP the PI must be a BME faculty or FIU faculty operating within the framework of a BME research center, the co-investigator is from a Partnership Program member organization in good standing with the Partnership Program. The PI must obtain a commitment for a minimum of 100% match from the Partnership Program member organization. Among the evaluation criteria are the PI’s Biomedical Partnership Research Initiation Program awarding history, past performance on a Research Initiation Program project, where applicable, potential for additional funding through 3rd party and/or commercialization, soundness of experimental design and technical approach to the problem, and an appropriate budget.
To the extent possible, the review panel is comprised of representatives of Partnership Program members in three categories: large company, small company, and clinical, and is selected and chaired by the Chair of BME. The program is administered by BME that sets guidelines, solicited proposals, and sets deadlines. The proposal is limited to three pages (CTIP Phase I) and five pages (CTIP Phase II) plus a letter of commitment from the partnering organization. Among the issues addressed in the proposal are methods including specific measurable endpoints for feasibility, specific plans for further funding/commercialization, specific address of intellectual property issues, and budget and timeline appropriate to the task on hand.

Summary

The Biomedical Engineering Partnership Program is an innovative integrated approach that was successful (how do you define success?), in its four years of existence, at creating an environment where industry, academia, and clinical organizations partner in the education of biomedical engineers and in the creation of innovative biomedical technologies. The program provides the infrastructure, the mechanics, the programmatic vehicles, and the fiscal means that allow for its success, induce enthusiasm, and make the program engaging and vibrant. The Biomedical Engineering Partnership Program positions the Department of Biomedical Engineering as the hub of new technology creation and as a unifying economic force in South Florida. The program proves itself key to enabling the Department of Biomedical Engineering to achieve its goals.

As both the Program and the Department mature program effectiveness and longer term effects on the industry, the academic and research programs, and on new technology deployment into the clinical setting will be gauged.

Useful Links

http://www.fiu.edu/
http://www.eng.fiu.edu/
http://www.bme.fiu.edu/
http://www.bme.fiu.edu/PartnershipProgram.htm
http://www.entrepreneurship.fiu.edu/
http://www.entrepreneurship.fiu.edu/technology_innovation.htm
http://www.idea.fiu.edu

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