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Multi-Disciplined Ecosystem-Centric Bioentrepreneurship Education: Case Study – University of San Francisco (USF)

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ABSTRACT

Bioentrepreneurship education has evolved into at least three different types, all of which co-exist: Education 1.0 – In Service of Biotechnology Startups, Education 2.0 – In Service of Biotechnology Innovation Ecosystems, and Education 3.0 – In Collaboration with Biotechnology Innovation Ecosystems. Examples are given at all levels, along with a Case Study of the Bioentrepreneurship (BioE) program at the University of San Francisco (USF). The USF program draws from twelve expertise disciplines described by the Bioenterprise Innovation Expertise Model (BIEM 2.0), those essential disciplines bioenterprise requires to bridge the science/technology discovery/invention through to viable commercial product life cycle. As a result, the USF program reaches graduate students across the university. The utilization of the BIEM 2.0 model throughout the BioE courses is discussed, as well as the incorporation into the curriculum of BioTech Nation interviews with biotechnology industry executives and scientists. Due to the COVID-19 Pandemic and the requirement to move the BioE courses to a remote modality, future plans include the development of a fully online Bioentrepreneurship (BioE) certificate, primarily targeting the California state biotechnology corridor of San Francisco, Los Angeles, Orange County, and San Diego Biotechnology Innovation Ecosystems. Additional new BioE courseware will address the growing sector of Digital Health.

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INTRODUCTION

What builds innovation ecosystems and clusters within the global biotechnology industry? Is it driving more and more scientific breakthroughs? Is it creating new technologies which enable these breakthroughs to become deliverable products? Is it fostering, incubating and funding startups to bridge that expanse? These efforts are undoubtedly key to fueling the engine which drives the commercial biotechnology economy. Does this suggest this is where universities must solely focus?

This paper examines several educational models in which universities may engage with the biotechnology innovation ecosystem. It further provides a Case Study of the University of San Francisco's (USF's) bioentrepreneurship (BioE) program, which serves as an exemplar within one of these educational models, and which can be replicated within other innovation ecosystems, ultimately providing substantial benefit to the ever-evolving biotechnology industry.

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EDUCATION 1.0 – EDUCATION IN SERVICE OF BIOTECHNOLOGY STARTUPS

The central myth of the successful biotechnology startup is that a life scientist makes a breakthrough at the lab bench, meets a daring venture capitalist, and the two

create a stunning biotech company. In other words, Herb Boyer meets Bob Swanson, and the result is Genentech. Adding substance to the myth, Genentech is often mistakenly referred to as the first biotech company. Even the esteemed journal *Nature* made that mistake in 2019, and corrected itself in 2020.[1,2] It seems that Cetus was founded some five years earlier, and that others must also be counted among the bold. That would include Gamma Biologicals and Irvine Scientific.[2] Also lost in the mythological construct – Herb did not "pitch" Bob; Bob went looking for Herb.[3]

Thus, the perception of what entrepreneurship has come to mean today seems to overlook the visionary serendipity of the founding of Genentech and translates itself into a fueled mission which starts with embracing a potential commercial idea from science and/or technology, commencing an indefatigable search for funding, and ultimately proceeding to company startup.

This perception and similar non-biotech founding myths have wended their way into general entrepreneurship education. A case-in-point can be found among the Stanford Center for Professional Development's impressive array of professional education offerings, while also offering credited individual courses, degree programs and certificate opportunities.[4] Its 10-week, online "Idea-to-Market" course enables a "step-by-step guide to prepare your idea for launch", collaboration and networking "with an international cohort of entrepreneurs", and "feedback on your completed pitch deck and presentation from our industry expert mentors".[4]

To be fair, every enterprise has to start somewhere and somehow, but professional education in the biotech startup space is necessarily more complex. First of all, the need for funding is legendary. In biopharmaceuticals, the largest biotech industry sector, a March, 2020 London School of Economics and Political Science study published in *JAMA*, the *Journal of the American Medical Association*, focused on publicly-available data for 355 FDA-approved drugs between 2009 and 2018.[5-6] Accounting for the cost of failed trials, the median capitalized investment to bring a new drug to market was found to be $985 million, while the average was calculated to be $1.3 billion (in 2018 dollars).[6]

This level of investment invites risk, and in the biopharmaceutical space, the failure rate of such endeavors cannot be ignored. A 2018 study published in the journal *CTS (Clinical and Translational Science)* examined pre-clinical studies in the United States, Europe and Japan, and calculated pre-clinical failure rates for biologics at 68.2%.[7] For those drugs which then move on to FDA clinical trials, a recent MIT study published in the journal *Biostatistics* indicated that 86% of all drugs entering FDA clinical fail.[8] And unfortunately, they may not fail quickly.

Even when successful, the time required to develop a new biopharmaceutical is truly remarkable. In 2010, it was estimated at 10 years on average by PhRMA, a consortium of US biopharmaceutical companies, but the elements of these timelines have also been changing over time.[9-10] A 2020 Harvard study published in *JAMA*, the *Journal of the American Medical Association*, examined FDA approvals between 1983 and 2018.[10] It found that biopharmaceuticals benefited from advances in technology, that approvals under the Orphan Drug Act (increased to 41% of all approved drugs), and that 81% of all drugs approved benefited from one or more of these schedule-improving designations: Accelerated Approval, Fast-Track and Priority Review.[10] Still, even with roughly half the drugs now solely requiring only one pivotal trial instead of two, the average time of approval through all clinical trials remains at 8 years.[10]

In the current COVID-19-related climate, the FDA has approved vaccines under emergency use with less than a year for all clinical trial phases.[11] Whether this has an impact on the timelines of future clinical trials remains to be seen. In any event, all commercial biotechnology endeavors require significant investment capital that must be put at risk for many years.

Specialized entrepreneurship education in the biotech startup space recognizes these considerations as the higher level challenge it is. One example with respect to initiating a bioenterprise is the relatively new, ten-week online course from the UCSF Entrepreneurship Center: "Entrepreneurship for Life Science and Healthcare Startups: Master Class Direct from Silicon Valley".[12]

Another example is the annual Biotechnology Entrepreneurship Boot Camp, a two-day intensive created by senior bioentrepreneurship academics from Carnegie Mellon University and Wharton Business School, and supported by industry.[13] It is a part of the annual Biotechnology Innovation Organization (BIO) conference. Having evolved over 15+ years, the boot camp is experiential in nature and today covers Product/Company Assessment and Qualification, Reimbursement and Pricing, Global Regulatory Implications, U,S, Regulatory Planning, Intellectual Property, Board Membership Design, and Entrepreneurial Management Teams. This goes beyond the idea of a single or first pitch for funding and portrays instead the multiple, successive search for funding typically needed. It includes Pre-Seed/Seed Funding Pitches, Early Stage Funding Pitches, and Exit Triggers within the framework of the total capitalization needed by the biotechnology venture over time.[13] Similarly, it starts with qualifying the idea and gaining initial funding, but it quickly moves on to delivering the reality of the total bioenterprise. Future boot camps will be online while the BIO conference retains its temporary digital

format, and will resume on an in-person basis in step with the annual BIO conference.[13]

Degree-oriented university science programs have also sought to incorporate bioentrepreneurship in support of startup ideation, creation and participation upon graduation. At the masters' level, the University of Pretoria's Karl Kunert and Case Western Reserve University's Christopher Cullis encapsulate this philosophy in their editorial, "Universities must teach their budding scientists entrepreneurship".[14] It further points out the opportunity afforded by universities offering Professional Science Masters (PSM) degrees. These PSM degrees require business curriculum and internships as a complement to science and other technical fields; over 40 PSMs in Biotechnology are offered within the United States.[15] In the case of Case Western, its unique PSM degree is decidedly entrepreneurial: a PSM in Entrepreneurial Biotechnology.[16]

From an educational pedagogy standpoint, these examples begin to be a departure from the professional education startup paradigm. While students may well have in mind starting up a bioenterprise, the courses and internships speak for themselves – participation in biotechnology innovation ecosystem. It's arguable that these degree programs actually belong in the next transitional category: Bioentrepreneurship Education 2.0.

EDUCATION 2.0 – EDUCATION IN SERVICE OF BIOTECHNOLOGY INNOVATION ECOSYSTEMS

Many times labelling any activity "2.0" suggests that it replaces "1.0". That is not suggested here. In fact, that which has been identified as Education 1.0 remains much needed, and it will continue to evolve and thrive, as it should. Let us remember that the biotechnology industry, and bioenterprise along with it, is relatively new, measured only in single-digit decades. As any entity matures, more will be recognized about achieving success in the science-to-product cycle.

In fact, participating in any bioenterprise at any level could be considered entrepreneurial, independent of the company founders and the ongoing need for investment funds. Thus, Education 2.0 focuses on the expansive and expanding job of work required by the bioenterprise to achieve success in the science-to-product life cycle. Several examples of Education 2.0 are provided.

Given the premise that the engine of biotechnology begins with breakthroughs in science, and recalling the entrepreneurial points made by Kunert and Cullis, the evolution within bioentrepreneurship education inside academia is evolving.[14] One well-known and innovative construct can be found at the University of California, Davis. UC Davis's Biotechnology program offers a Designated Emphasis in Biotechnology (DEB) to PhD's within 29 STEM doctoral areas.[17] The DEB emphasis seeks to "develop an understanding of the 'business of biotech'", including an internship and requiring a microbiology course taught by a complement of working research scientists from Novozymes' Davis, California R&D facility.[17] This brings graduate students from multiple STEM disciplines directly into the Davis biotechnology innovation ecosystem in a variety of ways. The point for the student is not necessarily to start up a bioenterprise, but rather to find his or her place in it.

Another program somewhat challenges the premise that university biotechnology entrepreneurship degree programs must start with science. Johns Hopkins University's fully online Master of Biotechnology Enterprise and Entrepreneurship appears to prefer applicants to possess a bachelor's degree in the life sciences, or "with a strong background", they may take a single, additional undergraduate course, *Foundations in Bioscience*.[18] A close look at the master's curriculum finds it reminiscent of an MBA-like program within a biotech environment. With most courses including the term "Biotech" in their titles, the core curriculum is familiar: management, leadership, marketing, finance, ethics, regulatory practices, intellectual property, and so on. Students choose electives from over 100 available Johns Hopkins' courses, and there is also an optional concentration in Biotechnology Legal and Regulatory.[19] Since students attend classes entirely online and come from many backgrounds, this university program arguably serves multiple biotechnology ecosystems regionally, nationwide, and worldwide, and in many different ways.

A more regionally-centric program at the University of San Francisco's (USF's) Bioentrepreneurship program reflects elements of each of these in its quest to serve the San Francisco biotechnology innovation ecosystem. It's case study is described subsequently.

WHAT SERVES A BIOTECHNOLOGY INNOVATION ECOSYSTEM?

A central question for any educational program with the intent to serve any innovation ecosystem is: "What serves a biotechnology innovation ecosystem?" And this truly can be answered in many ways. The USF perspective looks first to the nature of the challenge being undertaken by the ecosystem. Gunn's 2013 paper, "An agile, cross-discipline model for developing bio-enterprise professionals", describes the science-to-product

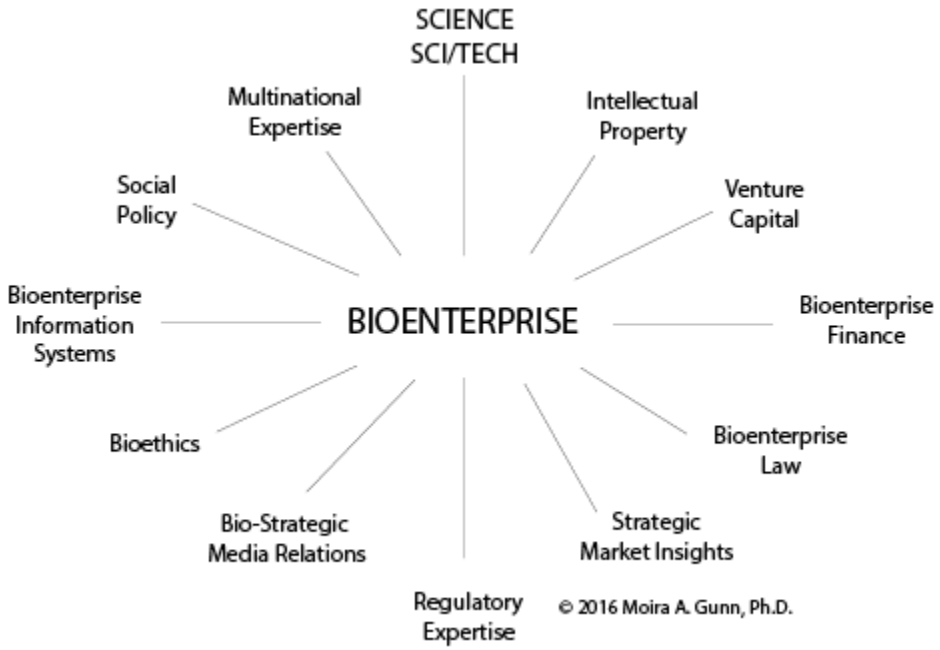

Figure 1. BIEM 2.0 (Bioenterprise Innovation Expertise Model) – Essential Capabilities.

innovation phase of bringing a biopharmaceutical to registered product as follows.[20]

> *"The endeavor carries innate risk. Simply stated, the bioenterprise must drive nascent science to stable, commercially-available and ultimately profitable products and services, an exercise for which success can neither be predicted from the outset, nor at numerous points along the way. Achieving commercial success requires a multi-disciplinary and creative entrepreneurial organization, which can operate within a continually-challenging and unprecedented business context."* [20]

This paper further described the various disciplines required in a Bioenterprise Innovation Expertise Model (BIEM), the result of both observation of success and examination of failure.[20]

> *"Successful bioenterprises were observed to assemble the right expertise at the right time at every turn in the biotechnology innovation life cycle. Agile organizations had an appreciation for a larger spectrum of expertise than did less flexible ones. … While breakthroughs in science are expected, there are also scientific setbacks. The creativity and resilience required to ensure that investment capital is in place goes hand-in-hand with a readiness to construct previously unexplored investment vehicles … How last year's marketplace behaves may be completely different from this year's marketplace – there are competitor's products, a changing regulatory scene, negative and/or positive media, and much, much more. … The Bioenterprise Innovation Expertise Model reflects a dynamic of the expertise needed to address the challenges of bioenterprise, which itself must be both robust and creative, and is frequently called upon to address situations which are arguably unprecedented. Such is the nature of science-business."* [20]

By 2016, the BIEM model evolved to incorporate biomedical devices, which simply added "**SCI/TECH**" to "**SCIENCE**" into a single, combined node reflective of the innovation disciplines. [21] The newly-terms BIEM 2.0 model has remained unchanged since that time. It is depicted in Figure 1.

A priority was made of validating the BIEM 2.0 model, and an effort to assess the BIEM 2.0 model was undertaken in 2016. The relative importance of each of innovation expertise disciplines was directed via questionnaire at 20 biopharmaceutical venture capitalists with an average of 30 years of experience in the biotechnology industry.[21] As a group, their experience represented a substantial portion of the venture capital invested in the successful biologics available today. Along the way, they also experienced many, many failures. All had served on biopharmaceutical company boards, most as board chairs, and significantly, 80% has been CEO's and/or presidents of biopharmaceutical companies. From the Gunn, et al. 2016 paper "The BIEM Verification Study: Experienced Venture Capitalists Assess a Biopharmaceuticals Innovation

Expertise Model" published in the Journal of Commercial Biotechnology" [21]:

> *"20 biopharmaceuticals venture capitalists with 30 years average biotechnology industry experience … rated the innovation expertise disciplines of BIEM 2.0 as to their importance in the scientific discovery through market-ready product innovation phase of biopharmaceutical development. Despite a small sample size, statistically significant insights were produced, verifying the BIEM model. The most important innovation expertise disciplines were intellectual property, science, regulatory expertise, and venture capital, in that order. Further, the strongest correlations linked regulatory expertise and science, and equally so, intellectual property and venture capital."* [21]

With respect to the development of biomedical devices, verification of the BIEM 2.0 model has not been conducted as yet. While the cost to develop and bring a medical device to market is significantly lower than biopharmaceuticals, there are also challenges in defining the biomedical device market itself since categorizing the devices can be somewhat complicated. Are they standalone devices? Are they part of a diagnostic? Are they part of treatment regimen. Do they collect information and store it in the cloud? Is the analysis of the data considered a part of the medical device? Are they meant for commercial use by multiple people? Are they meant to interact with other medical devices and/or other data entities? While biomedical devices require less investment capital and are generally able to reach market on a shorter timeline, there are more dissimilarities between devices than similarities. It became clear that none of the innovation expertise disciplines could be fully eliminated, but that no new disciplines need be considered. Formal verification of the BIEM 2.0 model with respect to biomedical devices is on hold unless and until a workable verification protocol can be developed.

Even so, with biopharmaceuticals and biomedical devices a substantive part of the greater San Francisco Bay Area biotechnology innovation ecosystem, the BIEM 2.0 model is essential USF's BioE courses.

THE SAN FRANCISCO BAY AREA BIOTECHNOLOGY INNOVATION ECOSYSTEM

The University of San Francisco primarily serves the San Francisco Bay Area. This ecosystem is home to some 1,059 biotechnology companies, of which San Francisco proper hosts 144 companies, and South San Francisco hosts 134 companies.[22] The remainder largely ring the San Francisco Bay.[22] The "California Life Sciences Report 2019" places direct employment in the biotech sector in the San Francisco Bay Area at 82,568, outpacing the Southern California ecosystems of Los Angeles County at 57,117, Orange County at 44,957, and San Diego County at 48,430.[23] Taken together, the state of California creates an unparalleled, integrated and larger biotechnology innovation ecosystem, in and of itself.

While primary focus in the San Francisco Bay Area has been in biopharmaceuticals and biomedical devices, there is near meteoric recent growth with respect to venture capital investment in digital health. In 2017, $1.8 Billion was invested in San Francisco, and in 2018, this investment increased to $3.9 Billion.[23] Combining Los Angeles, Orange and San Diego counties over that same time period, digital health venture capital investment was $139 million in 2017 and $288 million in 2018.[23] This shows that 93% of the digital health venture capital investment went to the San Francisco Bay Area in the years 2017 and 2018.[23]

UNIVERSITY OF SAN FRANCISCO (USF) WITHIN THE SAN FRANCISCO BAY AREA BIOTECHNOLOGY INNOVATION ECOSYSTEM

The University of San Francisco (USF) is a private Jesuit university with its main campus in San Francisco, and additional campuses in Downtown San Francisco, Pleasanton, Sacramento, and Orange County. With a Carnegie classification as a Master's focused institution, its academic organization is a College of Arts and Sciences, School of Law, School of Management, School of Education, and School of Nursing and Health Professions. The total student body approaches 10,000 students, of which 4,200 are graduate students.

Viewed as a whole, the university provides graduate education opportunities in all twelve BIEM 2.0 expertise disciplines through master's degrees and graduate degrees, such as MBA in the School of Management and J.D. in the School of Law. Recalling that the breakthrough science which catalyzes the engine of biotechnology are most often found at such nearby institutions as UC San Francisco (UCSF) and Stanford University, USF's profile matches more closely the innovation expertise disciplines identified within Bay Area bioenterprise in the over 80,000 jobs identified within the San Francisco biotechnology innovation ecosystem. With Bioentrepreneurship (BioE) courses available to every graduate student at the university, the ability to serve the

local biotechnology innovation ecosystem is possible on many levels.

CASE STUDY: BIOENTREPRENEURSHIP (BIOE) EDUCATION AT USF

Bioentrepreneurship at USF was first conceived in 2007 as a proposed concentration in the Masters in Information Systems (MSIS). By the time of implementation in 2010, it had expanded to include MBA students and JD/MBA students. In 2012, it became the entrepreneurship portion of the new Professional Science Masters (PSM) in Biotechnology being offered by the College of Arts and Sciences. Other students who have taken advantage of these courses include students from master's degree programs in Professional Communications, Organizational Leadership, Nonprofit Administration, Public Administration, and Nursing. In 2018, Bioentrepreneurship transferred from the School of Management to the College of Arts and Sciences, where it reports to the Dean's Office. Currently, there are 78 students enrolled in the PSM in Biotechnology, including approximately a dozen students with delayed graduation due to COVID-19.

Impact of the COVID-19 Pandemic on Bioentrepreneurship Education at USF

Due to COVID-19 safety precautions, in Spring, 2020, all BioE courses began their transition to remote modality, completing this transition by the end of Spring, 2021. Of necessity, the biotech global study tours were immediately suspended, and an additional course, Biotech's Response to the COVID-19 Pandemic, also in the remote modality, was developed as a replacement. All are more fully described in a subsequent section.

USF Bioentrepreneurship Educational Pedagogy

While the BIEM 2.0 model addresses individual expertise disciplines which come into play over the innovation lifetime of a bioenterprise, they do not operate in isolation. To be effective in the constantly changing dynamic of the innovation phase, individuals from these BIEM disciplines must be able to work together. Thus, the vision of the bioentrerpreneurship educational pedagogy at USF has four requirements:

- The Learning Objectives of all graduate BioE courses are based on the integrated BIEM 2.0 model and its relation to bioenterprise
- All graduate students with a discipline reflected in the BIEM 2.0 model are eligible to take any BioE course
- All BioE course may have a complement of students from any of the BIEM disciplines.
- All presentations and papers must be written/delivered in a manner comprehensible by all BIEM disciplines

At the same time, BioE courses do not teach science, per se, but rather they teach minimalist science to relate those elements of science which relate to the value proposition and risk of the bioenterprise. Furthermore, and particularly challenging for science students, the requirement that all communications be comprehensible by all BIEM disciplines may seem difficult, but the principle behind it is simple and straightforward: All members of an innovation team must be able to communicate and have an appreciation for each other's discipline. Dovetailing with this, every bioenterprise team must also be aware of what may be missing in any effort; having knowledge of the BIEM disciplines can deliver on this challenge.

The BIEM disciplines are incorporated into each type of course in a variety of ways. These can be found with each course type in subsequent sections, and several are described in more detail in Gunn, 2016, "When Science Meets Entrepreneurship: Ensuring Biobusiness Graduate Students Understand the Business of Biotechnology" in the *Journal of Entrepreneurship Education*.[24]

The Bioentrepreneurship (BioE) Courses

All USF Bioentrepreneurship (BioE) courses have been designed to be taken singularly or as a complement within a number of degree programs. The Professional Science Masters (PSM) in Biotechnology program requires a BioE study tour in addition to four BioE core lecture courses. As indicated above, the BioE study tours have been temporarily replaced with a biotech COVID course, which will continue until study tours may be resumed.

BioE Lecture Courses

Lecture courses utilize the BIEM model in several ways. One central example is that each course requires listening to *BioTech Nation* podcasts, a biobusiness interview segment of Gunn's *Tech Nation* program on NPR on SiriusXM and other public radio venues. Students listen

to the interviews and determine which elements of the BIEM model are – and are not – present. For example, an interview with a person from the FDA would not include references to Intellectual Property, which is appropriate. Perhaps, an interview with the founder of a new startup does not give enough information to clarify where a particular product is in the FDA regulatory cycle. All of this provides further material for threaded online Discussion Boards in which the entire class may interact.

The *BioTech Nation* interviews can also be used in a number of contexts. For example, Dr. Gunn's 2005 *BioTech Nation* interview with Elizabeth Holmes, founder and former CEO of now-defunct Theranos, can be used as part of a regulatory course, or a course in biomedical device management, or perhaps a legal/ethical inquiry.[25]

Another element of every BioE course is the individual tracking of a publicly-traded biotech stock. Students select one at that beginning of their first course and there is a set of requirements to follow the stock's movement and news which affects it. This can be relative to the company itself, or the stock market in general, or any number of emergent issues. At the conclusion of each course, students are required to put their daily change tracker on a collective spreadsheet. Questions on the final are directed to this collective spreadsheet. The effect of the COVID-19 pandemic, as well as the U.S. presidential election, made Fall, 2020 an instructive time to participate. Students may elect to keep their stock in the next course, or they may select a new publicly-traded biotech stock.

Global and US Regulatory Affairs

Course Catalog: "Studies US and global regulatory requirements in the biopharmaceutical and biomedical device sectors. Primary focus is on Pre-Clinical development thru Phase IV clinical trials and FDA filing/approval, identifying comparable actions in the EU/Japan, and other significant global markets." [26]

Additional Notes: Each student must prepare a report and deliver a presentation on a Failed Drug (Phase 3 or Phase 4 failures) and a Failed Biomedical Device. All include reason for the failure, potential for failure being avoided, impact on the company, etc.

Legal, Social and Ethical Implications of Biotech

Course Catalog: "Studies the ethical, social and legal impact of biotech, both in the US and globally. Includes HIPAA, GINA, the developed vs. developing world, Supreme Court decisions, national/global intellectual property, the orientation of organized religions, and the potential impact of synthetic biology." [26]

Additional Notes: Each student must debate either a PRO or a CON side to a major bioethical debate, as outlined in Caplan and Arp's "Contemporary Debates in Bioethics." [27]

Bioinnovation Management

Course Catalog: "Develops skills in managing bioentrepreneurship projects in the bioscience and biomedical device fields. Students learn how to be responsive team members as well as communicative team leaders. Also covered is sustaining innovation in organizations and team dynamics." [26]

Additional Notes: In two successive three-week sessions, each student must operate as a team leader. At the same time, each student with be a team member in four other teams. Students learn to create agenda, lead meetings, make reports, and ultimately solve a unique team puzzle with clues distributed among team members. As in science-business, sometimes the clues deliver wrong information, as would happen when a scientific test was ill-structured, sometimes team members are absent or simply don't respond, sometimes the project team leader is absent but the meeting must be conducted in any event with reports to management, etc. Still, the team must continue driving the project forward.

Local, National and Global Biotech

Course Catalog: "Studies the global biotechnology industry, the US biotech landscape, and the impact of the San Francisco Bay Area – the largest biocluster – both nationally and globally. Focuses on the nature of biobusiness and significant bioclusters, while featuring lectures from local biotech professionals." [26]

Additional Notes: Each student must prepare reports and deliver presentations on a San Francisco company (or local site of a multi-site company), a national biocluster, and a global biocluster.

Biotech's Response to the COVID-19 Pandemic (Temporary Replacement Biotech Study Tour) of

Course Catalog: "An overview of the response to the COVID-19 pandemic by the US and global biotech community. Includes potential diagnostics, treatments, vaccine development, and biomedical devices, and reflects the convergence of biobusiness pivots, accelerated scientific research and bioengineering. Topics include accelerated FDA changes, lessons from media coverage, challenges for the CDC, and government response." [26]

Additional Notes: In addition to prepared lectures his course shall be run as a collaborative research seminar. Each student (in two successive sections) shall select a unique global region or country to research. Guest

Figure 2. Exemplar BioE Study Tour Site Visits.

lecturers include the Gilead Sciences head of clinical trials for Remdesivir. A number of recent *BioTech Nation* interviews involving corporate COVID pivots will be utilized.

BioE Biotech Study Tours:

Since January, 2011's inaugural study tour to London/Oxford/Cambridge, USF's Bioentrepreneurship (BioE) program has offered multiple one-week BioE study tours. Other venues have included Switzerland, Washington, DC, Montreal, San Diego, Puerto Rico, Australia, and Ireland/Northern Ireland, this last of which was cancelled due to COVID-19.

In addition to a unique project and presentation related to the cluster or ecosystem visited and speaker reports, students are required to keep a personal journal of the study tour, with elements that were encountered in the BIEM 2.0 model. Students are often able to meet *BioTech Nation* guests, whose interviews they have listened to for an earlier course. At the end of the course, a separate BIEM Report must be made, which rewrites the Personal Journal but in terms of each BIEM category.

Exemplar site visits on earlier tours are described in Figure 2.

EDUCATION 3.0 – EDUCATION IN COLLABORATION WITH BIOTECHNOLOGY INNOVATION ECOSYSTEMS

As pointed out with Education 2.0, the concept of Education 3.0 is not a successor. It describes a different university-ecosystem relationship which can be highly productive. To be clear, this is not the prototypical corporate-university relationship which has been familiar for many years. Instead, with highly receptive innovation ecosystems and the ability of a university to have both breadth and depth in bringing forth breakthrough science and building unprecedented technologies, a new dynamic can emerge. Such is described with regard to UC San Diego in the Abremski and Roben article in this same special issue of the *Journal of Commercial Biotechnology*.[28] They demonstrate an "Innovation Ecosystem Virtuous Cycle" over time.[28] At its core, collaborative in nature, it goes beyond the more typical corporation-university liaison, and also reaches back to the university's graduate research and engineering capabilities and the design of programs which support them.

More consideration must be given as to what is tentatively called Education 3.0 in the confines of this paper. All such constructs with value, scale, and thus, this educational model may well evolve in other places in the greater biotechnology industry. Certainly, its initial description by Abremski and Roben reveals an advanced model of education and entrepreneurship within a world-class biotechnology innovation ecosystem. In other words, Education 3.0 presents a new opportunity.

DISCUSSION AND FUTURE DEVELOPMENT

One of the silver linings of the COVID-19 Pandemic was the absolute necessity to deliver bioentrepreneurship courses in a remote modality. It proved that nearly all

of the courses were readily translatable. In fact, some of the teaching tools improved delivery and student experience. As a result, USF's Bioentrepreneurship program is pursuing:

- The development of a fully online Certificate in Bioentrepreneurship
- The development of courseware supportive of the Digital Health sector
- The intention to continue delivering Bioentrepreneurship courses online in the evening with one meeting per week in the Pacific Time Zone
- The participation of enrollees from a larger segment of the biotechnology industry, particularly with California state biotechnology corridor of San Francisco, Los Angeles, Orange County, and San Diego
- The participation of enrollees who have expertise in one or more of the BIEM disciplines, and who wish to join the Biotechnology Industry in the future
- The resumption of BioE study tours visiting global innovation ecosystems in person when that becomes possible

Bioentrepreneurship education and its related educational research has, as yet, no proven set of pathways; it is itself in a formative state. There are no "best practices" at this early date, and all who develop and teach bioentrepreneurship courses of any sort and at any level are truly innovators, themselves. In fact, they are innovating education for an industry that itself is in constant change. Viewing bioentrepreneurship education as an ever-evolving dynamic may yield the clearest perspective.

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