



# Training the Next Generation of Innovators in Dermatology

Since the 1950s, the number of new drugs approved by the Food and Drug Administration per \$1 billion invested in research and development has fallen 80-fold (Scannell et al., 2012). Dermatology is not immune to this trend. Topical drug innovation has fallen by 45% from 2000 to 2004 compared with 2010 to 2014 with the majority of approvals constituting dosage form changes (Walter and Xu, 2015). Certainly, there have been impressive drug developments for melanoma and psoriasis over the last decade. Dermatology is a field with several very common skin conditions and many rare genetic syndromes, providing numerous unmet clinical needs in the field.

Breakthrough biomedical innovation is driven primarily by highly motivated individuals with direct exposure to the underlying clinical need and a deep understanding of the technology and science space—physicians have played central roles in the discovery and development of nearly every transformative medical innovation used today, including imatinib, trastuzumab, coronary artery stents, and statins (Xu and Kesselheim, 2014). However, the commercialization of new biomedical innovations requires a unique toolset of skills. Entrepreneurship and product development is the pragmatic transformation of innovation into commercial enterprises that provide patients and consumers access to new treatments and services, and generates financial returns to investors.

Classically, entrepreneurship is the subject of business schools, but this area has exhibited significant growth among undergraduate colleges over the past decade. However, entrepreneurship education has yet to penetrate the traditional medical school or residency curricula in a meaningful way. Although the philosophies and motivations of an academic physician and the entrepreneur can differ, supporting entrepreneurship within academic medical centers represents an opportunity to realize the commercial value of cutting-edge science to address unmet clinical needs and potentially fund further research initiatives from the subsequent financial return (Loscalzo, 2007).

Recent graduates create technology companies an order of magnitude more frequently

compared with more senior faculty (Astebro et al., 2012). Trainees and young faculty will be a critical source of future innovation in dermatology. As a field, dermatology has several advantages. Compared with other areas of medicine, product development in dermatology can require significantly less funding and time. For example, VICEPT Therapeutics was able to take a new topical treatment for rosacea through two phase II trials with \$16 million in venture funding before being acquired by Allergan over the span of only 2 years (Gromley, 2011). Next, given the expertise dermatologists have in noninvasive aesthetics, this multibillion-dollar market will continue to represent a high growth area. Indeed, dermatologists have made the most seminal contributions to the development of noninvasive aesthetic procedures (Bangash et al., 2016). Turning to medical dermatology, currently there are also exciting advancements being made. As examples of important product innovation, Anacor Pharmaceuticals has been developing crisaborole, a nonsteroidal boron-based PDE4 inhibitor topical drug, for the treatment of atopic dermatitis, and Aclaris Therapeutics is testing A-101 as a topical treatment for seborrheic keratosis and common warts (2016). As evidence of validation and value creation, Pfizer acquired Anacor for approximately \$5.2 billion in 2016, and Aclaris Therapeutics secured several successful rounds of private financing, leading to what has been rated as one of the top performing initial public offerings of 2015 (Steele, 2015).

Meaningful entrepreneurship education requires both traditional coursework and the opportunity for experiential exposure. There are existing pathways for future scientific investigators in dermatology for future training (e.g., 2+2 programs). The Society of Investigative Dermatology has long hosted a successful resident and physician-scientist retreat for future academicians. For medical dermatologists, there are several dual dermatology/internal medicine residency programs while the Medical Dermatology Society provides career guidance. Translational medicine has incredible promise in bringing breakthroughs in the laboratory to drugs and devices that address unmet clinical needs. However, there still remain major challenges in driving scientific discoveries from academic medical centers into new drugs and devices

(Parrish et al., 2015). For individuals interested in translational medicine and product development, there is a gap in training opportunities. Often times, practicing dermatologists have a unique advantage. As clinicians, they have direct exposure and a real-world understanding of worthwhile problems that need solutions (Xu et al., 2012, Xu and Kesselheim, 2014). Furthermore, the aspiration to apply know-how and tools to find a new solution for their patients that they deeply care about can result in a highly motivated “user.”

Supporting clinician-led innovation is particularly critical, particularly given a 55% decrease in National Institutes of Health funding for MD-only work from 2009 to 2014 (Cheng et al., 2016). Although there are existing entrepreneurship educational programs (e.g., Kauffman Foundation, Stanford BioX), identifying opportunities and initiating early-stage commercialization of innovations specific to dermatology require more specialized knowledge and a supportive ecosystem.

Our group, Advancing Innovation in Dermatology, feels that there is benefit to the field of dermatology to have a resource and nexus for scientists, clinicians, and entrepreneurs interested in dermatological innovation. As a nonprofit organization started in 2011, Advancing Innovation in Dermatology is dedicated to spurring science-based innovation by bringing together key stakeholders to address unmet clinical needs in the field. The organization’s Dermatology Summit and Dermatology Entrepreneurship Conference are now coming up to their fourth and third annual meetings, respectively, and have attracted 350 attendees yearly. Each year, the Dermatology Entrepreneurship Conference hosts a select group of dermatology residents, identified as interested in innovation and nominated by their department chairs, to participate in the meeting. To date, 70 residents have attended the Dermatology Entrepreneurship Conference in 2 years, suggesting a strong, underlying interest in dermatology innovation amongst trainees.

At the 2014 Dermatology Summit, Anacor Pharmaceuticals, Kythera Biopharmaceuticals, and Suneva Medical were all clinical research stage companies in the meeting’s *Entrepreneurial Showcase*. The showcase offers an opportunity for earlier stage companies to engage with the broader dermatology community. Fast forward to 2016. Anacor has submitted its crisaborole topical ointment new drug application for atopic dermatitis to regulatory authorities and has been since acquired by Pfizer for \$5.2 billion (Pennumudi, 2016); Kythera has launched Kybella in 2015 after Food and Drug Administration approval to contour submental fat and has been acquired by Allergan for \$2.1 billion (Stynes, 2015); and Suneva has commercialized Bellafill for acne scars and has received a sizeable equity investment from Almirall SA, a global pharmaceutical company primarily focused on dermatology (Meiling, 2015). Clearly, there are exciting advances being made in dermatology. However, there remains a need to renew the pipeline with inspired and well-trained innovators targeting unmet needs in the field.

To this end of further encouraging and enabling biomedical innovation to substantially improve health and with an eye to the future, Advancing Innovation in Dermatology launched a dermatology-focused innovation curriculum in

July 2016. The curriculum includes presentations by experts on key areas of entrepreneurship, including clinical needs finding, intellectual property considerations, university technology transfer, Food and Drug Administration regulation, fundraising, and other areas. Collectively, these areas are requisite in the continuum of moving an idea to a commercial product that will be meaningful to and accessible to patients. This curriculum is designed to be directly applicable to the unique opportunities and challenges in dermatology. Beyond this, we will facilitate externships and a seed grant program for motivated individuals, particularly residents, graduate students, and postdoctoral fellows, to pursue high-risk, high-reward endeavors. By building a community of innovators equipped with the necessary skills, we hope that more clinical and scientific insights will ultimately be translated to new dermatology-directed product and service innovations.

The future of dermatology depends on our ability to discover and then commercialize new diagnostics and treatments for our patients. Central to this goal is equipping the next generation of dermatology innovators to succeed. As a field, we already attract among the best and brightest committed to the highest levels of clinical care and scientific excellence. By training the next generation of dermatology innovators in product development and early commercialization, we are investing in future breakthroughs.

### CONFLICT OF INTEREST

The authors are members of the Education Committee of Advancing Innovation in Dermatology, a not-for-profit organization.

### AUTHOR CONTRIBUTIONS

All authors were involved in the drafting and critical revision of the manuscript. SX and WJ were responsible for the conception of the manuscript.

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