Abstract: Prof. David W. Grainger, University of Utah, USA

Title: Commercializing Medtech Technologies: Overcoming Challenges to Clinical Translation

David W. Grainger, Ph.D.

Departments of Biomedical Engineering; and of Pharmaceutics and Pharmaceutical Chemistry, Health Sciences, University of Utah, Salt Lake City, UT; USA. email: david.grainger@utah.edu

Clinical technology translation from discovery to humans is stymied by several common challenges. These barriers include the academic inventor "culture", the reproducibility, robustness and reliability of preclinical testing, the formidable costs of conducting clinical trials, and manufacturing at scale and economy. To make an impact on human therapies and medical progress, basic research concepts must appreciate requirements of industrial partners required to commercialize technologies.[1-3] Additionally, regulatory agencies must recognize that the risky exercise of translating new medical technologies to humans is often cost-prohibitive currently. Improved preclinical and human assessment/trial models are needed. Increased clinical trial evidence for efficacy and human benefit/economy is needed.[4,5] Analysis of the translational impasse for any medical devices is complex, confounded by problems in fundamental research models, commercial manufacturing and scaling, regulatory reviews and requirements, and risk-benefit assessments from industry.[6] Nonetheless, technology translation to validated medical application and the eventual transfer of this technology to commercialization is now a common expectation for academic faculty across a broad variety of health-related disciplines. Many models for translation are proposed and only a few are notable successes: despite over 300 dedicated academic technology transfer offices in USA universities, few of these entities generate revenues from commercialization activities sufficient to offset their operating costs.   Utah has a unique model for technology translation with some interesting performance metrics to date in getting faculty and students to innovate and translate, as well as in getting home-spun new technology licensed. This talk will assess the medical device translational landscape and describe the Utah model and some personal examples of medical device translation.

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