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Innovation, Discoveries, and Entrepreneurship

I have worked with Olympus Medical Systems Corporation (Tokyo, Japan) to commercialize fluorescently-labeled peptides that are specific for pre-malignant lesions in esophagus. Stanford OTL filed US Patent No. 8,247,529 entitled "Neoplasia Targeting Peptides and Methods of Using the Same" on these peptides. Olympus optioned the patent and provided funding to support GMP synthesis of the peptide for the pharmacology/toxicology study in animals and the Phase 1 study in humans. The results of the clinical study were recently published in Science Translational Medicine 2013 (PMID: 23658246).

I have had experience with the regulatory challenges involved in the commercialization of novel medical imaging technologies. I have successfully obtained FDA approval for two IND applications (#110,444, #116,907) for novel peptide imaging agents developed in my lab. Also, I have served as PI of the NIH-funded Michigan Research Center in the Network for Translational Research (http://sitemaker.umich.edu/ntr). In this program, I worked on a team consisting of members from academia, industry, and government (NIH, FDA, CMS) to develop guidance documents to accelerate translation of novel optical imaging agents developed in the university setting for cancer diagnostics. We developed consensus documents to establish best practices for academic investigators to validate novel medical imaging devices with companion biomarkers, published in Biomedical Optics Express 2012 (PMID: 22574264). We also defined processes by which optical imaging agents should be synthesized, qualified, and validated for preclinical testing and ultimately for "first-in-humans" studies, published in Biomedical Optics Express 2013 (PMID: 23304655). We met several times with the FDA, including the Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), and Center for Devices and Radiological Health (CDRH), to obtain their input for streamlining this process. We also met with CMS to elicit feedback on the types of data needed to achieve successful CMS determination for future Medicare and Medicaid reimbursement for novel imaging platforms.

In this program, I also worked with a number of industrial partners, including Olympus, GE Healthcare, and Mauna Kea Technologies, Inc, on translation of medical devices to develop standard operating procedures (SOP's) for operational and performance qualification processes to verify medical devices to meet performance specifications. This effort to standardize methods for clinical use is intended to insure reproducibility of data and facilitate the adoption of new technologies by other institutions. Standardization will also allow for traceability of all measurements and requirements, including those that require GMP/GLP processes.

Consulting

2000 – 2000 **Optical Biopsy Technologies Inc**, Santa Clara, CA. This start-up medical device company develops miniature confocal endomicroscopes for performing in vivo histology. My role in this commercialization effort was to develop the prototype instrument, prepare the clinical study protocol, and collect clinical data. The results of the first-in-human clinical study were published in JBO 2012 (PMID: 22463020).

2011 – 2012 **ImBios, LLC**, Minneapolis, MN. This medical imaging company licensed US Patent No. 8,901,276 entitled "Peptide Reagents and Methods for Detection of Colon Dysplasia." These fluorescently-labeled peptides are specific for pre-malignant lesions in colon as a novel diagnostic imaging agent for the early detection of colorectal cancer. on these peptides. My role in this commercialization effort was to support their effort to perform a market analysis, develop a commercialization strategy, define project milestones, establish a timeline, identify competitors, and devise a regulatory plan.

U.S. patents issued

1. **Wang TD**, Feld MS, Wang Y, Van Dam J, Fulghum SF. "Fluorescence Imaging Endoscope," US Patent No: 6,537,211, filing date 01/26/1999, publication date 03/25/03.
2. **Wang TD**, Feld MS, Wang Y, Van Dam J, Fulghum SF. "Fluorescence Imaging Endoscope," US Patent

No: 7,235,045, filing date 03/20/2003, publication date 06/26/2007.
3. Kino GS, Mandella MJ, **Wang TD**, "Two Beam Fluorescence Microscope," US Patent No: 7,130,042, filing date 03/05/2004, publication date 10/31/2006.
4. **Wang TD**, Lu S. "Neoplasia Targeting Peptides and Methods of Using the Same," US Patent No. 8,247,529, filing date 05/15/2009, publication date 08/21/2012.
5. Oldham KR, **Wang TD**, Liu Z, Ye J. "Two-Photon Endoscopic Scanning Assembly for Inflammatory Disease Detection," US Patent No 8,807,801, filing date 01/23/2012.
6. **Wang TD**, Miller SM, Joshi BP. "Peptide Reagents and Methods for Detection of Colon Dysplasia," US Patent No. 8,901,276, filing date 12/19/2011, publication date 09/02/2014.

U.S. patents in process

1. **Wang TD**, Li M. "Targeted Detection of Dysplasia in Barrett's Esophagus with a Novel Fluorescence-labeled Polypeptide," US Patent Application No 12/763,033, filing date 04/19/2010.
2. **Wang TD**, Kurabayashi K, Oldham K, Qiu Z. "Targeted Dual Axes Confocal Imaging Apparatus with Vertical Scanning Capabilities," US Patent Application No 12/916,159, filing date 10/29/2010, publication date 05/26/2011.
3. **Wang TD**, Zhou J, Joshi BP. "Peptide Reagents and Methods for Detection of Dysplasia and Early Cancer," US Patent Application No 62/040,590, filing date 08/22/2014.
4. **Wang TD**, Rabinsky EF, Joshi BP. "Claudin-1 peptide reagents and methods," US Patent Application pending.