

From Bench to Bedside

HJF's technology transfer staff facilitates collaboration between scientists and private industry on research and development projects, with the goal of making innovative medical technologies available for clinical use.

The USU-HJF Joint Office of Technology Transfer (JOTT) was created to advance inventions by Foundation and University researchers.

HJF, in coordination with the USU General Counsel, pioneered the development of a multi-project CRADA for companies wishing to work with University researchers across several projects. Under the arrangement, business and legal issues are negotiated once, then individual projects are added to the agreement as appendices. Multi-project CRADAs facilitate research by streamlining otherwise lengthy negotiation and approval processes.

Breast Cancer Vaccine Trials

A prospective, randomized Phase II clinical trial for a vaccine to prevent recurrence of breast cancer is underway at several military medical centers, thanks to \$2.7 million in funding from sponsor Antigen Express. The trial is testing the HER2/neu peptides GP2 and AE37 to determine if they can prevent breast cancer recurrence in women who have completed standard therapies but are deemed at high risk for recurrence. The researchers also will examine immune system response to the vaccines and will continue to collect information on the vaccines' safety and dosing.

The study is being conducted at multiple military and civilian sites including Brooke Army Medical Center under Colonel George Peoples, M.D. (the study's principal investigator), at Walter Reed Army Medical Center under Lieutenant Colonel (P) Alexander Stojadinovic, M.D., at Madigan Army Medical Center under Lieutenant Colonel David McCune, M.D., at Tripler Army Medical Center under Major Rich Smith, M.D., and at The University of Texas M.D. Anderson Cancer Center under Beth Mittendorf, M.D. (formerly U.S. Air Force). HJF's Clinical Trials Office is providing administrative and management support for the trial.

Another HER2/neu peptide, E75, that was exclusively licensed to Aphera, Inc., from The University of Texas M. D. Anderson Cancer Center and the USU-HJF Joint Office of Technology Transfer is under Special Protocol Assessment by FDA for approval to enter into a pivotal registration clinical trial.

BIO 300

Under an exclusive worldwide license agreement, Minneapolis-based Humanetics Corporation, is testing, developing and making plans to commercialize BIO 300—an oral agent designed to strengthen and protect the immune system against exposure to ionizing radiation—as a treatment for acute radiation syndrome. BIO 300 was discovered by scientists at the Armed Forces Radiobiology Research Institute (AFRRI) and NIH.

Humanetics is collaborating on the development of BIO 300 with AFRRI, the nation's leading center for radiation injury countermeasure research. BIO 300 emerged in 2005 as the leading candidate for commercialization from a group of several oral countermeasures pursued by AFRRI and Humanetics. Two human safety trials with BIO 300 have been successfully completed by Humanetics, and in 2007, FDA granted orphan drug status to the oral agent.

Licensed USU Technologies Lead to Products

Patients with end-stage cancer who develop malignant pleural effusion (MPE)—excess accumulation of fluid around the lungs—can spend much of their last months receiving hospital-based treatments to ease breathing and relieve coughing and chest pain. Often, this treatment involves repeated thoracentesis, in which a needle is inserted between the ribs to remove excess fluid, reducing pressure on the lungs.

The Aspira Pleural Drainage System® from C.R. Bard is designed to provide compassionate home treatment, eliminating the need for frequent hospital visits to treat MPE symptoms. The Aspira kit was enabled by licensed technology for a portable hand pump for fluid evacuation that was invented by a team of USU researchers.

Patented technology from USU has led to an approved, marketed diagnostic test—BioStar®OIA@Shigatox—for Shigatoxins produced by the pathogenic bacteria enterohemorrhagic *E. coli* (EHEC). Alison O'Brien, Ph.D., USU professor and chair of the Department of Microbiology and Immunology, and others in her laboratory are the named inventors of the patented technology, which was licensed by Thermo Electron Point of Care and Rapid Diagnostics, now Inverness Medical-Biostar, Inc. O'Brien is a distinguished researcher who has conducted multiple seminal studies on EHEC, and who serves as President of the American Society for Microbiology, the world's largest scientific society.

Using a core technology for producing solid phase conjugate vaccines invented by researchers in the USU Department of Medicine and licensed from HJF, GlaxoSmithKline has created a vaccine against bacterial meningitis caused by *Neisseria meningitidis* that has been launched in one European country and awaits approval in others and a vaccine against *Streptococcus pneumoniae* that causes life-threatening pneumococcal diseases such as meningitis and sepsis that has been submitted for regulatory review in several European countries.