



TRANSLATION **BUILDER**

FEBRUARY 2017



A Note from the Executive Director

**Welcome to the inaugural issue of
TRANSLATION BUILDER,
the monthly newsletter of the
Advanced Platform Technology Center**

This is one example of our renewed efforts to maintain open lines of communication and build a sense of community among APTC investigators, staff and trainees. As we approach the midway point of our current five year cycle, I wanted to let you know about several new initiatives that are underway, and encourage you to take advantage of what the APTC can offer to help your research program succeed.

1. We recently conducted the first meeting of our new Industrial Advisory Board, consisting of developers and manufacturers of commercial medical devices, to help us improve our interactions with industrial partners, move projects through the translational process and better protect our IP.

2. Investigators and staff now have access to new resources, including a Communications Specialist/Technical Writer (Rebecca Polito) to help tell your story in professionally polished grants and press releases, an Administrative Assistant (Trinity Albertson) to keep us all organized and on track, and a medical illustrator to help us better communicate our work graphically. A statistical consultant will also be available through the APTC soon!

3. We were instrumental in establishing a VA Innovator's Network site at the LSCVAMC,

which solicits ideas for services or processes, including medical devices, that will improve the outcomes of treatment and general health of veterans. VA employees (and active, non-VA appointee collaborators) can apply for up to \$200,000 in funding to translate their innovations into practical solutions.

4. Introducing the APT Center Distinguished Lecture Series – a seminar series in collaboration with CCF designed to feature top scientists in our respective research areas and foster new interactions and collaborations. Look for future seminar announcements, and encourage your peers and trainees to attend.

These are just a few of the new things going on at the APTC. So, please, continue to participate, contribute and be engaged with the Center and each other. **Share your accomplishments** with your peers through this new forum. The Center is only as successful as its investigators. **Let us know how we can help.**

RJT



Investigator's Corner

Ela Plow, PhD, PT

Lerner Research Institute at the Cleveland Clinic
Assistant Professor, Cleveland Clinic Lerner College of Medicine
APTC Research Area: Neural Interfaces

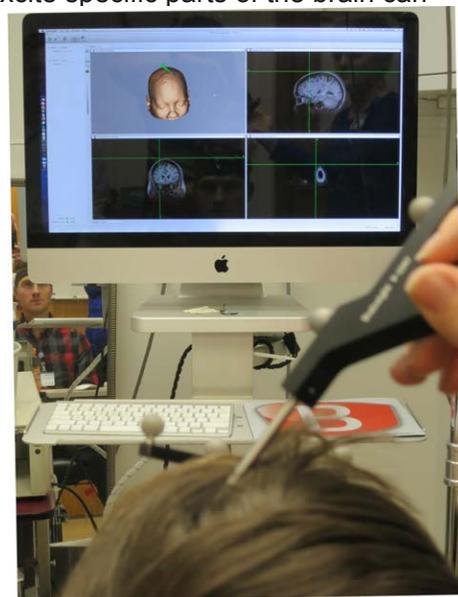
Dr. Plow is working on two clinical neuroscience studies to **restore upper limb function in stroke and SCI patients using brain stimulation**. Her work aims to investigate how the combination of a noninvasive method of brain stimulation, such as Transcranial Direct Current Stimulation (tDCS) or repetitive Transcranial magnetic stimulation (rTMS), enhances the effect of training of an impaired upper limb (for SCI) or hand (for stroke).

NEW DEVELOPMENTS

A new development (not yet in clinical trials) is Dr. Plow's goal of **tailoring the application of brain stimulation** to the level of a patient's impairment of upper limb distal and proximal motor functions after stroke. Using brain stimulation to excite specific parts of the brain can enable proximal motor function, to a certain degree. Like rehabilitation, a stroke patient can retain these benefits with daily work. Unfortunately, all upper limb brain stimulation studies for stroke are effective only for those with mild impairments.

Building from this, Dr. Plow's lab is currently assessing how acute treatments of brain stimulation to varying areas of the brain can improve upper limb function in patients with differing levels of paralysis. Using **targeted, tailored techniques**, Dr. Plow's group is **seeing positive results with the moderately to severely impaired stroke patients**, although the effects do not last long. They have begun to evaluate how the long-term application of tailored stimulation can affect upper limb impairment in stroke.

Dr. Plow's lab is also using neuroimaging (MRI, *right*) and neurophysiological technologies to help develop new, targeted treatments based on the type of impairment and affected area(s).



LAB TEAM

Dr. Plow's team consists of Postdoctoral Fellows Kelsey Potter-Baker, PhD (specialty: SCI) and Yin Liang-Lin, PhD (specialty: stroke), as well as Research Technologist Kyle O'Laughlin, MS. Dr. Potter-Baker is also an APTC Investigator.

RECENT ACCOMPLISHMENTS

Dr. Plow received **funding from the American Heart Association** (\$154,000) for her project titled "Novel Brain Stimulation Therapies in Stroke Guided by Expressions of Plasticity" to

focus on developing a treatment model to personalize brain stimulation treatment for stroke patients and increase the rehabilitative recovery of the upper limbs. She is also a **Co-Investigator on VA Merit Review** “Hand Therapy after Stroke with Contralaterally Controlled FES Plus Video Games” that started earlier this year.

In her career, Dr. Plow has co-/authored over 45 publications, been invited to speak at numerous conferences including the upcoming World Confederation for Physical Therapy in Africa, reviews manuscripts for over 30 scientific journals and has been a grant and/or peer reviewer for such agencies as the NIH, AMA and DOD.



FDA & Quality Fast Facts

Failure modes and effects analysis (FMEA)

Performing a risk analysis, such as a FMEA, is one core activity that all investigators should undertake during their research. **FDA** Design Controls require a risk analysis and most regulatory agencies will request one for your project before reviewing any other data. Having a detailed plan for when an adverse event occurs prevents unnecessary questioning from regulators.

FMEA (ISO 14971:2007)

ISO 14971:2007 specifies a process for a manufacturer to 1) identify hazards, 2) estimate and evaluate associated risks, 3) control the risks and 4) monitor the effectiveness of the controls associated with medical devices, which applies to all stages of the medical device life-cycle.

WHAT IS AN FMEA?

Failure modes and effects analysis (FMEA) is a step-by-step approach for identifying all possible failures in a design, manufacturing or assembly process, or product or service, and to take actions to eliminate or reduce failures.

- **Failure modes** is the way in which something might fail. Failures are any errors or defects, especially ones that affect the customer, and can be potential or actual. Failures are prioritized according to: seriousness of the consequences, frequency and how easily they can be detected.
- **Effects analysis** refers to studying the consequences of those failures.

The primary concerns for most APTC investigators are the risks associated with safety and effectiveness, as well as efficiency and cost.

REMEMBER: When preparing an FMEA, it is important to develop a cross-sectional team; and the scoring of the FMEA should be realistic in regards to Severity, Occurrence and Detectability.

WHEN DO I NEED AN FMEA?

- When a process, product or service is being **designed or redesigned**.
- When an existing process, product or service is being **applied in a new way**.
- When **planning improvement goals** for an existing process, product or service.
- **Periodically** throughout the life of the process, product or service.

HOW DO I START?

The APTC has templates and experts to help guide you through the process. Please contact Edward Panek at (216) 791-3800, ext. 6067, or Edward.panek@va.gov with questions or for assistance regarding quality/design controls.

The APTC offers regulatory and quality support, including consulting services, to investigators at any point along their research and development continuums, from earliest concept to human trials. If you are developing a medical device with the ultimate goal of investigation via human studies, there is a variety of resources to assist you.

FEBRUARY NEWS

Congratulations to Drs. [Jeffrey Capadona](#) and [Dustin Tyler](#) for their selection into the College of Fellows of the American Institute for Medical and Biological Engineering (AIMBE). **AIMBE Fellows** represent the top 2% of the most accomplished and distinguished medical and biological engineers internationally. Their induction ceremony will be held in Washington D.C. in March.



Dr. [Kelsey Potter-Baker](#) received the Outstanding Trainee Researcher award from the Academy of Spinal Cord Professionals. The award is for a project titled “**Transcranial Direct Current Stimulation with Massed Practice to Alleviate Maladaptive Plasticity.**” Our results suggest that long-term pairing with tDCS applied to the motor cortex could result in significant functional improvements by facilitating more permanent plasticity of weaker cortical representations.



Dr. [Steve Majerus](#) reached his 10-year mark with LSCVAMC in January and received a **10-year pin** in recognition of the occasion. As with all military branches, **service recognition** is an important part of the VA's employee recognition and awards program and celebrates the longevity of an employee. Service pins and certificates are available starting with 10 years of service through 50 years at 5-year intervals.

Introducing Dr. Rachel B. Ramoni, our new Chief Research and Development Officer



Dr. Rachel B. Ramoni has been selected as Chief Research and Development Officer, Office of Research and Development, Veterans Health Administration, Washington, DC. Dr. Ramoni is a highly regarded and highly skilled researcher and leader, lauded for her keen understanding of informatics, genomics, and precision medicine. Dr. Ramoni earned a Doctor of Medicine in Dentistry from Harvard School of Dental Medicine as well as a Master of Science and Doctor of Science in Epidemiology from Harvard School of Public Health. She currently holds faculty academic appointments as an Assistant Professor (secondary) at the Department of Biomedical Informatics at Harvard Medical Schools as well as Assistant Professor, Epidemiology and Health Promotion at New York University College of Dentistry.

Congratulations to Dr. [Dustin Tyler](#), recipient of the **Kent H. Smith II Professorship of Biomedical Engineering**. Dr. Tyler's appointment began July, 2016 and the Dean of Engineering at Case Western Reserve University, Dr. Jeffrey Duerk, will hold a grand charring ceremony for him and other professors receiving endowed chairs in March.



TRAINING AND EVENTS

APT Center Distinguished Lecture Series

Semi-active foot prostheses for low-power gait restoration

Presented by Dr. Peter G. Adamczyk

February 24, 2017

11:00a - 12:00p



Abstract: A common biomimetic approach to active lower limb prostheses is to add control to the prosthetic ankle, injecting power to push-off and adjusting angle for different terrain. Yet, artificial limbs offer an opportunity to improve function in novel, non-biomimetic ways as well. One such approach is through modulation of prosthesis mechanical properties, without the addition of mechanical power. This presentation discusses several such "semi-active" devices and the concepts underlying their biomechanical function.

FDA WEBINAR

Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions Final Guidance

February 23, 2017

12:00p - 2:00p

APTC Collaboration Room

(for APTC members only)

<http://www.fda.gov/medicaldevices/newsevents/workshopsconferences/ucm536930.htm>

VENDOR AUDITS

Our Quality Systems Specialist, Ed Panek, will be conducting audits of Ardiem Medical and Cosmed/iuvo Bioscience this Spring.

Please contact Ed at Edward.panek@va.gov if you are having any issues or concerns with these vendors.

UPCOMING GRANT DEADLINES

MARCH

5 - NIH: R01, U01, Renewal, Resubmission, Revision Applications

10 - VA BLRD/CSRD: Merit, CDA, Pilot Applications

12 - NIH: K, Renewal, Resubmission, Revision Applications

12 - VA RRD: [SPiRE Applications](#)

16 - NIH: R21, Renewal, Resubmission, Revision Applications

31 - DOD: [Army Research Office \(ARO\) BAA for Basic and Applied Scientific Research Proposals](#)

APRIL

28 - DARPA: Full Biological Technologies Office (BTO) proposals for 2017

LINKS TO ANNOUNCEMENTS

[ARO BAA](#)

[DARPA Announcement](#)

[NIH Parent Announcements](#)

[VA RFAs](#)

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