Over three years ago, I pitched the idea of starting a research quarterly magazine to celebrate the exciting work that the Foundation is doing in the research space. As the quarterlies have evolved, we are now moving towards a quarterly magazine that celebrates all aspects of our mission. In our next issue, the research quarterlies will be rebranded to touch upon not just the work that we do to accelerate therapies forward, but the incredible advocacy and trainings that the Foundation and its network offer. As I reflect upon the last quarterly focused mainly on research, I think about one of my favorite quotes from Mohammad Ali, which I had selected for the first issue and is posted above.

As someone who is a huge believer of data-driven approaches, I think about this quote often. If something isn’t working, how do we course-correct? What can we learn to do better? In the age of COVID where funding might be scarce and some research activities had slowed, how do we think creatively and differently to push ourselves forward? This past quarter has been a celebration of what some might say was impossible when I first entered the epilepsy space. Around five years ago, there was a genuine fear that companies were giving up on epilepsy, and that we were going to be stuck with the status quo. But the Foundation is constantly thinking, experimenting and innovating for change and we are having an impact. This past August, the Foundation hosted our first ever virtual Pipeline Conference showcasing over 50 different companies and their products in the epilepsy space. There were conversations around not just improving seizure control but how do you go beyond that to improve all aspects associated with epilepsy from cognition to behavior to sleep. There is an incredible amount of innovation currently happening in epilepsy from the devices to monitor the condition to the new therapeutic options in development to the new products that have just hit the market or are about to. During the virtual event, we also hosted our first virtual Shark Tank, which showcases and supports entrepreneurs with unique solutions for epilepsy. Check out the winners and their stories on page 9. To continue supporting this type of innovation and entrepreneurship, we also partnered with the Danny Did Foundation, hosting a 5 week pilot startup course this past month that helped epilepsy companies think through their business plans and get them in front of investors for pitches.

At the Foundation, we continue to push ourselves and stretch what is possible. This fall, we launched the Seizure First Aid Challenge. Register for a free class at epilepsy.com/FirstAid. We want to have over 10,000 individuals certified by the end of the year. I want to hit that number out of the park. Remember, “Impossible is not a fact. It’s an opinion. Impossible is not a declaration. It’s a dare.” Get certified in seizure first aid and help save a life.

Kind regards,

Sonya Dumanis, PhD
VP of Research & Innovation
Galen of Pergamon, a physician and philosopher during the Roman Empire, through his scientific and philosophic writings strove to demystify the structure of the human brain recognizing the importance of anatomy in the understanding of disease. As interest in studying anatomy increased, physicians and scientists made steady progress in advancing knowledge as they dedicated their efforts to unraveling brain structure by applying careful dissection and illustration, intraoperative observations and in the past century the innovative technologies revolutionizing brain imaging. One of the most critical discoveries in visualizing the brain in high resolution came with the introduction of magnetic resonance imaging (MRI) in 1978 through the work of scientists Raymond Damadian, Paul Lauterbur and Peter Mansfield.

MRI evaluation has allowed for improved identification and characterization of brain lesions and provided insight into how alterations in brain structure contribute to neurologic disease. MRI has proven a valuable tool in revealing the underlying causes of epilepsy, for steering treatment decisions, monitoring progression of disease, prognosticating the course of an individual’s epilepsy, and supporting surgical treatments.

The breadth of MRI techniques emerging over recent decades have furthered the utility of this brain imaging bastion beyond structure and into the realm of biochemistry, metabolism and function. Functional MRI (fMRI) takes advantage of the fact that neural activity can be detected by increased cerebral blood flow and changes in oxygenation concentration (Blood Oxygen Level Dependent BOLD-fMRI). Diffusion tensor imaging (DTI) exploits water molecule diffusion and tissue differences in the brain, and has the ability to define microstructure in the brain, as well as to demonstrate the brain’s white matter fibers and tracts to visualize how the brain regions are connected. Both fMRI and DTI are high-powered brain imaging tools which have provided new capabilities that allow for neuroscientists and clinicians to better map and understand epileptic networks in the brain.

The ability to pair fMRI with simultaneously recorded EEG has allowed for brain wave data to be collected and analyzed with high spatiotemporal resolution to estimate the localization of epileptic foci during presurgical evaluation. Magnetic resonance spectroscopy (MRS) can provide supporting biochemical information on epileptogenic regions of the brain, and may be helpful in delineating seizure foci even in the absence of structural brain changes. Advances have also allowed for MRI to be paired with PET (Positron Emission Tomography) which measures brain metabolism. MRI-PET makes possible enhanced images that combine molecular, anatomic, and functional information that can help to direct treatment decisions. Imagine leveraging these new and evolving techniques to create a map of your unique brain traffic patterns to better understand how a seizure begins and how it spreads throughout the brain. This elevated understanding of epilepsy made possible through images helps to lay the groundwork for identifying key brain regions unique to each individual.

Beyond diagnostic capabilities, MRI has changed the way surgical epilepsy treatment is delivered as evidenced by 3D intraoperative renderings, MRI-guided laser therapy and neuromodulatory electrode implantation which rely on the information found in high-resolution MRI images, fMRI and DTI to elevate surgical precision with the goal of improved surgical outcomes and seizure freedom for people with epilepsy. The Foundation has previously invested in several of these areas to improve patient outcomes. For example, in 2011, we supported the development of Visualase® by Medtronic. Visualase® is an MRI-Guided Laser Ablation Technology for Minimally Invasive Neurosurgery to reduce the risk of open-brain surgery for people living with epilepsy. More recently, in 2018, we supported a 3D Machine Vision System for surgical navigation of the human brain (Advanced Scanners) which aims to reduce uncertainties and risks during open brain epilepsy surgery.
In a 2016 Epilepsy Foundation community survey, an overwhelming majority of respondents, regardless of seizure frequency and type, selected unpredictability of seizures as a top issue. Many wrote about the fear of not knowing when a seizure will start and not knowing what triggers the seizure onset.

The survey results inspired an October 2017 workshop, where the Foundation convened clinicians, engineers, data scientists, and pharma/device companies to assess the state of the science behind seizure forecasting. The discussions of the workshop were published in eNeuro in December 2017 and catalyzed the My Seizure Gauge Initiative, a $3 million multi-year grant to bring together an international team of scientists, researchers and interoperability experts to evaluate biosensors that can track an individual’s physiology, behavior, and environment to improve seizure forecasting.

Following a seven-month long, rigorous peer-reviewed process, in 2018, the Foundation selected an international team led by Dr. Benjamin Brinkmann (Mayo Clinic), Dr. Mark Richardson (Kings College London), and Dr. Dean Freestone (Seer Medical/Melbourne University) to move forward. The team’s plan is to recruit, and collect data from people with epilepsy who have received an implanted device that can measure brain activity — such as electroencephalogram (EEG) devices — and pair this with wearable devices to better understand changes in the body that induce or allow for seizure activity. Their charge is to definitively assess the types of measurements that are needed for a reliable seizure forecasting prototype device.

In year 1 of the award, the Solution team evaluated over 6 different biosensors in over 170 individuals and captured hundreds of seizures from wearable devices in the process. The team is committed to sharing its findings with the community and has created a data sharing platform on the epilepsy ecosystem, which is currently sharing some of the data collected from year one. The new frontier for epilepsy monitoring and seizure prediction is non-invasive wearable devices. This dataset affords a unique opportunity to develop new algorithms for epilepsy monitoring seizure detection and seizure prediction. What makes this data set unique is that we are sharing long-term recordings of epilepsy patients, which means there are more seizures per patient, and this offers more data to develop reliable patient-specific algorithms. Click here to check it out!

In year 2 of the award, the teams paired peripheral sensors such as the Fitbit or the Embrace watch with individuals that had implanted EEGs (so that they could track brain activity with the wearable activity in real time). The ambulatory EEG system used depends on the...
recruitment site: Mayo Clinic (Medtronic RC+S intracranial device or NeuroPace), King’s College London (UNEEG 24/7 ambulatory subscalp EEG), and the University of Melbourne (Seer Medical ambulatory video EEG, SeerGP app, and subscalp EEG). There are currently over 15 individuals participating in the study, with more waiting to have their EEGs implanted once COVID restrictions are eased to allow for surgeries to take place.

In year 3 of the initiative, we will be hosting a series of crowd-sourcing challenges to bring the community of innovators and algorithm developers together to tackle personalized seizure forecasting. At the end of the third year, we want to have a prototype for a minimally invasive seizure forecasting device. Just like we can forecast the weather, we want to forecast a seizure.

PUBLICATIONS SUPPORTED BY THE MY SEIZURE GAUGE INITIATIVE

Since the My Seizure Gauge initiative officially began over two years ago, there has been an enormous amount of thought leadership generated by the group. Below is a summary of 9 different publications published by members of the team supported by this effort:

**CIRCADIAN AND MULTIDAY SEIZURE PERIODICITIES AND SEIZURE CLUSTERS IN CANINE EPILEPSY**
This study followed 16 dogs that were diagnosed with focal epilepsy and monitored with ambulatory intracranial EEG devices that have been designed for human use for an average of 65 weeks. The recordings indicated that seizure timing in dogs with naturally occurring epilepsy is not random. Moreover, there were clear circadian, 7-day, and monthly seizure cycles independent of anti-seizure medication dosing suggesting that there are underlying brain rhythms of seizure risk that could be used to forecast a seizure event. Check out the publication here.

**A NEW ERA IN ELECTROENCEPHALOGRAPHIC MONITORING? SUBSCALP DEVICES FOR ULTRA-LONG-TERM RECORDINGS**
The limitations of existing hospital- and home-based monitoring solutions are motivating the development of minimally invasive, subscalp, implantable electroencephalography (EEG) systems with accompanying cloud-based software. This new generation of ultra-long-term brain monitoring systems is setting expectations for a sea change in the field of clinical epilepsy. This paper reviews the converging solutions developed independently by researchers and organizations working at the forefront of next generation EEG monitoring. Check out the publication here.

**MACHINE LEARNING AND WEARABLE DEVICES OF THE FUTURE**
Machine learning is increasingly recognized as a useful tool in healthcare applications, including epilepsy. In this review, the authors summarize the state of the art of using wearable devices and machine learning in epilepsy and potential applications that could radically the way we diagnose and manage patients with epilepsy. Check out the publication here.

**FORECASTING CYCLES OF SEIZURE LIKELIHOOD**
The Epilepsy Foundation’s My Seizure Gauge Initiative wants to create a seizure forecasting tool. Recently, Dr. Pip Karoly published her work that looked at whether data in seizure diaries could be used to forecast the likelihood of when future events would occur. The goal is to create personalized forecasting from mobile seizure diaries. Check out the publication here.
CRITICAL SLOWING DOWN AS A BIOMARKER FOR SEIZURE SUSCEPTIBILITY
My Seizure Gauge researchers looked at recorded long-term brain signals to understand what features in the signal could be used as reliable warning signals before a seizure. They write about a feature known as “critical slowing” that was observed and how it can be incorporated into seizure forecasting algorithms. Check out the publication here.

SIGNAL QUALITY & PATIENT EXPERIENCE WITH WEARABLES FOR EPILEPSY
In year one of the My Seizure Gauge initiative, commercially available wearable sensors were placed on people undergoing in-hospital or in-home EEG monitoring for epilepsy. The goal was to understand which devices have good signal quality and which devices people consistently rated for high usability and comfort. The goal was to better understand the landscape of what could actually work, and where the unmet needs are. Check out the publication here.

SEIZURE DETECTION AT HOME — DO DEVICES MATCH THE NEEDS OF THE EPILEPSY COMMUNITY?
There is a lot of enthusiasm for seizure detection devices and we are all excited about the possibilities that they can bring. But we also need to make sure that the voice of those living with epilepsy and/or caring for those living with epilepsy have their voices heard about what they want. Here, My Seizure Gauge researchers reviewed the evidence on the needs and preferences of users and provide an overview of how current marketed devices for seizure detection stack up. Check out the publication here.

PATIENT AND CAREGIVER PREFERENCES FOR THE POTENTIAL BENEFITS AND RISKS OF A SEIZURE FORECASTING DEVICE: A BEST-WORSE SCALING
To ensure that the needs of those living with epilepsy and their loved ones were at the forefront of any seizure forecasting device developed, the authors sought to quantify patient and caregiver preferences for the potential benefits and risks of a seizure forecasting device. Individuals had to assess various attributes of a theoretical seizure forecasting device such as accuracy of the forecasting and cost. This information can be used to inform future device developers and regulatory agencies about what the community is looking for. Check out the publication here.

SEIZURE FORECASTING FROM IDEA TO REALITY. OUTCOMES OF THE MY SEIZURE GAUGE EPILEPSY INNOVATION INSTITUTE WORKSHOP
This publication provides an overview of seizure forecasting based on the discussions of a diverse group of stakeholders from people impacted by epilepsy and clinicians, to device developers and data scientists, to basic science researchers and regulators convened by the Epilepsy Foundation. For a comprehensive review on the state of the science in seizure forecasting, check out the publication here.
The Epilepsy Foundation is committed to being the voice of the community. Here we provide a summary of two recent community survey reports released through the Foundation.

Access to affordable, quality, provider-directed and person-centered health care is critical for people with the epilepsies. The Epilepsy Foundation conducted a survey of our community in October 2019 to better understand what challenges—if any—people with the epilepsies are facing with accessing the health care they need. The participants for the survey were not recruited through random selection and therefore any results should not be generalized to a broader population. Participants were recruited through convenience sampling; the survey was distributed through the Epilepsy Foundation’s and partner organizations’ communications channels. The Epilepsy Foundation is committed to doing representative samples in the future, but with this data, we can start to better understand the experiences of people with the epilepsies, improve systems that connect people to epilepsy health care and advocate for improved access to care.

In addition to this survey, recognizing that the COVID-19 pandemic is impacting people with the epilepsies’ needs and how people are accessing health care, the Epilepsy Foundation sent an additional survey in April–May 2020 near the beginning of the COVID-19 pandemic to learn about potential emerging trends that could impact access to care. The COVID-19 survey was distributed through epilepsy.com and social media channels.

ACCESS TO CARE SURVEY HIGHLIGHTS

- **59% reported challenges with health insurance.** Of those with health insurance challenges, the most often cited challenge (42.2%) was that the amount they pay is too high, followed by paperwork getting in the way (29%) and a needed service, test or treatment being denied (24.4%).
- **For their epilepsy care and treatments,** most (61.8%) see a neurologist, 26% see a primary care physician and 18.6% see an epileptologist.
- **59% have never been to an epilepsy center for treatment** and of those, 96% have never been referred.
- **45% reported challenges seeing a neurologist or epileptologist.** Of those, the biggest challenge (58.9%) was a long wait for an appointment.
- **70% reported challenges with anti-seizure medications.** Of those, the top challenges were side effects (53.86%), cost (34.14%) and challenges with formulary switches (31.71%).

Click here to read the Access to Care Report.
WE RECEIVED MORE THAN 600 RESPONSES — 75% OF WHOM LIVE WITH EPILEPSY. THIS SURVEY WAS OPEN APRIL 20-MAY 16, 2020, A LITTLE MORE THAN 3 MONTHS INTO THE U.S.-DECLARED PUBLIC HEALTH EMERGENCY. WE RECOGNIZE THAT THE IMPACT ON INDIVIDUALS AND FAMILIES HAS LIKELY EVOLVED AS THE PANDEMIC AND PUBLIC HEALTH EMERGENCY HAVE CONTINUED. DURING THE INITIAL PHASE OF THE COVID-19 RESPONSE, THIS IS HOW PEOPLE RESPONDED: ACCESS TO CARE SURVEY HIGHLIGHTS.

- Of the overall challenges created by the COVID-19 pandemic, the biggest reported challenge was delayed routine medical appointments (35.84%). 25.56% reported no challenges or delays.
- 84% reported no change or delays in taking their epilepsy medications, while 14% said it’s been harder for them to take their epilepsy medications as prescribed.
- With people accessing care through telehealth, 33% felt very prepared for their virtual medical appointments, 37% felt somewhat prepared and 17% did not feel prepared. 9% had not been able to get a virtual medical appointment and 4% did not know what one is.
- People indicated that the following have been negatively impacted due to COVID-19: 42% emotional health; 35% sleep; 22% employment.
- 42% of respondents have not been able to access needed mental health and/or social services.

Click here to read the COVID report.

WHO RESPONDED
Over 600 respondents
75% person with epilepsy
25% answering for loved one

19% of respondents asked to be and were directly connected to an Epilepsy Foundation representative for support

Click here to read the COVID report.
THE EPILEPSY FOUNDATION AWARDED $200,000 TOTAL TO TWO OF THE FINALISTS WHO COMPETED IN THE 9TH ANNUAL SHARK TANK COMPETITION ON AUGUST 27 AT THE 2020 EPILEPSY PIPELINE CONFERENCE, WHICH THIS YEAR WAS HELD VIRTUALLY. INSPIRED BY THE TELEVISION SHOW “SHARK TANK,” THE EPILEPSY FOUNDATION’S ANNUAL COMPETITION INVITES ENTREPRENEURS FROM AROUND THE WORLD TO PITCH THEIR PRODUCTS AND COMPETE WITH FIVE OTHER FINALISTS FOR FUNDING. THE WINNERS, SELECTED BY A PANEL OF “SHARKS,” WILL USE THE FUNDING IN THE DEVELOPMENT AND COMMERCIALIZATION OF A NEW PRODUCT, TECHNOLOGY, OR THERAPEUTIC CONCEPT TO BENEFIT THE EPILEPSY COMMUNITY.

“The Epilepsy Foundation is committed to supporting solution-oriented innovative research,” said Sonya Dumanis, PhD., Vice President, Research & Innovation. “Over the years, we have funded concepts ranging from seizure alert systems, to educational platforms, which have made a huge impact in helping to improve the quality of life of people with epilepsy. We have an incredibly talented community, and we want to empower individuals who have an innovative idea to take on the challenges that people living with epilepsy face every day, and work together with us to find solutions that will benefit the 3.4 million people in the U.S. living with epilepsy.”

Winners of this year’s Shark Tank competition are:

- Jong Woo Lee, MD and Andres Rodriguez (Soterya) for a medical-grade smart-mattress device known as Chorus to reposition individuals and stimulate them post-seizure to prevent Sudden Unexpected Death in Epilepsy (SUDEP). Received $75K based on the audience voting; and $50K from the judges.
- Keely McCarthy, PhD, parent of a child living with epilepsy, for an emergency epilepsy band accessory to ensure that rescue medications are always where a person needs them to be. She received $75K from the judges.

Check out the innovator spotlight interviews with our winners to learn more about their connections to epilepsy and what inspired their product ideas!

The remaining finalists include:

- Attila Borbáth (Synergia Medical) for a vagus nerve stimulation (VNS) therapy called NAO•VNS™, a non-metal implantable neurostimulator that delivers personalized stimulation therapy through fMRI analysis, associated with full body MRI capability and a precise, efficient rechargeable battery.
- Boris Goldstein, PhD, (Brain Scientific) for a next-generation stamp-size EEG with graphene based imprint electrodes that can improve the sensitivity of detection and allow for better remote monitoring of individuals living with epilepsy.
- Aditya Kadambi (Mocxa) for an automated privacy enhancement system known as the 360DID that morphs faces in videos to allow the sharing of seizure features in videos among clinicians and researchers while protecting the privacy of the patient.
The winning entries were selected through voting by conference attendees via a virtual poll following the pitches, as well as a panel of expert judges representing physicians and scientists, corporate executives, leading industry investors, people with epilepsy, and advocates. Among other things, criteria included the potential benefit and appeal to people with epilepsy and their families, and the likelihood of development of their product.

Since 2012, the Epilepsy Foundation has distributed $1.2 million to 16 Epilepsy Foundation Shark Tank winners. Nine previous Shark Tank winners have already made significant advances for people with epilepsy, and five have made it to market, including: SAMi by HiPass Design, UNEEG Medical (CE approved 2019), Embrace (FDA-approved December 2018), Fafanuka (launched in Kenya in 2018), and Zeto (FDA-approved April 2018), which technology is currently part of a groundbreaking EEG study at Methodist University Hospital in Tennessee.

This year’s Shark Tank competition also featured updates from last year’s winners, Curadite and Eysz. Following Epilepsy Foundation seed funding, Curadite has won additional awards for its smart pill packaging and medication adherence platform. They have begun testing their prototype in users for smart pill packaging and has optimized their design based on user feedback. Similarly, Eysz was able to receive follow-on funding including an investment from UCB and a grant from Greenwich Biosciences. In the past year, Eysz has expanded its IP portfolio and completed a Pre-Sub meeting with the FDA confirming the regulatory path forward. In addition, Eysz has initiated a multicenter clinical study towards FDA clearance using analysis of passive eye movements to detect seizures.

For more information about the Shark Tank Competition, please visit: epilepsy.com/SharkTank. If you would like to submit an idea to the 2021 Shark Tank, please send an email to sharktank@efa.org.

We would also like to thank our sponsors, UCB, Otsuka, Pediatric Epilepsy Research Foundation and the Epilepsy Foundation of Minnesota for making this event possible.

Shark Tank Winners

Jong Woo Lee, MD
Keely McCarthy, PhD
Attila Borbáth
Boris Goldstein, PhD
Aditya Kadambi

Finalists
Meet Keely McCarthy, founder of Talia Newman Wearables, LLC. Her product is a line of accessories to ensure that emergency epilepsy medication is always where a person needs them to be. She was also a winner of this year’s Shark Tank competition.

**Q: How you are connected to the epilepsy community?**
**A:** My oldest child Talia was diagnosed with epilepsy in 2015 when she was 9. Before then I knew no more about epilepsy and seizure disorders than anyone else and in many cases much less. Like many parents, we were suddenly in this community, trying to catch up.

**Q: What was an unmet need that you saw?**
**A:** While we were new to epilepsy, this was not the first deep dive into a medical condition as a family: our son was born in 2009 with microtia atresia and unilateral hearing loss. In addition, we had a nephew with severe food allergies. I was already thinking through how every part of a day needed to be set up to be safe and inviting to a child with special needs, how to have systems and plans in place so that they could still do be included in everything. When our daughter was diagnosed with epilepsy, like her cousin with allergies who had an EpiPen, she needed to have her rescue medication on her at all times. She was still an active child with friends and activities, and I wanted that to continue but for her safety plan to follow her wherever she went. I didn’t want there to be barriers to what she could do, as much as we could avoid it. But there was nothing available for her to be able to have her rescue medications easily on hand.

**Q: How did you use your talents to address that unmet need?**
**A:** I am good at putting systems into place, and I did that for Talia—at school, with friends, dance, camp, swimming, theater... her plan and her rescue meds went with her. That process meant educating everyone around her, which was positive for them and empowering for Talia. It taught her right away that there was a lot of value in talking openly about epilepsy. And I am pretty good at problem solving and created several homemade bands to carry her medicine. This inspired me to create Talia Newman Wearables (in honor of my daughter). The company is about creating an accessory line to hold rescue medications for the epilepsy community.

**Q: What does winning the Shark Tank mean to you?**
**A:** It means that I can make something that can become part of everyone’s seizure action plan. I am grateful to the Epilepsy Foundation for supporting this project because it definitely would not come to the market (at least through me!) without this support.

**Q: Anything else you would like the community to know?**
**A:** There are a lot of needs for epilepsy — better and more targeted medicine, less intrusive EEG monitoring, more knowledge and safe guards for Sudden Unexpected Death in Epilepsy (SUDEP)...but there are smaller needs that can make a big difference in supporting people with epilepsy and their loved ones, like protocols, safety plans, education, coordination between doctors around the world, research into sleep and more. This band is one of those smaller things that I hope can make a big difference.
Innovator Spotlight

ANDRES RODRIGUEZ & JONG WOO LEE, MD

Dr. Jong Woo Lee, MD, and Andres Rodriguez, co-founders of Soterya, won this year’s shark tank for their product, a medical-grade smart-mattress device known as Chorus to reposition individuals and stimulate them post-seizure to prevent Sudden Unexpected Death in Epilepsy (SUDEP). We sat down with them to learn a little bit more about what inspired their idea.

Q: How are you connected to the epilepsy community?

DR. JONG WOO LEE: I am an epilepsy neurologist at the Brigham and Women's Hospital in Boston where I direct the critical care EEG monitoring program, see patients in clinic, and run some of the clinical trials. I am on the professional advisory board of the Epilepsy Foundation of New England and long-time co-leader of the Brigham and Women's EFNE Walk for Epilepsy team, the Rhythmic Runners. I serve a variety of roles for the American Clinical Neurophysiology Society, the Critical Care EEG Monitoring Consortium, and the American Epilepsy Society.

ANDRES RODRIGUEZ: I met Dr. Jong Woo Lee in 2017 through the Translational Accelerator at Brigham and Women's Hospital. Since then, Jong and I have been working on finding solutions to prevent Sudden Unexpected Death in Epilepsy (SUDEP). I had participated in a variety of projects with several diseases, and laboratory technologies but at the time, epilepsy was new to me. During this two-year process, I have been finding out that many people around me (family members and friends) were connected to epilepsy. Their experiences have helped me to understand better all the challenges an epilepsy patient faces every day.

Q: What was an unmet need that you saw?

DR. JONG WOO LEE: Six of my patients died of sudden unexpected death in epilepsy (SUDEP), which is a devastating tragedy that strikes otherwise healthy young patients with epilepsy. Although SUDEP is considered rare, it is the leading cause of death in young people with epilepsy. In terms of potential life lost, SUDEP is second only to stroke amongst neurological disorders. Patients who experience generalized convulsive seizures (“grand mal seizures”) are at greatest risk for SUDEP.

Many of these patients die during the night when seizures tend to be more severe and may occur unwitnessed. We believe that SUDEP is a preventable cause of death in many of these vulnerable patients if the patient receives rapid intervention. Most patients succumbing to SUDEP die in the prone (“face down”) position, and because they have impaired arousal after a convulsion, they are unable to reposition themselves. The full mechanism of SUDEP is complicated and not fully understood, but the association of prone position and SUDEP has been well recognized for a long time, and just turning and stimulating them is likely sufficient to prevent SUDEP in many patients. Although seizure detection devices have become quite sophisticated in recent years, we still saw a key unmet need in the lack of intervention after a convulsion. There is about a 3-minute window during

Soterya, a medical-grade smart-mattress device known as Chorus, is designed to reposition individuals and stimulate them post-seizure to prevent Sudden Unexpected Death in Epilepsy (SUDEP). The product was developed by co-founders Dr. Jong Woo Lee, MD, and Andres Rodriguez to address the significant unmet need in the epilepsy community.
which any intervention can be performed, and that’s simply not enough time for most patients to receive help. To address this need, we are developing a nighttime seizure management system, the key component being a smart mattress to turn the patient away autonomously and safely from the prone position after a convulsion, and to stimulate them gently.

The fundamental unmet need remains that seizures in many patients are not well controlled by medications alone, and despite the introduction of many new medications in the past 30 years, it has not made a significant difference. Greater SUDEP awareness will continue to play a key role in further reducing the risk of SUDEP.

[If you need more information on SUDEP, please go to epilepsy.com/SUDEP. Our SUDEP Institute is here to help those looking for answers and/or needing bereavement support.]

ANDRES RODRIGUEZ: When we started the problem was clear; we need to prevent the prone position and assist patients after the seizure and that intervention has to be fast. However, as we brainstormed on solutions, we realized that we needed to have something that could be incorporated in daily life. We didn’t want to modify the way people go to bed or make epilepsy patients feel sick by implementing the solution of constantly waking them up if not needed. We want to offer independence and safety for patients while living a normal life. Chorus does not modify patients’ sleeping habits or lifestyles.

Q: How did you use your talents to address that unmet need?

DR. JONG WOO LEE: After my 5th patient died of SUDEP 2017, I met with my former PhD supervisor, Dr. David Reutens, at that winter’s American Epilepsy Society. We brainstormed about SUDEP prevention and decided that similar to sudden infant death syndrome (SIDS), the post-seizure prone position was a major targetable risk factor of SUDEP, and that the combination of repositioning and stimulating the patient would potentially have a large impact on preventing SUDEP. Once a potentially effective intervention was identified, it became a matter of finding an engineering solution to accomplish this; the system would have to be reliable, sustainable by patients, not interfere with their sleep, not injure them in some way, and be affordable. As I did not have any experience in this area, I needed a lot of help. I hired two medical engineering/device firms to explore a variety of options. The Brigham and Women’s Hospital Translational Accelerator program connected me with my partner Andres Rodriguez, who is an amazing medical device designer and currently the CEO of Soterya. Our advisors at the Consortia for Improving Medicine with Innovation & Technology (CIMIT), Michael Dempsey and Dr. Steven Schachter, introduced to us the Guidance and Impact Tracking System (GAITS) platform to help us think of technical, clinical, regulatory, and marketing in parallel. Susan Linn at the Epilepsy Foundation of New England arranged for a patient focus group and pricing surveys. Greg Mayes, CEO of Engage Therapeutics, whom I’ve met while I was the site PI for the Staccato study, introduced us to his legal team who helped us found Soterya earlier this year; he continues to set an example for us as to what it takes to run a successful small epilepsy-based company. The Massachusetts Biotechnology Council (MassBio) program allowed us to further obtain advice from seasoned medical device experts. Most importantly, my colleagues at the Brigham and Women’s Hospital, particularly our sleep and epilepsy expert, Dr. Milena Pavlova, provided us with support and advice throughout the entire process.

So, as you can see, it takes a village to accomplish something as seemingly mundane as turning a patient safely in bed.

ANDRES RODRIGUEZ: When Jong contacted me, I was immediately on board. I design patient-oriented solutions, first understanding users and exploring problems systemically. As the developer of Chorus, I faced the most challenges at the prototyping level. I had to rethink the mattress entirely, thinking about how to create a seamless user-friendly solution. It took us six months to put together a viable architecture of the product and many different prototypes to get to where we are. Our product has been through different levels of refinement during these two years of development. Throughout the innovation process challenges are inevitable, but it is a very enjoyable process. It is important to be receptive, constant, and curious along the process.
Q: What does winning the Shark Tank mean to you?

**ANDRES RODRIGUEZ:** The Epilepsy Foundation Shark Tank is a very important milestone for us. We are very proud of our achievement but even more proud of having won the vote of the public. This is one of the most important endorsements symbolizing a favorable reception of our solution on behalf of the epilepsy community. Of course, the money will help us to continue building our product but during my career, I’ve learned that money does not solve everything. The real challenge is to achieve a strategic vision and communicate that vision clearly to the team. That was the most amazing aspect of the Shark Tank.

**DR. JONG WOO LEE:** This funding is absolutely critical. Andres and I have bankrolled the development of our alpha prototype entirely with our own resources until now. More importantly, this endorsement, as Andres mentions, is an affirmation of not only our strategy to prevent SUDEP, but also a confirmation that there is a viable business that can support our mission. We will need a lot more funding to see this through, but this has given us a great head start. During the development of this device, my 6th patient died of SUDEP and another colleague lost her patient to epilepsy at a nearby hospital in Boston, so for us, it’s a bit of a race against time.

Q: Anything else you would like to add?

**ANDRES RODRIGUEZ:** Innovation is a ladder but with the support of organizations like the Epilepsy Foundation, this process is stimulated and enhanced. We believe our solution can make a difference and have a relevant impact on the way we manage seizures in bed. The mechanisms of SUDEP are not well understood yet but, we know that the recovery position is the standard procedure to assist epilepsy patients after a seizure, and that is exactly what Chorus does. Chorus adds an important layer of safety in the everyday life of epilepsy patients. We want more independency for patients and less worries for families. We aspire to prevent SUDEP.

**DR. JONG WOO LEE:** We are grateful to the Epilepsy Foundation for selecting Soterya as a finalist and giving us the chance to compete. We continue to be inspired by the incredible technological advances that we see in our every day lives that translates to improve health for our patients. Nobody could have predicted 20 years ago that we would be able to wear computers as powerful as a workstation on our wrists, or that software would be intelligent enough to outperform people in seemingly “human” tasks. We strive to bring the same innovation to mattresses.

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**We need your voice!**

Epilepsy leaders are gathering in January 2021 to SET NEW BENCHMARKS and explore NEW TRANSFORMATIVE IDEAS toward cures and making lives better for everyone touched by the epilepsies. To gather ideas and create a conversation, the National Institute of Health (NIH) has launched a crowdsourcing tool called Ideascle where everyone from the person living with epilepsy as well as top doctors can all share their challenges and visions for change. We want to hear from you!

Sign up here and start adding your stories, photos and ideas.

**NEED HELP?**

- [Step by step instructions are here.](#)
- [Watch a how-to video here.](#)
- [Or submit your comments or get help via email at NINDSIdeaScaleSupport@mail.nih.gov](#)
Pipeline Report

In the midst of COVID, we still have a lot of news coming out of the epilepsy pipeline. See below for the last quarter’s activities

CLINICAL TRIAL RESULTS

- Takeda Pharmaceutical Company Limited and Ovid Therapeutics Inc announced positive topline results from the randomized Phase 2 ELEKTRA study of soticlestat in children with Dravet syndrome (DS) or Lennox-Gastaut syndrome (LGS). Soticlestat is a potent, highly selective, oral, first-in-class inhibitor of the enzyme cholesterol 24-hydroxylase (CH24H). Read the press release.

- Cerebral Therapeutics recently announced results from its Phase 2a clinical trial demonstrating its intracerebroventricular Valproate (CT-010) therapy appears safe and well tolerated for those with drug-resistant epilepsy. Read the press release.

ON THE MARKET

- In late June, the FDA approved FINTEPLA® (fenfluramine) oral solution for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older. In clinical trials, the average seizure frequency decreased by nearly 75% in persons with Dravet syndrome who received the higher dose of active medication compared to only 19% in those receiving placebo. Treated patients had significantly improved quality of life compared to those who received placebo. Zogenix, the manufacturer of Fintepla®, has initiated a patient assistance program to assist those who cannot afford to financially pay for the drug. Read the press release.

OTHER NEWS

- Stoke Therapeutics recently announced that the first patient was dosed with STK-001 in the company’s first clinical trial, a Phase 1/2a study called MONARCH, which is being conducted in children and adolescents ages 2-18 with Dravet syndrome. If successful, this could be the first disease modifying therapy targeting the genetic underpinnings of the condition. Read the press release.

- Epilepsy Foundation former awardee, Epitel, was recently selected for the Pediatric MedTech Innovator Accelerator Program. MedTech Innovator is the premier nonprofit startup accelerator in the medical technology industry whose mission is to improve the lives of patients by matching health care industry leaders with innovative early-stage medtech companies for mentorship and support. Read the press release.

- Epilepsy Foundation awardee Zeto launched its first EEG study at Methodist University Hospital in Tennessee to improve brain monitoring during COVID. Read the press release.

- Neurelis, Inc., announced that it will begin investigating safety and pharmacokinetics of the company’s lead product, VALTOCO® (diazepam nasal spray), in children with epilepsy aged two to five. VALTOCO® is currently available for adults and pediatric patients 6 years of age and older. Read the press release.

Learn more about the Pipeline at epilepsy.com/pipeline
THINK BIG
with Dr. French

EPILEPSY PIPELINE MEETING GOES VIRTUAL

There is one thing (of many) that is true about the COVID pandemic, and that is that one must learn to adapt, in order to accomplish one’s predetermined goals. Although nothing will get done in the same way, during these strange “quarantimes,” it is indeed possible to get things done.

The quarantine hit almost exactly when the Epilepsy Foundation’s pipeline meeting and community day was originally scheduled, on March 12–14, 2020. On March 3rd we made the very difficult decision to cancel the meeting on short notice. At that moment, both the world, and our hopes for the pipeline meeting looked pretty bleak.

Over the next several months we made the decision to go virtual. We faced a daunting task. Did we have time to produce a virtual meeting? What would it be like? Would anyone attend? Would we lose the community spirit and comradery that is an integral part of the meeting? Well, on August 27–29 we finally got a chance to find out.

Would anyone come? Yes, in fact the virtual nature of the meeting meant that people from all over the world could attend from their living rooms, and we ended up with an audience twice as large as we originally expected at the in-person meeting. Over 591 individuals registered for the Pipeline Days and over 500 individuals registered for the Community Day that followed.

Was there community spirit? We think so – there was an active “chat” discussion between participants throughout the event. Overall there were over 50 presentations on drugs or devices currently in the pipeline, which speaks extremely well for future epilepsy innovation. There were panel discussions on wide ranging topics from unmet needs in devices to what is needed to move beyond seizures to how to get reformulated therapies to the marketplace. We even managed to have a virtual “Shark Tank,” our annual competition which highlights 5 different pitches from the community that seek to advance innovative ideas in epilepsy seizure treatment and care. Despite some technical difficulties, there was an active discussion in the audience chat and two winners were crowned.

In the end, we are thrilled that the “virtual” pipeline and community day were as successful as they were. There may be elements that we retain for future meetings, to allow people to attend for whom it otherwise might be a challenge. At the same time, we are hoping that in 2 years, when the next pipeline meeting takes place, we can once again discuss our ideas face to face.
Clinical Trial Portal List

Clinical trials are the way new treatments are tested for safety and effectiveness before being approved and made available to people with epilepsy.

Go to epilepsy.com/clinical_trials to learn more.

RARE EPILEPSY SYNDROME TRIALS

CANNABIDIOL AS AN ADD-ON THERAPY IN TUBEROUS SCLEROSIS COMPLEX
This study is looking at how effective and safe cannabidiol (CBD) is in people 1 year to 65 years old living with Tuberous Sclerosis Complex (TSC). CBD is given in addition to their current anti-seizure medications.

PREVENTING EPILEPSY USING VIGABATRIN IN INFANTS WITH TUBEROUS SCLEROSIS COMPLEX
This Phase IIb trial will test whether earlier treatment versus standard treatment with vigabatrin in infants with tuberous sclerosis complex (TSC) will have a positive impact on developmental outcomes at 24 months of age. It also tests whether early treatment prevents or lowers the risk of developing infantile spasms and refractory seizures. It is a randomized, double-blind, placebo-controlled clinical trial design. Infants under the age of 6 months diagnosed with TSC but without history of seizures or infantile spasms may be eligible.

FOCUSED ULTRASOUND FOR TREATMENT OF EPILEPSY
The University of Virginia Comprehensive Epilepsy Program is conducting a research study on the use of focused ultrasound to treat deep lesions in the brain causing intractable epilepsy in adults 18 to 80 years old. The study will evaluate the effectiveness and safety of an investigational device that uses ultrasound or sound waves from outside the head to treat seizures that are not well controlled by medication and are due to a small growth of abnormal cells in the middle of the brain, most commonly hypothalamic hamartomas.

PERAMpanel STUDY FOR INFANTS WITH EPILEPSY
This clinical research study is being done to learn more about the safety of Perampanel (E2007), the study drug, and how well it’s tolerated in infants, from 1 month to less than 24 months old (<2 years), who have epilepsy.

FOCAL (PARTIAL-ONSET) SEIZURES TRIALS

XEN1101 AS ADJUNCTIVE THERAPY IN FOCAL-ONSET EPILEPSY, WITH AN OPEN-LABEL EXTENSION
Do you still experience seizures despite taking medications for your focal-onset epilepsy? Xenon Pharmaceuticals Inc. is enrolling adult patients with focal-onset epilepsy into a clinical trial for XEN1101, a novel investigational anti-seizure medication. The study drug is taken once a day and study subjects will continue taking their prescribed epilepsy medications during the trial.

ESLICARBZEPINE ACETATE (ESL) AS FIRST OR LATER ADD-ON THERAPY FOR THE TREATMENT OF PARTIAL-ONSET SEIZURES
This study is looking at how effective and safe eslicarbazepine acetate (also known as ESL) is in people 18 years of age or older with partial-onset (focal) seizures, when it is added to their current anti-seizure medication(s).

PFIZER A0081096: LOOKING FOR CHANGES IN EYESIGHT FROM USING PREGABALIN
This study will look at people between 18–65 years old, taking their own anti-seizure medications in addition to either the study drug (Pregabalin) or a placebo. The aim is to look for changes in eyesight.

Epilepsy Foundation’s Human Epilepsy Project (HEP2): Resistant Focal Seizures Study
This study, the Human Epilepsy Project 2: Resistant Focal Seizures (HEP2) is designed to better understand the challenges of living with focal seizures that do not respond to medication and determine biomarkers of epilepsy severity and treatment response.

FOCAL OR GENERALIZED SEIZURES TRIALS

STEREOTACTIC LASER ABLATION FOR TEMPORAL LOBE EPILEPSY (SLATE)
This study is looking at the safety and efficacy of MRI-guided laser ablation therapy with Visualase™ (laser ablation may also be called laser interstitial thermal therapy or LITT) for seizures coming from the temporal lobe in people who are taking seizure medicines.
Mission

Epilepsy Foundation is a nationwide network organization on a mission to lead the fight to overcome the challenges of living with epilepsy and to accelerate therapies to stop seizures, find cures, and save lives. We’re mobilizing action to END EPILEPSY TOGETHER.