RESEARCH QUARTERLY

ISSUE 10: JUNE 2019

Shark Tank Awards
Innovator Spotlight Series
NextGen Scientist Awards
Clinical Trials
With thirty to forty percent of those living with epilepsy being treatment resistant and living with persistent seizures, something radical needs to be done. We need to find new therapies and new innovations that revolutionize the diagnosis, care and treatment of epilepsy. In the June Research Quarterly, you’ll meet entrepreneurs who participated in our Shark Tank event, our early career awardees representing the next generation of scientists, and parents who started companies to tackle challenges that their families are facing.

The creativity and problem-solving capabilities of our community are amazing. Through the Research and New Therapies programs, we are creating opportunities for our community to put those problem-solving capabilities to work. The Foundation is building a stellar track record in supporting epilepsy solutions getting to market. In the last two years alone, five products that received seed funding by the Foundation have reached the marketplace and received regulatory approval including UNEEG Medical (CE approved 2019), Embrace (FDA approved December 2018), Epidiolex® (FDA approved July 2018), Visualase (FDA approved April 2018) and Zeto (FDA approved April 2018). However, our work is not done. As Thomas Edison, arguably one of the most prolific inventors of the last century, once said, “There are no rules here – we’re trying to accomplish something”.

If you have a unique solution that could transform the epilepsy community, we want to hear from you. Please submit your idea through our Shark Tank Awards or Commercialization grants! If you are early on in your career, consider submitting to the American Epilepsy Society (AES) early career funding program. Please go to epilepsy.com/research to learn more.

Kind regards,
Brandy Fureman, PhD
VP of Research and New Therapies
www.epilepsy.com/research

There are no rules here – we’re trying to accomplish something
- Thomas A. Edison
Inspired by the TV show Shark Tank, finalists give a 5-minute pitch to our judges about why the Foundation should invest in their idea to solve the challenges that people living with epilepsy face every day. The audience also gets to vote on their favorite project to fund. Thus far there has been a wide range of novel concepts presented ranging from:

- therapeutic devices,
- seizure alert and self-management systems,
- devices that prevent personal injury from seizures,
- a public awareness campaign abroad.

Winner(s) of the competition walk away with designated funding, ranging from $50,000–$200,000, to help in the development and commercialization of a new product, technology, or therapeutic concept that support our epilepsy community.

In 2019, 35 individuals or teams entered the competition from across the United States and 8 countries around the world. From this pool, 5 teams were chosen as finalists. The finalists presented on May 24, 2019, at the 2019 Antiepileptic Drug & Device (AEDD) Trials Conference in Florida.

2019 Shark Tank Competition Winners

$75,000 AUDIENCE CHOICE AWARD AND $75,000 JUDGES AWARD

DETECTING SEIZURES WITH AN EYE-OPENING SOLUTION

Rachel Kuperman MD
CEO OF EYSZ, INC.

Dr. Kuperman’s mission is to give clinicians and patients the tools they need to improve outcomes and quality of life. The Eyzs solution will help provide specific, sensitive means for detecting seizures through eye-tracking, a relief from EEG monitoring currently needed to detect seizures and seizure-related events. Dr. Kuperman’s desire to bring this project was motivated by the families she cared for during her ten years of clinical practice at the University of California San Francisco (UCSF) Bennioff Children’s Hospital as a pediatric epileptologist.

With this project, Dr. Kuperman plans to develop and deploy 100 eye-tracking wearables that will be used in a clinical study at UCSF. The clinical study will refine the wearables’ patented seizure-detection algorithm for absence seizures.

2019 Shark Tank Competition Winners and Finalists

R. Kuperman J. McNannay M. Musser A. Turabi S. Chiang R. Moss H. Daneels B. Vandendriessche
$50,000 JUDGES AWARD
FALLING DOWN THE RABBIT HOLE OF MEDICATION ADHERENCE
Jody McNannay
Co-Founder, Curadite, Inc.
and parent of a daughter with epilepsy
Curadite plans to optimize its innovative medication management platform for the epilepsy community. The platform incorporates intelligent packaging, patient reminders, and a clinician dashboard. Jody brings her experience as a mother of a child with epilepsy to the project. She has experienced firsthand the difficulty of managing medication adherence and transitioning responsibility for medicine regimens to her daughter as she grows older.
The Curadite platform provides timely support for individuals with epilepsy. It also alerts care teams when loved ones are struggling to take medication as prescribed. Shark Tank funds will be used to develop and customize the platform assisting with medication management. They will also work closely with their research partner to complete the pilot design and recruit the clinicians, patients, and care teams needed for the pilot.

Shark Tank Finalists
SEIZE THE WHEEL: IMPROVING PATIENT CARE THROUGH VR
Matthew Musser
CEO & Founder, Seize the Wheel
Areeba Turabi
CTO, Seize the Wheel
• A virtual reality driving simulator, coupled with the diagnostic abilities of an EEG, that allows physicians to determine the level of consciousness of patients during short epileptic discharges.
• The simulator will help doctors make more informed decisions with patients about day-to-day activities like driving and medication managements.

EPISAT: AN EHR-INTEGRATED CLINICIAN DECISION SUPPORT TOOL FOR DETECTING SEIZURE RISK
Sharon Chiang MD, PhD
Neurology Resident at the University of California, San Francisco and creator of EpiSAT
Robert Moss
Co-Founder of Seizure Tracker
• EpiSAT is an algorithm that has been developed in collaboration with SeizureTracker.com. It uses seizure diary data to estimate a patient’s current level of seizure risk. This data can be sent to both the user and their clinicians’ electronic health record (EHR) system and can be diary agnostic.
• This project will carry out an extension of the EpiSAT algorithm. The extension will increase flexibility to accommodate large scale EHR data. EpiSAT will also be deployed as a clinical decision support tool for beta testing with SeizureTracker.com.

SENSOR DOT: LOGGING SEIZURES AND EPILEPSY BIOMARKERS AT HOME
Hans Daneels PhD
CEO and Co-Founder, ByteFlies
Benjamin Vandendriessche PhD
Chief Medical Officer, ByteFlies
• ByteFlies has developed Sensor Dot, a tiny wearable that can continuously monitors the cardiovascular, respiratory, nervous, and musculoskeletal systems. Sensor Dot can record brain activity (EEG), heart rate, activity and motion, respiration, electromyography (recording of the electronic activity of muscle tissues), andelectrodermal activity.
• ByteFlies also encourages clinicians and researchers to connect with their developing platform to build novel applications that can help people with epilepsy.

Shark Tank Judges
Thank you to the Epilepsy Foundation of Minnesota for supporting this event and to our 2019 Shark Tank judges!
• Page Pennell MD, Professor of Neurology, Harvard Medical School, Director of Research, Division of Epilepsy, Brigham and Women’s Hospital, Boston, MA
• May Liang, Co-Founder, General Counsel and Chief Financial Officer, OpenConcept Systems, Inc.
• Terrence O’Brien MD, Professor of Medicine, Department of Neuroscience and Medicine, Monash University, Australia
• Tracy Dixon-Salazar PhD, Director of Research and Strategy, LGS Foundation
• Timothy Feyma MD, Gillette Children’s Specialty Healthcare
Do you have an idea for the next Shark Tank? Submissions will open in the fall of 2019, with the finalists presenting at 2020 Epilepsy Foundation Pipeline Conference in Santa Clara, CA. www.epilepsy.com/sharktank
UPDATE FROM 2018 SHARK TANK WINNERS

3D MACHINE VISION SYSTEM FOR SURGICAL NAVIGATION OF THE HUMAN BRAIN
Aaron Bernstein PhD
President and CEO, Advanced Scanners

Jeff Levine MIM, Advanced Scanners
Open resective brain surgery for epilepsy begins with the surgeon creating an opening in the skull. The surgeons rely on image-guided navigation systems to guide their movements within the brain. These navigation systems rely on previously scanned images of the patient’s brain. The problem is that when you open the skull, the brain changes its shape. Advanced Scanners wants to improve navigational systems and surgical outcomes with a rapid, noninvasive 3D scanning approach. Working with neurologists and neurosurgeons at the Dell Children’s Comprehensive Center in Austin, Texas, Advanced Scanners has been developing an intelligent 3D machine vision system. This system watches during surgery and tracks the exposed brain with sub-millimeter accuracy to improve results in each of the 3 major steps of a typical 2-stage epilepsy surgery. These steps include providing accurate locations of the grid electrodes, mapping the surface of the brain at high resolution during surgery to improve what the neurosurgeon sees and updating the brain shape changes during real time. This all contributes to a more precise navigation system for the surgeon to rely on. This also should make the brain surgery procedure safer for the patient.

Since their shark tank award last year, they were able to:
• Move out of Aaron’s garage into actual office space (through an award with WeWork)
• Submit patents to the US Patent Trade Office
• Hire 2 additional staff members to further their prototype development
• Establish partnerships with Medtronic, Medline and Ansys
• Secure 1.5 million in follow on funding
• Product to be available by the end of 2020!

VIRTUAL REALITY MEDICAL SIMULATION FOR THE MANAGEMENT OF STATUS EPILEPTICUS

Joshua M. Sherman MD
Faculty Attending – Division of Emergency Medicine, Children’s Hospital Los Angeles

Todd Chang MD, MACM
Assistant Professor of Pediatrics, USC-Keck School of Medicine

Drs. Sherman and Chang develop virtual reality simulations to allow the community to better train both medical and non-medical professionals for highly stressful emergency epilepsy situations. Usually trainings are done using mannequins and actors, which are expensive and constrained to when the actors are available. In contrast, a virtual reality (VR) module is portable, standardized, and still allows for an immersive experience. VR allows for training at any time of day. The doctors had partnered up with Oculus’ VR for Good program and companies AiSolve and Bioflight to design a prototype module for status epilepticus in the pediatric population. This simulation won Best Virtual Reality Education Project at the 2018 VR Fest and was written up in USA Today and Buzzfeed. Using an Occulus Simulator, trainees can be assessed on their training readiness and taught what to do in high-stakes situations like treating a child in status epilepticus.

Since their award, they were able to:
• Establish their own company known as SBC Medical Simulations
• Improve training and assessment tests for medical resuscitation during status epilepticus
• Provide diagnostic testing options for doctors to train on evaluating during emergency situations
• Add an adult status epilepticus module
Charles and Cynthia Anderson are the co-founders of HiPass Design LLC, makers of SAMi - The Sleep Activity Monitor for Individuals. SAMi is an infrared camera-based motion detection alert system used to detect and record unusual movements at night. Charles is personally connected to epilepsy. We spoke with Charles to learn a little bit more about his connection to epilepsy and what motivates him to do the work that he does.

What is your personal connection to epilepsy?
In 2006, my son had his first tonic-clonic seizure while we were out of the country. He went on medications right away and we thought he was well controlled. What we didn’t realize was that he was still having seizures in his sleep. We had no idea that someone could have seizures in their sleep and not be aware that they were happening. It was only when we were on another family trip sharing a hotel room that we witnessed his night-time seizures.

How often was he having nighttime seizures?
When we got home, we rigged up a baby monitor in his room. It turns out that he was having them a couple of times a month. My wife was losing sleep listening to the baby monitor throughout the night in fear that he would have a seizure and that we wouldn’t know about it. Sleep, Seizures and Impact on Families

What did you decide to do?
I looked for night-time monitors but couldn’t find anything suitable. I am an engineer by training and put those skills to use. I bought a networked security camera and created software that would stream the video to a program I wrote that could analyze our son’s movement in the night. Anytime there was abnormal movement, the computer would turn on in our room with an alert and live video so that we could check to see if everything was ok. Over time, we began to refine the algorithm to try and reduce the false alarms. For example, if movement starts at the edge of the camera and goes to the center, this was one of us going in to check on our son and wouldn’t require an alarm alert.

How did this turn into SAMi (a commercially available seizure activity monitoring camera)?
In 2011, I read about the Epilepsy Therapy Project’s new “Shark Tank” competition. I presented the concept and my prototype and won the award. I used the award money to fund turning my prototype into the product we have been selling for the last seven years.
How does the system currently work?
SAMi uses a camera in the bedroom that works in complete darkness. The video data is sent to an iOS device (iPhone/iPad/iPod) that is running an app I wrote to look for unusual movement. The parent or other care-partner typically has this on a nightstand by their bed. While the app is running it displays a clock. When unusual movement is detected an alarm is sounded and the iPhone turns on the live video and audio feed from the room where the person with epilepsy is. Moreover, all of these events are recorded, time-stamped and archived for your review later as well. Since the award and the improvements in design, we have sold around 6,000 of these devices around the world.

“It [SAMi] makes sleep possible for us,” said Leslie D. on the Epilepsy Foundation Facebook page.

How is your son doing now?
My son is seizure free! In his last year of high school, he decided the risk of surgery was outweighed by the benefit of having more seizure control and independence. At that point we had tried all the available medications. After doing the work-up at the epilepsy center and determining that he was a good candidate he had a temporal lobe resection. He is still on medications, but he is living a seizure free life.

Learn more about the journey through epilepsy surgery on epilepsy.com/surgery
Visit The Brain Recovery Project, a nonprofit focused on helping navigate the decisions around epilepsy surgery and support after surgery.

Is there anything else that you would like to add?
I wanted to thank the Epilepsy Foundation for the early support through the Epilepsy Therapy Project. But more importantly, I wanted to stress the importance of monitoring for night time seizures. Whether you use our system or another system, please consider using one!

If you are considering seizure detection devices, here are some of the questions to think about:
• What do you want the device to do once a possible seizure is detected?
• What is your living situation, and does it fit with the device requirements?
• Do you want to use the device outside of the home?
• Do you want data from the device to be shared with other people?
• How much does the device cost?
• Are there any downsides to using the device?
• Can the device prevent sudden unexpected death in epilepsy (SUDEP) or any of the factors that may lead to SUDEP?

When considering a device, please talk to a healthcare professional. If you need assistance or want to learn more about devices, the DannyDid Foundation is an excellent resource.

3.4 MILLION PEOPLE IN THE UNITED STATES LIVE WITH EPILEPSY AND SEIZURES
1 IN 10 PEOPLE WILL HAVE A SEIZURE IN THEIR LIFETIME
1 IN 26 PEOPLE WILL BE DIAGNOSED WITH EPILEPSY IN THEIR LIFETIME

“I AM AN ENGINEER BY TRAINING AND PUT THOSE SKILLS TO USE.”
- CHARLES ANDERSON
Greg Mayes is the president, CEO, and founder of Engage Therapeutics. Engage Therapeutics is an epilepsy company founded in 2017 to clinically develop and progress a product called staccato alprazolam. Staccato alprazolam has the opportunity to become the first FDA-approved inhaler therapy to abort an active seizure. Greg is also personally connected to epilepsy. We sat down with Greg to learn a little bit more about his connection to epilepsy and what motivates him to do the work that he does.

**What is your personal connection to epilepsy?**
In the summer of 2014, I was on vacation with my family. We were at the breakfast table when my son dropped his face in the bowl of cereal. At first, I thought he was horse playing, then I realized he might be choking. It was his first generalized seizure.

**Had you ever witnessed a seizure before?**
Looking back, my son had probably had other seizures. We always assumed that seizures were the type shown in the movies, the tonic-clonic motor movements. We hadn’t realized the many different ways that a seizure could manifest.

**What was one of the hardest aspects of watching your son’s seizures?**
The rules of seizure first aid are simple: stay calm, time the seizure, keep him safe, and stay with him until he is alert again. Most seizures end in a few minutes, but those can be the longest few minutes of your life. I knew that if the seizure lasted longer than 5 minutes, I needed to call 911. But other than that, there was nothing I really could do.

**Go to epilepsy.com/firstaid to learn about seizure safety**
When my son went on school trips, I had to check the box that said that there is a medical condition the school field trip organizers needed to know about. I would always get the question about whether I could send some rescue treatment along. But there wasn’t a viable option. We didn’t have an EpiPen option for epilepsy. That is what excites me about Engage Therapeutics. When I heard about this product, I wanted to help bring it to market. We need rescue therapy options.
Go to www.engagetherapeutics.com to learn more about the product and the trial.

What experience do you bring to the epilepsy space?
I had been a pharma executive for over 20 years. My entire career was in the business and legal departments of life science companies. In 2014, I was working in the cancer field. It was extremely rewarding to be in that space. But with my son, watching his seizures, I felt so helpless. I wanted to use my experience and expertise to help the epilepsy community in some way.

What has been your biggest challenge so far at Engage Therapeutics?
We want sound science to ensure that the product works before it gets to market. For this, we need to complete the clinical trials. Recruitment can be really tough because we need participants who are known to have weekly seizures that last a few minutes. This is critical, because we want to be positive that our inhaler is working and stopping the seizures. We want to test this on over 120 individuals to be confident in the product. We are now halfway through recruitment and have 42 sites around the US, Caribbean, Australia and Canada.

Is there anything else that you would like to add?
I wanted to genuinely thank the Epilepsy Foundation. It was through the Foundation leadership that I got connected to the resources our family needed. It was also through the Foundation, that I was able to learn about potential business investment opportunities and the licensing opportunity with this product. More than half of the Engage team is personally affected by epilepsy and we are in full support of the Foundation’s mission, both nationally and locally. The Engage team is actively participating in many of the Foundation’s sponsored Walks to END EPILEPSY®. So, if you are listening and attending, please come by and see us at the booth to learn more about how you can help bring this important product to market.

“\nI WANTED TO USE MY EXPERIENCE AND EXPERTISE TO HELP THE EPILEPSY COMMUNITY IN SOME WAY.\n
- GREG MAYES"
We are proud to partner with American Epilepsy Society (AES), to attract the best and the brightest in the field. Since the 1960s, the Epilepsy Foundation has supported the careers of over 3,000 researchers.

AES/EF CLINICAL RESEARCH & TRAINING FELLOWSHIP: BEHNAZ ESMAEILI MD
TITLE: INTRACRANIAL EEG SUPPRESSION AND HEART RATE VARIABILITY IN EPILEPSY
INSTITUTION: BRIGHAM AND WOMEN’S HOSPITAL

AES/EF JUNIOR INVESTIGATOR RESEARCH AWARD: WILLIAM NOBIS MD, PHD
TITLE: THE ROLE OF THE EXTENDED AMYGDALA IN RESPIRATORY CONTROL AND SUDEP
INSTITUTION: VANDERBILT UNIVERSITY MEDICAL CENTER

SUDEP is the sudden, unexpected death of someone with epilepsy, who was otherwise healthy. In SUDEP cases, no other cause of death is found when an autopsy is done. Each year, about 1 in 1,000 people with epilepsy die from SUDEP. The mechanism(s) of SUDEP are still under intense investigation by researchers in the US and across the world.

The most consistent risk factor for SUDEP is frequent generalized tonic-clonic (GTC) seizures. Certain individuals experience a dramatic suppression of brain activity after a GTC seizure. This phenomenon is also linked to the altered state of consciousness post-seizure, which can last between 5 to 30 minutes. In addition to the change in brain activity, clinicians have also observed decreased heart rate variability in individuals post seizure. In a healthy heartbeat, you would experience healthy irregularities. For example, if you place a finger on your pulse, you would notice that your pulse can change based on how you breath (exhale versus inhale). These heart rate variabilities are dampened post-seizure. The question remains about whether the characteristics of the brain activity suppression and the decrease in heart rate variability post-seizure could be indicators of increased risk for SUDEP.

To answer this question, Dr. Esmaeili’s will be mining data from a data repository from the epilepsy monitoring unit of 5 major academic epilepsy centers to understand the range of characteristics of the brain activity and heart rate variability post-seizure, and whether there are any significant factors in either of these two measurements in confirmed SUDcP cases. This work could highlight physiological factors that indicate who is at higher risk of SUDcP.

Sudden unexpected death in epilepsy (SUDEP) is the leading cause of death in people with uncontrolled seizures. Seizure-related apneas (cessation of breathing during a seizure) are being observed in epilepsy units where respiratory status is consistently monitored. When SUDEP has occurred in a healthcare setting, apnea has been observed prior to the terminal cardiac arrhythmias. This suggests that SUDEP might be a lethal combination of a seizure related apnea along with impaired consciousness in the individual post-seizure.

In previous work, Dr. Nobis established that an area of the brain known as the extended amygdala, which when stimulated causes apnea. Dr. Nobis hypothesizes that this region or the parabrachial nucleus, another area implicated in respiratory control, may be activated during a seizure and thus cause the observed seizure-induced apneas. Using animal models that study SUDEP, he will test whether and how these brain regions are impacted during a seizure, and how this can impact respiratory control. Understanding this pathway and its role could open up new prevention strategies for those at high risk of SUDEP.
A somatic mutation is a genetic mutation that occurs as a cell divides in the developing body. If there is a genetic mutation that occurs during the division, this would be contained to the cell that the mutation occurred in and the other cells that this cell helped to create afterwards. There is evidence of somatic diversity in the brain, which means that specific brain cell populations have a genetic mutation in their DNA not associated with other brain cells or organs in the body. Some of these somatic mutations in the developing brain have been linked to focal cortical malformations associated with pediatric drug-resistant epilepsy.

To better understand how somatic mutations could impact epilepsy and brain circuits, Dr. Gamboa has created a mouse model that causes brain cell specific genetic mutations that activate the mTOR pathway during cortical development. There are many studies that observe a frequent hyperactivation of mTOR signaling in epilepsy. For example, seizures associated with Tuberous Sclerosis, a rare genetic epilepsy syndrome, is treated by mTOR inhibitors. In this research proposal, she will explore how somatic mutations in the mTOR pathway in a contained population of neurons result in network abnormalities that lead to epilepsy. The disease mechanisms that arise from this research could lay the groundwork for new therapeutic approaches.

**SUDEP**

Learn more about SUDEP by going to the SUDEP Institute, a program within the Epilepsy Foundation at epilepsy.com/SUDEP or SUDEP Institute/Epilepsy Foundation on Facebook. The Institute promotes and supports research to eradicate SUDEP, brings awareness and education around it and supports the bereaved.

**UPCOMING RESEARCH GRANTS**

**SUDEP BIOMARKER CHALLENGE**
Submissions open now
Prize for $800,000

**EPILEPSY FOUNDATION MY BRAIN MAP RESEARCH GRANTS**
Extended deadline: Letters of Intent due July 26, 2019
Award up to $200,000

**EPILEPSY FOUNDATION SHARK TANK AWARDS**
Letters of Intent due September 16, 2019
Award up to $200,000

**AES EARLY CAREER DEVELOPMENT AWARDS**
Letters of Intent due October 1, 2019
Award up to $50,000 over 1 year

**EPILEPSY FOUNDATION CLINICAL RESEARCH TRAINING APPRENTICESHIP AWARDS**
Applications due October 1, 2019
Award up to $35,000 for three months of research spread out throughout the year

**SUSAN S. SPENCER CLINICAL RESEARCH FELLOWSHIP**
Applications due October 1, 2019
Award up to $150,000 over 2 year

**EPILEPSY FOUNDATION NEW THERAPY COMMERCIALIZATION GRANTS**
Information on deadline coming soon
Award up to $200,000

Do you have questions or a research funding opportunity to share?
Email grants@efa.org

Want to donate funds to research?
Go to: donate.epilepsy.com/donate-research
The Epilepsy Learning Healthcare System (ELHS) is building a quality improvement and research network dedicated to improving outcomes for children and adults with epilepsy.

Confirmed clinical sites now include:

- Barrow Neurologic Institute (AZ)
- Beth Israel Lahey Health (MA)
- Children’s Hospital of Atlanta (GA)
- Children’s Hospital of Philadelphia (PA)
- Partner’s Healthcare (MA): Brigham & Women’s and Massachusetts General Hospitals
- Penn State Hershey Children’s Hospital (PA)

The 2nd ELHS Learning Session took place on Monday May 6th in Philadelphia, PA. Ms. Monika Jones (The Brain Recovery Project Childhood Epilepsy Surgery Foundation) and Ms. Priscilla Kobi (Epilepsy Foundation) graciously provided Ignite Talks sharing their experiences with epilepsy - focusing the attendees on the reason for the work.

Site teams (made up of clinicians and patient & family partners from the Community Engagement Core) are currently working on improving seizure documentation both on the clinician and patient sides.

The next phase of work will focus on medication adherence (a key driver of seizure control) – this will begin with an evidence review and roll-out of the next change package at the October 27th ELHS Learning Session in Charlotte, NC.

For more information on the Community Engagement Core of the ELHS please contact Ms. Alison Kukla. Work is currently underway to connect REN and other organizations, as well as local Epilepsy Foundation teams, with clinical sites as they come on board – please share with your networks the news of this opportunity!

For more information on the Clinical Core, please contact Dr. Kathleen Farrell - kfarrell@efa.org
In May, the U.S. Food and Drug Administration approved the use of NAYZILAM® (midazolam) nasal spray for use in children age 12 and over and adults with epilepsy.

- Nayzilam is a rescue therapy for acute (immediate, short-term) treatment of intermittent, stereotypic episodes of frequent seizure activity. This means that the medicine can be used to treat seizure clusters, bouts of increased seizures, or acute repetitive seizures.
- It can be given by a non-medical person outside of a hospital setting – when a person needs it!
- It’s a nasal spray that can be given easily by the person with epilepsy between seizures. Or it can be given by someone else to a person during a seizure.
- Nayzilam (midazolam) is from a group of drugs called benzodiazepines. It is very good at stopping seizures quickly when used intermittently or “as needed” for specific situations.
- It is NOT approved as a seizure medicine to be used on a daily basis. And it should not take the place of a person’s usual seizure medication.

**FDA: BREAKING NEWS!**

**RESCUE THERAPIES CAN BE CRITICAL TO HELP STOP PERIODS OF SEIZURES THAT COULD LEAD TO SEIZURE EMERGENCIES, HOSPITALIZATIONS AND EARLY DEATH**

**MY SEIZURE GAUGE**

**PUBLICATION ALERT**

We are getting better and better at forecasting the weather. What if we could do the same with seizures? The Epilepsy Foundation My Seizure Gauge initiative is leading an effort to create an individualized seizure gauge that will allow a person with epilepsy to monitor the likelihood of a seizure on a daily basis. For this effort, we are promoting user-centered design concepts and asking our community what they would want in a hypothetical seizure forecasting device. For this effort, we created 18 prototype device descriptions that systematically varied across six attributes: seizure forecasting probability, seizure forecasting range, inaccuracy of forecasting, amount of time required to use the device, how the device is worn, and cost. Respondents of the survey indicated what would be the best and worst features of the device and whether they would use the prototype if it existed. Our survey findings were recently published and extend previous calls for seizure forecasting devices by demonstrating the value that they might provide to patients and caregivers affected by epilepsy and the feature that might be most and least desirable. In addition to guiding device development, the data can help inform regulatory decisions makers. To review the article, click here. To learn more about the My Seizure Gauge Initiative go to www.epilepsy.com/myseizuregauge

**EPILEPSY LIFETIME ACCELERATOR AWARD**

The Epilepsy Foundation awarded the Epilepsy Lifetime Accelerator Award to Professor Martin J. Brodie, M.D., president of the International Bureau for Epilepsy. Dr. Brodie has been involved in epilepsy drug development for more than 30 years and was principal investigator on numerous trials that brought new therapies to market. He was an innovator of novel trial designs and is arguably the most recognized speaker on new anti-epileptic drugs in the world.
Each year, more than 1 out of 1,000 people with epilepsy die from sudden unexpected death in epilepsy (SUDEP). If seizures are uncontrolled, the risk of SUDEP increases to more than 1 out of 150. SUDEP is the leading cause of death in young adults with uncontrolled seizures.

Among the 65 million people worldwide living with epilepsy, nearly one-third have ongoing seizures despite existing therapies.

To accelerate the identification of effective treatments for SUDEP, the Epilepsy Foundation SUDEP Institute is sponsoring a $1 million challenge to develop a predictive biomarker to identify people at risk for SUDEP. If we can know who is at risk, we can develop prevention strategies and intervene before it is too late.

With the help of our partners at InnoCentive, all of the challenges allow us to take advantage of interdisciplinary approaches and alternative perspectives. Through combining and contrasting ideas, the best and most valuable solutions will be identified and financially supported.

**PLEASE CONSIDER DONATING** to funding the winning solution – it will be a win for ALL who have a loved one living with epilepsy.

**Current Challenge!**

The Final Challenge of our Final Challenge is live now and open until October 10, 2020!

Biomarkers may be genetic, structural within the body, metabolic, physiological, or something else that is quantifiable.

The winning biomarker will be easily and safely measured, cost-efficient to detect, modifiable with intervention (something we can actively treat or prevent), be consistently associated with SUDEP or life-threatening seizures, and will drive human intervention. For example, the biomarker may identify a high-risk patient group to allow testing of existing interventions such as seizure detection devices.

Learn more go to epilepsy.com/sudep
Clinical trials are the way new treatments are tested for safety and effectiveness before being approved and made available to people with epilepsy.

**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.

**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.

Effectiveness of Inhaled Staccato Alprazolam in Treating an Episode of Focal or Generalized Seizures
A new clinical trial is looking at how effective and safe orally-inhaled alprazolam (also known as STAP-001) is in people 18 years of age or older with focal or generalized epilepsy when given at the time of a seizure episode. This study is commonly referred to as STATES (Staccato Alprazolam Terminates Epilepsy Seizures).

Go to epilepsy.com/clinical_trials to learn more.
UPCOMING CONFERENCES

2019 DUP15Q ALLIANCE SCIENTIFIC SYMPOSIUM
July 17-18, 2019, Houston TX
https://www.dup15q.org/events/scientific-conferences/2019-dup15q-alliance-scientific-symposium/

BRAIN RECOVERY PROJECT
July 19-20, 2019, Cleveland OH
https://www.brainrecoveryproject.org/parents/programs/conferences/2019conference/

3RD FAMILIESCN2A FAMILY AND PROFESSIONAL CONFERENCE
August 1-3, 2019, University of Washington, Seattle, WA
https://www.scn2a.org/conference.html

SUNFLOWER SYNDROME FAMILY CONFERENCE
August 4, 2019, Massachusetts General Hospital
https://because.massgeneral.org/event/sunflower-syndrome-family-symposium/e182170

BRIDGE SYNGAP FAMILY MEET UP
August 16-17, 2019, Baylor College of Medicine-Texas Children’s Hospital, Houston, TX
https://bridgesyngap.org/houston-family-meetup/

INTERNATIONAL CONFERENCE FOR TECHNOLOGY AND ANALYSIS OF SEIZURES, 2019 (ICTALS2019).
September 2-5, 2019, University of Exeter, UK
http://www.exeter.ac.uk/livingsystems/newsandevents/events/ictals2019/

5TH INTERNATIONAL LAFORA EPILEPSY WORKSHOP
September 8-10, 2019, Alcala, Spain
Contact Cheylene.plummer@uky.edu

4TH INTERNATIONAL SYMPOSIUM ON HYPOTHALAMIC HAMARTOMAS
September 12-14, 2019, Washington DC
http://www.hopeforhh.org/4th-international-symposium-on-hypothalamic-hamartomas/

PARK CITY EPILEPSY MEETING
October 6-8, 2019, Park City, UT
http://www.parkcityepilepsymeeting.com

CHILD NEUROLOGY SOCIETY 48TH ANNUAL MEETING
October 23-26, Charlotte, NC
https://www.childneurologysociety.org/meetings/future-cns-annual-meetings

BRIDGE THE GAP FAMILY MEET UP
November 9-10, 2019, Johns Hopkins School of Medicine and Kennedy Krieger Institute, Baltimore MD
https://bridgesyngap.org/syngapinternationalconference/attachment/baltimore-meetup/

AMERICAN EPILEPSY SOCIETY ANNUAL MEETING 2019
December 6-10, 2019, Baltimore, MD
https://meeting.aesnet.org/about/future-meetings

PIPELINE CONFERENCE 2020
February 20-22, 2020, Santa Clara, CA
https://www.epilepsy.com/pipeline2020

Have a conference that you want to share? Email lschreiber@efa.org