“So many of our dreams at first seem impossible, then they will seem improbable, and then, when we summon the will, they soon become inevitable.” – Christopher Reeve

About a third of people living with epilepsy do not have seizure control because no available treatment works for them. Those whose seizures are controlled are still at risk of breakthrough seizures. This may seem like an insurmountable challenge, but we at the research department believe that nothing is impossible. But we cannot do it alone.

Together, with our local Foundations across the US and through our external partners, so much is possible. Our vision is a world without epilepsy and lives free from seizures and side effects. Our purpose is to develop an epilepsy research ecosystem that covers the entire spectrum of discovery – from the idea to market.

A successful research environment is one where partnerships spur innovation and exciting discoveries for epilepsy. Under the vision and leadership of Warren Lammert, the Epilepsy Therapy Project was established to advance novel epilepsy projects and companies through promoting innovative ideas and entrepreneurship. In 2012, the Epilepsy Therapy Project merged with the Foundation. That same year, the Foundation began hosting an annual competition event where entrepreneurs pitch products, technologies or therapeutic concepts, all of which must benefit people with epilepsy, to a panel of judges. The event was inspired by the TV show Shark Tank. In this issue, we look back to celebrate some of the work that we have supported through these competitions and how we have helped catalyze products to the marketplace in a timeframe that matters. Go to page 2-3 to learn more.

We believe in supporting conferences that bring all voices to the table. This past quarter, we helped organize and co-sponsor the “Accelerating the Development of Therapies for Anti-Epileptogenesis and Disease Modification” workshop in partnership with the host organization, the National Institute of Neurological Disorders and Stroke (NINDS), and fellow co-sponsors Citizen’s United for Research in Epilepsy (CURE) and the Tuberous Sclerosis Alliance (TSA). Please go to page 5 to learn more. We also attended the Partners Against Mortality in Epilepsy Conference, go to page 6 to learn more.

As Christopher Reeve pointed out, nothing is impossible. What we support today can have a huge impact on tomorrow. Working together, the possibilities become limitless.

Sincerely,

Brandy Fureman, PhD
VP of Research & New Therapies
www.epilepsy.com/research

Have Feedback or Questions about the Research Quarterly?
Please send your feedback to Sonya Dumanis, sdumanis@efa.org.
Solving the challenges of living with epilepsy in a timeframe that matters #EpilepsySolutions

Each year, the Epilepsy Foundation hosts a competition where entrepreneurs pitch products, technologies or therapeutic concepts to a panel of judges. Each competitor must demonstrate how their idea will directly benefit people living with epilepsy. The event was inspired by the TV show Shark Tank. The goal is to convince the panel of judges and the audience that their idea and business plan is the best option for Foundation investment.

Thus far there has been a wide variety of novel concepts presented, ranging from seizure alert and self-management systems to public awareness campaigns and educational tools.

Winner(s) of the competition walk away with financial investment awards ranging from $50,000-$200,000. All funds are designated to help in the development and commercialization of a new product, technology, or therapeutic concept.

These awards are making an impact! Here, we highlight the progress from our 2016 winners zEEG and M-Kifafa.

2016 awardee update—zEEG by ZETO – Making EEGs Easier to Perform

An electroencephalogram (EEG) measures brain activity. Since 1924, the EEG reading procedure in the hospital has not significantly changed. The process normally entails a trained technician measuring the head, sorting through hair, marking electrode locations, and applying paste and electrodes to the scalp with the goal of eventually tethering the patient to a box with wires. It is an hour-long procedure that is tolerated well by most, but for some people it can be more difficult. Not to mention having to leave the EEG lab with sticky paste in your hair!

A new company proposed a radical change. At the 2016 Shark Tank, a company called Zeto was awarded $150,000 to further develop their prototype into a comfortable, wireless, dry-electrode headset that could be used to perform a routine or urgent EEG anywhere without the need for a technician.

Since their award, Zeto has altered the prototype design and expanded recording capabilities to improve the quality of EEG recordings. Moreover, the headset design has been modified to look more like a bike helmet and ensure the best possible reading. The device can also stream EEG records to a secure cloud platform, enabling remote interpretation. Zeto was getting closer to achieving their goal of a wear, share and diagnose technology that eliminated the trip to the hospital, increased the comfort level for people and made the possibility of having an EEG more likely for others.

In 2017, the Foundation provided further investment through our New Therapy Commercialization program to assist in the manufacturing of the device prototypes.

In 2018, zEEG was the first dry EEG headset technology approved by the Food and Drug Administration (FDA). Zeto is starting to work with hospitals across the country to implement the new EEG systems.

“Epilepsy Foundation funding set the ball rolling for us. The validation helped position Zeto as a disruptive startup, gain credibility, raise investor funding, and expedite our overall progress.” — Aswin Gunasekar, Founder, Zeto, Inc.

How could this new technology transform your life? Email us at sharktank@efa.org or share your thoughts on social media. Tag us @EpilepsyFdn

#EpilepsySolutions

Do you have an innovative idea for the epilepsy community? www.epilepsy.com/sharktank

Accepting new submission ideas starting September 28, 2018.
2016 awardee update –
M-Kifafa – Creating an Epilepsy Information Service in Kenya

Currently, 800,000 people in Kenya suffer from epilepsy, or Kifafa, in Swahili, where fewer than 20% of cases are identified, diagnosed, and treated. In Kenya, many still believe that epilepsy is supernatural in nature. This coupled with the lack of medical expertise, and few services in rural and semi-urban areas makes it hard for those living with epilepsy to receive medical treatment.

To reduce this epilepsy treatment gap, Rosemary Gathara wanted to create an epilepsy information service through M-Kifafa, a mobile technology designed to increase epilepsy awareness in Kenya and empower individuals with the information they need. Through a partnership with the nonprofit Text to Change, Rosemary wanted to develop an SMS platform to send Kenyans reminders and information on epilepsy care. In turn, people impacted by epilepsy and their caregivers would send epilepsy related information back to M-Kifafa which would then be aggregated and shared with the Kenyan Ministry of Health to aid in their plans of addressing access to important medications and the training needs of primary health workers.

In 2016, Rosemary Gathara was awarded $50,000 in seed funding to support this initiative. Within a few months, M-Kifafa was up and running on Safaricom, the largest mobile provider in Kenya, which has over 80% of the market.

The M-Kifafa mobile phone epilepsy information service initiated by KAVE has now been scaled up to an NCD (Non-Communicable Diseases) information service dubbed FAFANUKA. Thank you for helping make this possible. — Rosemary Gathara, Program coordinator for Kenya Association for the Welfare of People with Epilepsy

What are other ways that technology could help spread information and improve access to care? Email us at sharktank@efa.org or share your thoughts on social media.

Tag us @EpilepsyFdn #EpilepsySolutions

These incredible stories are examples of how the Epilepsy Foundation makes strategic investments in a timeframe that matters for people living with epilepsy today.

Do you have an innovative idea for the epilepsy community? www.epilepsy.com/sharktank

Accepting new submission ideas starting September 28, 2018.

New App Available on Google Play Store for Seizure Detection

Amir Helmy was in the seventh grade when he heard a family friend talking about the expensive monitoring equipment people with epilepsy had to rely on to monitor their seizures. The year was 2012, five years since the launch of the first smartphone. Amir had a simple thought. Our smartphones have accelerometers that can detect motion. Why not use the smartphone to better aid people living with epilepsy, their families and caregivers in managing their daily lives? With this question, the concept of the mobile application Seizario was born.

The Seizario app includes both:
- automatic detection of several emergency scenarios through motion detection
- easy and immediate communication of critical information to family members and caregivers.

The Seizario app is now available for free on Google Play! Let us know how it works! #EpilepsySolutions

In 2014, Amir presented his Seizario concept at the Epilepsy Foundation Shark Tank competition. He won $75,000 to develop a free phone app for detection of motor seizures. Seizario is now available for free on Google Play!
New Seizure Medicine - Diacomit

“For many years families of patients with rare forms of epilepsy such as Dravet syndrome have struggled to obtain stiripentol from other countries where it is approved for use . . . It will now be available in the United States, a very welcome change, that will provide improved access for children who might benefit.” – Dr. Jacqueline French, chief scientific officer of the Epilepsy Foundation and professor at NYU Comprehensive Epilepsy Center

DIACOMIT, also known as stiripentol, recently was approved by the U.S. Food and Drug Administration (FDA) to treat seizures associated with Dravet syndrome in children 2 years of age and older who are also taking clobazam.

- Dravet syndrome is an epilepsy syndrome seen in children that can be quite severe. Seizures are very difficult to control. Children with this type of epilepsy have a higher number of seizure emergencies and carry a higher risk of early death from sudden unexpected death in epilepsy (SUDEP). Other neurologic and developmental problems may occur in children with Dravet syndrome too.
- Diacomit, manufactured by Biocodex, was found to be helpful in children with Dravet syndrome who had clonic and tonic-clonic seizures during two clinical trials. 67 and 71% of children had a decrease in seizures by at least 50% from their baseline.

Promising Results for an Investigational Drug for Treating Dravet Syndrome

In July of this year, Zogenix, Inc reported positive results from its secondary confirmatory Phase 3 study for its investigational drug, ZX008 (low-dose fenfluramine hydrochloride), for the treatment of children and young adults with Dravet syndrome. The study results, which are consistent with those reported in Zogenix’s first pivotal Phase 3 study, showed that at a dose of 0.5 mg/kg/day, ZX008 performed better as an add-on seizure medication compared to a placebo for changing the number of monthly convulsive (for example, tonic clonic) seizures. Due to the positive results, they are now focused on submitting applications for regulatory approvals in the U.S. and Europe in the fourth quarter of 2018. Thank you to all of the volunteers who participated in testing the drug in clinical trials. Are you interested in clinical trials? Go to www.epilepsy.com/clinical_trials

Insurance Coverage of Laser Ablation by Aetna

In December 2017, Cara, a young woman with epilepsy was denied coverage by Aetna for laser ablation surgery recommended by her epilepsy team. The story caused an uproar in our community. We are pleased to announce that Aetna health insurance has recently changed its policies regarding the use of laser ablation procedures for the treatment of some forms of refractory epilepsy. Thank you, Cara, for sharing your story and fighting for this important change that can help so many people with epilepsy! Sharing your stories matter!

Did you know? The Epilepsy Foundation supported the early development of laser ablation for epilepsy surgery. In 2011, we gave out a new therapy commercialization grant to Ashok Gowda, to test whether MRI-guided laser ablation would reduce the risk of open-brain surgery in epilepsy. Later, this technology was acquired by Medtronic and is now used in epilepsy centers across the country. #EpilepsySolutions
COMMUNITY LEARNING

The epilepsy community often lacks the resources to come together to tackle issues that impact the community. We want that to change. We believe in creating open channels of communication between people living with epilepsy, their families, advocates, researchers, healthcare professionals, industry, and investors. To accelerate and advance research and epilepsy medical care, it must be shared, modeled upon, and expanded. That is why we actively support conferences and workshops throughout the year.

If you need support for hosting a conference, reach out to us. We have set aside limited funds to sponsor ongoing conferences in our community. We will prioritize conferences that satisfy the following 3 criteria:

1. An agenda with highly innovative topics on epilepsy
2. Inclusion of both basic and clinical science perspectives
3. Conference hosts provides travel support for young investigators and members of under-represented groups, so they can attend the proceedings

Please contact grants@efa.org for more information.

MOVING FORWARD TOGETHER

Current epilepsy medications do not treat the underlying cause of epilepsy, but instead only treat seizures, which is a symptom of epilepsy. Knowledge gaps in understanding biological underpinnings of epilepsy are currently precluding the field from developing treatments. That is why focusing on epileptogenesis, how the brain develops epilepsy, is a top priority.

Epileptogenesis is the term used to describe the biological processes that lead otherwise normal brain tissue to develop epilepsy.

This past quarter, we helped to organize and co-sponsor a workshop on “Accelerating the Development of Therapies for Anti-Epileptogenesis and Disease Modification” in partnership with the host organization, the National Institute of Neurological Disorders and Stroke (NINDS), and fellow co-sponsors Citizen’s United for Research in Epilepsy (CURE) and the Tuberous Sclerosis Alliance (TSA).

The goal of the workshop was to develop a roadmap for how to move the field forward. The workshop organizers are preparing a detailed summary of the meeting for publication. Stay tuned to learn more about what we can do to catalyze the field forward.

Workshop Publication Alert

In October 2017, the Epilepsy Foundation helped host the Cannabinoids in Epilepsy Therapy workshop. This workshop brought together researchers, clinicians, and advocates for people with epilepsy to discuss the science on how cannabinoids control seizures and identify knowledge gaps. The proceedings of the workshop were published in August in Epilepsy and Behavior.

Learn more about the workshop and publication here: https://bit.ly/2o3kryo
SUDEP stands for sudden unexpected death in epilepsy and refers to deaths in people with epilepsy that are not caused by injury, trauma, or other known causes. A lack of seizure control is the primary risk factor for SUDEP, which takes the lives of approximately 1 in 1,000 people with epilepsy each year – when seizures are uncontrolled, the individual risk of SUDEP rises to 1 out of 150 annually. For people with uncontrolled generalized tonic clonic seizures who experience 3 or more seizures per year, the risk of SUDEP is increased 15-fold.

Determined to bring an end to SUDEP and help people with seizures live to their fullest potential, the Epilepsy Foundation launched the SUDEP Institute in 2014. The goals of the institute are to

- Carry out SUDEP education and awareness for people impacted by epilepsy and medical professionals
- Drive and support research into the causes of and ways to prevent SUDEP
- Offer bereavement support services and a secure online community for those affected by SUDEP
- Work together with other epilepsy organizations to find the answers to SUDEP and help families with epilepsy

The SUDEP Institute took part in the 2018 Partners Against Mortality in Epilepsy (PAME) Conference held June 14-16 in Alexandria, Virginia, which brought together and engaged people focusing on preventing death from epilepsy. Attendees included researchers, medical professionals, and families from around the world. Together, attendees shared progress and set an agenda on what work is next.

This year’s conference was led by co-chairs Tom Stanton, executive director, Danny Did Foundation; Dr. George Richerson, University of Iowa; and Dr. Elizabeth Donner, Hospital for Sick Children. Conference sessions included these topics:

- Where we are with the science
- Trends in frequency of SUDEP and other causes of early mortality

Note that in addition to SUDEP, there was also a focus on all forms of preventable premature mortality in people living with epilepsy. Other causes of mortality in epilepsy that are not considered SUDEP are related to injury, drowning, higher suicide rate and deaths related to status epilepticus (when a seizure lasts too long).

The SUDEP Institute will be sharing additional details on the various sessions, links to presentations, as well as recordings of certain conference sessions as they are made available.

www.epilepsy.com/SUDEP

Determined to bring an end to SUDEP and help people with seizures live to their fullest potential, the Epilepsy Foundation SUDEP Institute is currently challenging Solvers worldwide to identify specific and sensitive biomarkers of SUDEP to facilitate the development of interventions for people at high risk. A biomarker is a biological molecule that can be found in blood, other body fluids or tissues that signal a normal or abnormal process of a condition or disease.

The Epilepsy Foundation SUDEP Institute partnered with InnoCentive to offer the Biomarker Challenge. The Challenge is open to anyone, across the world, who has a Solution that can address the specific Challenge request.

Learn more at www.epilepsy.com/research under Upcoming Grants

Want to join the Epilepsy Foundation Research Team?

JOB OPENING: Clinical Research Coordinator

https://www.epilepsy.com/make-difference/careers/clinical-research-coordinator
Clinical Trials Portal – Studies Actively Recruiting

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.

Partial-Onset (Focal) Seizures Trials

Eslicarbazepine 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

The Epilepsy Foundation is launching a new partnership, called the Human Epilepsy Project, in collaboration with the Epilepsy Study Consortium. 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

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).

Epilepsy Genetics Initiative (EGI)

The Epilepsy Genetics Initiative (EGI) was created by Citizens United for Research in Epilepsy (CURE) to bridge the gap between people with epilepsy, clinicians, and researchers and tailor advances in medical care and decision-making to individual patients. The EGI has created a centralized database to hold and analyze the genetic data of people with epilepsy.

Learn more at: www.epilepsy.com/clinical_trials
Upcoming Research Grants

Shark Tank Ideas
Submissions open September 28
Letter of Intent due December 14, 2018
Award up to $200,000

Susan S. Spencer Clinical Research Training Fellowship
Submissions open
Applications due October 1, 2018
Award up to $150,000 over 2 years

SUDEP Biomarker Challenge
Now accepting submission entries
Award up to $800,000

AES Early Career Funding Opportunities
Submissions open November 1
Letter of Intent due December 20, 2018
Awards range from $30,000 to $50,000

Rare Epilepsy Network
Now accepting research data requests

Learn more at www.epilepsy.com/research under Upcoming Grants
Have a conference that you want to share? Email ahansell@efa.org