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*“Talent wins games, but teamwork and intelligence win championships” – Michael Jordan*

Through our research program, we strive to create a rich ecosystem that continually drives innovation forward to solve the challenges and remove the roadblocks that stand in the way of ending epilepsy.

## GOALS



### Innovation

*Pushing new areas and ideas for epilepsy*

- ▶ Epilepsy Innovation Institute
- ▶ Epilepsy Therapy Project
- ▶ Targeted Research Programs



### Engagement

*Building collaborative networks between people with epilepsy, their families, healthcare providers, researchers and investors*

- ▶ Learning Healthcare System
- ▶ Human Epilepsy Project
- ▶ Rare Epilepsy Network
- ▶ Research Roundtable



### Next Generation Scientists

*Supporting our developing workforce*

- ▶ Clinical Research Fellowships
- ▶ Junior Investigator Research Awards
- ▶ Clinical Apprenticeships



### Digital Tools

*Developing tools to support research infrastructure*

- ▶ Clinical Trials Portal
- ▶ Pipeline Tracker
- ▶ My Seizure Diary

Here at the Foundation, we are constantly growing our championship team to tackle the challenges of living with epilepsy. This team consists of many partners and collaborations throughout the community. In 2018, we are focusing on enhancing this ecosystem. For the June Research Quarterly, we want to highlight the connections and partnerships that we have made over the past quarter.

On page 2, we announce the launch of the first Epilepsy Foundation clinical study – The Human Epilepsy Project 2 to better understand drug-resistant focal seizures. This is a partnership between the Epilepsy Foundation and the Epilepsy Study Consortium. The study is also co-sponsored by UCB, a global pharmaceutical company in the epilepsy space.

On page 3, we announce our new 2018 Next Generation Scientist Awards. In partnership with the American Epilepsy Society (AES), we have a long history of supporting the career development of young investigators. We believe in pooling resources to reduce administrative overhead and thank AES for their partnership in this effort.

On page 4, we discuss the Research Roundtable in Epilepsy, an Epilepsy Foundation initiative to bring together patient organizations, senior scientists from pharmaceutical, biotechnology, and diagnostic companies as well as regulatory agencies such as the U.S. Food and Drug Administration and the European Medicines Agency to address roadblocks to research and development. On pages 5-6, we continue to discuss other stakeholder engagement initiatives from attending conferences to supporting the National Institutes of Health All of Us Initiative.

In 2017, we launched a clinical trials portal to connect people with epilepsy to research studies that need them. On page 7, we list 9 different studies that are currently seeking volunteers.

As Michael Jordan said, “teamwork and intelligence wins championships.” We at the Foundation are committed to winning the fight for those living with epilepsy. Together, with our local Foundations across the US and through our external partners, we grow stronger.

Sincerely,  
*Brandy Fureman, PhD*  
**VP of Research & New Therapies**

**EPILEPSY IS...**  
MORE COMMON  
THAN YOU THINK



**65 MILLION**  
people around the world  
who have epilepsy



**1 IN 26**  
people in the United States  
will develop epilepsy at  
some point in their lifetime

### Have Feedback or Questions about the Research Quarterly?

Please send your feedback to Sonya Dumanis,  
[sdumanis@efa.org](mailto:sdumanis@efa.org).



## Human Epilepsy Project: Resistant Focal Seizures Study (HEP2)

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.

### What is the HEP2 Study?

The HEP2 study will monitor 200 people with [treatment-resistant](#) focal epilepsy (with seizures that occur at least 4 times per month) over a two-year period to measure changes in seizure frequency, treatments used, adverse events, presence of comorbidities such as depression and anxiety, healthcare costs, and quality of life.

### Who can participate?

Participants can join the HEP2 study at any of nine recruiting study epilepsy centers selected because of their track record of conducting high-quality research in epilepsy and efficiently recruiting participants into studies. **The designated nine sites for the HEP2 study are located in New York, California, Pennsylvania, Connecticut, Minnesota, and Tennessee in the United States, and in Finland.**

Study participants will be asked to track their seizures, symptoms and medications using [My Seizure Diary](#), a self-

management web tool developed by the Epilepsy Foundation specifically for seizures and epilepsy. In addition, participants will need to share their medical records with the research investigators and travel to the clinical site two or three times over the course of the study for health visits and blood samples. A participant may enroll in the HEP2 study but continue to receive their standard epilepsy care with their current physician.

Help us learn more about epilepsy by sharing your experience.

### Join the Human Epilepsy Project today!

Call: **1-800-332-1000**, email: [info@humanepilepsyproject.org](mailto:info@humanepilepsyproject.org) or visit: [www.HEPStudy.org](http://www.HEPStudy.org) to learn more.

*We currently don't have biomarkers for epilepsy to help us predict what treatments might work best for a specific patient, or when a patient's seizures might get better or worse . . . [HEP2 will look] for patterns in the molecules that are shared by people who have similar kinds of seizures, or who have similar responses to medication. The goal is to one day develop targeted treatments with the potential to control seizures faster.*

- Jacqueline French, M.D., Chief Scientific Officer of the Epilepsy Foundation and Professor of Neurology, NYU Langone Health's Comprehensive Epilepsy Center.



#### HUMAN EPILEPSY PROJECT (HEP2) RESISTANT FOCAL SEIZURES STUDY

200 people with treatment-resistant focal epilepsy from around the United States have the opportunity to change the lives of millions by joining in the newest Human Epilepsy Project study on focal seizures. Could you be one of them?



#### THE STUDY

#### UNDERSTANDING THE CHALLENGES



This project will look at changes in seizure frequency, treatments used, comorbidities like depression, healthcare costs, and quality of life over time.

#### NATIONAL EFFORT



Enrolling 200 participants from across the U.S. who have frequent focal seizures that do not respond to medications

#### ANNUAL CHECK-UPS



Participants complete seizure diaries and other online surveys, along with annual in-person visits to collect biosamples over a two-year period.



Learn more at [www.HEPStudy.org](http://www.HEPStudy.org)

Interested? Enroll at [Info@humanepilepsyproject.org](mailto:Info@humanepilepsyproject.org)

*This new research study is another step in our efforts to better understand focal epilepsy and uncover data that will help accelerate therapies to help people with epilepsy have seizure-free lives. We believe HEP2 could have a major impact on prevention strategies, treatments and cures for those who have not responded to current treatments.*

- Dr. Brandy Fureman, Vice President for Research & New Therapies, Epilepsy Foundation



## Next Generation Scientists

The Epilepsy Foundation, in partnership with the American Epilepsy Society (AES), supports young investigators. More information on 2018 awardees and what they will be studying is to the right and below.

### AES/EF Clinical Research & Training Fellowship

Garnett Smith, MD

University of Michigan

**Research Topic: Using Biomarkers to Construct Spatial Models of the Epileptic Network**

The goal of this project is to combine information from electroencephalograms (EEGs) between seizures and during seizures to make a 3-D tool to help physicians localize the epileptic network. Epileptic networks are the brain regions that are involved in producing and propagating seizures. These brain regions often produce abnormal electrical activity. Computerized analysis of EEG signals has allowed researchers to detect this abnormal activity and use it to better understand where seizures might be coming from in a patient's brain. The proposed study uses previously published methods to combine information about electric signals that occur between seizures (called high frequency oscillations or HFOs) with information about activity that occurs at the time that seizures start and spread (called an epileptogenicity index). Dr. Garnett Smith will map these HFOs and epileptogenicity index onto a 3-D map of the patient's brain to show areas of the brain that are likely involved in producing seizures. Improved knowledge of where seizures arise has the potential to improve the success rate of epilepsy surgery.

### AES/EF Junior Investigator Research Award

David Scott Auerbach, PhD

University of Rochester

**Research Topic: Mechanisms for Seizures in Long QT Syndrome Type 2**

The goal of this project is to understand how cardiac abnormalities may contribute to sudden unexpected death in epilepsy (SUDEP). Dr. Auerbach is interested in the cross-talk between the heart and the brain. Specifically, he studies genetic diseases that develop electrical disturbances in the brain (seizures) and in the heart (arrhythmias) which result in sudden death. Previously, Dr. Auerbach demonstrated that in Dravet (a severe genetic form of epilepsy), there is not only alterations in electrical function in the brain but also in the heart. These findings suggested that cardiac dysfunction could be a risk factor and underlying cause for SUDEP. Now, he is approaching the brain-heart link in the opposite direction.

Specifically, he is focusing on Long QT Syndrome-2 (LQTS2), a classically studied cardiac disease associated with sudden death. Recently, he showed that LQTS2 can also be associated with higher rates of seizures. Yet, the mechanisms for why LQTS2 can lead to seizures is unknown. Around 60% of LQTS2 patients have a mutation that alters their potassium channels, which are important in stabilizing neuronal electrical activity. Dr. Auerbach has developed a rabbit model of LQTS2 to better study how the potassium channels are changed in the brain. Understanding the brain-heart connection can help shed new light on sudden death and lead to future prevention strategies.

**Susan S. Spencer Clinical Research and Training Fellowship** *Cosponsored by the American Academy of Neurology, the American Brain Foundation, the American Epilepsy Society, and the Epilepsy Foundation*

Hiroki Nariai, MD

UCLA Medical Center

**Research Topic: High Frequency Oscillations (HFOs): A Specific Biomarker of Pharmaco-resistant Epilepsy**

The goal of this project is to test whether high-frequency oscillations could be a predictor of who would respond well to surgery as a treatment option for drug-resistant epilepsy. Traditionally, EEG analysis for clinical interpretation is analyzed at frequencies under 30Hz. With advances in technical equipment and optimized analysis, researchers are starting to look at high frequency oscillations (HFOs) observed on the EEG. In contrast to traditional EEG analysis, these are frequencies detected above 80Hz. These HFOs have generated a lot of interest, as they are a relatively new frontier for assessing brain activity. The community is still trying to understand what this activity could mean.

Dr. Hiroki Nariai will be using his fellowship to prospectively sample and analyze HFOs in scalp EEG for individuals undergoing pre-surgical evaluation. Dr. Nariai can then use this technique to potentially better localize seizure onset zones and test whether the analysis can predict who would be a responder versus non-responder to surgery.



## Engagement with Stakeholders



The Research Roundtable for Epilepsy (RRE) is an initiative of the Epilepsy Foundation to facilitate the development and implementation of new treatments and diagnostic tools for people with epilepsy, by collectively addressing roadblocks to research and development.

Each roundtable focuses on a single critical issue and allows an in-depth discussion in a pre-competitive space. Our consortium is composed of patient organizations, senior scientists from pharmaceutical, biotechnology, and diagnostic companies as well as regulatory agencies such as the U.S. Food and Drug Administration and the European Medicines Agency. This year, twenty-five industry organizations were in attendance.

The 2018 Research Roundtable for Epilepsy (RRE) centered on the topic “[Evolving concepts in endpoints and populations in epilepsy trials](#),” and was held on May 17-18 in Washington, DC. The Organizing Committee consisted of:

- Dr. Kathleen Farrell (Director of Clinical Research, Epilepsy Foundation),
- Dr. Brandy Fureman (VP, Research and New Therapies, Epilepsy Foundation),
- Dr. Billy Dunn (Director, Division of Neurology Products, Center for Drug Evaluation and Research, Food and Drug Administration),
- Dr. Jacqueline French (Chief Scientific Officer, Epilepsy Foundation and RRE Co-Chair), and
- Dr. Nathan Fountain (Professor of Neurology, University of Virginia, RRE Co-Chair)

The goals of this meeting were:

1. Review of the current landscape of pediatric epilepsy clinical trials
2. Consider the rationale for grouping vs. splitting populations by seizure type or by syndrome
3. Discuss the full spectrum of disease and how to assess epileptic conditions that comprise more than just seizures

4. Learn which co-occurring conditions with seizures are a priority to study from the perspective of those living with epilepsy and their caregivers
5. Learn from the experiences of drug and device companies who have incorporated multiple outcomes into their epilepsy trials
6. Identify potential methodologies and statistical considerations for incorporating non-seizure domains into epilepsy studies going forward

Caregivers and leaders representing the Dravet Syndrome Foundation, the Lennox-Gastaut Syndrome Foundation, and the Tuberous Sclerosis Alliance highlighted the unmet need to look at epilepsy-related conditions holistically. They highlighted the need to consider the quality of life of the person living with epilepsy and the whole family, and to develop therapies with patient and caregiver input and guidance.

A detailed summary of the 2018 RRE meeting discussion is being prepared for publication.

**To view the agenda:** <https://bit.ly/2xs6Hop>

**To view the attendee list:** <https://bit.ly/2Jd8XVk>

If interested to learn more – please contact Dr. Kathleen Farrell, Director of Clinical Research, Epilepsy Foundation, at [kfarrell@efa.org](mailto:kfarrell@efa.org).



### **FDA Alert: Issued Warnings**

**Drug Alert:** Lamotrigine and Risk for Immune Systems

<https://www.epilepsy.com/article/2018/4/drug-alert-lamotrigine-and-risk-immune-system-reaction>

**Device Alert:** MRI Guided Laser Interstitial Thermal Therapy and Risk of Overheating

<https://www.epilepsy.com/article/2018/4/device-alert-mri-guided-laser-interstitial-thermal-therapy-and-risk-overheating>



## Conference Updates

### epiXchange

The 2018 epiXchange conference took place on May 23 in Brussels, Belgium. This meeting was a unique community building event, bringing together seven large European Union (EU) funded epilepsy projects to discuss the latest progress in research aiming to improve the way epilepsy is diagnosed and treated and thereby increase the quality of life of affected people.

*The seven EU projects that were represented included:*



These programs span many initiatives from developing a European clinical network for rare epilepsies to prevention of epilepsy to studying whether genetic markers could explain differences in drug response and occurrence of rare adverse reactions. The talks focused on what we have accomplished but also where we still need to go.

The Epilepsy Foundation believes in building strong ecosystems for research. We were excited to attend this conference to learn about the epilepsy initiatives in Europe and identify areas that we could partner together to strengthen the research community.

**For more information about the conference:**  
<http://www.epixchange2018.eu/press>

### EPILEPSY INNOVATION CONFERENCE

On June 2, the Epilepsy Foundation of Michigan hosted its first ever Epilepsy Innovation Conference in Grand Rapids. All the presentations focused on the latest advances in the field and exciting changes on the horizon. The Epilepsy Foundation's Senior Director of Innovation, Dr. Sonya Dumanis, was thrilled to kick off the conference, highlighting the exciting research initiatives of the Epilepsy Innovation Institute and Epilepsy Therapy Project. For more information about research at the Foundation, go to [www.epilepsy.com/research](http://www.epilepsy.com/research).



Biotechnology  
Innovation  
Organization



The Bio International

Conference took place on June 4-7, in Boston, MA. This is the largest conference of its type providing exposure to biotech and pharma industry thought-leaders with over 1,500 education sessions, and networking opportunities with over 17,000 participants from around the world. This year, Bio set the Guinness world record for most partnering events scheduled.

We were part of that historical record. Our objective at the Bio Convention was to meet with leaders from biotech/pharma companies to explore ways in which the Epilepsy Foundation could support them in bringing new therapies and devices to market, engage with other foundations to advance our advocacy mission, create awareness for epilepsy, and stay abreast of current trends. Some key activities included:

- Meetings with 22 companies and institutions to explore potential alliances and explain ways in which the foundation could support their research through its multiple programs and grants,
- Presentation about the Epilepsy Foundation research activities



PARTNERS AGAINST MORTALITY IN EPILEPSY

The PAME conference brings together a diverse group of stakeholders with the shared goal of improving our understanding of mortality in epilepsy, including sudden unexpected death in epilepsy (SUDEP). The conference is taking place on June 14-16 in Alexandria, VA, during the issue of this quarterly. Stay tuned for a conference report in our next issue. Learn more about the conference here: <https://pame.aesnet.org/>

In the meantime, you can join the SUDEP Institute Facebook page to stay up to date on SUDEP news.

[www.facebook.com/SUDEPInstitute](http://www.facebook.com/SUDEPInstitute)



Epilepsy Foundation has been named an All of Us Champion by the National Institutes of Health

## What is the *All of Us* Research Program?

The *All of Us* Research Program is an effort by the National Institutes of Health to gather data from one million or more people living in the United States to accelerate research and improve health. The program will be open to people both healthy and sick, from all communities.

This is a long-term research effort that is expected to last for at least a decade. The long-term data may help researchers understand the impact of environmental factors on health, track the progression of a disease, or chart the effectiveness of a type of treatment for individuals over time. Data that the program would like to collect over time includes electronic health records, responses to questionnaires, information from wearable devices, and blood and urine samples.

**The Foundation supports the *All of Us* research program efforts to:**

- Leverage the rich diversity of America to ensure that historically underrepresented populations are included in research.
- Enhance research and science to identify new treatments for health issues. The program and its participants could change health and health care for generations to come.

## Participating in the *All of Us* Research Program

Participants will be asked to complete questionnaires and share information about their health history, lifestyle habits, and environmental exposures. They may also be asked to provide access to their electronic health records and to go to a local enrollment center to have physical measurements taken and to provide blood and urine samples.

Visit <https://www.epilepsy.com/clinical-trials/all-us-research-program> or <https://www.joinallofus.org/en> to learn more.



## *Epilepsy Foundation Shark Tank Awardees in the news*

### **Congratulations to Zeto and its CEO/Founder Aswin Gunasekar.**

The FDA recently approved their product for clinical use. Zeto's "dry electrode" headset, is the first of its kind to obtain FDA approval, enabling doctors to obtain EEGs quickly and conveniently.

The Zeto system was selected as the winner of the 2016 Epilepsy Foundation Shark Tank and also awarded a New Therapy Commercialization Investment in 2017

Watch the video of Zeto at the Shark Tank [here](#). An update on how they used our funds is [here](#). Learn more at: <https://www.epilepsy.com/learn/diagnosis/eeq/dry-electrode-headset-eeq>

### **2018 Shark Tank Winner features on CBS News**

2018 Epilepsy Foundation Shark Tank Winner Dr. Josh Sherman was recently showcased on CBS News for his work on developing virtual reality simulations to train medical professionals during emergency seizure situations. [Click Here](#) to watch the CBS clip.

[Click here](#) to learn more about our Shark Tank Program.



## *Other FDA NEWS*

### **NEW THERAPY APPROVED!**

The U.S. Food and Drug Administration (FDA) granted approval for the use of Deep Brain Stimulation (DBS) therapy by Medtronic as add-on treatment for focal epilepsy.

<https://www.epilepsy.com/article/2018/5/fda-approval-medtronic-deep-brain-stimulation-medically-refractory-epilepsy>



## Clinical Trials Portal – Studies Actively Recruiting

**Learn more at:**

**[www.epilepsy.com/clinical\\_trials](http://www.epilepsy.com/clinical_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.

### **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**).

### **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 three-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.

### **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**

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. See page 2 for more information.

### **All Of Us Research Program**

The *All of Us* Research Program is an effort by the National Institutes of Health to gather data from one million or more people living in the United States to accelerate research and improve health. The program will be open to people both healthy and sick, from all communities.

See page 6 for more information.

**Go to the clinical trials portal to learn more!**

## Upcoming Conferences for 2018

### *4<sup>th</sup> International CDKL5 Family Education & Awareness Conference*

June 29-30, Denver, CO

<https://www.cdkl5.com/for-families/resources-support/family-conferences/>

### *United in Hope: Phelan-McDermid International Family Conference and "Phelan-McPosium"*

July 18-22, Dallas, Texas

<https://www.facebook.com/PMSF22q13/>

### *Dravet Syndrome Foundation: Biennial Family & Professional Conference*

July 19-22, Aurora, Colorado

<https://www.dravetfoundation.org/2018-dsf-conference/>

### *Angelman and Duq15Q Syndromes: Shared Pathways to Discovery – Research Symposium*

August 6-7, Chapel Hill, NC

<https://www.dup15q.org/events/scientific-conferences/2018-asf-dup15q-alliance-research-symposium/>

### *Gordon Conference on Epilepsy and Neuronal Synchronization*

August 19-24, West Dover, VT

<https://www.grc.org/mechanisms-of-epilepsy-and-neuronal-synchronization-conference/2018/>

### *6<sup>th</sup> Global Symposium on Ketogenic Therapies for Neurological Disorders*

October 5-9, Jeju North Korea

<http://keto2018jeju.org/>

### *47<sup>th</sup> Child Neurology Society Annual Meeting*

October 15-18, Chicago, IL

<https://www.childneurologysociety.org/meetings/2018-cns-annual-meeting>

### *2018 American Epilepsy Society Annual Meeting*

November 30-December 4, New Orleans, LA

[https://www.aesnet.org/annual\\_meeting](https://www.aesnet.org/annual_meeting)

Have a conference that you want to share?

Email [ahansell@efa.org](mailto:ahansell@efa.org)

## Epilepsy Foundation upcoming research grants

### New Therapy Commercialization Grants

Submissions now open

Letter of Intent due July 20, 2018

Award up to \$350,000 over 2 years

### SUDEP Biomarker Challenge

Now accepting submission entries

Award up to \$800,000

### Rare Epilepsy Network

Now accepting research data requests



### Interested in grant opportunities?

The Epilepsy Research Connection is a collaborative effort to assist epilepsy researchers in looking for funding opportunities across different organizations.

<http://epilepsyresearchconnection.org/>

### Interested in learning more about the Epilepsy Foundation Research Programs?

[www.epilepsy.com/research](http://www.epilepsy.com/research)

### SAVE THE DATE

Saturday April 27<sup>th</sup>, 2019

National #EpilepsyWalk

National Mall, Washington, DC

Registration opens in July!