Our word for 2018 is ecosystem. This past February, the Epilepsy Foundation hosted their Pipeline Conference, which provided updates on the different therapies coming through the epilepsy pipeline. It was amazing to see how the number of new companies in the room ready to learn about epilepsy has grown in the past 10 years. Out of the many speakers that presented on their pipeline product, over half of them had been seeded by the Epilepsy Foundation! Thank you to Epilepsy Foundation of Northern California for hosting this event with us! Feel free to watch the live-stream of the event on epilepsy.com/pipeline2018.

Although the Foundation network can feel proud of the work we have done to accelerate new therapies, we want to do better. This year, we are adding a new workstream to the research department, Digital Tools. Our purpose as a research program is to ensure a rich ecosystem for research and discovery, and that is why we are also prioritizing the development of digital tools that can help us achieve that goal.

In 2017, we launched a clinical trials portal to connect people with epilepsy to research studies that need them (see the trials actively recruiting on page 5). We also revamped our Seizure Diary to allow it to be a more useful tool for researchers (see page 6). We have always been committed to tracking the pipeline (see page 7). The digital tools workstream will seek to create tools to help people with epilepsy, families, research and healthcare providers to improve outcomes and care.

We are really excited about the progress we have made, but we are even more excited about the progress to come. As we continue to evolve and grow, we would love to have your feedback. Please send your feedback to Sonya Dumanis, sdumanis@efa.org. As Helen Keller said, alone we can do so little, together we can do so much. The epilepsy community is the reason that we exist, and we are here to serve you.

If you would like to stay up to date with Epilepsy Foundation news, please sign up at www.epilepsy.com/newsletter.

Sincerely,
Brandy Fureman, PhD
VP of Research & New Therapies
Shark Tank Award Updates

Our annual Shark Tank competition was held at the Pipeline Conference in San Francisco, California.

Inspired by the TV show Shark Tank, finalists can give a 7-minute pitch to our judges about why the Foundation should invest in their idea to solve a challenge that people living with epilepsy face every day. The audience also gets to vote on their favorite project to fund.

Listed below are the winners of the 2018 Shark Tank Competition.

Best Virtual Reality Education Project at the 2018 VR Fest and was written up in USA Today and Buzzfeed. Using an Oculus Simulator, trainees can be assessed on their training readiness and taught what to do in high-stakes situations like status epilepticus.

Drs. Sherman and Chang will use the Shark Tank funds to create other virtual reality simulations for other use-case epilepsy scenarios recreating the stressful emergency environment to better prepare providers and improve care.

Virtual Reality Simulations for the Management of Status Epilepticus
Joshua Sherman, MD
Todd Chang, MD MACM
Faculty Attending – Division of Emergency Medicine
Children’s Hospital Los Angeles
Assistant Professor of Pediatrics
USC-Keck School of Medicine
$50,000 Judges Award

Drs. Sherman and Chang want to develop virtual reality simulations to allow the community to better train both medical and non-medical professionals for high emergency epilepsy situations. Usually trainings are done using mannequins and actors, which are expensive and time-constrained to when the actors are available. In contrast a virtual reality module is portable, standardized, and still allows for an immersive experience. Moreover, 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 module for status epilepticus in the pediatric population. This simulation won

3D Machine Vision System for Surgical Navigation of the Human Brain
Aaron Bernstein, PhD
President and CTO
Advanced Scanners
Austin, Texas
$75,000 Audience Choice award + $75,000 Judges Award

Open brain surgery begins with the surgeon creating an opening in the skull. The surgeons rely on image-guided navigation systems to track 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 that inter-operatively watches 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 location of the grid electrodes, mapping at high resolution the surface of the brain 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. Which in turn, should make the brain surgery procedure safer for the patient.

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Updates from 2017 Shark Tank Winners

At the 2018 Pipeline Conference, former Shark Tank winners from 2017 gave updates on where they are in their projects.

24/7 Portable, Ultra-long-term EEG Recording

Jonas Duun-Henriksen, PhD
Senior Scientific Researcher
UNEEG medical A/S
Lynge, Denmark
$75,000 Audience Choice award

Description: 24/7 EEG™SubQ is a portable EEG recording system that provides a robust and easy way of monitoring epilepsy patients for weeks, months, or years without the need for an inconvenient and costly stay at the hospital wearing uncomfortable wires and electrodes. The system comprises an implantable monitor under the skin and a small external recorder.

Post-Award Update: The company had originally focused on the diabetes space. Since their Epilepsy Foundation award, they have begun implanting their device in people with temporal lobe epilepsy. They have applied for a CE mark in Europe, and are preparing to enter the United States marketplace.

Device for Epileptic Seizure Prediction

Paula Gomez, PhD
CEO, Epistemic
Hilda A. Cerdeira, PhD
Fellow of the American Physical Society
São Paulo, Brazil
$50,000 award

Description: A wearable device that sends an SOS message in advance of a seizure to an application in the smartphone of the care-partner. The algorithm to create this seizure-predicting device was created using approximately 1,000 EEGs from people with epilepsy.

Post-Award Update: Epistemic used their award from last year towards product development, making the device smaller while increasing processing power. They are currently in clinical trial negotiations in Canada with the NACTRC (Northern Alberta Clinical Trials and Research Centre) to start testing their device in the clinic.

New Therapy Commercialization Grant Awarded

Aswin Gunasekar, MS
Zeto, Inc.
Santa Clara, CA

Since 1924, the EEG reading procedure in the hospital has not really changed. A trained technician measures the head, sorts through hair, marks electrode locations, and applies paste and electrodes to the scalp, eventually tethering the patient to a box with wires. The procedure requires about an hour, and one leaves with goo stuck in the hair. In 2016, Zeto won a shark tank award from the Epilepsy Foundation to improve EEG technology using dry electrodes and wireless technology.

This past year, Zeto applied for a New Therapies Commercialization Grant as they prepare to come to the market. Following a business and science peer-review, the Foundation is investing $200,000 in their company. Here is a little about their product.

Zeto is developing a turnkey solution for Routine EEG tests by providing EEG to facilities that do not have access to trained EEG operators or neurologists. The goal of Zeto is to have a system that satisfies the following:

1. Dry electrode headset providing medical grade EEG
2. No need for skin preparation or gel/paste
3. Comfortable and convenient to wear
4. Easy size adjustments that fit children and adult head sizes and most hair types
5. Accurate 10-20 EEG placement
6. Designed for re-use and easy cleanability
7. Snap on/Snap off electrodes (different heights and hot swappable) for good electrode contact for various head sizes and hair types
8. Seamless data sharing and interpretation

Epilepsy Innovation Institute Update:

We are getting better and better at forecasting the weather, could we do the same with seizures?

The Epilepsy Innovation Institute published a review entitled “Seizure Forecasting from idea to reality – Outcomes of the My Seizure Gauge Epilepsy Innovation Institute Workshop” in eNeuro this past December.

Dr. Greg Worrell talked about seizure forecasting at the February Pipeline conference. You can watch at http://bit.ly/2I3umgn starting at 43 min, 28 seconds into the live-streamed recording of the event.
The Rare Epilepsy Network (REN) is spearheaded by the Epilepsy Foundation in partnership with Columbia University and RTI International. It is a network of over 30 different organizations, and any rare epilepsy organization can be part of the network.

**Purpose of the REN**
The purpose of the network is to conduct and facilitate research to improve outcomes for people with rare conditions associated with epilepsy and seizures. Specifically, we want to unlock the causes of rare epilepsies, improve diagnosis (avoiding delay and misdiagnosis), treatment and quality of life, and find cures.

**Accomplishments**
2017 was a great year for us. Listed below are 10 reasons why.

1. We conducted 3 collaborative studies that ranged from understanding sleep, creating a caregiver impact scale, and understanding how families are impacted by epilepsy.
2. We held a multi-stakeholder workshop on additional key outcome measures for rare epilepsies. We will continue the conversation at our May Research Roundtable with companies and regulatory agencies.
3. We created a REN dashboard, which provides an at-a-glance overview of the epilepsy subtypes represented, prescribed medications, and associated conditions with the different disorders.
4. We added three new rare epilepsy organizations to our network: CFC International, Chelsea’s Hope, and the Brain Recovery Project. If you are part of a rare epilepsy organization, join us!
5. We launched a collaboration with CURE’s Epilepsy Genetics Initiative to develop a genetic sequencing study for REN participants. We believe that partnerships are what make us strong.
6. We developed a communication plan. This past year, we released four REN Newsletters to share our activities with the community and presented at multiple conferences from the 2017 American Epilepsy Society to the National Institutes of Health Rare Disease Day.
7. We piloted a cloud-based medical-record collection system.
8. Opened discussions about collaboration with the European Union’s rare epilepsy network EpiCARE.
9. Increased our enrollment 12.7% growth in enrollment (from 1200 to 1351).
10. We were awarded a grant to expand the Rare Epilepsy Network into a Learning Healthcare System that seamlessly integrates quality improvement measures into care.

We are thrilled to be part of the Rare Epilepsy Network and see it grow over the years.

**Want to learn more?**
[REN.RTI.ORG](https://REN.RTI.ORG)

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### Research Opportunities in the REN

**Rare Epilepsy Network Registry Data**
Now accepting research requests
Contact: ren@rti.org.

**Lennox-Gastaut Syndrome Foundation Research Grant**
Full Grant due April 1, 2018
Awards range from $30,000 to $50,000
Contact: Tracy@LGSfoundation.org

**PCDH19 Alliance Research Grant**
Full Grant due May 1, 2018
Awards range from $25,000 to $75,000
Contact: julie@pcdh19info.org

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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 month 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.

Fenfluramine Assessment In Rare Epilepsy (FAiRE): ZX008-Study 2/1504

The FAiRE program of clinical trials is exploring whether an investigational drug (ZX008) can improve seizure control in children and young adults with Dravet syndrome. FAiRE stands for “Fenfluramine Assessment in Rare Epilepsy.” The goal of the ZX008-Study 2/1504 trials is to show that ZX008 is a safe and effective treatment for children and adolescents with Dravet syndrome when added on to their other seizure medications.

Preventing Epilepsy Using Vigabatrin In Infants with Tuberous Sclerosis Complex

This Phase Ib 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.

Go to the portal to learn more!
The Epilepsy Foundation My Seizure Diary is a self-management tool to help you record, track, and manage your seizures and epilepsy. The Diary lets you record your medical history, seizures, medications, side effects, moods, or other personal experiences.

You can track changes over time, keep records of your medications, and create a Seizure Response Plan to share with your family, friends and health care team.

Using a diary can help you understand your specific seizures, identify your triggers to avoid and create action plans for when those triggers happen.

My Seizure Diary also helps you remember what to do - you can have reminders of when to take your medicines, when to refill a prescription, or when you have medical appointments or tests. My Seizure Diary lets you print out reports or send them to others, including your health care team electronically.

The Epilepsy Foundation is continually working on improving the diary. For example, we have upgraded features to allow the diary to be used in clinical trials and other research studies. We are proud to announce that the diary will be integrated into the Human Epilepsy Project 2, which will track seizures in those with drug-resistant focal epilepsies.

We want to hear from you! Please provide feedback and let us know what works and doesn’t work for you.

Contact: diary@efa.org

Please note that My Seizure Diary is one of several seizure tracker mobile tools available. Our goal at the Foundation is to ensure that you have the tools you need for epilepsy management. Find what works best for you and let us know!
Supporting Therapies from Pipeline to Lifeline – Case Example

The Epilepsy Foundation believes in supporting an epilepsy research ecosystem that covers the entire spectrum from idea to market. In the research department, we work closely with other departments within the Foundation as a therapy moves from clinical trials onto the market. Here is an example of how we do this.

In 2013, the Epilepsy Therapy Project supported the first Epidiolex® (CBD) trial by GW Pharmaceuticals (Greenwich Biosciences) for Dravet and Lennox-Gastaut. “The origin of the Epidiolex trial began with a pivotal meeting of researchers from across the US and representatives of the Epilepsy Foundation. This was followed the next year by an Epilepsy Foundation’s research award that provided critical seed funding for the open label study. Positive results from that study convinced GW Pharmaceuticals to proceed with the randomized controlled trials - 3/3 of which have been positive!” — Orrin Devinsky, MD

The FDA is now currently reviewing Epidiolex as a CBD-derived therapy for the treatment of Dravet and Lennox-Gastaut syndromes (LGS), Tuberous Sclerosis Complex (TSC) and potentially other rare epilepsies. This potential treatment option has both Orphan Drug Designation and Fast Track Designation from the FDA and could be approved as soon as summer 2018.

This is why creating a state pathway for therapies derived from CBD and approved by FDA is a time sensitive priority for our public policy team. The Epilepsy Foundation continues to bring together the epilepsy community to advocate for changes to state scheduling laws to allow therapies derived from cannabidiol (CBD) and approved by the Food and Drug Administration (FDA) to become available to people living with epilepsy in a timely manner. Each state has its own laws and processes for scheduling prescription medications separate from the federal system and we will continue to collaborate with affiliates and chapters to ensure timely access to FDA-approved therapies derived from CBD.

During the 2018 state legislative session, bills to ensure timely access to FDA-approved therapies derived from CBD have been introduced in California, Colorado, Hawaii, New York, and Wyoming. On February 28, the Governor of New Mexico signed their bill into law. Follow our advocacy efforts on state scheduling for FDA-approved therapies derived from CBD at advocacy.epilepsy.com/statefda_pathway.

Please go to epilepsy.com/pipeline to see the latest in drug and device development for epilepsy.

Did you find any information out of date?
Let us know by emailing aphansell@efa.org with PIPELINE UPDATE in the subject line.

We want your feedback!

Please let us know what you think about the quarterly newsletter.

Email: sdumanis@efa.org

If there is a specific topic you would like to learn more about, do not hesitate to let us know (email sdumanis@efa.org and put Hot Topic in the subject line).
Upcoming Conferences for 2018

American Academy of Neurology
April 21-27, Boston, MA
https://www.aan.com/conferences-community/

ELIAT conference on New Antiepileptic Drugs and Devices
May 13-16, Madrid Spain
https://www.eliatxiv.com/

PCDH19 Alliance Professional and Family Conference
June 9, Rohnert Park, CA
https://www.pcdh19info.org/events-calendar

Partners Against Mortality in Epilepsy
June 14-16, Alexandria, VA
http://pame.aesnet.org/

4th International CDKL5 Family Education & Awareness Conference
June 29-30, Denver, CO
https://www.cdkl5.com/for-families/resources-support/family-conferences/

Gordon Conference on Epilepsy and Neuronal Synchronization
August 19-24, West Dover, VT

6th Global Symposium on Ketogenic Therapies for Neurological Disorders
October 5-9, Jeju North Korea
http://keto2018jeju.org/

47th 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

Interested in learning more about the Epilepsy Foundation Research Programs?
www.epilepsy.com/research

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/

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