

# Epilepsy Foundation

Sonya Dumanis, PhD

Senior Director of Innovation

ICARE Meeting

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

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**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



**EPILEPSY  
FOUNDATION**

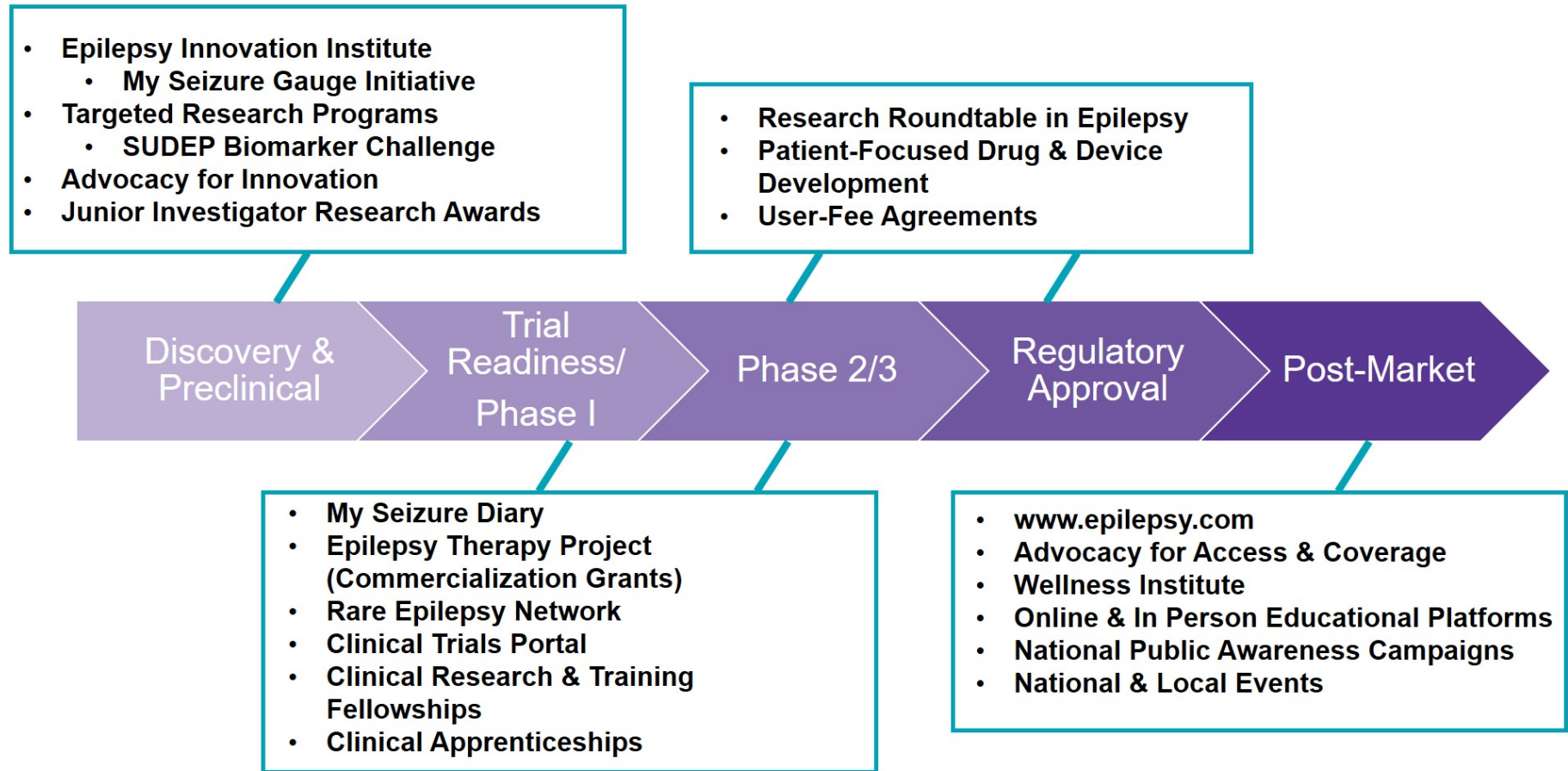
# EPILEPSY FOUNDATION

Our Mission: To lead the fight to overcome the challenges of living with epilepsy and to accelerate therapies to stop seizures, find cures, and save lives.

Execute the mission through:

- Education & Public Awareness
- Program Services & Public Policy Advocacy
- Research & Innovation

# EPILEPSY FOUNDATION ENGAGES IN RESEARCH ALONG THE CLINICAL PIPELINE



# RESEARCH OVERVIEW

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, advocates, 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
- ▶ Seizure Diary

**Epilepsy Therapy  
Project**

**Epilepsy Innovation  
Institute**



**INNOVATION  
PROGRAMS**

# EPILEPSY THERAPY PROJECT



Founded in 2002 by Warren Lammert and Orrin Devinsky MD, the Epilepsy Therapy Project merged with the Epilepsy Foundation in 2012.

**Purpose:** To drive the development of new therapies for epilepsy, accelerating the advancement of research from laboratory to the patient. Our focus is on later-stage development projects to catalyze ideas onto the market, with an interest in:

- Novel approaches to treatment.
- Platform technology to advance screening techniques that can be utilized by multiple laboratories, including utility of techniques for early proof-of-concept trials.
- Adaptation of treatment in development for another therapeutic area to assess utility for epilepsy (while maintaining patent protection).

## Grant Mechanism:

- **New Therapy Commercialization Grants** – \$350,000 over a two-year period.
- **Shark Tank Awards** – up to \$200,000

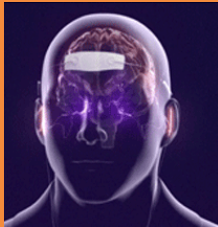


# WHAT DOES LATER STAGE DEVELOPMENT MEAN?

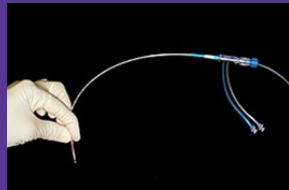
- **Diagnostics and/or device applications** should be at later stage feasibility testing or in the proof of value stage (i.e. there should be a minimal viable product [MVP] prototype with a product IFU [instructions for use])
- **Small molecule and/or biologic applications** must have at least one lead compound identified in the proposal. Note that this compound may be in pre-IND (Investigational New Drug phase of FDA). Investigators of drugs are strongly advised to have their compounds screened, as appropriate, by the [NINDS Epilepsy Therapy Screening Program \(ETSP\)](#) prior to submitting an application.
- **Clinical programs applications** must have a reasonable protocol and sample size to assure that the results will be meaningful; studies of patients should describe the type of seizure/epilepsy that will be investigated.

# PREVIOUS ETP GRANTS INCLUDE

Trigeminal  
Nerve  
Stimulation  
2008



Laser  
Ablation  
Surgery  
2011



Cannabidiol  
2013



Ataluren  
2017

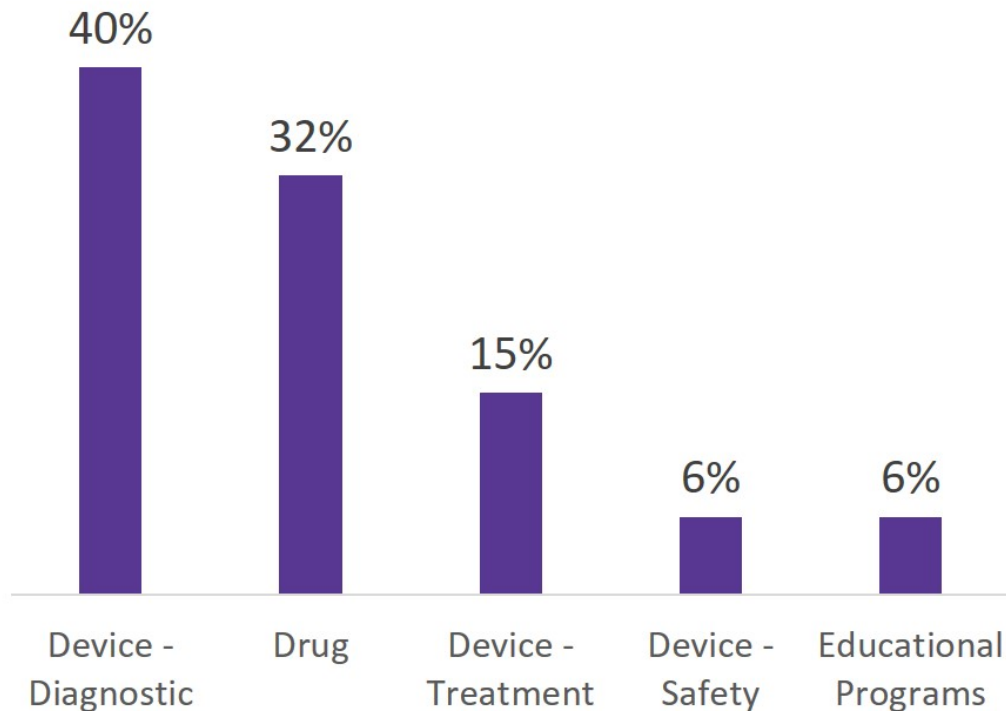


*THE EPILEPSY THERAPY PROJECT ACCELERATES LATE STAGE  
DEVELOPMENT THERAPIES ONTO THE MARKET THROUGH  
COMMERCIALIZATION GRANTS*



# BREAKDOWN OF ETP INVESTMENTS

Breakdown of ETP Investments  
2007 – 2018 (~ \$8M )



From what's currently active in the pipeline:

- Diagnostics
- New Molecular Entities
- Reformulations/Enhanced Delivery
- Dietary Therapies

**43%** of those projects supported with ETP

# EPILEPSY INNOVATION INSTITUTE (EI<sup>2</sup>)

*An innovation incubator to funnel new ideas into the clinical pipeline*



1



## SELECT TOPIC

Through surveys of people with epilepsy and caregivers, we define which area to tackle first.

2



## DEFINE CHALLENGE

We invite experts across disciplines to Innovation Workshops where we assess the major scientific roadblocks to addressing unmet needs of people living with epilepsy.

3



## FUND SOLUTION

We support multi-disciplinary teams to tackle the defined scientific roadblocks investing \$1 million per year for up to 3 years.

4



## PROVIDE MENTORSHIP

We provide our Solution Teams with support and specialized expertise throughout the process.



Ei<sup>2</sup>



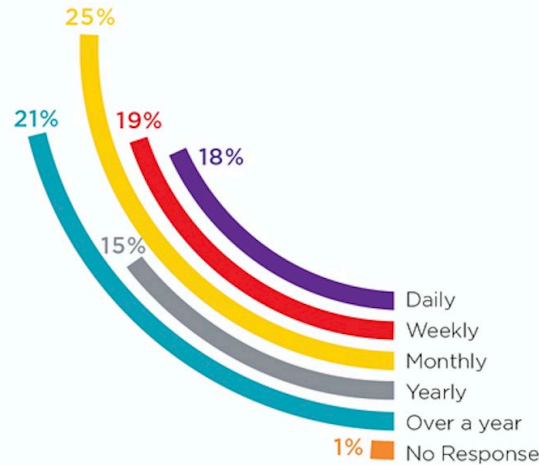
# OUR PROCESS FOR EI<sup>2</sup>

*An innovation incubator to funnel new ideas into the clinical pipeline*



1,056

INDIVIDUALS PARTICIPATED  
IN THE SURVEY



- What aspects of epilepsy impact you the most?
- Where should researchers focus?
- What is your biggest frustration with epilepsy?
- What is your biggest hope for epilepsy in the next 5 years?



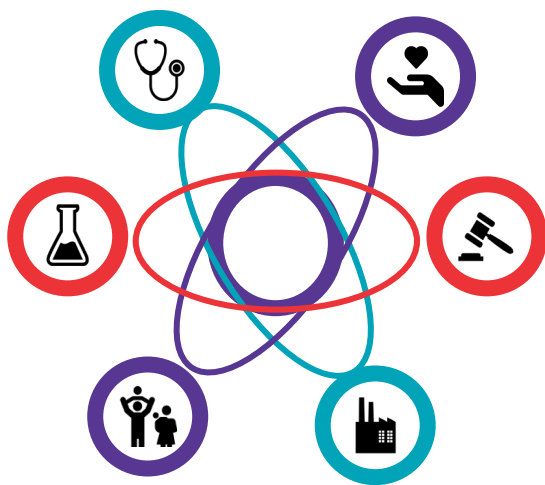
SELECT  
TOPIC

## Unpredictability

# DEFINING THE CHALLENGE

## *ASSESSING THE STATE OF THE SCIENCE THROUGH INNOVATION WORKSHOP*

### **Convening Stakeholders**



- 1.5 Day Workshop in DC
- Co-Chaired by Christophe Bernard & Greg Worrell
- 50 Attendees with an emphasis on bringing outside people in:
  - IBM
  - Verily (Google Life Sciences)
  - Lawrence Livermore Labs
  - MDIC (Medical Device Innovation Consortia)
  - Eccrine Systems (Sweat Sensing Technology Company)

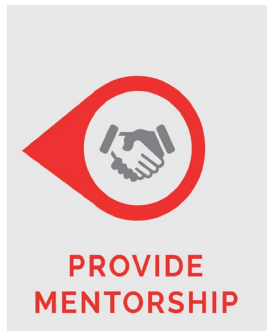
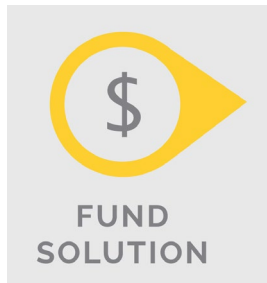
Dumanis et al. (2017) Seizure Forecasting from idea to reality – Outcomes of the My Seizure Gauge Epilepsy Innovation Institute Workshop. eNeuro

# EI<sup>2</sup> NEXT STEPS

*Fund Solution & Provide Mentorship to Team*



## Bringing Big Data to Personalized Health



Recruit cohort with  
ambulatory EEG implants  
& follow for a year

Pair EEG with Non-EEG  
measures

Sync to data collection  
platform

Crowdsource for insights

**Goal:** Identify and better understand the changes in the body that may precede the onset of a seizure, at a time course that may be hours or days before the clinical (observable) seizure.

**Ultimate End-goal:** Create a noninvasive seizure forecasting device

# THINKING ABOUT THE END USER

*Survey to understand what type of seizure gauge device would be used*



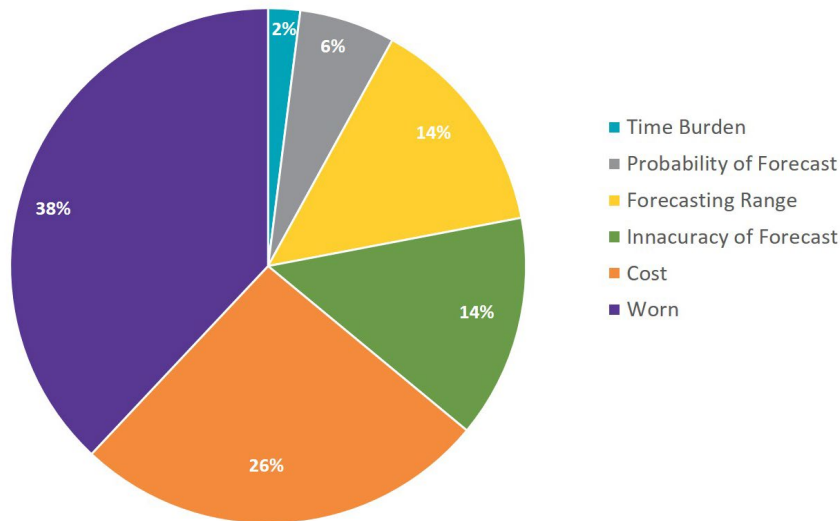
518

INDIVIDUALS PARTICIPATED  
IN THE SURVEY

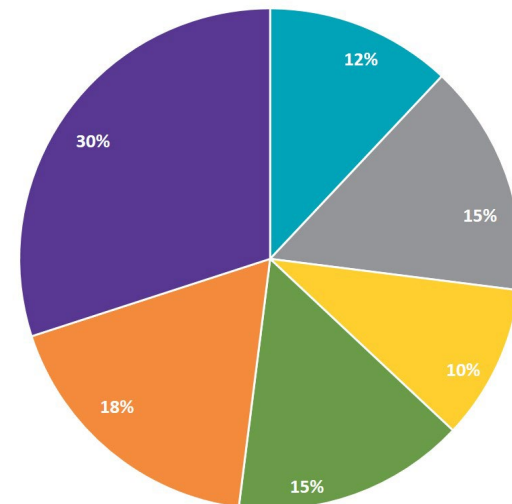
Out of the options listed below, please choose the one best aspect and the one worst aspect of the device.

Best		Worst
<input type="radio"/>	\$50 in additional out-of-pocket expenses	<input type="radio"/>
<input checked="" type="radio"/>	Worn externally	<input type="radio"/>
<input type="radio"/>	Forecasts moderate probability of seizure	<input type="radio"/>
<input type="radio"/>	Gives inaccurate seizure forecast 30% of the time	<input checked="" type="radio"/>
<input type="radio"/>	High time burden for data uploading/ Dr. visits	<input type="radio"/>
<input type="radio"/>	Forecasts seizure likelihood in next 1 to 6 hrs	<input type="radio"/>

Influence of Purchasing Power



Valued Features of Device



Working with a consultant to do more modeling

# NEXT EI2 TOPIC: MY BRAIN MAP

*Defining Individualized Brain Networks to Enhance Diagnosis and Care*

We know people living with epilepsy are not having seizures 100% of the time. So why are seizures happening when they do? What pathways in the brain are activated in the particular moment before the start of a seizure? And what is it about a person's brain activity that activates those pathways in that specific area of the brain in that specific moment?

## USE-CASES FOR CHALLENGE INCLUDE:

- Identify brain regions critical for seizure control
- Improve surgical options and outcomes
- Optimize neurostimulation therapies
- Understand how consciousness is impacted

**Epilepsy Foundation**  
**My Seizure Diary**

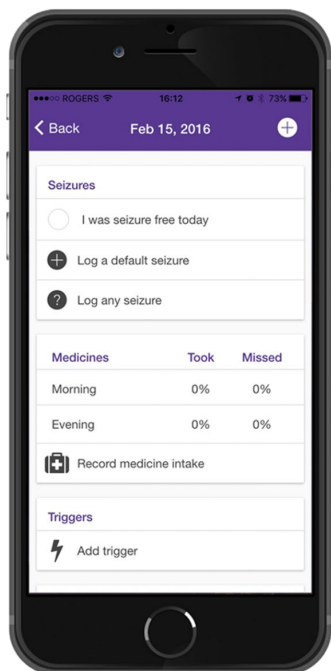


**DIGITAL TOOLS**  
**PROGRAMS**



# DIGITAL TOOLS

## *Epilepsy Foundation My Seizure Diary*



[diary.epilepsy.com](http://diary.epilepsy.com)

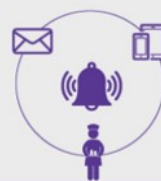
Our seizure diary can help you . . .



Log your  
medicines and  
seizures



Share your  
diary  
information



Set your  
reminders



Create your  
reports



Take care of  
your health

Our seizure diary can also be used for research purposes:

- Clinical Trials (HEP2)
- Research Survey Modules for Investigators

### **Future Updates Planned:**

- Add new seizure terminology,
- update treatments lists,
- add mood scales,
- upgrade ability to create APIs for wearable devices,
- translate into additional languages

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

## Thank You

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