

Epilepsy Therapy Project

*Accelerating ideas into new therapies
for people with epilepsy*

Joyce A. Cramer

Chief Scientific Officer (formerly President)

Associate Research Scientist, Yale University

ICARE Member Report

- Epilepsy Therapy Project
 - Mission: *Accelerating ideas into new therapies for people with epilepsy*
- ETP is a 501 (c) (3) nonprofit organization dedicated to a singular focus: overcoming the funding gaps and roadblocks that slow the progress of new therapies from the lab to the patient.
- ETP seeks to improve incentives and encourage commercial investment in new therapies.
 - (Treatments reach patients only by commercial routes)
- Acting as both a catalyst and clearing house for innovative research and the early commercialization of new therapies, ETP brings together financial resources, scientific insights and business expertise from leading academic and commercial industry participants.

ICARE Member Report: EPILEPSY THERAPY PROJECT

- Major topics of interest in epilepsy research
 - **Providing support to companies** from target molecule selection to proof of concept for drugs, biologics, and devices, as well as platforms to improve preclinical development (e.g., animal models)
 - **Providing support in developing efficient clinical trial designs** to reach regulatory approval for new therapies
 - **Providing support for investment and business development** groups to understand the value of the epilepsy space (For epilepsy alone or as an entry into the broader CNS arena)

Types of research support or other activities

Epilepsy Pipeline Updates: annual conferences to showcase ongoing developments in drugs, devices, biologics for epilepsy.

http://www.epilepsy.com/etp/pipeline2010_webcasts

Grants: 2 cycles/year

New Therapy Grants: supporting the research and development of new therapies in academic and commercial settings worldwide. Truly translational research: proposals must demonstrate a clear path from the lab to the patient

Commercialization Grants: matching grants to support the commercialization of novel approaches; leveraging other resources.

Investments: Seed/Angel investments in selected companies with the imprimatur of our support to demonstrate our enthusiasm for the program to investors.

ICARE Member Report: EPILEPSY THERAPY PROJECT

- Resources available for collaboration:
 - www.epilepsy.com reaches >300,000 individuals in the community every month with articles (written by epilepsy professionals), as well as social media blogs, chats, forums, podcasts, etc.
 - [My Epilepsy Diary](#) is a new feature for patients and researchers to track seizures, adverse effects, etc. (>9,000 diaries)
 - eJournal, clinical trials, social media of all types.
 - www.epilepsy.com/professionals for education of healthcare providers within neurology and outreach to primary care.
 - Both websites contain thousands of pages of high-quality information
 - Opportunities to share content and messaging to >50,000 viewers/month

Scientific Advisory Board for review of scientific quality of proposals

Business Advisory Board for review of business potential of proposals

A 'face' to present opportunities in epilepsy to the business world
(investors and pharma/device companies)

ICARE Member Report: EPILEPSY THERAPY PROJECT

- Priorities for future activities
 - Expand support for entrepreneurs
 - Expand connections with investment and business development sources of support for the epilepsy pipeline.
 - Expand funding, matching and networking efforts, to help us bridge critical stages of development, and to identify and advocate for highly competitive pipeline programs that should be accelerated through development and to the patient.
 - Increase seed investments in start-up companies
 - **We constantly monitor innovation and clinical progress in the epilepsy and CNS field to seek out deserving, high-value programs that have commercial potential.**

Nothing reaches patients with investor support!

ETP Drug & Biologics Collaborations

- ETP supports ongoing development efforts for all large and small pharmaceutical companies:
 - Catalyst Pharmaceuticals Partners, Inc.
 - Concert Pharmaceuticals, Inc.
 - Eisai, IncSunovion Pharmaceuticals, Inc.
 - Icagen, Inc
 - Lundbeck Pharmaceuticals
 - Marinus Pharmaceuticals
 - Medkura, Inc.
 - NeuroGenomeX
 - Neurologix, Inc.
 - NeuroTherapeutics Pharma, Inc.
 - Novartis International AG
 - SK Life Science, Inc.
 - SynapCell,
 - UCB Pharma, Inc.
 - Upsher-Smith Laboratories, Inc

ETP Device Collaborations

- **Cyberonics**
 - Ongoing development of an external seizure detector
 - Potential to export data to *Epilepsy Diary* on www.epilepsy.com server.
- **NeuroVista**
 - Ongoing development of an implanted Seizure Advisory System (SAS)
 - Warn patient of expected seizures

ETP Investments

- **ICVrx:** to support the development of a targeted epilepsy drug technology for patients whose seizures are not controlled by current therapies.
 - Their strategy combines a standard drug delivery pump technology with established epilepsy medications for spinal drug delivery to the brain at low dose.
 - This approach may reduce systemic toxic effects of selected oral anti-epilepsy drugs, facilitate increased local drug concentrations at the site of action, and offer the potential to improve overall tolerability of the effective dose.
- **NeuroTherapeutics:** to support development of a novel compound into Phase 1 studies.
 - Our investments in these 2 start-up companies was critical for assuring other investors that ETP experts considered them important programs with high potential for success.
- **NeuroGenomeX:** to support development of 2 Deoxy-Glucose (2DG) for chronic treatment of epilepsy.
 - Our investment/grants will support a proof-of-concept study needed to proceed.

Programs Funded for Development of Seizure Detection Devices (with potential to prevent SUDEP)

Since 2004

EPILEPSY RESEARCH FOUNDATION

*A Collaborative Program Funded by
Epilepsy Therapy Project and Epilepsy Foundation*

SmartWatch: Monitoring, Detection, Alerts and Tracking

- Chandan Gope, Ph.D.
Smart Monitor Corporation, San Jose, California
-
- 2010 Grant to develop a novel device that continuously monitors, detects, alerts upon and records rhythmic, repetitive convulsive movements of the limbs, caused by a generalized tonic-clonic or grand-mal seizure. It is low cost, passive, non-invasive device that is easy to use. It contains a miniaturized 3D motion / accelerometer sensor that detects fine and gross movements of the body part (arm wrist or ankle) on which the watch is worn. A mathematical detection algorithm embedded in the Smart Watch analyzes the movements to determine if they are consistent with those caused by a seizure. This grant will continue patient testing and commercialization for the SmartWatch.

Epilepsy Alert Device

- Amos Shaham, M.S.
Biolert Ltd., Israel
-
- 2010 Grant to develop and refine a seizure-identification algorithm for an epilepsy alert device based on limb movement called **Epilert**. Embedded in the EpiLert microprocessor, the algorithm - basically a computer program - draws from a unique hospital database of seizure and normal movements.
- The group will construct EpiLert prototypes for hospital evaluation that include a *sensor unit* similar to a wristwatch; an *alert unit* the size of a cell phone; and software for a personal computer that will interface with My Epilepsy Diary™, an online service provided by the Epilepsy Therapy Project and Irody that automatically reports seizures in real-time detail.

Closed-looped microstimulation with multi-electrode arrays to suppress epileptic seizures

- Robert E. Gross, M.D., Ph.D.,
Emory University School of Medicine, Atlanta, Georgia
- 2007 Grant to develop a novel electrical stimulation approach that directly controls the activity of the brain to attain a more stable state from which seizures will not arise. By continuously controlling the activity of epileptogenic brain areas with distributed low-voltage stimulation, the researchers have shown that small arrays of multiple electrodes can completely suppress epileptic activity in cultured brain tissue. They hope to maintain the brain in a seizure-free or seizure-resistant state, therefore bypassing the need to detect or prevent seizures, and are investigating this treatment in animal models of epilepsy

Noninvasive Nonlinear Seizure Prediction Device

- Robert Savit, Ph.D., University of Michigan, Ann Arbor, Michigan
- 2004 Grant to complete testing and produce definitive proof of a concept for an ambulatory non-invasive recording device capable of providing advanced notice of an impending seizure. In previous research, Dr. Savit and his collaborators had developed a measurement of marginal predictability (MP) for nonlinear time series. Under an R01 grant from the National Institutes of Health, Dr. Savit and his collaborators observed significant, consistent changes in MP several tens of minutes prior to a seizure in patients with focal epilepsy. Based on these findings, Dr. Savit and Dr. Edwards' project aims to test the efficacy of changes in MP as a predictor of impending seizures as well as determine if the algorithm used for prediction is universal across epilepsy patients. The ability to predict seizure onset could be the foundation for future intervention devices and therapies preventing seizures before they occur.

Low Power Analog Seizure Detection Device

- Naresh Bhavaraju, PhD, Flint Hills Scientific, LLC
Lawrence, Kansas
- 2004 Grant towards the development of low-power, implantable seizure detection and treatment devices that will allow prolonged operation without the need for frequent battery recharging or replacement. The grant supports the development of an analog circuit implementation of FHS's seizure detection algorithm that reduces power consumption, prolonging battery life.

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 - Upsher-Smith Laboratories, Inc