

SPECIFIC AIMS – EPIBIOS4RX PUBLIC ENGAGEMENT CORE

The overarching goal of the Public Engagement Core is to actively engage voluntary organizations with the EpiBioS4Rx CWOW in public outreach and knowledge transfer for the development of effective strategies to successfully design and complete rigorous multicenter clinical research studies, including future trials of prevention therapy in epilepsy.

Scientific premise: Epileptogenesis after traumatic brain injury (TBI) can be prevented with specific treatments; the identification of relevant biomarkers and performance of rigorous preclinical trials will permit the future design and performance of economically feasible full-scale clinical trials of antiepileptogenic therapies.

The specific aims are to:

Create a consortium of consumers and consumer organizations, scientific (professional) societies, health organizations and EpiBioS4Rx investigators to assist with public outreach to facilitate interactions and communication among our partners to effectively promote participatory action research.

Develop and test strategies for involving both consumers (actual patients and their caregivers) and consumer groups in the design of studies including strategies for successful enrollment and retention of study participants as epilepsy may be a late manifestation of TBI (which serves as the epileptogenic insult).

Deliverables: 1. Formation and training of working group members in qualitative methodology and participatory action research and eventual release of a webinar on Participatory Action Research as an online publicly available resource; 2. Development of a conceptual strategy for recruitment and retention; 3. Creation of a Knowledge Exchange Forum with patients and stakeholder groups; 4. Development of a number of consumer satisfaction questionnaires co-designed with members of the working groups; 5. Development of online webinar and educational material on participatory action research for study personnel, consumers and consumer groups; 6. Evidence of improvement in recruitment and retention over time through improvement in the tools developed in the above steps; 7. Development of a mock therapeutic trial by the consumers/consumer groups, compare with existing therapeutic trials and the preliminary trial designed by EpiBioS4Rx and reach a consensus on final design of the therapeutic trial; 8. Submission of a PCORI grant for a future trial of antiepileptogenesis in TBI using the meaningful outcome measures, the successful enrollment and retention strategies determined in this Core, and data from the scientific component of the EpiBioS4Rx CWOW; 9. Publications of the collected data; 10. Sharing of the information with other groups developing studies with consumer participation, advice and consent.

The ultimate objective of the Core is to create a universal shared resource for epilepsy involving consumers, consumer organizations and professionals that could be used to design and execute large-scale intervention studies.