Summary Report of Community Consultations
University of Michigan

This is a report of findings from community consultations regarding a clinical trial that can only be performed with exception from informed consent for emergency research. Community consultations were performed pursuant to 21 CFR 50.24 and related regulatory guidance documents.

The report consists of a two page overview of the findings, and then additional pages including further descriptive statistics of the community consultation (CC) events and more detailed descriptions of the feedback provided by participating community members.

Trial **ESETT Established Status Epilepticus Treatment Trial**

IND # 119,756

Report Date: Sep 4, 2015
Narrative: This report includes findings from community consultation events that took place between Apr 21, 2015 and Aug 19, 2015. It includes findings from 16 events/activities reported by 1 of the 22 NETT Hubs and 15 PECARN Sites. These events involved 0,567 participants in the consultation process. Guidance documents suggest that community may be defined geographically or by orientation to the specific condition or disease being studied. Of the reported events, 50% involved a geographic community, 0% a condition-oriented community, and 50% involved both. Of all participants 0,211 provided feedback including 1,248 answers to closed ended questions and 0,074 open ended comments. Among responses expressing an opinion 91% of closed ended and 69% of open ended comments were supportive

Overview

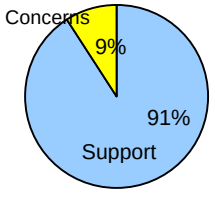
Number of Hubs reporting:	1
Number of activity reports:	16
Number of participants:	567
Types of community involved	
Percent geographic community:	50%
Percent condition-oriented community:	0%
Percent both types of community	50%
Type of consultation activities	
Existing Group Meeting	31%
Self-Administered / In-Person Interview	50%
Booth Event	19%
Focus Group	0%
Convened Meeting (by invitation)	0%
Other	0%
Town Hall	0%
Internet Survey	0%
Phone Survey	0%

Participant Demographics

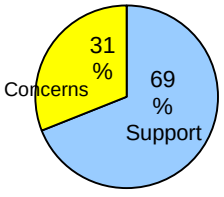
Age (average)	45 years
Female	67%
Male	33%
Race	
White	84%
Black/African American	8%
Asian	3%
Native Hawaiian or Pacific Islander	0%
American Indian or Alaska Native	1%
More than one race	0%
Other race	3%
Ethnicity	
Hispanic/latino	4%
Non-hispanic	96%

Feedback Summary

# of individual survey respondents	211
Total # of closed ended responses	1,248
Total # of open ended comments	74



Closed Ended Responses
Expressing Opinion
n= 1160



Open Ended Comments
Expressing Opinion
n= 29

Overview (continued)

Intended event audience		intended audience versus community type (number of events)	
		geographic	condition-oriented
General	100%	16	8
Medical professionals	0%	0	0
Parents	0%	0	0
High risk specific	0%	0	0
Ethnic/racial community	0%	0	0
Age specific	0%	0	0
Formal community leader	0%	0	0
Civic group/informal leaders	0%	0	0

totals greater than 100% because some events included more than one intended audience or community type

Detail on types of community consultation activities

	no. of events	no. of participants
Existing Group Meeting	5	77
Focus Group	0	0
Phone Survey	0	0
In-person Interview	8	120
Internet Survey	0	0
A Booth Event	3	370
A Convened Meeting	0	0
Town Hall Meeting	0	0
Other	0	0

Detailed View of Individual Events

Hub	Date	Name of Event	Type of Consultation	Number of Participants
PECARN	04/21/15	Surveys in Children's Emergency Services	In-person Interview	30
PECARN	05/16/15	Healthy Kids Day (YMCA)	A Booth Event	20
PECARN	06/02/15	Pediatric Neurology Clinic	In-person Interview	15
PECARN	06/04/15	Pediatric Neurology Clinic	In-person Interview	15
PECARN	06/08/15	Family Advisory Council: Patient and Family Centered Care, Adult Services	Existing Group Meeting	22
PECARN	06/09/15	Children's Advisory Council, UM Family Center	Existing Group Meeting	23
PECARN	06/12/15	Adult Neurology Clinic, University of Michigan Hospital	In-person Interview	10
PECARN	06/15/15	Adult Neurology Clinic, University of Michigan Hospital	In-person Interview	10
PECARN	06/17/15	Adult Neurology Clinic	In-person Interview	10
PECARN	06/17/15	Teen Advisory Council	Existing Group Meeting	15
PECARN	06/24/15	Adult Emergency Department	In-person Interview	20
PECARN	06/26/15	Adult Emergency Department	In-person Interview	10
PECARN	07/16/15	Racial and Economic Justice Task Force	Existing Group Meeting	6
PECARN	07/19/15	Health and Safety Fair	A Booth Event	200
PECARN	07/22/15	Farmers Market	A Booth Event	150
PECARN	08/19/15	Brain Injury Support Group Meeting	Existing Group Meeting	11

Summary of closed ended questions.

# indicates questions for which "strongly agree" or "agree" are coded as supportive and in which "strongly disagree" or "disagree" are coded as concerned
* indicates questions for which "strongly agree" or "agree" are coded as concerned and in which "strongly disagree" or "disagree" are coded as supportive

Questions (in descending order by the number of respondents)	**Yes** or **Strongly Agree**	**Agree**	**Neutral**	**Disagree**	**No** or **Strongly Disagree**		Number of Respondents
ESETT is an important study to do.	56%	41%	3%	0%	0%	#	211
	119	86	6	0	0		
If you developed a seizure that would not stop, you would be okay with being included in ESETT without giving your consent ahead of time.	51%	34%	9%	5%	2%	#	211
	107	71	18	10	5		
If you are/were a parent, and your child developed a seizure that would not stop, would you be okay with him/her being included in ESETT without giving your consent ahead of time.	47%	31%	11%	8%	4%	#	211
	99	65	23	16	8		
Do you think that ESETT researchers will seriously consider what community members like you have to say about this study before starting it?	74%	0%	20%	0%	7%	#	209
	154	0	41	0	14		
Do you feel that you have been given enough information to give your informed opinion about whether you think it is okay for researchers to do the ESETT study?	88%	0%	0%	0%	12%	#	205
	181	0	0	0	24		
Would you like to tell doctors that you do not want to participate in ESETT?	14%	0%	0%	0%	86%	*	201
	29	0	0	0	172		

Summary of open ended comments.

# indicates comments coded as supportive
* indicates comments coded as concerned
+ indicates comments truncated at 430 characters

Selected Comments	
I think it's an important study but I don't like the idea of anything being done to me without my permission	*
If me or my children were in this situation I would want the medications used to be known to be the most effective. This is a very important study.	#
I would be the concern that it would end up hurting rather than helping the child.	*
I think this is very important; seizures can be so dangerous to the patients.	#
What if the patient has an adverse reaction to the medication given?	*
[Considering] the benefits versus the risks... I would feel good about [being enrolled in ESETT]	#
Any pontential interactions the three medications would have with current seizure meds	*
Important study	#
I don't want my child to be a test subject.	*
This could save a life	#
Concern about blinding.	#

Selected Comments (continued)

Seems like a great idea, what took so long!	#
Concerns about not being able to know which medication is given in the acute treatment period.	*

All Comments

It's good to know you are doing this study. More drugs need to be available for seizure patients!	#
Think it would help people to know these are not experimental drugs but a comparison of drugs already in common use.	#
Studies like these really give some insight on how to more effectively treat this diagnosis and how families would like to handle the treatment medication.	#
I would like the study done I think it should done before consent cause as it happen to late to ask.	#
Answer to Q 51-5: Have had much less in other trials, including those that were EFIC	#
Thank you for doing this work.	#
Very informative presentation.	#
Good luck!!	#
I think this is fine as long as enrollees find out after the fact so they can opt out if they choose.	#
Response to 51-5: I like to much because everyvary is so nice.	#
What a great study.	#
Thanks!	#
Answer to Q 51-5: Very well done presentation.	#
Run with this work. It seems very important. :)	#
The way I took this is if I think it would be ok to enroll people in the study without them knowing. I am against that. You need to ask for permission for any study and for any non-emergency care.	#
The study has risks and yet patients are participating without their consent.	#
Other Comments State in very plain language that the patient would be getting one of these 3 drugs anyway, this is a more controlled way to find out which is best.	#

Other Comments Questions are a bit leading in that no one would say they would wish for someone to have seizures.	#
Other Comments No one in my family including myself has ever had seizures.	#
Other Comments Possible to provide seizure prone pt. - w genetic test to determine which most efficacious.	#
Other Comments Might look into how St. Jude's "positions" their studies. Look into 1st respondent/EDs and urgent care clinics for access and educaiton.	#
Other Comments You should inform groups w/neurological issues, i.e. michigan parkinsons assoc.	#
Other Comments Idea for publicity - how about notices at pharmacy windows at least of major pharmacies - Rite Aid, CVS, Walgreens, Meijers, Target, Krogers	*
Other Comments Consider targeting alcoholic anonymous, ALNON etc since that would be contributing factor, health fairs, local chamber of commerce, support groups, other hospitals	*
Other Comments What about targeting individuals with restricted drivers licenses, due to seizures?	
Other Comments Response to Q 51-4: As long as I was informed after waking up and given the choice to get off.	
Other Comments How you present/explain to patients and families is your key to getting co-operation and consent.	
Other Comments I am in the medical profession.	
Other Comments In response to 51-5: Also a researcher	
Other Comments Thank you!	
Other Comments Response to 51-1: One time.	
Other Comments Response to 51-5: Sure.	
Other Comments Thank's for be nice and feel me better.	
Other Comments Thank you for contacting ICPJ. Are you contacting GroundCover? Mission?	
Other Comments Response to Q "Are you Male or Female?": Include other options.	
Other Comments Go cannabinoids	
Other Comments I would like names of meds so that I could do further research. They were stated, I was unable to write them down quickly enough. Problem solved, they were listed in hand out. Thank you.	
Info still needed: Answer to Q 51-5: "Unknown because it depends on the questions."	
Info still needed: Wanting to know how fPHT, VPA, and LVT were chosen.	
Info still needed: Answer to Q 51-5: "Epileptic - possibility of genetic predisposition? Trauma induced? Rate of injury/death same with both? With all Rxs?	
Info still needed: Answer to Q 51-5: More information about the medication	

Info still needed: Answer to Q 51-5: More background info on how decisions are made currently on which med to use. Are these three meds believed equal?	
Info still needed: Start with fact that you are studying meds that are already being used to determine which has the best results.	
Info still needed: It helps if people understand how long it takes for research to be published before they would otherwise benefit.	
Info still needed: Focus on how the computer will help determine which of the 3 drugs is working and then give that to more patients. This will focus the message on how the study will help you.	
Info still needed: Will the study end early if you see that one drug is doing better than other drugs?	0
Info still needed: Some populations are known, such as the epilepsy population. Can these patients be pre-consented? Can you characterize other populations that may go into status-epilepticus?	0
Info still needed: Response to Q 51-5: i need to know tha tbeing on the study offered MORE options as opposed to FEWER or limited options.	0
Info still needed: Mention that side effects of the 3 drugs are the same. Any specific conditions that patients may be more likely to develop? Brochure - I think it is a bit misleading to say on the "enrollment differ" section that the pt/family will be told when repre	0
Info still needed: I have never heard of "EFIC studies" before. I think it is important to stress that this study doesn't change the initial procedure, in that it is very random as it is right now - that Drs pick what they pick, so that parents aren't scared going into	0
Info still needed: Response to 51-5: I would like to know other standard information, but it sounds like a great study.	0
Info still needed: Response to 51-5: Are the three drugs you've choosen known to be successful?	0
Info still needed: Response to 51-5: When you say that they wear a bracelet how do they wear the bracelet again when they are in the middle of a seizure.	0
Info still needed: Response to 51-5: I think I would need to understand medicine.	0
Info still needed: In response to Q51-5: Is there a "placebo"/control? If so, I would think person's consent.	0
Info still needed: Response to Q51-5: Maybe?	0
Info still needed: Response to Q51-5: How long the study would be conducted? Where would information from study be published?	0
Info still needed: Answer to Q 51-5: What about Tegretol medication.	0
Info still needed: Answer to Q 51-5: Potential side effects of both all 3.	0
Info still needed: Answer to Q 51-5: I would want to know the side effects of all three.	0