

ESETT Investigator Meeting

Meeting The EFIC Regulations EOS PD

September, 2019

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Outline

- EOS Public Disclosure
 - Resources –
 - ESETT website
 - Milestone document (section c. part 2)
 - EOS PD activities conducted for prior EFIC trial
 - Capturing EOS PD events in WebDCU
 - To the FDA
- Your PR Office and the media

EOS PD Resources

www.esett.org
Study Team ONLY > Study Closeout

The screenshot shows a web browser displaying the "Study Closeout" page on the ESETT website. The browser's address bar shows the URL: <https://net.lumich.edu/clinical-trials/esett/study-teams-only/study-closeout>. The website header includes the NETT logo (Neurological Emergencies Treatment Trials) and navigation links for LOGOUT, WEB DCU, and CONTACT. A search icon is also present.

The main content area is titled "Study Closeout" and features a left-hand navigation menu with the following items: "on Español", "Fast Facts", "About Emergency Research", "Participating Sites", "Opt-out Form", "Protocol", "Study Teams ONLY" (highlighted in green), "Clinicians ONLY", "Investigator Meetings", and "Contact Us".

The main content area includes the following sections:

- Clinical Trials / ESETT / Study Closeout**
- Closeout Milestone Document**
Please note that this milestone document is for use at Spokes/sites that enrolled at least one ESETT subject. Spokes/sites that did NOT enroll can close with their local IRBs (documentation provided under IRB Closeout Acknowledgment) and provide a final eDOA log, adding end dates for all study team members and are not eligible for any milestone payments.
For spokes that enrolled at least one ESETT subject:
[Closeout Milestone Activities](#)
- ESETT Slides from Ann Arbor, Sept. 2019**
Coming in September
- End of Study (EOS) PD Resources**
[Public Disclosure \(PD\) Menu of Activities](#)
- EOS PD Plans**
EXAMPLE: [Maryland RAMPART EOS Plan](#)
- NOTE:** We are working through the academic process and specific EOS PD templates to tailor locally and notify the community about ESETT results will be forthcoming following the publication of the primary paper.
- The Regulations**
[21 CFR 50.24](#)
[FDA 50.24 Guidance](#)
- Media Related Resources**
[If a Reporter Contacts You](#)

The Windows taskbar at the bottom shows several open applications, including "Study Closeout", "2018 Address...", "Brief Statem...", "ESETT mMA...", "UM.19Sec.do...", "FY19 Valuat...", "Resume_20...", "EOS PD Pres...", and "Presentation...". The system clock indicates 1:31 PM on 9/17/2019.

EOS PD Resources

EFIC tasks – Milestone Google doc.

C. End of Study Public Disclosure Activities (EOSPD) - Part 2
Please do NOT initiate activities below until the ESETT primary paper has been published

These Milestone activities primarily relate to EFIC-required post-trial public disclosure (PD) activities.

A menu of suggested PD activities and template language will be made available. You will be able to use these materials to develop your own PD plan and materials. We will also facilitate sharing of materials across sites at that time. All materials will be posted in the ESETT Toolbox.

1. Maintain regulatory compliance until end of study activities have been completed.	<input type="checkbox"/>
2. Develop an EOS PD plan, which includes notifying subjects as one of your EOS PD events, for your site and upload the plan to WebDCU. We suggest that the IRB agree with this PD plan before you begin. Upload as regulatory document name: ESETT EOS PD Plan .	<input type="checkbox"/>
3. Confirm with your IRB that you have permission to contact subjects with results of the trial. Submit the ESETT Subject Notification Letter for IRB approval if needed.	<input type="checkbox"/>
4. Develop local EOS PD materials and send to the CCC (ESETT-milestone@umich.edu) for review. EFIC materials sent to the IRB must be reviewed by the sponsor via the CCC prior to IRB submission.	<input type="checkbox"/>
5. The IRB must review your completed EOS PD activities and determine that the EFIC regulatory requirement has been met.** Upload documentation under the regulatory document: ESETT EOS PD IRB Acknowledgement .	<input type="checkbox"/>
6. Complete Public Disclosure Summary Forms after completing each EOSPD activity. There should be a summary form for each unique PD activity completed. Notify the CCC (ESETT-milestone@umich.edu) once you have completed all of your PD summary forms for verification and approval (subject line: ESETT<site name> PD Form review requested). Any queries generated from the verification process must be resolved for this task to be marked as complete.	<input type="checkbox"/>
7. Inform IRB of final study closure following conclusion of PD events.	<input type="checkbox"/>
8. Upload documentation of IRB approval of final study closure in WebDCU under: ESETT IRB Close Out Acknowledgement . (if the letter from task 5 above applies, copy the letter to both regulatory documents in WebDCU)	<input type="checkbox"/>
9. Update eDOA log to reflect end dates for all study team members in WebDCU.	<input type="checkbox"/>

****Sample language for IRB acknowledgment statement:** *"Per 21 CFR 50.24 (a)(7)(iii), The IRB has found and documented the ESETT trial end of study public disclosure to contain sufficient information needed to apprise the community and researchers of the study about: the demographic characteristic of the research population and its results."*

Total Close Out Milestone payment 2 to each Hub will be as follows:

EOS PD Activities Conducted for RAMPART

	EOS PD		
<i>METHOD</i>	% used	% reached	Examples
<i>Online post</i>	26%	44%	Online releases: local radio, tv and newspaper, institution newspaper, YouTube, and other online media sites, e.g., news-medical.net, Sci Guru, Newsedge, BrainTalk Communities, etc.
<i>Presentation</i>	14%	< 1%	Grand rounds, community groups, conferences, etc.
<i>Email circular</i>	12%	1%	Internal employee & department email groups
<i>Newspaper</i>	10%	44%	Local newspapers
<i>Mailing</i>	10%	< 1%	Local community groups reached during CC
<i>Material distribution</i>	7%	< 1%	E.d waiting rm., outpatient neurology clinic, national conferences, religious organizations
<i>Radio announcement</i>	5%	4%	PSA
<i>Website article</i>	4%	<1%	NETT, institution & department websites
<i>Letter to subjects</i>	4%	n/a	
<i>Newsletter</i>	3%	4%	Local epilepsy, TBI, chapter newsletter
<i>T.V.</i>	2%	2%	Local news station
<i>Press release</i>	2%	6%	To media outlets
<i>Social media</i>	1%	none given	Twitter & fb
<i>Billboard</i>	<1 %	none given	Public transit
<i>Total</i>	n = 277	5,734,475	

Capturing EOS PD events in WebDCU

The screenshot displays the WebDCU main menu with the following components:

- Header:** WebDCU logo (Data + Information + Knowledge), BOOST logo, and a progress indicator: "Enrolled 0.1% (1 / 1094) of recruitment target."
- Navigation Grid:**
 - Row 1: Add New Subject, Subject CRF Binder, Study Progress, Data Management, Project Management, Site Management
 - Row 2: Central IRB, Data Monitoring, CRF Data List, Graphic Reports, Project Setup, User Management
 - Row 3: Regulatory Document, Toolbox, Emergency Help, EFIC, Alerts
- Form Selection Table:**

CC Form	CC Site Activity Summary	CC Closed Ended Summary	CC Open Ended Coding	CC Question List
PD Form	PD Site Activity Summary	PD Closed Ended Summary	Informed Consent Summary	Local Context Form

A red arrow points to the "PD Form" button in the second row of the table. The browser address bar shows "https://webdcu.musc.edu/net/MainMenu.asp". The Windows taskbar at the bottom includes icons for Outlook, File Explorer, and several open applications, with the system clock showing 1:54 PM on 9/17/2019.

Capturing EOS PD events in WebDCU

No.	Item Description	Data Value
1	Hub	Please Select
2	Spoke (if needed by the Hub)	No Option Provided
3	Phase of trial locally during this PD event	<input type="radio"/> Before open enrollment <input type="radio"/> During enrollment period <input type="radio"/> After close of enrollment <input type="radio"/> Ongoing (before-after) <input type="radio"/> After results published
4	Title of event (Specify exact source)	<input type="text"/> (100 char.)
5	Date of event	<input type="text"/> (dd-mm-yyyy) Complete
6	Method	Please Select
7	If Other, specify	
8	Price to use this method (\$)	<input type="text"/> (do not include study team time or manpower hours)
9	Community Category	<input type="radio"/> Geographical (general) community <input type="radio"/> Disease-associated community
10	Language	<input type="radio"/> English <input type="radio"/> Spanish <input type="radio"/> Other
11	If Other, specify	
12	Primary intended audience	Please Select
13	If Other, specify	
14	Number of people reached category	<input type="radio"/> Actual <input type="radio"/> Estimate <input type="radio"/> Unknown
15	Number of people reached	
16	Time Zone (when applicable)	Please Select
17	Time of event	
18	Duration (when applicable)	<input type="text"/> (30 sec, 5 min, 1 hr, etc. (25 char.))
19	Run time (when applicable)	<input type="text"/> (1 day, 2 wks., ongoing, etc. (25 char.))
20	Summary of feedback received	<input type="text"/> (250 char.)
21	# of out-opt mechanisms requested in response to this event	<input type="text"/> Leave blank if unknown
22	Web link to source event	<input type="text"/> (50 char.)
23	Attach published source here	
24	Notes	<input type="text"/> (250 char.)
25	First Entered On	(to be assigned by the system)
Attach published source here:		<input type="button" value="Choose File"/> <input type="button" value="No file chosen"/> <input type="button" value="Upload File"/>
<input type="button" value="Save Record"/>		<input type="button" value="Cancel Edit"/>

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Title must be unique and please no acronyms.

To the FDA Docket!

www.regulations.gov/#!docketDetail;D=FDA-1995-S-0036

Where can I learn more about the study?
Before the study starts, some sites will hold community meetings to provide information about the study.

Neurological Emergencies Treatment Trials (NETT)
University of Michigan Health System
Department of Emergency Medicine
1167D Dr. Lobby H
MI 48106
29-6388
umich.edu
tact@umich.edu

Contact Us
Neurological Emergencies Treatment Trials (NETT)
University of Michigan Health System
Department of Emergency Medicine
1167D Dr. Lobby H
MI 48106
29-6388
umich.edu
tact@umich.edu

Do You Or A Family Member Have Seizures?

Network
Neurological Emergencies Treatment Trials (NETT)
Network, made up of
, was created by
Health to conduct

Learn more about a study that may be opening in your community.

RAMPART - IND # 102,254 PD Docket Report 12/12/12

Public Disclosure Docket Report
Neurological Emergencies Treatment Trials (NETT) network

This report includes examples of the different kinds of materials and formats used to perform pre-trial Public Disclosure activities for the RAMPART trial pursuant to 21 CFR 30.24. This portfolio includes a demonstrative sample of the materials developed, but is not comprehensive.

Oregonian
Community Edition
DIA, Portland, OR
City: Portland, OR
State: OR

Oregon plays role in fight against

If the drug trial succeeds, people with the disorder and their families could give emergency injections.

IN ANOTHER
ORANGEVILLE

Oregon paramedics will start testing a drug that could save lives for people treating dangerous seizures when an ambulance arrives.

If the new medicine could give a new and safer tool not only to paramedics but also to people with serious seizures and their families. But to test the drug, paramedics will have to inject it into people having seizures so severe they can't agree to join the trial. A federal regulation allows these trials to go on without patient consent in rare circumstances where there's no other way to see life-saving treatment.

These "emergency use" medicines, which can be used on 200,000 U.S. residents a year, killing about 20 percent of them. The article can last making it hard to translate into a news story.

Paramedics carry a drug, lorazepam, to treat these seizures. But it has to be given through a needle inserted into a vein. While IV drugs start to work fast, it can be tough to start an IV on someone having convulsive seizures. Another seizure drug, midazolam, can be injected into a muscle. That's quicker but takes longer to act on in the body.

Each drug "can be quite painful" for people to receive, said Dr. Robert Lowe, a professor of emergency medicine at Oregon Health & Science University. Lowe said the research did not mean that people have never compared the two drugs head-to-head in a clinical trial.

"It was crucial to give the treatment in very, very quick," Lowe said. "The question is, how fast to get an IV in and give it in the best medicine to someone who already has an IV or is better to give the injection into the muscle that can be given quickly."

Low said the research did not mean that people have never compared the two drugs head-to-head in a clinical trial.

"It was crucial to give the treatment in very, very quick," Lowe said. "The question is, how fast to get an IV in and give it in the best medicine to someone who already has an IV or is better to give the injection into the muscle that can be given quickly."

Adults and children over about 20 pounds who are having prolonged seizures in Clatsop County will offer get that midazolam injection or the traditional lorazepam IV. Which drug to give will be determined randomly, to allow

FOR MORE INFORMATION
Call us at RAMPART.Trial@emory.edu
or call 404-778-1719

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Do You or a family member have seizures?

From Steve Miller's 3. Healthline Medical News Service. In a RAMPART trial, researchers are testing a new medicine to help people with severe seizures. The search is still in its early stages, but researchers are looking for people who are having seizures that last longer than five minutes. If you or a family member has had a seizure that lasted longer than five minutes, you may be interested in the trial. For more information, call 404-778-1719 or visit www.rampart.org.

Neurological Emergencies Treatment Trials (NETT)
Network, made up of
, was created by
Health to conduct

Learn more about a study that may be opening in your community.

RAMPART
Rapid Anticonvulsant Medication Prior to Arrival Trial

Summary Report of Public Disclosures
Neurological Emergencies Treatment Trials (NETT) network

Title: RAMPART: the Rapid Anticonvulsant Medication Prior to Arrival Trial
IND #: 102,254

Report Date: Dec 12, 2012

Executive Summary: This report includes findings from pre-trial and ongoing public disclosure (PD) events that took place between April 26, 2010 and August 26, 2011. It includes findings from 288 events/disclosures reported by 17 of the 27 NETT investigators. These events involved reaching an estimated 14,427 (77) community members nationwide while through the PD process. Among the estimated community members reached, 18 individuals requested an actual presentation.

Overview	Type of disclosure activities		
No. of lay speaking	17	Newsletters/articles	10%
No. of activity reports	286	Website articles	10%
No. of community members reached	14,427 (77)	Printed materials	6%
No. requesting an actual presentation	18	Study material distribution	6%
Type of community involved		Other poster/presentation	6%
Healthcare professionals	1%	Newsletters/articles	6%
Parent condition/oriented community	25%	Mail	5%
Parent only type of community	4%	Press releases	1%
		Billboards	1%
		Telephone call	1%

Intended audience versus community type

Intended audience	Community type		
General public	70%	Healthcare professionals	1%
Medical professionals	1%	Parent condition/oriented community	25%
Other	1%	Parent only type of community	4%
Age-specific groups	3%		
Ethnic/racial communities	3%		
Other geographical areas	1%		
Other community leaders	1%		

Detail on type of public disclosure activities

Activity	No. of events	No. community members*
Study material distribution	10	624,874
Newsletters/articles	36	5,543,878
Website articles	36	861,314
Printed materials	30	204,848
Study material distribution	18	141,023
Other poster/presentation	19	1,046,289
Mail	15	2,075,422
Newsletters/articles	13	22,522
Press releases	9	1,500
Phone releases	5	620,000
Billboard	4	345,000
Telephone call	1	25,000

*Not all events include both type of activity and an estimate number for community reached.

You Live or Work Fullerton County?

Fullerton Research Study May Involve You!

City of Department of Emergency Medicine and Orange Health Services are participating in a clinical trial that includes who are having a prolonged seizure and are by Orange, CA. Seizures that start stop suddenly are being medical emergency. The Rapid Anticonvulsant Medication Prior to Arrival Trial is a research study that compares generalized convulsions for seizures on these children to the best of emergency medicine. Medications are already used every day to treat seizures and are hospital setting.

Such research is important to the government for it is in which medicine that is given to take part. Lowe said the research did not mean that people have never compared the two drugs head-to-head in a clinical trial.

"It was crucial to give the treatment in very, very quick," Lowe said. "The question is, how fast to get an IV in and give it in the best medicine to someone who already has an IV or is better to give the injection into the muscle that can be given quickly."

Adults and children over about 20 pounds who are having prolonged seizures in Clatsop County will offer get that midazolam injection or the traditional lorazepam IV. Which drug to give will be determined randomly, to allow

FOR MORE INFORMATION
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or call 404-778-1719

RAMPART Public Disclosure Summary

Date	City	Event Type	Topic	Type of Disclosure	Estimated reach
4/26/10	Orange	Public Hearing	Seizures: A Rare but Serious Condition	Study material distribution	100
5/10/10	Orange	Public Hearing	Seizures: A Rare but Serious Condition	Newsletters/articles	100
5/10/10	Orange	Public Hearing	Seizures: A Rare but Serious Condition	Printed materials	100
5/10/10	Orange	Public Hearing	Seizures: A Rare but Serious Condition	Study material distribution	100
5/10/10	Orange	Public Hearing	Seizures: A Rare but Serious Condition	Newsletters/articles	100
5/10/10	Orange	Public Hearing	Seizures: A Rare but Serious Condition	Printed materials	100
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5/10/10	Orange	Public Hearing	Seizures: A Rare but Serious Condition	Newsletters/articles	100
5/10/10	Orange	Public Hearing	Seizures: A Rare but Serious Condition	Printed materials	100
5/10/10	Orange	Public Hearing	Seizures: A Rare but Serious Condition	Study material distribution	100
5/10/10	Orange	Public Hearing	Seizures: A Rare but Serious Condition	Newsletters/articles	100
5/10/10	Orange	Public Hearing	Seizures: A Rare but Serious Condition	Printed materials	100
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5/10/10	Orange	Public Hearing	Seizures: A Rare but Serious Condition	Newsletters/articles	100

Press - How to

Contact your PR Office now

- Learn who your PR person is
- Let them know the study results are forthcoming

Media resources available at esett.org

- If a reporter contacts you
- Guidelines for support staff
- Tips for working with the news media

Press: Cont.

Notify the CCC & sponsor at esett-milestone@umich.edu when:

- you have given a statement to a reporter, or
- you become aware of any bad press published about ESETT

Questions?