ESETT Investigator Meeting

Meeting The EFIC Regulations
EOS PD

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Established Status Epilepticus Treatment Trial

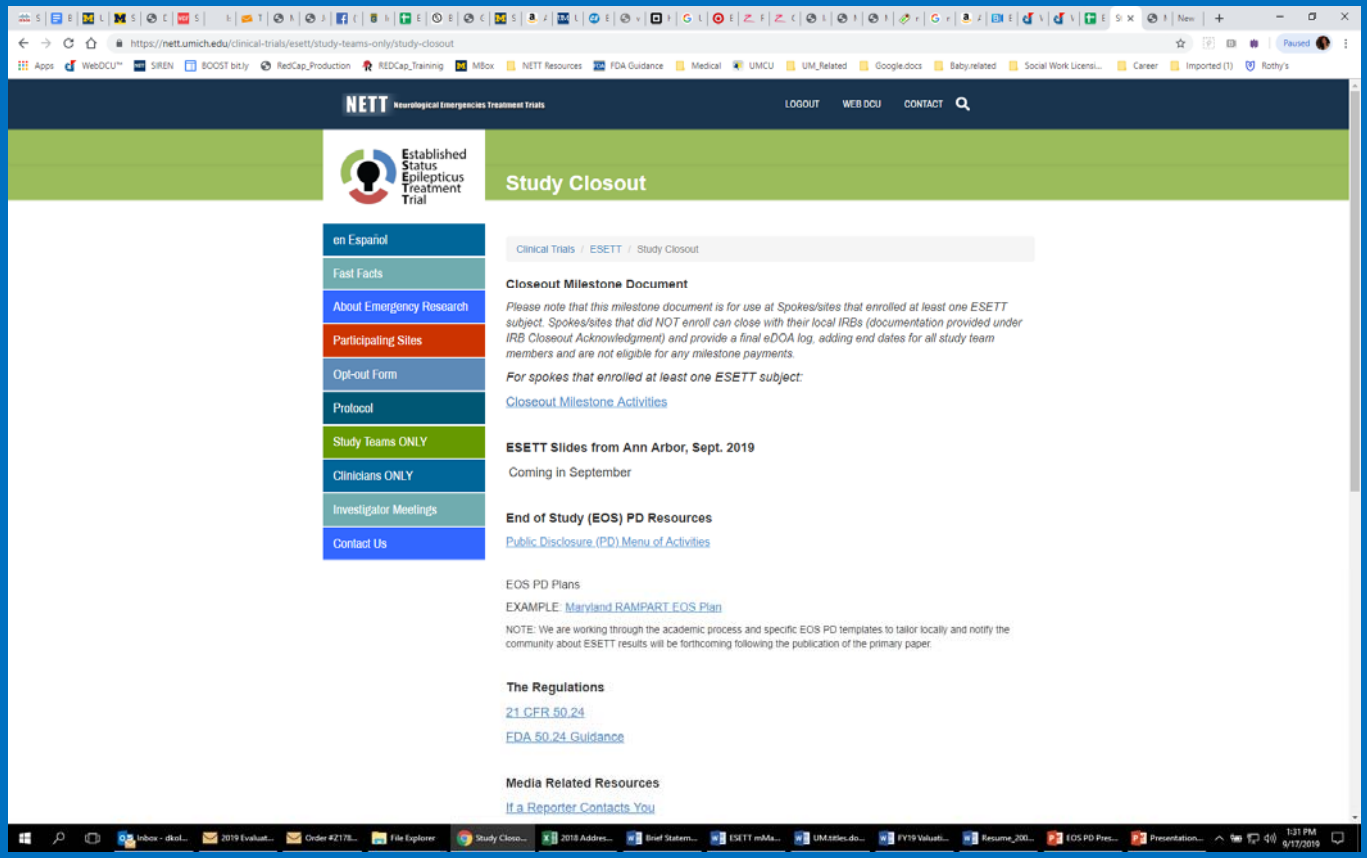
Outline

- 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

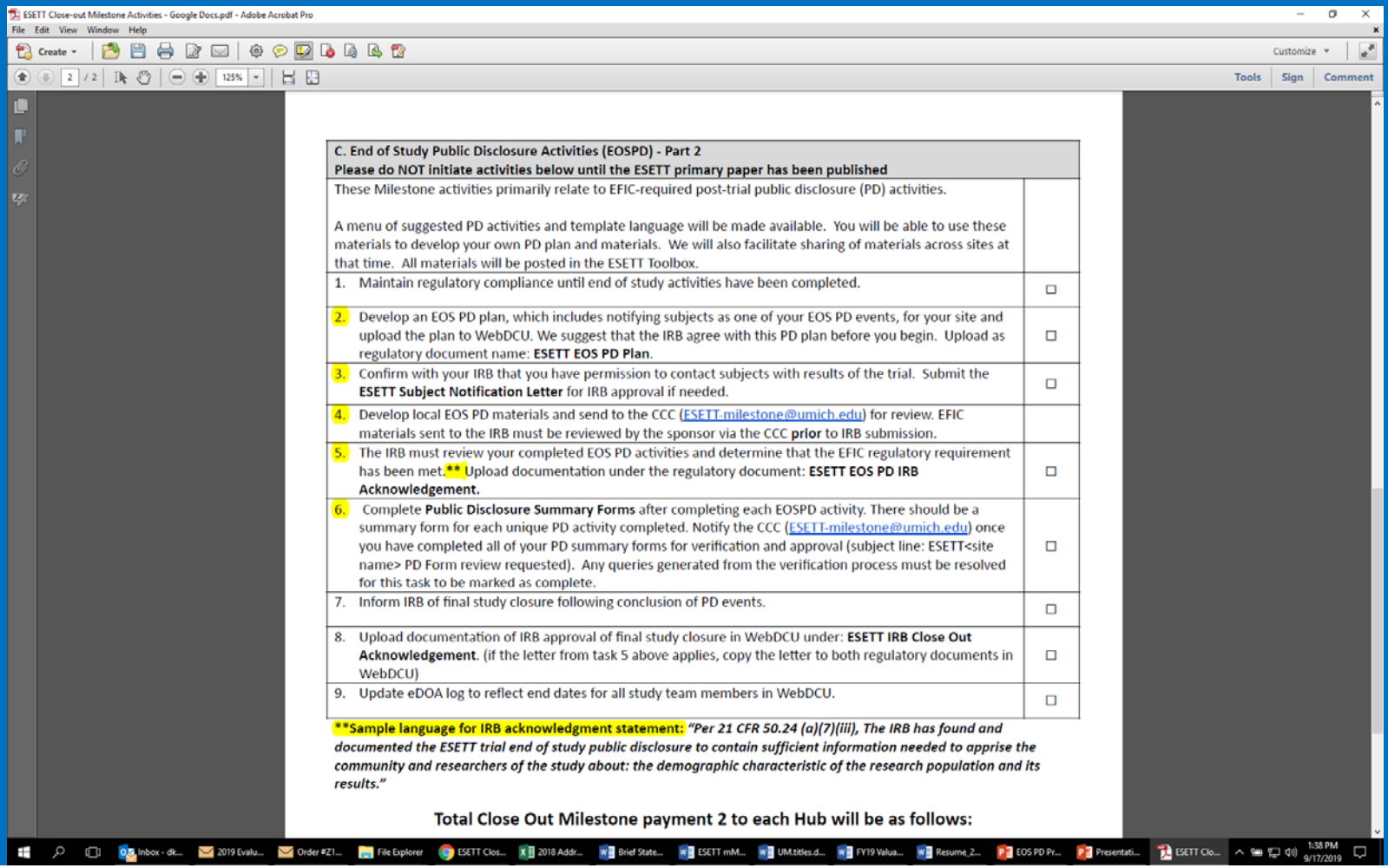
www.esett.org

Study Team ONLY > Study Closeout



EOS PD Resources

EFIC tasks – Milestone Google doc.



ESETT Close-out Milestone Activities - Google Docs.pdf - Adobe Acrobat Pro

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.	☐
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**.	☐
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.	☐
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.	
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.**	☐
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.	☐
7. Inform IRB of final study closure following conclusion of PD events.	☐
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)	☐
9. Update eDOA log to reflect end dates for all study team members in WebDCU.	☐

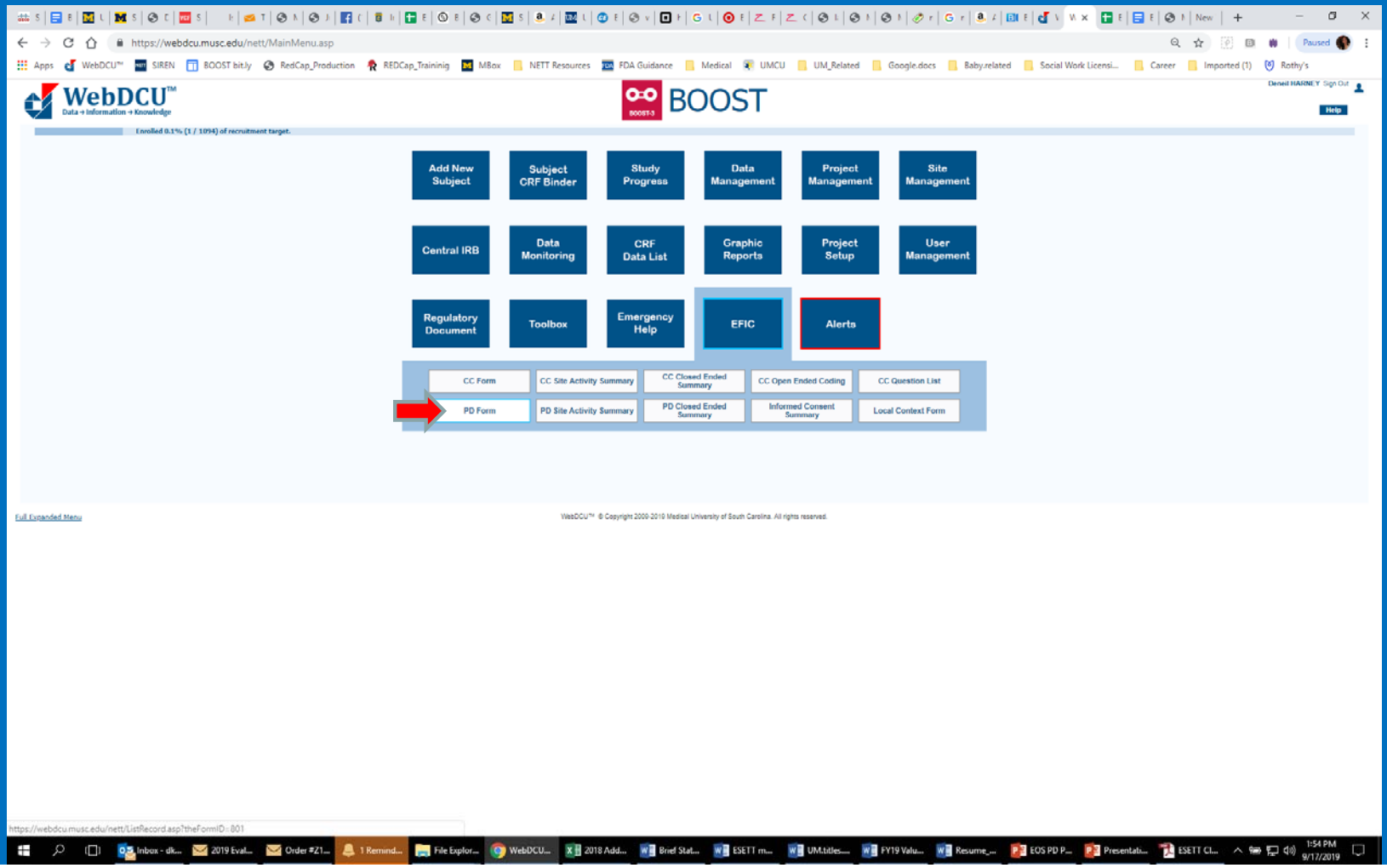
**Sample language for IRB acknowledgment statement: *"Per 21 CFR 50.24 (a)(7)(iii), The IRB has found and documented the ESETT trial end of study public disclosure to contain sufficient information needed to apprise the community and researchers of the study about: the demographic characteristic of the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

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

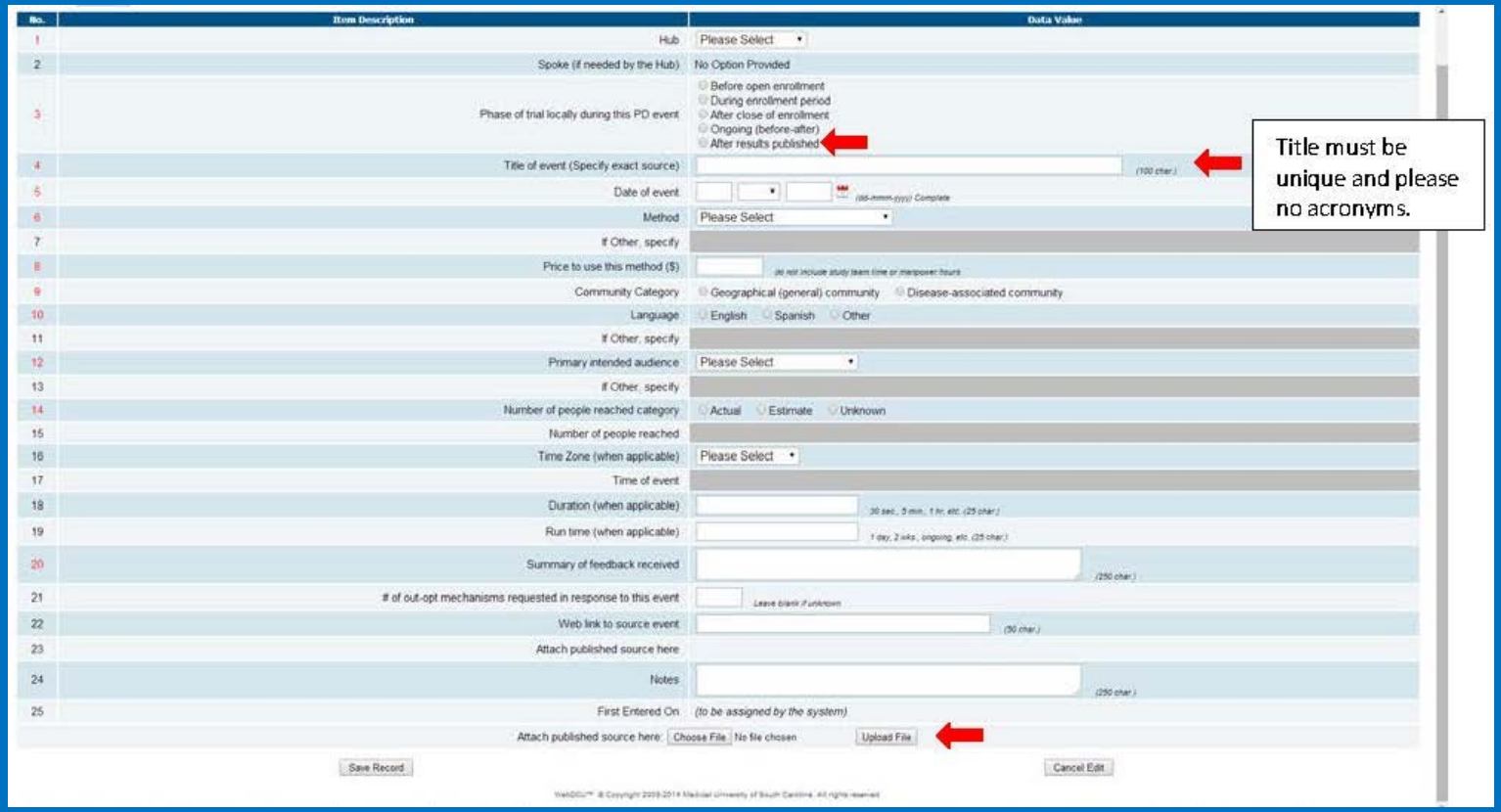
EOS PD Activities Conducted for RAMPART

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

Capturing EOS PD events in WebDCU



Capturing EOS PD events in WebDCU



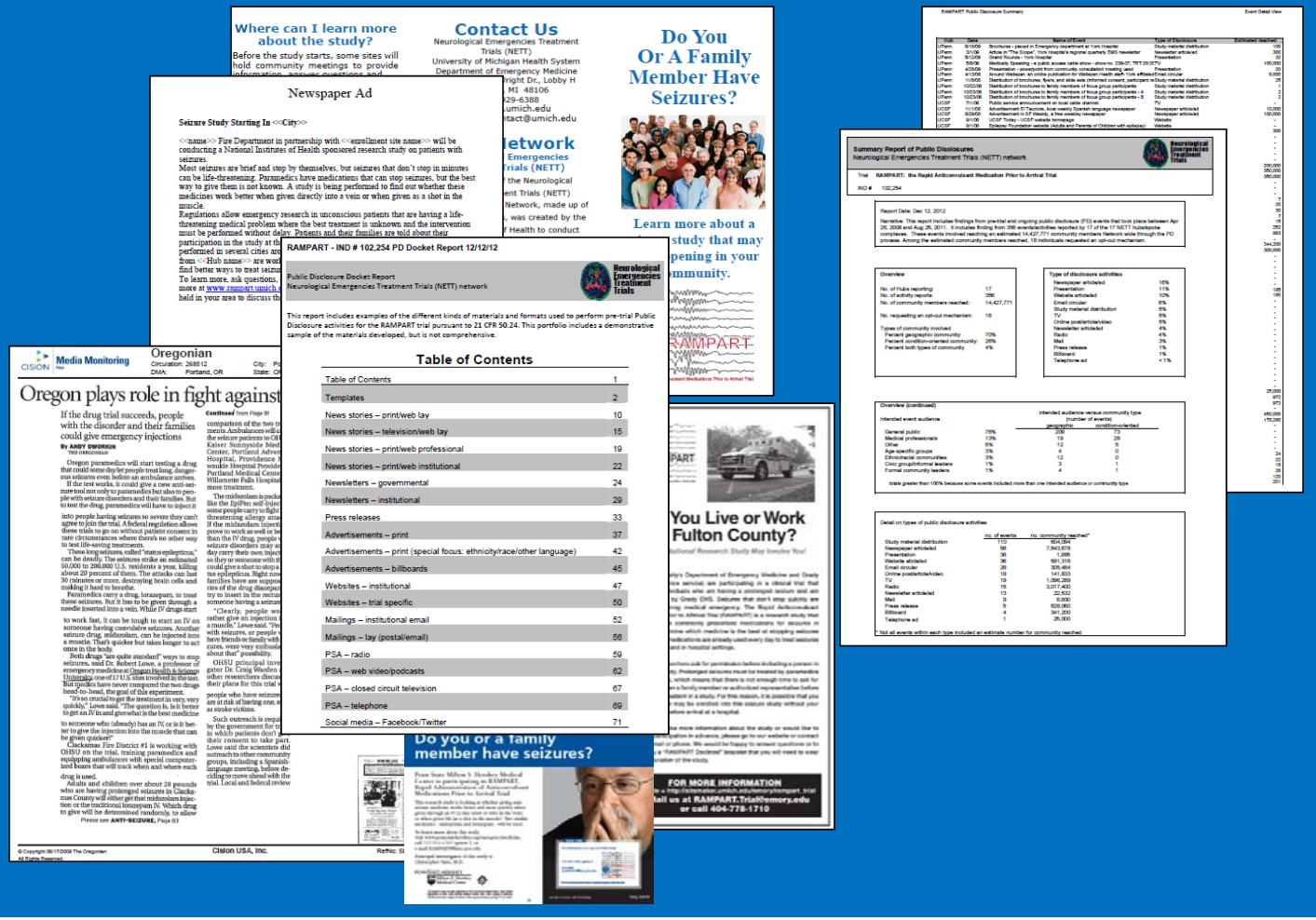
No.	Item Description	Data Value
1	Hub	Please Select
2	Spoke (if needed by the Hub)	No Option Provided
3	Phase of trial locally during this PD event	Before open enrollment During enrollment period After close of enrollment Ongoing (before-after) After results published
4	Title of event (Specify exact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

Save Record Cancel Edit

Title must be unique and please no acronyms.

To the FDA Docket!

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



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?