Monthly Update

8-September 2017

UW Health

School of Medicine and Public Health
UNIVERSITY OF WISCONSIN-MADISON

REMINDER!
Monthly Coordinator Call

The next coordinator call is scheduled for **Thursday, September 21st at 10.30am**

Neuro Teleconference Line:
USA Toll-Free: (877) 848-7030
Access Code: 3386580

Enrollment Update

- **iDEF** – 274
- **MISTIE III** – 504 **enrollment complete!**
- **CREST 2** – 742
- **Telerehab in Stroke** – 124
- **POINT –** 4586 – no update since July

RCC24 is currently enrolling in POINT and Crest2. The CREST-H protocol is being finalized.

The renewal grant will be submitted in just a few weeks.

UW-Madison, Aurora St. Luke, and Marshfield will be attending the ARCADIA investigator meeting will be Sept. 13 in Atlanta. We will have updates on the next coordinator call.

MISTIE-III completed enrollment in August after enrolling 504 subjects.
DEFUSE-3 has been permanently closed due to a high likelihood of efficacy in the endovascular treatment arm.

At the end, please find the latest bi-weekly StrokeNet newsletter and an opportunity to attend an NIH workshop.

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Trial Proposal Status

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
MOST	Opeolu Adeoye, Andrew Barreto, Joe Broderick, James Grotta	Acute	Council review September 2017.
I-WITNESS	Lee Schwamm, Ona Wu, Steve Warach, Larry Latour, Shlee Song	Acute	Awaiting summary statements from June 2017 study section review
Sleep SMART (C-PAP)	Devin Brown	Prevention	Council review September 2017.
IMPACT	Andrew Naidech	Acute	July 2017 resubmission

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
TRANSPORT 2	Wayne Feng, Gottfried Schlaug	Recovery	July 2017 resubmission
ARREST	Robert Brown, James Torner, David Hasan	Prevention	July 2017 resubmission
VERiTAS II	Sepideh Amin-Hanjani	Prevention	July 2017 submission
ASPIRE (formerly SCORPION)	Kevin Sheth	Prevention	July 2017 submission
ACQUIRE (formerly IRIIS)	Warren Lo, Sharon Ramey	Recovery	July 2017 submission
CAPTIVA (CRISIS)	Brian Hoh	Prevention	October 2017 submission
FURRThER	Bernadette Boden-Albala	Prevention	October 2017 submission
ALISAH 2	Jose Suarez	Acute	November 2017 resubmission
PreLIMBS II	Sebastian Koch, Nestor Gonzalez, Neeraj Chaudhary	Acute	November 2017 resubmission
SATURN	Magdy Selim	Prevention	November 2017 resubmission

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
PICASSO	Marc Chimowitz	Prevention	Redesigning as Phase I
PHAST	Kate Amlie-Lefond, Michael Rivkin, Joan Cox Gill	Acute	In concept development
ETHER	Stephan Mayer	Acute	In concept development
iTREAT	Andrew Southerland	Acute	In concept development
RAFT	Truman Milling, Steve Warach	ACUTE	In concept development
CAVIS	Mark Harrigan	Prevention	In concept development
SEACOAST 1	Radoslav Raychev, Dimiter Arnaudov, David Liebeskind, Jeffrey Saver	Acute	In concept development
TESLA	Albert Yoo, Sam Zaidat	Acute	In concept development
ASSIST	David F. Kallmes, (Radiology) Alejandro Rabinstein, (Neurology) Jeffrey Pasternak, (Anesthesiology) Rickey Carter, (Biostatistics)	Acute	In concept development
DEFUSE 4	Maarten Lansberg, Greg Albers	Acute	In concept development
START	Steve Warach, Truman Milling	Prevention	In concept development

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
Deep TMS Treatment of Stroke (Israel - Industry)	Abraham Zangen	Recovery	In concept development
SPLIT	Andrew Naidech	Prevention	In concept development
FOCAS	Heather Fullerton, Mitch Elkind	Prevention	In concept development
PAST-TIME	Jason McMullan, Opeolu Adeoye, Nerses Sanossian	Acute	In concept development; on ESC agenda for 18-August
PRECISE MRI-T2	Natalia Rost, Shyam Prabhakaran, Rebecca Gottesman, Clinton Wright	Prevention	In concept development
STEPSS (Dose Response Aerobic Exercise in Subacute Stroke)	Sandra Billinger	Recovery	Regrouping after review.
RISiS	Julius Fridrikkson, Ron Lazar, Ed Jauch, Jordan Elm, Leonardo Bonilha	Recovery	PPIs unsure whether they will resubmit.
Tempo-EMS	Nerses Sanossian, William Meurer, Jeffrey Saver, David Hess	Acute	Triaged at November 2016 Study Section

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
CREST-P	Brajesh K Lal, Ronald Lazar, Randolph Marshall	Prevention	Pending score/critiques Score not in funding range
CREST-T	Brajesh K Lal, Ronald Lazar, Randolph Marshall	Prevention	Pending score/critiques Score not in funding range
Bozoki study	Andrea Bozoki	Prevention	Discussed with ESC, have not received permission to move forward in its current form
DOSER	Alex Dromerick	Recovery	Discussed with ESC, have not received permission to move forward at this time Deferred
Contralateral Rehab	Jayme Knutson	Recovery	Discussed with ESC, have not received permission to move forward at this time More discussion needed
Ankle rehabilitation in acute stroke	Li-Qun Zhang	Recovery	In early stages of concept development Requested update 21-Sep Requested update 4-Nov *After RWG review, Dr. Cramer indicated this is in the PIs court; instructed him to seek out Dr. Janis in regard to the direction the proposal should take. PI did not respond to requests for update.

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
PATCH	Maarten Lansberg	Prevention	Inactive due to non-response from device company.
URIC	Enrique Leira	Acute	Inadequate data to support the trial in its current form. Needs published work prior to submission.
ICTuS 3	Pat Lyden	Acute	Indefinite hold.
NORRIS	Walter Kernan	Prevention	Not approved to move forward at this time.
ETOSHA	Tanya Turan	Prevention	Will not move forward in its current form.
Acute Biomarker	Robert Meller	Acute	Not coming into StrokeNet
SOPRANO	Karl Meisel, Wade Smith	Prevention	Not approved to move forward

NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY

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E. New Project Development Progress

Type	Project	NINDS Grant Submission					Project Initiation			
		Concept Synopsis Approved by NINDS ESC	Feasibility Assessment	Grant Submit to NINDS	Scientific Peer Review	Awarded	Protocol Submit to CIRB	CIRB Approval	First Site Released	First Subject Enrolled
	Summary		Min=-6 Max=89 Med=30	Min=30 Max=301 Med=78.5	Min=92 Max=195 Med=147	Min=97 Max=298 Med=197.5	Med=1	Med=15	Med=168	Med=35
	DEFUSE 3	5/7/2014	-6 1/26/2015	31 58	162 11/10/2014 92	97	1	15	168	35 5/6/2016
	ICTUS 3	6/4/2014	89	30	155 3/5/2015					
MOST		8/13/2014	-1 7/5/2015 12/11/2015	50 131 177	155 3/5/2015 156 11/13/2015 156 11/8/2016 6/23/2017					
IMPACT		6/2/2015	20 7/5/2016 7/11/2017	106 126	147 3/1/2016 126 11/8/2016					
	PreLIMBS	7/23/2015	21	54	147 3/1/2016					
	Tempo-EMS	2/22/2016	25	80	155 11/8/2016					
		3/23/2016	14	61	155 11/8/2016					
	I-WITNESS	3/23/2016	14	301	142 6/23/2017					
	PICASSO	10/16/2014	55 3/5/2016	53 124	144 6/25/2015 124 7/7/2016					
	ARCADIA	3/6/2015	21 1/27/2016	80 37	150 11/12/2015 125	298 5/1/2017		3/10/2017		
	SleepSMART	11/3/2015	22 3/3/2017	76 112	150 7/8/2016 112 6/23/2017					
	ARREST	11/3/2015	22 7/11/2017	76	150 7/8/2016					
Prevention (40.9%)	SATURN	2/3/2016	21	224 10/5/2016						
	VERITAS II	8/10/2016	84	251 7/11/2017						
	ASPIRE	10/21/2016	25	238 7/11/2017						
	CAPTIVA (formerly CRISIS)	6/7/2017	42 7/19/2017							
	FURRThER	6/13/2017	36 7/19/2017							
	RISiS	12/15/2015	45	128	156 11/8/2016					
Recovery (18.2%)	STEPSS	4/29/2016	56	103	195 4/18/2017					
	TRANSPORT-II	7/25/2016	36 7/11/2017	36	195 4/18/2017					
	ACQUIRE (formerly IRIIS)	3/17/2017	35	81 7/11/2017						

NIH StrokeNet
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Biweekly Update
1-September-2017

http://nihstrokenet.org/coming-events

NOTE: The next BWU will be 29-September, 2017

StrokeNet Enrollment Update
Telerehabilitation in Stroke – **108/124**
iDEF – **274/294**
CREST 2 – **742/2480**

StrokeNet Trial Updates

Last week we received the official summary of DEFUSE 3 DSMB meeting. The summary clarified that the study was stopped by the DSMB based on a high likelihood of benefit in both the overall cohort and the DAWN-eligible subset. In addition, there were no safety concerns or imbalances between treatment groups.

Final study results will be confidentially presented to investigators the evening before the ISC presentation. Please mark your calendars for the DEFUSE 3 Investigator Meeting on January 23 from 7-9:00 pm in Los Angeles.

The ARCADIA Team is excited to see investigators and coordinators in Atlanta September 12-13 at the first Investigator Meeting. The room block is full so please let us know if your availability has changed and you are unable to attend. You should be receiving your hotel confirmation numbers shortly. For those unable to attend the meeting, online training will be available after the Investigator meeting.

Protocol ver. 1.1, approved by the StrokeNet CIRB, was sent out to all sites two weeks ago, and protocol trial agreements should be on their way soon. The Investigator Meeting agenda was also sent last week. If you did not receive these documents, contact Irene

Ewing at the email below. The protocol is also available on the ARCADIA database in WebDCU.

Please remember NOT to submit the protocol to your IRB yet.

The ARCADIA Investigators also encourage colleagues to contact Dr. David Tirschwell <tirsch@uw.edu> with ideas for ancillary studies. We will devote a session at the meeting to potential ancillary studies; we already have 6-7 proposals percolating. It should be a lively discussion!
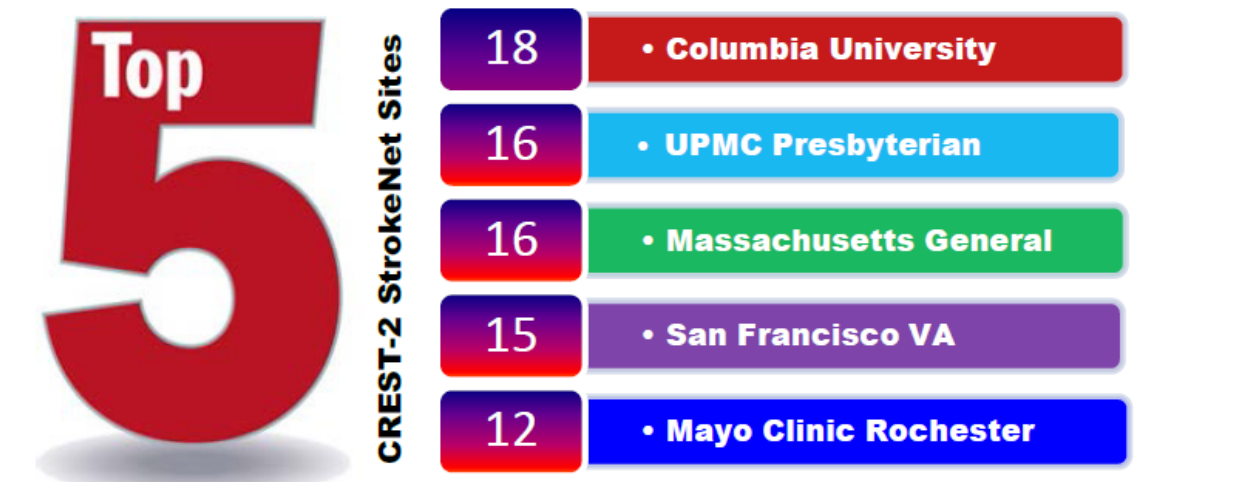
Please contact Irene Ewing <irene.ewing@uc.ed> with any questions.

From the CREST-2 Clinical Coordinating Center:

742 randomizations (364 CEA; 378 CAS)

39 randomizations in August (22 CEA; 17 CAS)

121 active centers of which 50 are StrokeNet Sites

Congratulations to the high-enrolling CREST-2 StrokeNet Centers

Top 5 — CREST-2 StrokeNet Sites

18	• Columbia University
16	• UPMC Presbyterian
16	• Massachusetts General
15	• San Francisco VA
12	• Mayo Clinic Rochester

CREST-H The protocol is being finalized, and the next wave of site recruitment is about to begin. If you are a CREST-2 site that has recruited at least one CREST-2 patient, keep your eyes peeled for an invitation to join CREST-H!

Randy Marshall, On Behalf of the CREST-H Co-PIs Ronald Lazar, David Liebeskind, Sander Connolly.

We have enrolled 108 patients and have only 16 more to go. This is great progress for recovery and rehabilitation research.

Thanks for your hard work! For non-emergent questions: telerehab@uci.edu.

Telerehab Trial

NINDS NEWS

NIH Collaboratory Launches New Website

The NIH Collaboratory announces a new website, *Rethinking Clinical Trials®: A Living Textbook of Pragmatic Clinical Trials*. The revised and updated Living Textbook is the **new home for all Grand Rounds content**, both upcoming and archived presentations. It also contains a wealth of new information about special considerations for pragmatic clinical trials at each stage of the research process.

Visit the new website at www.rethinkingclinicaltrials.org to view:

- 12 detailed chapters with expert insight on pragmatic trials

- Real-world examples from the NIH Collaboratory

- Up-to-date information on best practices for designing and conducting pragmatic trials

- Strategies for disseminating and implementing evidence from pragmatic trials

- Descriptions of unique challenges posed by pragmatic trials and solutions to these

- Information on the importance of pragmatic trials and their impact on healthcare

- Trusted resources and academic references that can help guide pragmatic trials

- Comprehensive information about the NIH Collaboratory program, including its Demonstration Projects, Core Working Groups, News, Events, and more

Please see the welcome video from the Living Textbook's Editor-in-Chief, Dr. Kevin Weinfurt. We hope you will find this new resource useful and share it with your colleagues. We also encourage you to provide your feedback on the new website.

This can also be found on the Education page under Research Enrichment Tools and Resources on the nihstrokenet.org website, https://nihstrokenet.org/education/

New Human Subjects and Clinical Trial Information Form

To learn about the new Human Subjects and Clinical Trial Information form which will be included in grant application packages and contract for all human subjects and/or clinical trial research applications beginning for January 25, 2018 due dates, please access the link below:

https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm

The most significant change with the new FORMS-E Application Package is the addition of a new PHS Human Subjects and Clinical Trials Information form. This form consolidates human subjects, inclusion enrollment, and clinical trial information previously collected across multiple agency forms. The form collects information on human subjects and clinical trials at the study level.

- Leads applicants through the human subject and clinical trial information collection requirements
- Expands the use of discrete form fields to capture clinical trial information to provide the level of detail needed for peer review
- Presents key information to reviewers and agency staff in a consistent format
- Aligns with ClinicalTrials.gov (where possible) and positions the NIH for future data exchange with ClinicalTrials.gov.

Key Dates

- **September 25, 2017** – New FORMS-E Application Instructions available on the How to Apply - Application Guide website.
- **October 25, 2017** - FORMS-E Application Packages will start being published for FOAs with due dates on or after January 25, 2018.
- Note that all new application packages will be published at least 60 days ahead of the first due dates
- **January 25, 2018** – First due dates for new FORMS-E Application Packages
- During the transition period from FORMS-D to FORMS-E, both form packages will be available for some FOAs. *It is important that applicants pay close attention and choose the announcement specific for their due date.*

Steering Committee Call

Steering Committee Calls are a requirement for all NIH StrokeNet RCCs
(one representative per RCC required)

The next Steering Committee call will be **12-September, 2017, at the in-person meeting in Atlanta, GA.** The presentations will be posted to the www.nihstrokenet.org website following the meeting.

Minutes from all Steering Committee calls can be accessed via the www.nihstrokenet.org website. After log in, click on the "Minutes" tab, then at the dropdown menu, select "Steering Committee". https://www.nihstrokenet.org/intranet/minutes/steering-committee.

If you need a log in, please contact your RCC Network Manager/Coordinator to request one for you.

Coordinator Webinar

Coordinator Webinars are a requirement for the NIH StrokeNet RCC Coordinators/Managers

Topic: **Challenges and Opportunities of 24/7 Coordinator Coverage for acute research enrollments**

Presenter: **Kathleen Miller, BSN, CCRC, Research Project Manager, University of Minnesota**

When: **Wednesday, 25-October, 2017 – 1:30 PM ET**

To join Coordinator Webinars*: https://nihstrokenet.adobeconnect.com/coordinator/* Please enter as a guest, then add your first and last name or email address. For Audio: Dial-In Number: (877) 621-0220 Passcode 434578.

Please send suggestions for future coordinator webinar ideas to beckmare@ucmail.uc.edu.

Professional Development Webinar

Professional Development Webinars are a requirement for the NIH StrokeNet Trainees

Presentations: **How to Present your Data – Enrique Leira, MD, University of Iowa**

When: **Thursday, October 12, 2017 – 2:00 PM ET**

Moderator: TBD

To join the meeting: https://nihstrokenet.adobeconnect.com/pdw/ **To take part in the conversation you must dial in. 1 (877) 621-0220 Passcode Number: 190825**

Grand Rounds

Grand Rounds are a requirement for the NIH StrokeNet Trainees, however all are welcome to participate.

Note: To view the 2017-2018 Grand Rounds series schedule please visit:
http://nihstrokenet.org/webinars

Presentations: **Acute Reperfusion Therapy as in Dawn & DEFUSE 3/ Wake up Strokes – Raul Nogueria, MD, Emory University**

When: **Thursday, September 28, 2017 – 4:00 PM ET**

Moderator: David Liebeskind, MD, UCLA

To join the meeting: **https://nihstrokenet.adobeconnect.com/grandrounds/** Please enter as a guest, then your email address or complete name.   To take part in the conversation you must dial in. 1 (877) 621-0220 Passcode Number: 190825

StrokeNet Network Meetings

2017: The NIH StrokeNet fall meeting will take place Tuesday, 12-September in Atlanta, GA, at the Atlanta Airport Marriott. Just a reminder, the presentations will be posted on the nihstrokenet.org website following the meeting.

2018: The International Stroke Conference is once again in Los Angeles, California. Look for information soon in regard to the NIH StrokeNet Network meeting, which will be held on Monday, 22-January.

Upcoming Conferences and Seminars

28-September, 2017   University of Utah **Stroke Echo** 12:00 – 1:00 pm MST
There will be Blood: The Evaluation and Management of Hemorrhagic Stroke – Contact Jaleen Smith to sign up 801-585-1586 jaleen.smith@hsc.utah.edu
See attached flyer

October 25-27, 2017   Baltimore 2017 – NIH Regional Seminar
https://regionalseminars.od.nih.gov/baltimore2017/

*For more information on these and other conferences and seminars, please see:
http://nihstrokenet.org/in-the-news

NIH StrokeNet Employment Opportunities

INTERVENTIONAL NEUROLOGIST
University of Cincinnati, College of Medicine

The University of Cincinnati is a premier, public, urban research university; ranked as one of America's top 26 public research universities by the National Science Foundation. U.S. News has ranked UC in the Top Tier of America's Best Colleges. The Chronicle of Higher Education calls UC a "research heavyweight". Forbes, Delta Sky and Travel + Leisure

magazines have named UC one of the most beautiful campuses. #HottestCollegeInAmerica

UC is one of the largest employers in the Cincinnati region, employing over 15,000 full time and part time faculty, staff, and student workers. The College of Medicine, Department of Neurology and Rehabilitation Medicine is recruiting a full-time Assistant Professor of Clinical – Geo faculty member with training and proficiency in Neurointerventional procedures.

Team: The University of Cincinnati Neuroscience Institute includes strong areas of Neurology, Neurosurgery, Neuroradiology, and Physical Medicine and Rehabilitation, which provides integrated care across the neurologic care continuum.

This faculty member will be joining a growing neurointerventional team composed of an endovascular neurosurgeon, an interventional neuroradiologist, and an interventional neurologist. This team works collaboratively to care for patients with complex cerebrovascular disease as part of the University of Cincinnati Neuroscience Institute. This individual will work closely with hospital-based acute care teams, comprised of 8 vascular neurologists, 12 neurointensivists, 6 neurosurgeons, a growing team of APPs, and a robust academic training program. Our internationally-recognized stroke team combines multidisciplinary expertise across vascular neurology and emergency medicine to provide continuous acute stroke coverage for hospitals in the greater-Cincinnati/Northern Kentucky region. Our intervention team is the only team providing neuro-intervention in the region. The University of Cincinnati's national coordinating role for StrokeNet places our team at the forefront of transformative stroke research.

The University of Cincinnati Medical Center is a 498-bed hospital, designated as both a Comprehensive Stroke Center and an Adult Level I Trauma Center. Emergency Department volume approaches 86,000 per year. There is a dedicated 20-bed Neuro Intensive Care Unit staffed by fellowship-trained neurointensivists and neuro critical care fellows. Infrastructure includes a GE Biplane neuro-angiography suite; a second dedicated Biplane suite has been approved by the hospital. Additional single-plane angiography suites are available for emergent use across the institution.

Responsibilities: Neurointerventional clinical responsibilities will include daytime and overnight coverage of the neuro angiography suite, as well as backup coverage in accordance with comprehensive stroke center requirements. Anticipated call responsibilities for the successful applicant will be roughly 1:4 and every 4th weekend, though this may change as the team grows. Additional clinical responsibilities will depend on the successful applicant's foundational clinical training.

This individual will have a full faculty appointment at the University of Cincinnati, College of Medicine, with academic responsibilities to include: the teaching of medical students, and supervision of residents, fellows, and APPs. The faculty member will be expected to contribute to the group's leading research in cerebrovascular disease.

Minimum qualifications:

M.D., D.O., or commensurate international medical degree

Accredited fellowship training in vascular neurology or neuro critical care, followed by fellowship training in neuro interventional surgery

Board certified/eligible in Neurology

If applicable, board certified/eligible in vascular neurology or neuro critical care.

Contact:

Dawn Kleindorfer MD
Professor, Department of Neurology
University of Cincinnati
260 Stetson Street, Suite 2300
Cincinnati, OH 45267
Phone - 513.558.5478
kleinddo@ucmail.uc.edu

For more information about StrokeNet employment opportunities, please visit
http://nihstrokenet.org/education/employment-opportunities

Please share this with your clinical performing and satellite sites!

Thanks,
Stephanie

Stephanie M. Wilbrand, PhD
Clinical Research Manager
Department of Neurological Surgery
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wilbrand@neurosurgery.wisc.edu

From: Kristin Ginnity [mailto:events@regonline.com]
Sent: Tuesday, September 05, 2017 12:29 PM
To: STEPHANIE M WILBRAND <wilbrand@neurosurgery.wisc.edu>
Subject: NIH Regional Seminar - Pre-Seminar Workshops

2017 NIH Regional Seminar & Pre-Seminar Workshops - Baltimore

Thank you for your interest in the 2017 NIH Regional Seminar. I am writing to let you know that there is still space available in the following pre-seminar workshops:

- eRA Commons Account Administration and Post Submission Processing (AM and PM)

- Administrator's Bootcamp (PM)

- Intellectual Property: Understanding Requirements and Recipient Responsibilities (AM)

- Intellectual Property: An In-Depth Look at iEdison (PM)

- Human Research Protections (Full-day)

Information and descriptions about the pre-seminar workshops can be found on our website: https://regionalseminars.od.nih.gov/baltimore2017/optional-pre-seminar-workshops-wednesday-october-25/. Please note that the cost for each half-day workshops is $55 and the full-day workshop is $110. Workshop space is first come, first serve.

If you are interested in adding any of these workshops to your registration, please email conferences@rippleeffect.com and we can assist you.

Conference Management Team

800.277.5708 x5 | conferences@rippleeffect.com