



NINDS INSPIRE Workshop

Improving Neurology Subject (and Provider) Participation In the Research Enterprise

June 20 – 21, 2013

NIH Neuroscience Center in Bethesda, MD

Group 4: More Than Metrics

Chair* / Facilitators & Core Members

Scott Powers, PhD* (CHAMP Study)
 Judy Spilker, RN (IMS III Trial)
 Patient / Parent
 Christine Pierre (metrics, cycle times)
 Nazem Atassi, MD (NEXT)
 Marianne Kearney (NEXT)
 Valerie Stevenson (NETT)

Invited Attendees:

Kim Hart
 Mariann Ward, ARNP
 Karen Johnston, MD
 Susan McMahan, RN

Thursday June 20, 10:00-12:00pm		
Agenda		
<p>Session 1: Discuss the attributes, skills, and needs of a project manager as a team member for large NIH-funded clinical trial in neurology. Goal would be to generate a sense of best practices and training needs.</p>		
Time	Topic/event	Convener
	Discussion: Evolution of PM role in NIH funded trials	
	Attributes of PM*	
	Skills of a PM*	
	Refine attributes and skills for best practice and training needs	
Thursday June 20, 3:00-4:30pm		
Agenda		
<p>Session 2: Project management and leadership applied to the central coordinating center context. Goal would be to identify the processes in terms of the lifespan of an NIH funded clinical trial in neurology from study planning to grant submission to trial launch to trial execution to trial closeout.</p>		
Time	Topic/event	Convener
20 min	How can the coordination center plan and test realistic recruitment strategies before trial launch?	Nazem Atassi, Mariann Ward
20 min	What performance metrics should the coordination center collect in order to improve trial recruitment and retention?	Nazem Atassi, Mariann Ward
10 min	Break	
20 min	How can the coordination center enhance recruitment?	Nazem Atassi, Mariann Ward
20 min	How can the coordination center help maintain good trial retention?	Nazem Atassi, Mariann Ward



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Friday June 21, 10:00-12:00pm

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Session 3: Project management and **leadership** applied to the **trial site context**. This session will explore the relationship between site management and recruitment. Goal would be to take the site perspective on needs, metrics, efficiencies, and how to best work with a project manager and central trial team (clinical coordinating center and data coordinating center).

Time	Topic/Event	Lead Discussant
20 minutes	Resources and facilities assessment –Site selection is more than just about machines and space, assessing and understanding site personnel and interpersonal dynamics needed for successful subject recruitment and retention. <ul style="list-style-type: none"> • Is there an appropriate trial team available? • What are the interpersonal dynamics for successful site recruitment and retention? • How do we assess the investigators commitment to randomization? • Are the skills available for obtaining ICS? • Are skills available for subject follow-up? • Does early site planning and evaluation prevent last minute “fixing”? 	Judy Spilker, RN
20 minutes	New dimensions in communication with sites - What is the best approach and frequency of contact for building and maintaining a study-wide team? <ul style="list-style-type: none"> • Face to face meetings/visits? • Voice communications - phone calls and conference calls and webinars • Electronic communication -email, list serves, websites, YouTube videos? • Printed resources including study tools and newsletters? • What are <i>other</i> incentives and rewards and recognitions? (personal vs. financial?) 	Judy Spilker, RN
10 minutes	Break	
20 minutes	How can sites use central coordinating and site generated metrics as tools – <ul style="list-style-type: none"> • What benchmarks are best to measure site efficiency? • How do (or not) recruitment tools inspire competition and if not at what point does it backfire? • Do (or can) PV/PD lists really improving quality-protocol compliance? • What are the efficiencies of site data entry and does it affect data quality? • What is the right balance of “Busy work” and recruitment? 	Judy Spilker, RN
20 minutes	Finding and fixing knowledge gaps in clinical and research knowledge at the site level	Judy Spilker, RN
20 minutes	“Sites” as customers – The “how can we help you” approach to site management	Judy Spilker, RN
Final 15-20 minutes	Additional Suggestions and Wrap-Up	All



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Friday June 21, 2:30-3:30pm

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Session 4: Bring the discussions from sessions 1-3 together into a framework for a deliverable. We have discussed the idea of project management along the time line of an NIH grant; what are the take home learnings?

Time	Topic/Event	Convener
15 minutes	What have we learned about skilled project management?	Scott Powers
15 minutes	How is “skilled project management” applied in the central coordinating center and trial site contexts?	Scott Powers
30 minutes	If we think about the life cycle of an NIH-funded trial, from inception to trial close out, what are the practical learnings from our working group that will advance recruitment and retention of participants, families, and staff?	Scott Powers, Marianne Kearney, Nazem Atassi, Valerie Stevenson, Judy Spilker