

Trial Innovation Network Hub Liaison Team Meeting

October 3, 2017

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Trial Innovation Network Hub Liaison Team Meeting

AGENDA

October 3, 2017
3:00 - 4:00 PM ET
 (60 minutes)

Meeting Co-Chairs: Daniel Ford, MD (Johns Hopkins) and Michelle Culp, MPH (NCATS)

<i>Time</i>	<i>Topic</i>	<i>Purpose</i>	<i>Speakers</i>
3:00 PM (5 min)	Welcome	Review Meeting Goals	Dan Ford Michelle Culp
3:05 PM (20 min)	Standard Agreements <ul style="list-style-type: none"> Umbrella Confidential Disclosure Agreement (CDA)/ Process 	Share Information	Gordon Bernard (Co-PI, Duke/VU TIC) Colleen Lawrence (Project Lead, VU)
3:25 PM (10 min)	Engagement Trial Innovation Network Website <ul style="list-style-type: none"> Network Dashboard 	Share Information	Paul Harris and Julia Dunagan (VU RIC)
3:35 PM (10 min)	Cohort Discovery Outreach-lessons learned	Share Information	Paul Harris (PI, VU RIC)
3:45 PM (15 min)	Chat Box Discussion Closing Remarks	Q&A Summary	Dan Ford Michelle Culp
4:00 PM	Next Meeting: November 7, 2017 @ 3PM ET Recurring Meetings: First Tuesday Each Month	Adjourn	



Standard Agreements & Streamlined Budgeting

Trial Innovation Network Umbrella CDA

Gordon Bernard & Colleen Lawrence (VU TIC)

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Umbrella Confidential Disclosure Agreement (CDA)

- Purpose: To streamline the sharing of protocols across potential Study sites without the need to obtain individual CDAs from each site
- Scope:
 - ❑ The Umbrella CDA is narrowly defined for use in sharing of Network-specific Study documents (e.g. protocols) and during consultations
 - ❑ Marking provision included, i.e. – all shared documents should be marked as “confidential”

How it works

- The Umbrella CDA was derived from the CTSA Accelerated Research Agreements initiative – ACDA (Accelerated Confidential Disclosure Agreement)
- The Umbrella CDA will be implemented into a REDCap survey
- Each CTSA site (and affiliates) will sign/execute the Umbrella CDA – two options:
 - Use electronic wet signature – digital capture of signature in REDCap survey
 - Upload hand signed copy of Umbrella CDA to REDCap survey

Umbrella CDA – Network Website

- The website will house a copy of the Umbrella CDA
- The website will house a list of all sites and affiliates who have signed the CDA and the contact information for the signatory (Figure 1)

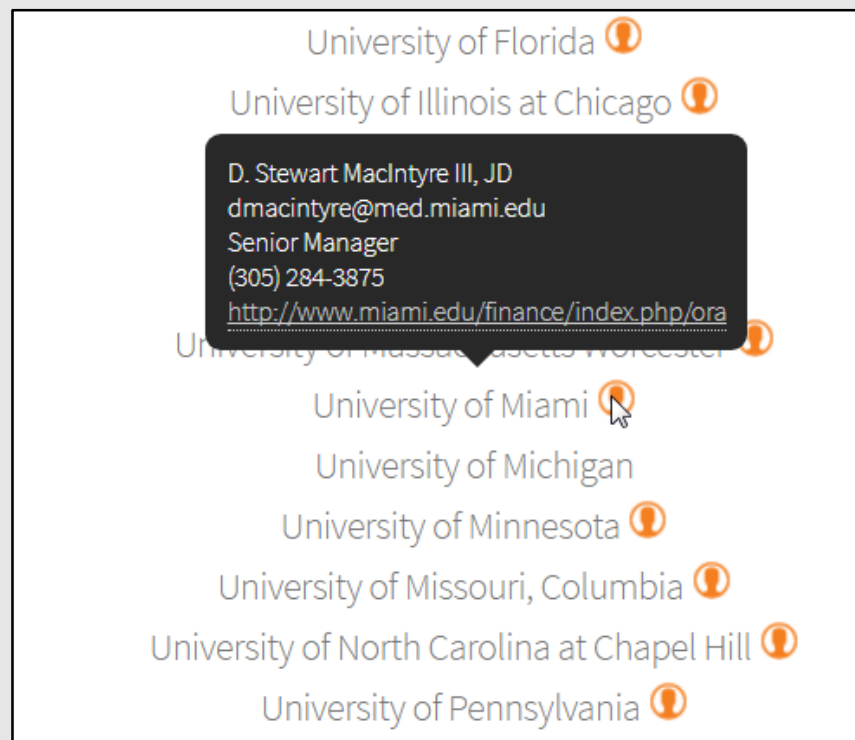


Figure 1. Site sign off EXAMPLE from the ara4us.org website (home of the CTSA-supported Accelerated Research Agreements initiative)

The “fine print”

- Effective date – the date each site or affiliate signs the agreement
- Termination date – the agreement will remain effective until June 30, 2023 (the end of grant period)
- When a protocol is sent to an investigator, the cover letter will state “your institution has signed the Trial Innovation Network Umbrella CDA – please visit the XXX website to review your obligations”

Next Steps

- Following this call, each of the points of contact for the Standard Agreements will receive a copy of the Trial Innovation Network Umbrella CDA
- CTSA Hubs (and their affiliates) should review the Trial Innovation Network Umbrella CDA with their Contracting Teams for acceptance
- When the Network website is finalized for housing the Umbrella CDA, the REDCap survey will be distributed for sites to sign/execute the Umbrella CDA

Engagement: Trial Innovation Network Website

Paul Harris & Julia Dunagan (VU RIC)

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Network Dashboards

Authentication Portal

Authentication piece created and undergoing testing

metrics

NETWORK PROPOSAL SUBMISSIONS		CRIS		STANDARD AGREEMENT (in FDP-CTSA)	
# of institutions	# of therapeutic areas	# of sites	# of studies awarded	# of sites	# of studies awarded
29	27	97	9	73	4

INVESTIGATORS
submit your proposal
Hear from us within 5 business days.

TRIAL INNOVATION NETWORK
Operational innovation, excellence, and collaboration.
The Trial Innovation Network continues to accept new proposals! Click the button below to get started.
Get Started now!

68 total proposals submitted

WELCOME!
The Trial Innovation Network is a collaborative national network that focuses on operational innovation, excellence and collaboration and will leverage the expertise and resources of the CTSA Program.

NETWORK / HLT LOGIN

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LOGIN **CREATE A PROFILE**

Email or REDCap Username

Password

Forgot Password?

Go

Network Dashboards

Current Dashboard Functionality



Proposals In Process **Proposals Ready for an Initial Consultation** Proposals Receiving Discrete Services Proposals Receiving a Comprehensive Consultation/Study Implementation Archived Proposals

Ready for Initial Consultation

Proposal ID	Proposal Title	PI Name	PI Institution	First Contact	Kick-off Meeting	Initial Consult Complete
1	Thyroid study	Anne Cappola	University of Pennsylvania	2017-05-01	2017-05-08	2017-05-15
15	GIK Study	Harry Selker	Tufts University			

The IMMEDIATE-2 Trial: A Double-blinded Randomized Controlled Trial of Intravenous Glucose-Insulin-Potassium (GIK) for Acute Coronary Syndromes in Emergency Care
 Tufts University
 Harry Selker

Primary Points of Contact

Study Description

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28	STEMI Study	Barry Collier	Rockefeller University			
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Network Dashboards

Future Dashboard Functionality

Phase 1:

- Access
- High-level information
- Basic Drilldown



Phase 2:

- Progress Indicators
- Filter/Sort Options
- Streamlined Access

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Proposals in Process Proposals Ready for an Initial Consultation Proposals Requiring Discrete Services Proposals Requiring a Comprehensive Consultation/Study Implementation Archived Proposals

Ready for Initial Consultation

Proposal ID	Proposal Title	PI Name	PI Institution	First Contact	Next Meeting	Initial Consult Complete
1	Phase 1 Study	Arvin Caples	University of Pennsylvania	2017-09-01	2017-09-08	2017-09-15
15	GR Study	Harry Sokler	Tulsa University			

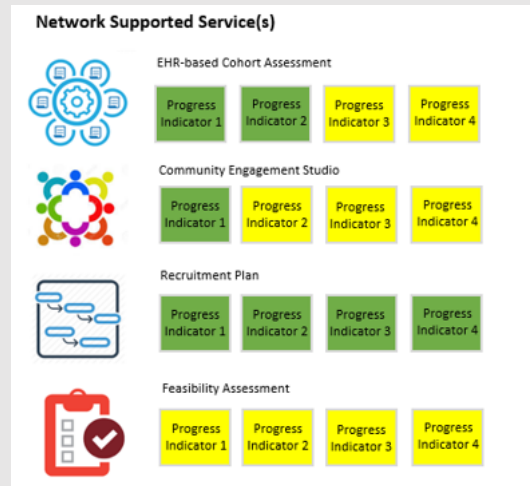
The AMEDATE-2 Trial: A Double-Blinded Randomized Controlled Trial of Intravenous Glucose-Insulin-Potassium (GIK) for Acute Coronary Syndromes in Emergency Care
Tulsa University
Harry Sokler

Primary Points of Contact

Study Description

Completed in 2013, the AMEDATE (Bromobutyl Mitochondrial Enhancement During Initial Assessment and Treatment in Emergency Care) trial was an NINDS-supported clinical trial of emergency medical service (EMS) paramedic-administered intravenous glucose-insulin-potassium (GIK) for acute coronary syndromes (ACS). LAMA 2012 (0118) 1925-1932, PMID 23442803. Differing from prior GIK trials in several respects, in the AMEDATE-2 trial GIK was given very early in the course of ACS, in communities, following 9-1-1 calls, rather than after hospitalization for documented acute myocardial infarction (AMI). Although GIK did not significantly reduce the primary endpoint, progression to AMI, it did significantly reduce the composite endpoint of cardiac arrest or mortality - by 50% for those presenting with suspected ACS, and by 60% for those presenting with ST elevation AMI (STEMI). Also, GIK reduced infarct size by 60%. These were striking effects, but because the primary endpoint of progression to AMI was not positive, and the results differed dramatically from prior GIK trials, GSK led that a confirmatory trial was needed. Noting that the previous trials typically had given GIK on average six hours after ACS, rather than as it had worked in several studies, very early in the course of ACS/AMI, also that none were double-blinded randomized controlled trials, another NIH-funded randomized controlled trial was seen as being important, including undertaking an AMEDATE-2 Trial. Based on the fact that GIK treatment is inexpensive (single treatment costing as little as \$20), safe, and easily administered, a demonstration of the effectiveness of GIK treatment in the AMEDATE-2 trial should lead to it's widespread adoption in the treatment of ACS.

28	STEMI Study	Barry Colter	Rockefeller University			
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Network Dashboard Access - Communications

Point of Contacts (POCs)	Hub Liaison Team Member (HLTs)
<ul style="list-style-type: none">• Automated system email from REDCap stating a user ID has been created for you with instructions to activate account• Email from Trial Innovation Network with (1) instructions on your administrative functions for managing HLT membership in the Persons Management Database (PMD) and (2) list of informational webinars for questions regarding PMD and/or dashboards	<ul style="list-style-type: none">• Email from Trial Innovation with (1) instructions on how to create a profile to activate account and (2) list of informational webinars for questions about dashboards.

ACTION: Please verify your membership on the Trial Innovation Network website.

<https://trialinnovationnetwork.org/liaison-teams/?key-element=1601>

Cohort Discovery Outreach – Lessons Learned

Paul Harris & Julia Dunagan (VU RIC)

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Chat Box Discussion: Q&A

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***Next Trial Innovation Network
Hub Liaison Team Meeting:
November 7, 2017, 3-4:00PM ET***