

Trial Innovation Network Hub Liaison Team Meeting

August 1, 2017

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**Trial Innovation Network Hub Liaison Team Meeting
AGENDA**

**August 1, 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 / Introduction	Review Meeting Goals	Dan Ford
3:05 PM (10 min)	Network Facts	Share Information	Michelle Culp
3:15 PM (30 min)	Sharing Network Experiences: <ul style="list-style-type: none"> • Initial Consult Feedback • Pilot Study Feedback 	Share Information	Dan Hanley and Jon Davis (JHU/Tufts TIC) Theresa Jasion (Project Lead, Duke)
3:45 PM (5 min)	Summary and Wrap Up	Share Information	Dan Hanley (PI, JHU/Tufts TIC)
3:50 PM (10 min)	Call for Topics	Request Information	Dan Ford
4:00 PM	Next Meeting: September 5, 2017 @ 3PM ET Recurring Meetings: First Tuesday Each Month	Adjourn	



Network Facts

Michelle Culp (Director, NCATS)

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A Few Trial Innovation Network Facts:

(What have we seen in the past year?)

Number of proposals submitted: 52

Types of services requested - 15 Proposals

CIRB: 7

Standard Agreements: 1

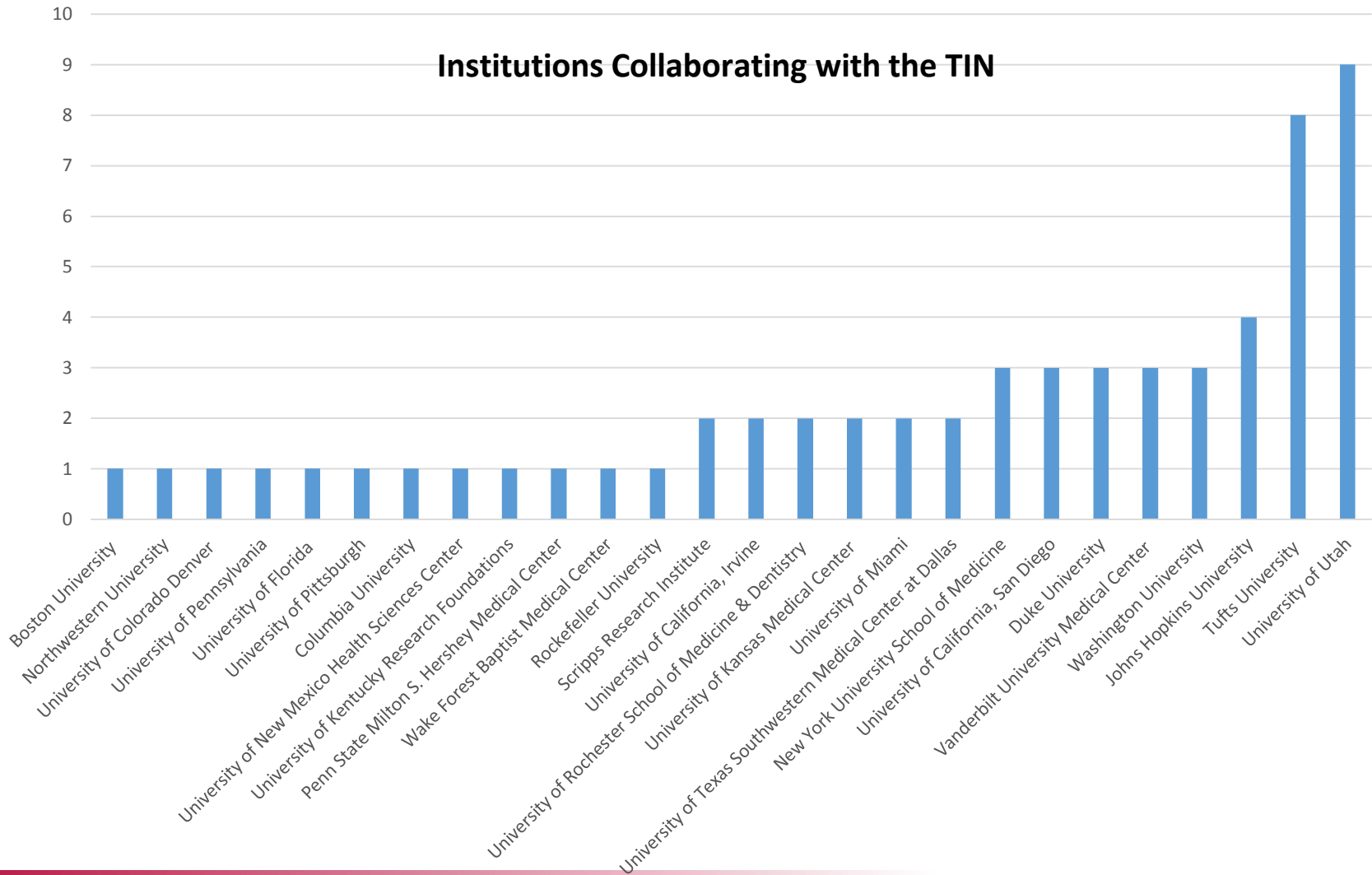
Recruitment Help (Materials, Studio, etc): 9

Cohort discovery: 4

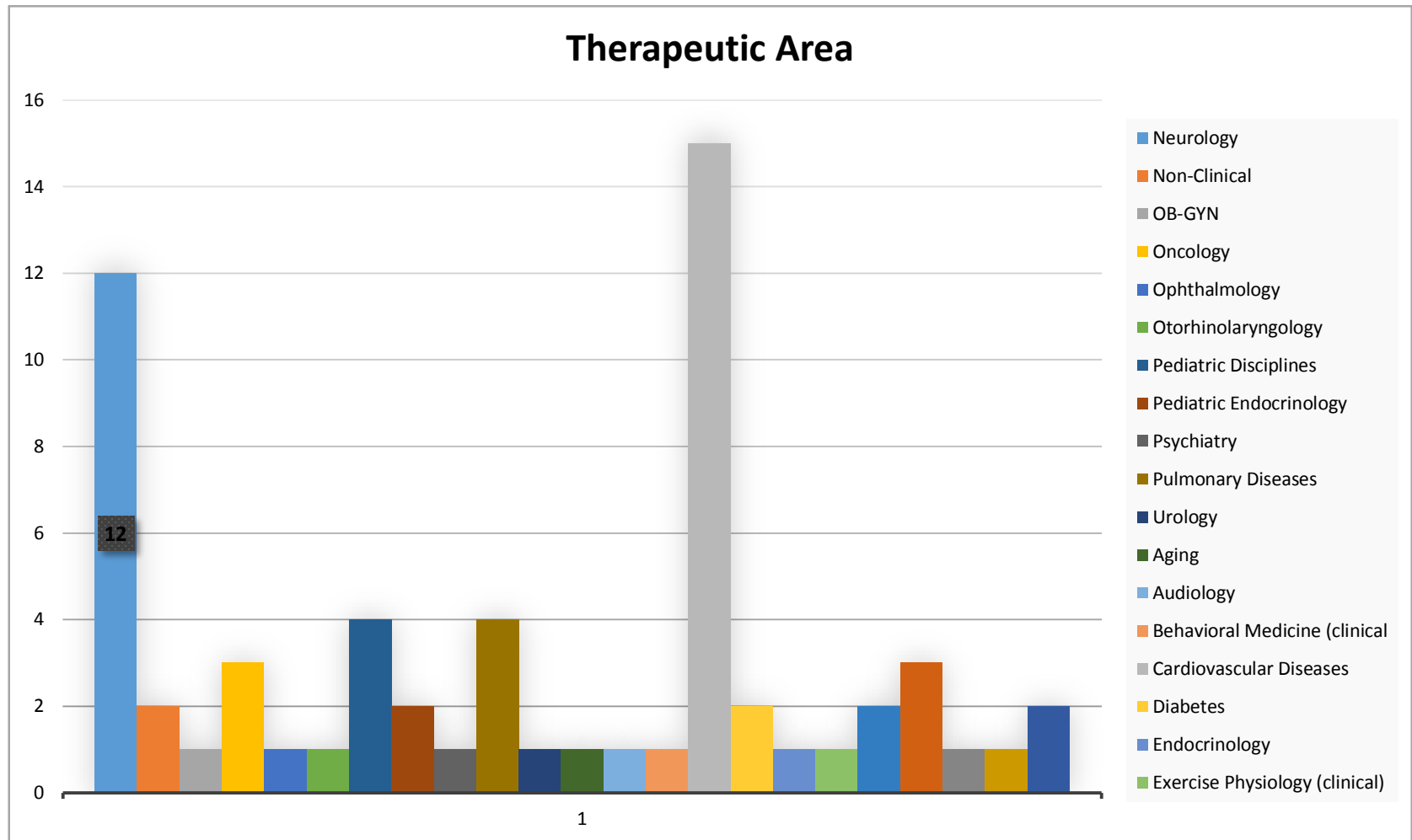
Budget Needs: 1

IRB that have started #s-

Institutional Submissions

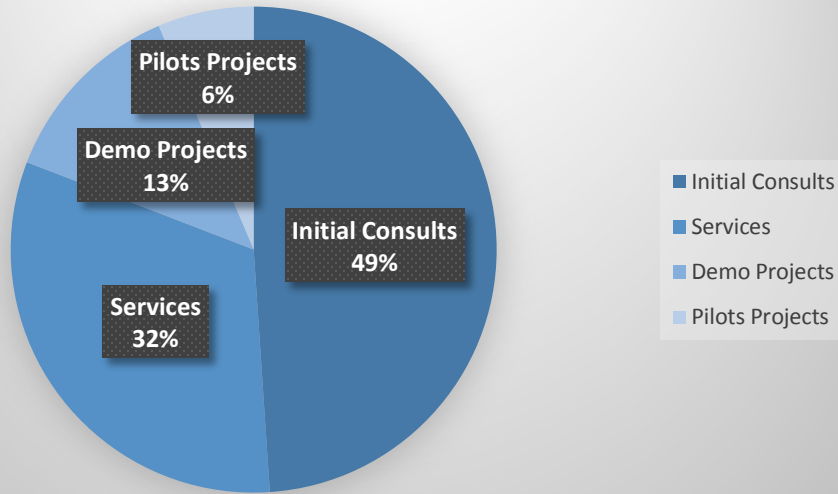


Diversity of Support

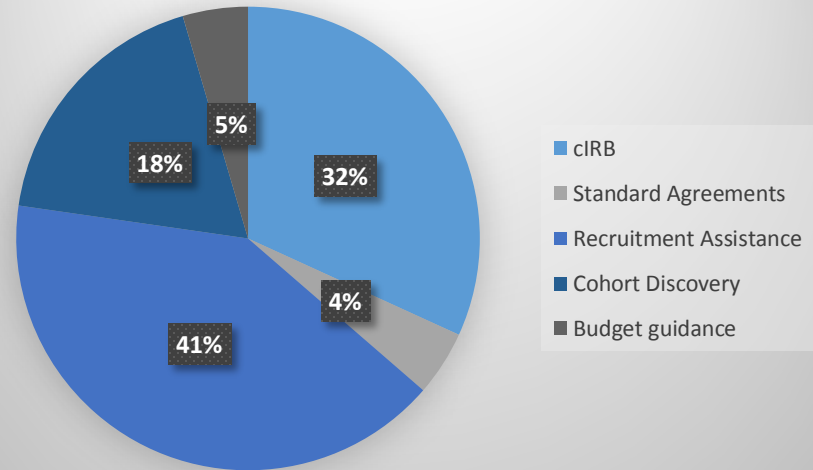


Breakdown of Support

Proposal Distribution



Services Distribution



IRB Approvals to date

Reviewing IRB	Title	# Sites	Lead Approval	Relying Site Approvals
JHU	A Placebo-controlled Effectiveness Study in NPH Shunting (PENS) Proof of Concept (Phase II)	3	Y	
Utah	Randomized Controlled Trial of Valganciclovir for Asymptomatic Cytomegalovirus Infected Hearing Impaired Infants (ValEAR Trial)	42	Y	0
Utah	Utah_TXA	4	ON CLINICAL HOLD	
VUMC	Zoster Eye Disease Study (ZEDS): A multi-center, randomized, double-masked, placebo-controlled study of valacyclovir in immunocompetent subjects with a history of dendriform epithelial keratitis, stromal keratitis, endothelial keratitis, and/or iritis due to Herpes Zoster Ophthalmicus (HZO) within the year prior to enrollment.	51	Y	12
VUMC	Efficacy of a Gluten-free diet in difficult-to-manage nephrotic syndrome: Utility of plasma zonulin level as a predictive biomarker	9	Reliance request packets will go out by 8/4	
VUMC	STeroids to REduce Systemic inflammation after neonatal heart Surgery (STRESS trial)	11	Reliance request packets sent out 7/28	

Initial Consult Feedback

Dan Hanley & Jon Davis (JHU/Tufts TIC)

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Initial Consult Feedback: Dr. Jon Davis

Targeted Next-Generation Sequencing (TNGS) to Improve Neonatal Outcome

Why did you choose the TIN? Involvement in the Tufts CTSI

Successes: The TIN provided excellent customer service and novel approaches to protocol development. I was impressed with the strong collaborative effort. We received a favorable review and hope to receive funding

Lessons Learned: Don't rush the process. Prior to submission, leverage resources at your hub and put a solid proposal together. Then will be better received and benefit from further consultations

Road Blocks: None.

Value added to study: The highlights were: the timeline, recruitment plan, and ethics and biostatistical discussions. The cIRB call was one of the best I've had!

Pilot Study Feedback

Theresa Jasion (Project Lead, Duke)

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Pilot Study: STRESS Study



STeroids to REduce Systemic inflammation after neonatal heart Surgery (STRESS trial)

- **Study Objective:** To determine the pharmacokinetics (PK)/pharmacodynamics (PD), safety and efficacy of methylprednisolone in neonates undergoing heart surgery with cardiopulmonary bypass.
- Unique design including registry data entry and a Dynamic Data Pool (DDP)
- Initially came to the TIC as a demonstration project for discrete services of CIRB and Standard Agreements – it had been recently funded and were looking to finalize the protocol soon
- The unique design had operational elements allowing for a mutually beneficial collaboration between the TIC/RIC and study team

Pilot Study: STRESS Study



Successes

- CIRB Lead site was approved
- CIRB outreach packets were sent to sites and an overview training with sites was completed
- Data standards (CDISC/CDASH) were discussed and the planning to implement is underway
- eConsent is being discussed using REDCap



Pilot Study: STRESS Study



Lessons Learned

- PK data to confirm the dose of Methylprednisolone took longer than anticipated. This delayed the planned investigator meeting.
- Duke's eIRB for the coordinating center review took much longer than expected due to the study having an IND under the study PI.
 - This delayed the outreach packets being sent to the sites for the CIRB submissions and the standard agreements

Pilot Study: STRESS Study



Value Added to the Study

- Discussions on integrating the data while standardizing the study have been helpful.
- Support from the TIC and RIC for data discussions, development of the study documents, and discussion of the eConsent have been very collaborative.

Summary and Wrap Up

Dan Hanley (PI, JHU/Tufts TIC)

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Call for Topics

Dan Ford (PI, JHU/Tufts TIC)

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Topics for Consideration

- **Proposal submission**
- **Recruitment**
 - **eConsent**
 - **EHR cohort discovery**
- **CIRB**
- **Standard Agreements**
- **Website**
- **Hub Liaison (Welcome to the new role)**

Upcoming Events

- **Webinar** - ResearchMatch.org Serving the Participants/Empowering the Researcher
 - Aug 7th 2017



- **Open Forum Monthly sessions-**
 - August 17th at 2:00 PM ET- Efficacy to Effectiveness (E2E)

Next Trial Innovation Network Hub Liaison Team Meeting

September 5, 2017, 3-4PM ET