

# Negotiating Complex Issues in Multi-Center Clinical Trials

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# Disclosures

- Research funding: NIH, DoD
- Co-PI ACTIV4 CCC/DCC, Co-Chair ACTIV4a platform trial, founding member of the multi-platform RCT (mpRCT)
- Research funding: Haemonetics, Instrumentation Laboratory
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- Scientific advisory board, equity stake: Haima Therapeutics
- US Patents: Dielectric Sensing to Characterize Hemostatic Dysfunction Serial Number: 16/837,704; Novel TLR4 Inhibitors for the Treatment of Human Infectious and Inflammatory Disorders Serial Number: 17/174,018

# Objectives and overview

- I will address all potential problems & complex issues with multi-center clinical trials in the next 9 minutes

# Objectives and overview

- Funding type/mechanism
- Infrastructure
- Contracting
- Enrollment
- Analysis and Communication
- Publication

# Know your mechanism and limitations!

- Contract vs grant – milestone driven vs fixed awards
- Industry/Pharma sponsorship – protection of IP
- Other Transactional Authority (OTA)
  - flexibility
  - “non-traditional” review
  - sponsor access/involvement
  - cost-sharing

# Infrastructure

- If someone built it...why build it again?

# Contracting

- Molasses of academia
- Know your institutional capabilities and limits
- One (potential) solution: standard NCATS Clinical and Translational Science Awards (CTSA) contracts

# Enrollment

- Co-enrollment, multiple arms  
--one solution: platform trial design
- FDA IND for drug or device
- More patients vs the “right” patients
- Think about the science 5-10 years from now...



# Analysis and Communication

- Your MIT trial lives or dies by the coordinating center – choose wisely
- Multi-platform RCT → 393 sites, 10 countries
- Do you have the expertise?
  - Bayesian analysis
  - Start your statistical analysis plan (SAP) before the trial begins
  - One solution: consider external partners

# Publication

- Register! (NCT) and update
- Publication policy – a quick way to make enemies and hurt feelings
- One solution – do it first, be fair, publicize widely, negotiate transparently

# Summary and conclusions

- Anticipate problems – like in surgery, have (many) back-up plans
- Know your mechanism, know your team, know your limits
- Make friends with the lawyers
- Focus on enrolling (the correct) patients
- Choose the correct coordinating center(s) – ask for references
- Emphasize transparency and communication