



Eastern Association for the Surgery of Trauma
Advancing Science, Fostering Relationships, and Building Careers

Multicenter Studies and the early faculty trauma & critical care surgeon



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Objectives

- Why MCTs?
- Join others' MCTs - Pearls and pitfalls
- Society/Association-sponsored MCTs
- Preparing your own MCT (retrospective, prospective observational, small interventional)

NOT

How to set up your own multisite randomized controlled trial...



Multicenter Research

Allows the accrual of sufficient numbers of diverse, patients in the shortest period of time in an otherwise rare condition/disease that would take years to acquire in a single institution

Improves the generalizability of study results and augments the potential for subgroup analyses

Types of MCTs

- Interventional Trials
- Prospective observational
- Retrospective (Registry)



So I'm early in my career how should I start?

- Will it add to my research portfolio?
- Should not be the sole content of your CV
- Balance:
 - Work to provide your site's data
 - Quality of a publication presentation
- Do I have the resources to acquire the data?
- Who is going to gather the data?
 - Me
 - CRC? Resident? Fellow? Student?
 - Be generous with authorship



Trauma Critical Care MCTs

- [EAST](https://www.east.org/research/multicenter-trials) (<https://www.east.org/research/multicenter-trials>)
- [AAST](http://www.aast.org/Research/MultiInstitutionalStudies.aspx) (<http://www.aast.org/Research/MultiInstitutionalStudies.aspx>)
- [WTA](https://www.westerntrauma.org/committees/multicenter.html) (<https://www.westerntrauma.org/committees/multicenter.html>)
- [SCCM](https://www.sccm.org/Research/Research/Discovery-Research-Network) (<https://www.sccm.org/Research/Research/Discovery-Research-Network>)
- Others...



Ok. been there. done that...

I want to launch my own Multicenter Trial.



Often First: Single Center Pilot Study

- Answers questions to inform design and conduct of larger MCT
- Evaluate subject availability
- Guide sample size calculation
 - Effect of the intervention
 - Test assumptions: consent, dropouts, noncompliance rate
- Refine protocol
- Trial case report forms, analysis plan, statistical analysis
- Project costs to help with budget preparation
- Generates Preliminary results

Single Center Pilot study: Preliminary results

- To convince other sites to join
- To convince Associations/Societies to support (*The Brand*)
- To justify funding applications for MCT launch
 - Additional funds for resources, enrollment etc.



Primary Site/Data Coordination Center

- Expertise in biostatistics, data management, “Good Clinical Practice”
- Develop case report forms, randomization scheme
- Carry out day-to-day communication with sites ie: answer emails, calls
- Monitor IRB status and renewals at multiple centers (vs central IRB)
- Collect, monitor, clean and analyze data from collaborating centers
- Conduct site visits
- Facilitate interim analyses

Design well... decrease inter-site variation

- Manual of operations (MOO)
 - All study activities (screening, randomization, inclusion/exclusion, data collection, interventions and cointerventions)
- Study-specific training (project initiation and with new staff)
 - Modules with post-test
 - Toolbox: Reminder cards, videos
 - Ongoing training
- Manage expectations
 - Authorship, Author order, Publication goal timeline, goal presentation meeting



Will they bite?

- Appealing clinical question? with equipoise?
- Practice knowledge gap in need of answers
- No center can resolve the question alone
- Practicable data gathering for spoke sites
- Short timeline
- Generous authorship
- Availability for questions/troubleshooting
- Minimal changes once started
- Palatable Society meeting/Journal



Multi-institutional
the Gastr

EAST PLENARY

Martin D. Zielinski,
Dante D. Yeh, MD, S
Jill Watras, MD, Kenneth
Valerie G. Sams, MD

Universal screening for intimate
in trauma

Tanya L. Zakr
David Turay, MD, PhD

J Loop ilec

WTA 2017 PLENARY PAPER

Contemporary management of subclavian
injuries—A Western Trauma Association

Christine J. Waller, MD, Thomas H. Cogbill, MD, Kara J. Kallies,
S. Rob Todd, MD, Kayla J. Chapman, MD, Marshall A. Beck,
Vincent P. Antos, MD, Evert A. Eriksson, MD, Stuart M. Leon, MD, R
Lisa Capano-Wehrle, Clay Cothren Burlew, MD, Charles J. I
Jennifer C. Roberts, MD, Paul B. Harrison, MD
James M. Haan, MD, and Kelly Lightwine, MD

The why and how our trauma patients die: A prospective
Multicenter Western Trauma Association study

Rachael A. Callcut, MD, Lucy Z. Kornblith, MD, Amanda S. Conroy, BSN, Anamaria J. Robles, MD,
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Michaela A. West, MD, PhD, Sarah Storrs, MD, Daniel C. Cullinane, MD, John F. Cordova, MD,
Ernest E. Moore, MD, Hunter B. Moore, MD, PhD, Alicia R. Privette, MD, Evert A. Eriksson, MD,
Mitchell Jay Cohen, MD, and Western Trauma Association Multicenter Study Group, San Francisco, California

WTA 2017 PLENARY PAPER

Cervical spine evaluation and clearance in the intoxicated
patient: A prospective Western Trauma Association
Multi-Institutional Trial and Survey

Matthew J. Martin, MD, Lisa D. Bush, PA-C, Kenji Inaba, MD, Saskya Byerly, MD, Martin Schreiber, MD,
Kimberly A. Peck, MD, Galinos Barmparas, MD, Jay Menaker, MD, Joshua P. Hazelton, DO,
Raul Coimbra, MD, PhD, Martin D. Zielinski, MD, Carlos V.R. Brown, MD, Chad G. Ball, MD,
Jill R. Cherry-Bukowiec, MD, Clay Cothren Burlew, MD, Julie Dunn, MD, C. Todd Minshall, MD,
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Trauma Critical Care MCTs

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- [AAST](http://www.aast.org/Research/MultiInstitutionalStudies.aspx) (<http://www.aast.org/Research/MultiInstitutionalStudies.aspx>)
- [WTA](https://www.westerntrauma.org/committees/multicenter.html) (<https://www.westerntrauma.org/committees/multicenter.html>)
- [SCCM](https://www.sccm.org/Research/Research/Discovery-Research-Network) (<https://www.sccm.org/Research/Research/Discovery-Research-Network>)
- Others...



- Questions?