



# Rapid Research in Disasters: U.S. Critical Illness and Injury Trials Group

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NIH SIG CII

# Transformative Approach



- Inclusive, transdisciplinary, time continuum
- “Network-of-networks”
  - Federally funded networks (ARDSnet, ROC, NETT)
  - Professional Organizations (CCSC)
- Triannual face-to-face meetings
  - Fall at NIH in Bethesda
  - Winter at SCCM (San Francisco)
  - Spring at ATS (San Diego)

# USCIITG 2014

- 200+ investigators across 68 ICU's
- Four large Programs
  - Prevention of Organ Failure (PROOF)
  - Critical Illness Outcomes Study (CIOS)
  - Early ICU Rehabilitation (PEIR)
  - Program for Emergency Preparedness (PREP)
- ~\$22m funding over last 4 years
  - NIH, CMS, ASPR, DOD



United States Critical Illness and Injury Trials Group  
**Program for Emergency Preparedness**  
(USCIITG-PREP)

# Aim

To significantly enhance the national capability to rapidly glean crucial information regarding the clinical course of acute illness and injury and guide clinical resource requirements during emergent events



J. Perren Cobb  
Mass General



Sats Bhagwanjee  
U Washington



Chuck Cairns  
U North Carolina

# USCIITG-PREP Deliverables

- Key Analytic Outcomes
- Communication infrastructure
- Core Data Set
- Specialized Data Sets
- Clinical Pilot: Core Data Set
- Rapid Analysis Plan
- Data Dissemination Plan



# Key Analytic Outcomes



Kevin Yeskey



Lewis Rubinson

- **Clinician end-users and researchers**
  - What was the nature of the insult and the resulting phenotype?
  - As a responder, what, if anything, did you have to do differently?
  - Did diagnostics, countermeasures, and therapies work as expected?
  - What was the impact on the patient and care setting?
- **Systems and operational evaluations**
  - Was there anything essential needed that you did not get?
  - What is the best/worst case that could happen next time?

# USCIITG-PREP Governance



Jon Sevransky  
Emory



Jimmie Holmes  
Wake Forest

- Steering Committee
- Data Set Working Group
  - Core Data Set
  - Specialized Data Sets
- Rapid Analysis Group
  - Electronic platform
- USCIITG-Burn
  - Clinical Feasibility Pilot



Jim Blum  
Emory



Bruce Cairns  
UNC



# Tactical Approaches



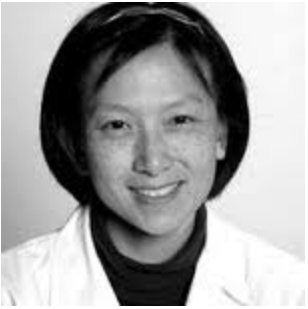
# Core Data Set

1<sup>st</sup> Face-to-face meeting, March 13-14, 2012

- ✓ All-hazard, “minimal” data set
- ✓ Modified Delphi process (4 rounds)
  - Prehospital phase
  - ED phase
  - ICU phase
  - Discharge/follow-up phase
- ✓ Electronic format (REDCap)

# Specialized Data Sets

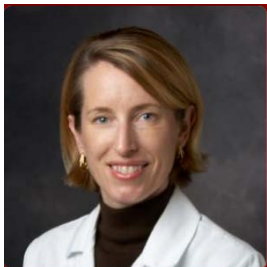
2<sup>nd</sup> Face-to-face meeting, November 7-8, 2012



Michelle Gong  
Albert-Einstein



Ziad Kazzi  
Emory



Kristan Staudenmayer  
Stanford

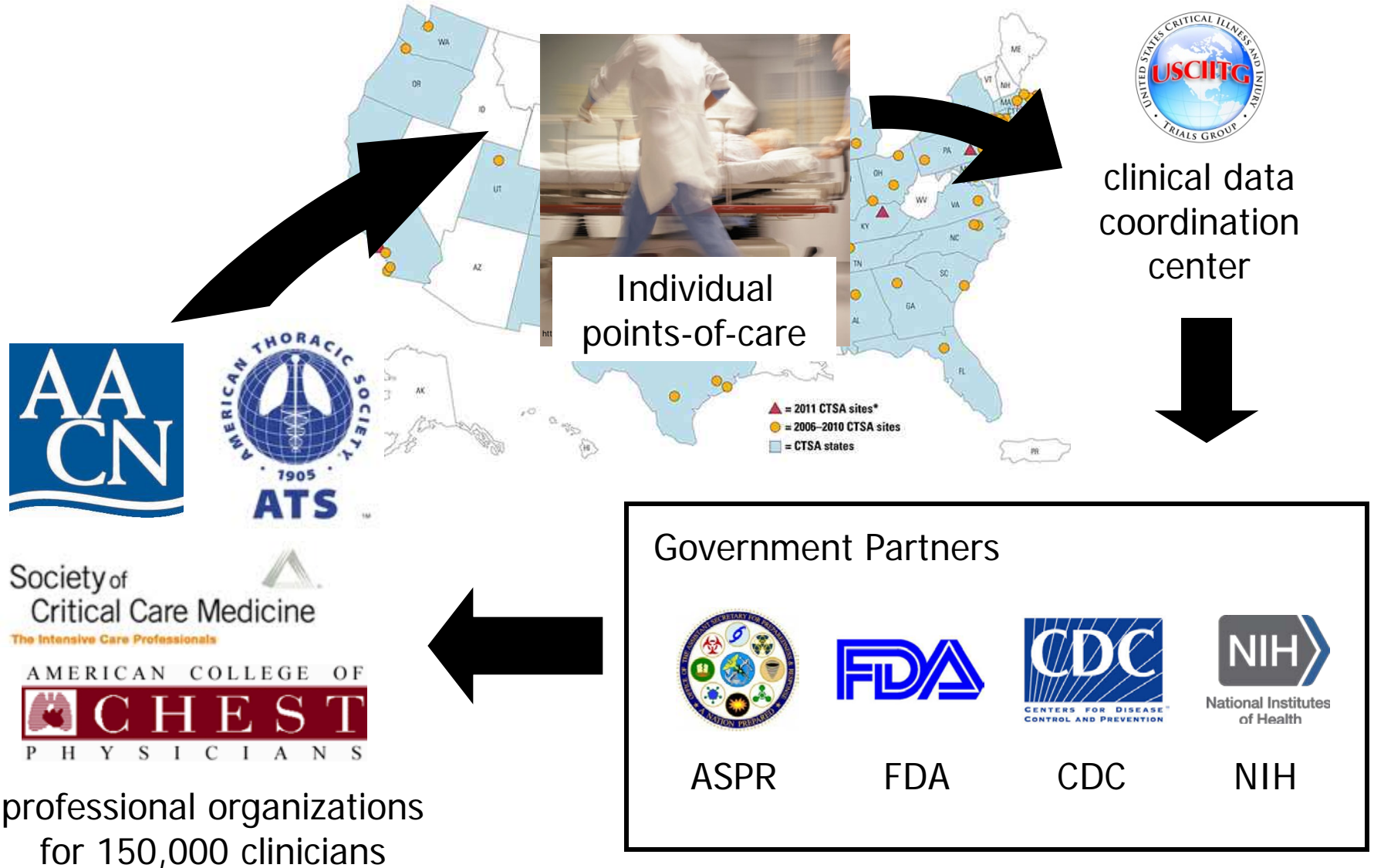
- ✓ Specific hazards
- ✓ Modified Delphi process (3 rounds)
  - Infectious injury (pandemic)
  - Radiation injury (IND)
  - Traumatic injury (IED, earthquake)

# Clinical Pilot: Feasibility Test

January 24-25, 2013

- Goals
  - Field usability of the Core Data Set
  - Logistics of human subjects research during public health emergency, *especially IRB*
- Requirements
  - 150 patients across 10 sites, minimum
  - Rapid analysis (24 hours)
- ✓ Results: 12 USCIITG-Burn Centers enrolled 195 patients in 24 hours

# USCIITG-PREP Response to PHE



## *Lessons Learned*

# Challenges for Clinical Research during public health emergencies

- IRB
  - What is defined as “research” (OHRP)
  - Expedited vs. full IRB review (9 months)
  - Variance in IRB responses (bureaucracy, use agreements, *etc.*)
- Requirements Moving Forward
  - Reliance Agreements
  - Public Health Emergency Research Review Board (PHERRB)
  - Needs to be in place by October 2014

# *Next Steps: Data Harmonization*

## Standardized Reporting Platforms for Public Health Emergencies

- Coordinate national efforts to evaluate Medical Counter Measure (MCM) product efficacy, safety, and quality across the care continuum
- Standardize and test data collection technologies for MCM, using seasonal influenza as a test case



## *Next Steps: Global Health*

# International Networks



- USCIITG helps represent U.S. interests
  - International Forum of Acute Care Trialists
  - International Severe Acute Respiratory Infection Consortium
  - World Federation of Societies of Intensive and Critical Care Medicine



# Conclusions

- Regional and national vulnerabilities
  - Be prepared—drills and simulation
- Lessons learned
  - Order without control: swarm intelligence
  - Data and communication control
- National Initiatives
  - USCIITG-PREP
  - Join today!

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[www.usciitg.org](http://www.usciitg.org)