

**NIH StrokeNET**  
**Acute Stroke Working Group:**  
**Update**

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# Acute WG Members

- Pooja Khatri (Chair – U-Cinci)
- Jeff Saver (Co-Chair - UCLA)

## **RCC REPS**

- Azam Syed Ahmed (U-Wisc-Madison)
- Ed Jauch (MUSC)
- Brett Meyer (UCSD)
- J Mocco (Vanderbilt)
- Kiva Schindler (Emory)
- Lee Schwamm (MGH)
- Phil Scott (U-Mich)
- Cathy Sila (CCF)
- Wade Smith (UCSF)
- Michel Torbey (OSU)

## **OTHERS**

- Bill Barsan (ex officio member)
- Joe Broderick (StrokeNET PI)
- Scott Janis (NINDS)
- Renee Martin (DCC)
- Max Wintermark (Imaging Advisory Group)

# Current WG Role

1. To provide **scientific and design input** to the PPIs regarding trial concepts prior to submission to NINDS for concept approval when requested by NINDS or directly by PPIs
2. To provide **feasibility assessment** of NINDS-approved concepts when activated by NINDS
  1. Estimate how many subjects StrokeNET can enroll per year at how many sites?
    - Use survey data for hard numbers and then make further calculations based on epidemiology assessment, literature, and clinical judgment
  2. Provide those recs to the StrokeNET Executive Committee
3. To **assess gaps in the field and provide guidance** regarding Acute Stroke clinical trial issues (including potentially growing clinical trials to fill those gaps from within StrokeNET)

## *PPI FAQs*

- *StrokeNET leadership do not formally participate in writing the science with PPIs unless members happen to be PIs or SC members.*
- *Joe and NCC staff will assist you in developing your grant budget based on StrokeNET infrastructural support.*

# Specific Activities To Date

- Two rounds of NINDS CDE input
- Trial discussions
  - Pre-“concept approval” reviews of trials
    - MOST, IMPACT
  - Feasibility assessments (post concept approval)
    - DEFUSE 3, ICTUS 3, MOST, DEFUSE 3 resubmission, IDEF (funded trial)

# DEFUSE 3 Trial

PI: Albers

- Phase III trial of endovascular therapy vs medical mgmt (+/- IV rtPA) in MRI-selected patients
- Activities to date
  - Feasibility assessment of first submission
  - Feasibility assessment of resubmission
- Updates
  - Design updated based on MR CLEAN results
  - Planned resubmission to NIH in March
  - Any other quick updates?

# ICTUS 3 Trial

PI: Lyden, Hemmen, Grotta

- Phase III trial of hypothermia for acute ischemic stroke patients
- Activities to date
  - Feasibility assessment
- Updates
  - Submitted to NIH in October grant cycle
  - Updates from Lyden:
    - There are plans to amend protocol to allow endovascular therapy
    - ICTUS (n=120) DSMB review in March
    - Completing basic science studies of 33 vs 35 degrees F as target temperature

# MOST Trial

PIs: Adeoye, Barretto, Broderick, Grotta

- Phase III trial of antithrombotics (eptafibatide or argatroban for IV rtPA treated patients)
- Activities to date
  - Pre-concept approval input
  - Feasibility assessment
  - Post MR CLEAN/endo results input
- Updates
  - Submitted to NIH in October grant cycle
  - Any quick updates?

# IMPACT Trial

PI: Naidech

- Phase 2b trial of desmopressin for antiplatelet-treated ICH patients
- Activities
  - Pre-concept approval input
- Update
  - Prelim budget being developed with NCC staff and then concept will be submitted to NINDS
  - Any quick updates?



# Upcoming WG Topics

- Gaps in our acute portfolio in SAH
- Gaps in our acute reperfusion knowledge based on recent endo results
- Trials in WG pipeline....
  - Preconcept review of SAH/albumin trial with Suarez to be scheduled in March per PPI request

Please feel free to contact us with  
any questions or suggestions.

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