NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY

Working Together within NIH StrokeNet

July 11, 2018

12:00-1:00pm ET

MUSC
MEDICAL UNIVERSITY of SOUTH CAROLINA

NIH
Funded by a grant from the National Institutes of Health

UNIVERSITY OF Cincinnati

Regional Coordinating Center (R26)
Awarded Institution – University of Alabama Birmingham

Toby I. Gropen, MD (MPI)

Ronald M. Lazar, PhD (MPI)

Mark R. Harrigan, MD (MPI)

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UAB THE UNIVERSITY OF ALABAMA AT BIRMINGHAM
Knowledge that will change your world

Regional Coordinating Center (R27)
Awarded Institution – Wake Forest University (Western NC)

Cheryl Bushnell, MD, MHS, FAHA (PI)

Stacy Wolfe, MD (Co-PI)

Pamela Duncan, PhD, FAPTA, FAHA (Co-PI)

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Wake Forest™ Baptist Medical Center

Regional Coordinating Center (R28)
Awarded Institution – Washington University (MARCC)

OSF HealthCare

OSF St. Mary's Hospital Galesburg (IL)
OSF St. Elizabeth Hospital Ottawa (IL)
St. Margaret Hospital-Spring Valley (IL)
Pekin Memorial Hospital (IL)
Graham Hospital-Canton (IL)
KSB Hospital-Dixon (IL)
Illinois Valley Community Hospital-Peru (IL)
CGH Medical Center-Sterling (IL)
Hammond-Henry District Hospital (IL)
OSF St. Luke Hospital-Kewanee (IL)

Saint Luke's Hospital of Kansas City

St. Luke's Hospital North (MO)
St. Luke's Hospital East (MO)
Western Missouri Medical Center (MO)
Hedrick Medical Center (MO)
St. Luke's Crushing Hospital (KS)
Wright Memorial Hospital (MO)
Golden Valley Memorial Hospital (MO)
Shawnee Mission Medical Center (KS)
Cameron Regional Medical Center (MO)

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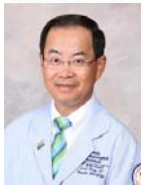
Jin-Moo Lee, MD, PhD (MPI)

Washington University in St. Louis
School of Medicine

Peter Panagos, MD (MPI)

OSF HealthCare



David Wang, DO (Site PI)

Saint Louis University

Randall Edgell, MD (Site PI)

Saint Luke's Hospital of Kansas City

Karin Olds, MD (Site PI)

Saint Louis University

John Cochran VA (MO)
Memorial Hospital Belleville (IL)
HSHS St. Elizabeth's Belleville (IL)
Gateway Regional Hospital (IL)
SSM Good Samaritan Hospital
SSM St. Mary's Hospital Centralia (IL)
Anderson Hospital (IL)
Sparta Community Hospital (IL)
Ste Genevieve Memorial Hospital (MO)
Touchette Regional Hospital (IL)

BJC HealthCare

Christian Hospital (MO)
Missouri Baptist Hospital (MO)
Belleville Memorial Hospital (IL)
Memorial Belleville East (IL)
BJH West County Hospital (MO)
Alton Memorial Hospital (IL)
Parkland Health Center (MO)
Anderson Hospital (IL)
BJH Saint Peters Hospital (MO)
Progress West Hospital (MO)

Regional Coordinating Center (R29)
Awarded Institution – Yale University (Southern NE)

Kevin N. Sheth, MD (MPI)

Karen L. Furie, MD, MPH (MPI)

Mark Alberts, MD (MPI)

Yale New Haven Health

BROWN NEUROLOGY
BROWN PHYSICIANS, INC.
A Clinical, Research and Teaching Affiliate
of the Warren Alpert Medical School of Brown University

Hartford HealthCare
Ayer Neuroscience Institute

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NIH StrokeNet Infrastructure

- NIH StrokeNet (Acute Treatment, Prevention, and Recovery & Rehab)
  - National Coordinating Center (NCC) (UC)
    - Central Institutional Review Board (CIRB) (UC)
    - StrokeNet Central Pharmacy (NCC) (UC)
  - National Data Management Center (NDMC) (MUSC)
    - StrokeNet Imaging Repository
  - 29 Regional Coordinating Centers (RCC)
    (4 New Centers and 5 Legacy Centers)
    - Satellites (SS)
    - Performance Sites (PS or CPS)

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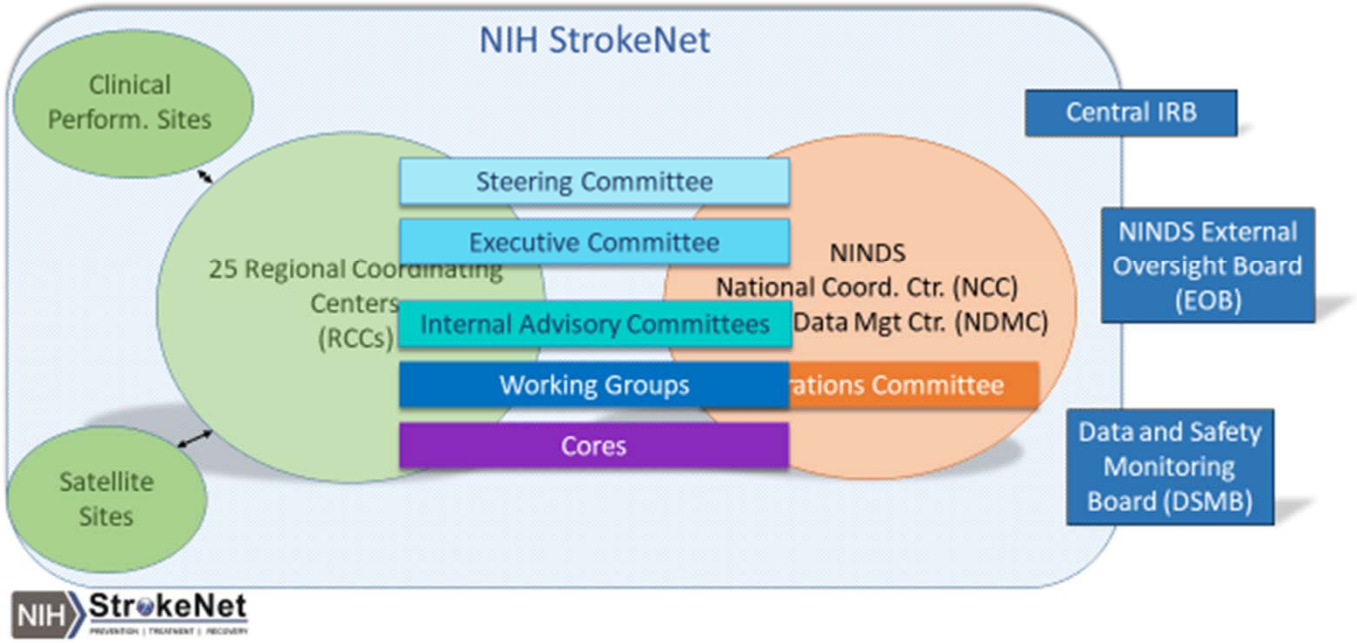
Organization and Governance



Strategic Network Leadership and Management

NIH StrokeNet Executive Committee Members

- NINDS Scientific Program Director: Scott Janis, PhD
- NCC MPI: Joseph Broderick, MD & Pooja Khatri, MD
- NDMC MPI: Yuko Palesch, PhD & Wenle Zhao, PhD
- Working Group Chairs: Pooja Khatri, MD, Marc Chimowitz, MD, and Steve Cramer, MD
- RCC: Three rotating PIs
- NCC: Jamey Frasure, PhD, Judith Spilker, BSN
- NDMC: Catherine Dillon, MS, Jessica Griffin, BS

Non-Network adjunct members (from other Stroke consortia), working and core groups as needed

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Strategic Network Leadership and Management

NIH StrokeNet Steering Committee Members

- Main scientific governing body of the network
- All major network decisions will be made by a majority vote
- All decisions must be concurred by NINDS leadership
- Membership:
  - NINDS: Scott Janis, PhD
  - NCC MPIs: Joe Broderick, MD, and Pooja Khatri, MD
  - NDMC PI: Yuko Palesch, PhD
  - RCC PIs and Coordinators

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Strategic Network Leadership and Management

NIH StrokeNet Operations Committee

- Oversees network operational issues
- Monitors trial performance
- Members
  - NCC MPIs: Joseph Broderick, MD, and Pooja Khatri, MD
  - NDMC PI: Yuko Palesch, PhD
  - NINDS: Joanna Vivalda, RN, MBS
  - NCC and NDMC staff
  - Trial Specific PIs and Project Managers
  - NINDS Directors and/or trial specific designees, as needed

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Strategic Network Leadership and Management

Three Scientific Working Groups

- **Prevention** (Chair Marc Chimowitz, Co-chair Ralph Sacco)
- **Acute Stroke Treatment** (Chair Pooja Khatri, Co-chair Jeff Saver)
- **Recovery/Rehabilitation** (Chair Steve Cramer, Co-chair Steve Wolf)

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Training Core Planned Activities

- Didactic Sessions
  - Creation of webinar curriculum
  - In-person didactics at the ISC associated StrokeNet meetings
    - May be on hold as no in-person StrokeNet meeting at ISC next year…
- Professional Development Webinars
  - Career development topics
  - Research presentations by trainees
- Basic Science Journal Club Webinars
  - Based on current StrokeNet trials, exploring the science behind the trial

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Training Core Planned Activities

- Supervision of the RCC Training Programs
  - Ensure that adequate focus on stroke research
  - Review education plans for trainees
  - Development of core curriculum
- Serve as a resource for trainees and mentors
  - Maintain contact info for current and past trainees
  - Post training opportunities, such as NINDS Clinical Trials Workshop
  - Job postings
  - Assist with finding mentors for trainees off-site
    - Away rotations

Imaging Core Activities

- Provides guidance on study design issues related to imaging of study patients, imaging workflow, image selection and image interpretation
- Works closely with the three working groups and investigators
- Guides investigators on standard operating procedures for the image management of trials
- Partners with NINDS on reviewing the imaging common data elements for trials

Strategic Network Leadership and Management

Internal Advisory Committees

Clinical & Translational Science Awards Program (CTSA)	Telemedicine
Neuro-Interventional	Minority Recruitment
Cerebrovascular Surgery	Pediatric Stroke
Emergency Medicine/EMS	Biomarkers
Physical Medicine and Rehabilitation/ Physical Therapy	Preclinical
Neurocritical Care	

*Activated

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NIH StrokeNet Central Institutional Review Board (CIRB) Leadership

NIH StrokeNet CIRB Infrastructure

- Michael Linke, PhD, CIP, Chair UC IRB
- David Ficker, MD, Vice Chair UC IRB-Neurologist/safety reviewer
- Angela Braggs-Brown, RAC, CIP, Director, HRPP
- Sue Roll, RN, BSN, StrokeNet CIRB Liaison

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NIH StrokeNet Central Institutional Review Board (CIRB)

Central IRB for all StrokeNet Trials

- As the IRB of Record – Executes Primary activities as defined by Reliance Agreement
- Local IRB has can execute secondary activities only
- Manages
  - Protocol approvals and all amendment processing and continuing reviews
  - OHRP required regulatory documentation
  - CIRB communication with RCC and satellite site Local IRBs
  - Processes reports of UPIRSOs's, Unanticipated Events, Unanticipated Adverse Device Effects, adverse events including serious, related , unexpected events as well as Complaints, Protocol violations/deviations and other Reportable events

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StrokeNet Central Pharmacy

- Works with trial team to get pharmacy quotes for budgets
- Assists with planning the blinding if needed
- Plans the shipping logistics and frequency
- Central distribution pharmacy for StrokeNet Trials involving Study Drug

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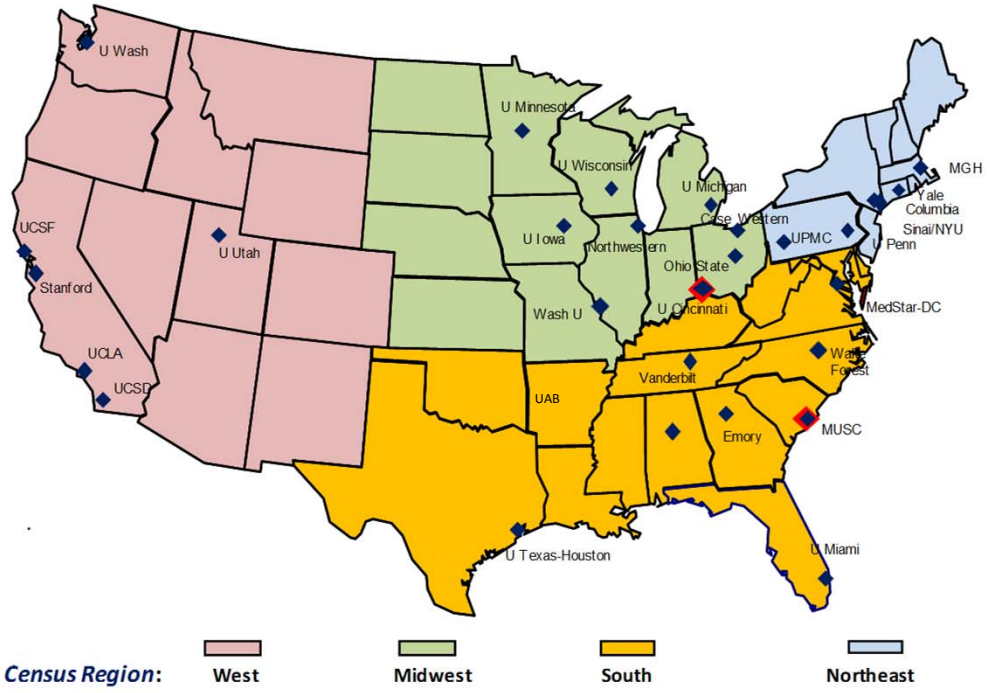
National and Regional Coordinating Centers



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Developing Regional Networks, “Partnering” for StrokeNet Projects

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A Team Approach for Partnering

- Power of Physician Champion- RCC PI or MPI
  - Recognized Clinical Content Expert
  - Resource for Community Colleagues

- Power of the Network Coordinator/Program Manager
  - Must think beyond the “Study Coordinator ”
  - Understands staff, facility and research GCP requirements for Network Trials
  - Understands responsibilities of Federally Funded projects

Barriers to RCC Partnering

- All politics are local
- Combining institutional structures add complexities
- Lack of or incomplete understanding of the request
- Lack of incentive
- No in-house champion
- Satellite IRBs may be reluctant to agree to the use of a CIRB and /or unfamiliar with how to share IRB responsibilities with a CIRB

Performance Site Experiences

Institutional differences and learning how to help navigate the barriers is key to StrokeNet efficiencies

- Who should be your first contact?
- Who at a facility do you negotiate with?
- Who can legally sign agreements for that facility?
- Who knows the system and how to use it expeditiously?

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Trial Participation

- RCCs, Satellites, and Protocol Principal Investigators (PPIs) assess resources for specific trials
- RCC may not but have one or more of its Satellites participate
- RCC may but none of its Satellites will participate
- RCC and all of its Satellites participate

And…

- The choice of participating sites in a trial is the responsibility of the PPI based on feasibility data and trial criteria

To Do List

- Establish Master Agreements between NCC and RCCs
- Execute Central IRB Reliance Agreement between NCC and RCCs and satellites
- RCC Coordinator/Manager Orientation with NCC Administrative Directors via teleconference
  - Review Network Standard Operation Procedures (SOPs)
    - Submission of RCC SOP describing interactions with and management of affiliated sites

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RCC Key Responsibilities

- Orient and manage Satellites to do their responsibilities
- Advise and assist Satellites in efficient trial start-up requirements
  - Respond to the Central IRB requests expeditiously
  - Facilitate the execution of trial agreements
- Share StrokeNet communications with Satellites
- Complete feasibility surveys in a timely manner

Performance Metrics

WebDCU™ Dashboard Numbers

https://webdcu.musc.edu/

- Enrollment - Number of subjects enrolled
- Retention - Percent of participants not retained
- Regulatory Document Collection - Percent of outstanding documents
- Case Report Collection- percent of outstanding documents
- CIRB Submission - Number of days from receipt of CIRB packet to submission. Expected to be less than 90 days per trial.
- CTA Execution - Number of days from receipt of the CTA to CTA execution. Expected to be less than 45 days per trial.

Performance Metrics

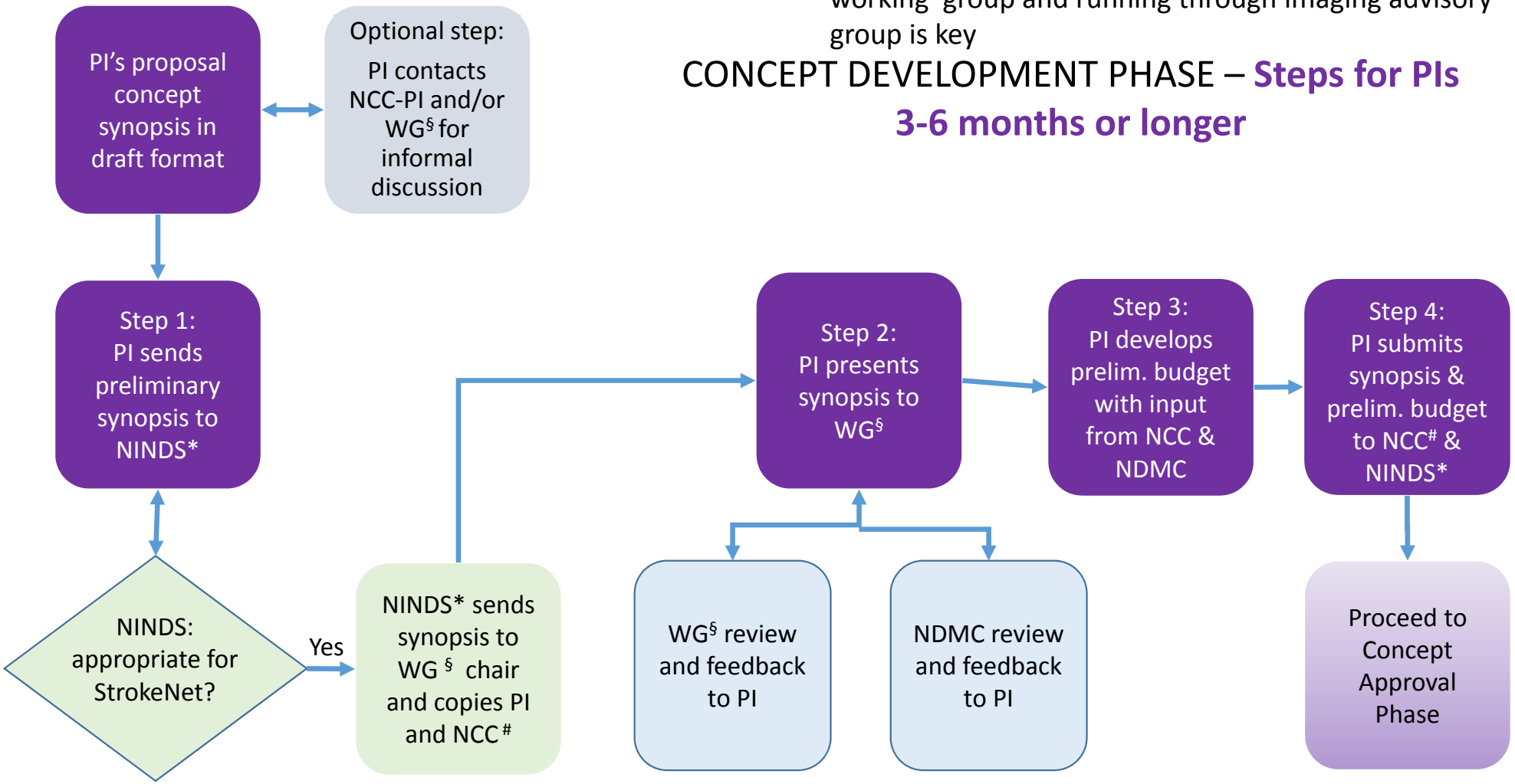
Data Reported on the Quarterly Activity Report (QAR)

- Number of QARs submitted on time
- Self-reported but confirmed by NCC, participation in network activities such as working groups, relevant StrokeNet calls, and in-person meetings
- Self-reported but confirmed by NCC, participation in StrokeNet educational activities including faculty/trainees/staff presentations, and outreach to SS/PS

For those who have imaging. Imaging member of working group and running through imaging advisory group is key

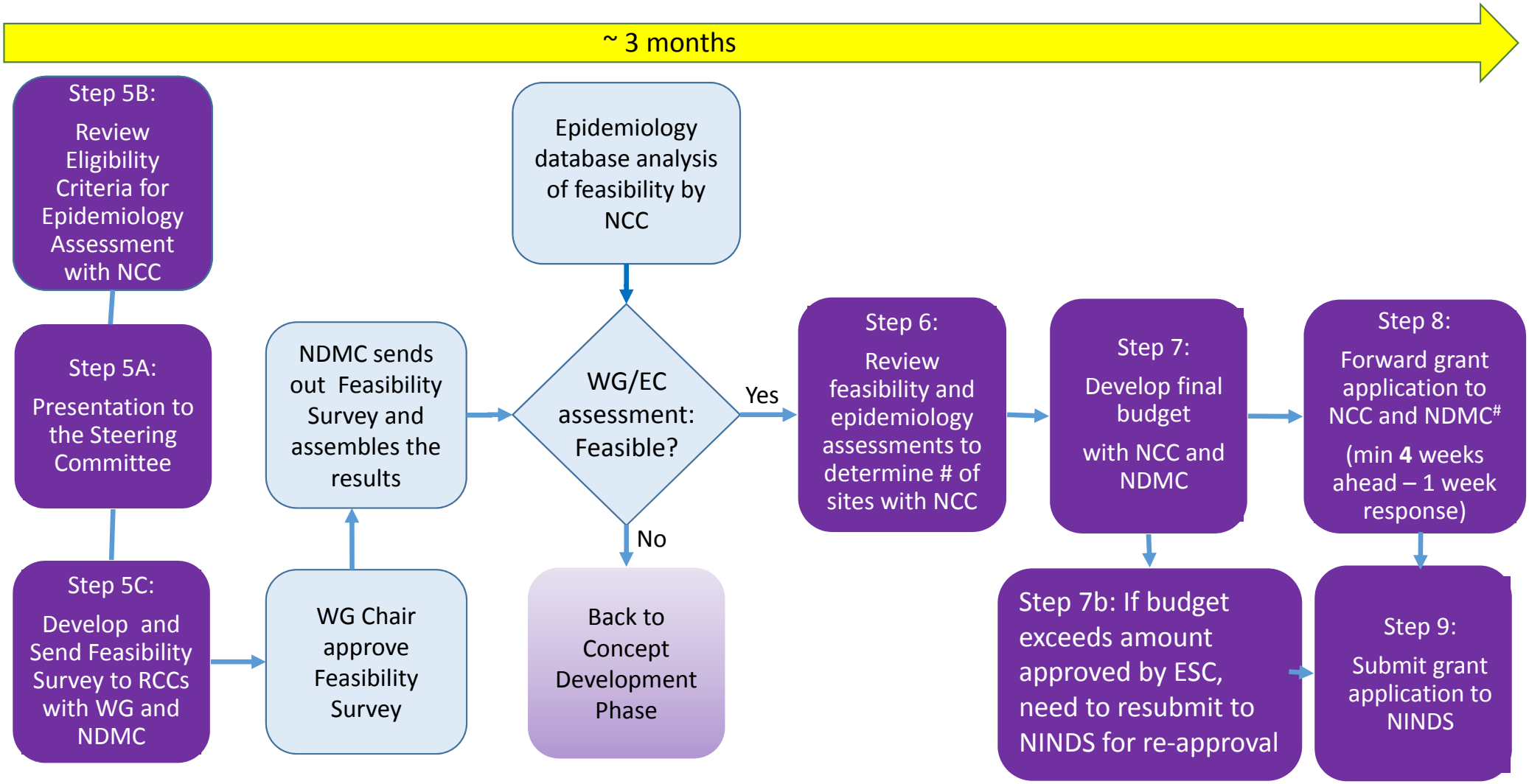
CONCEPT DEVELOPMENT PHASE – **Steps for PIs**

3-6 months or longer

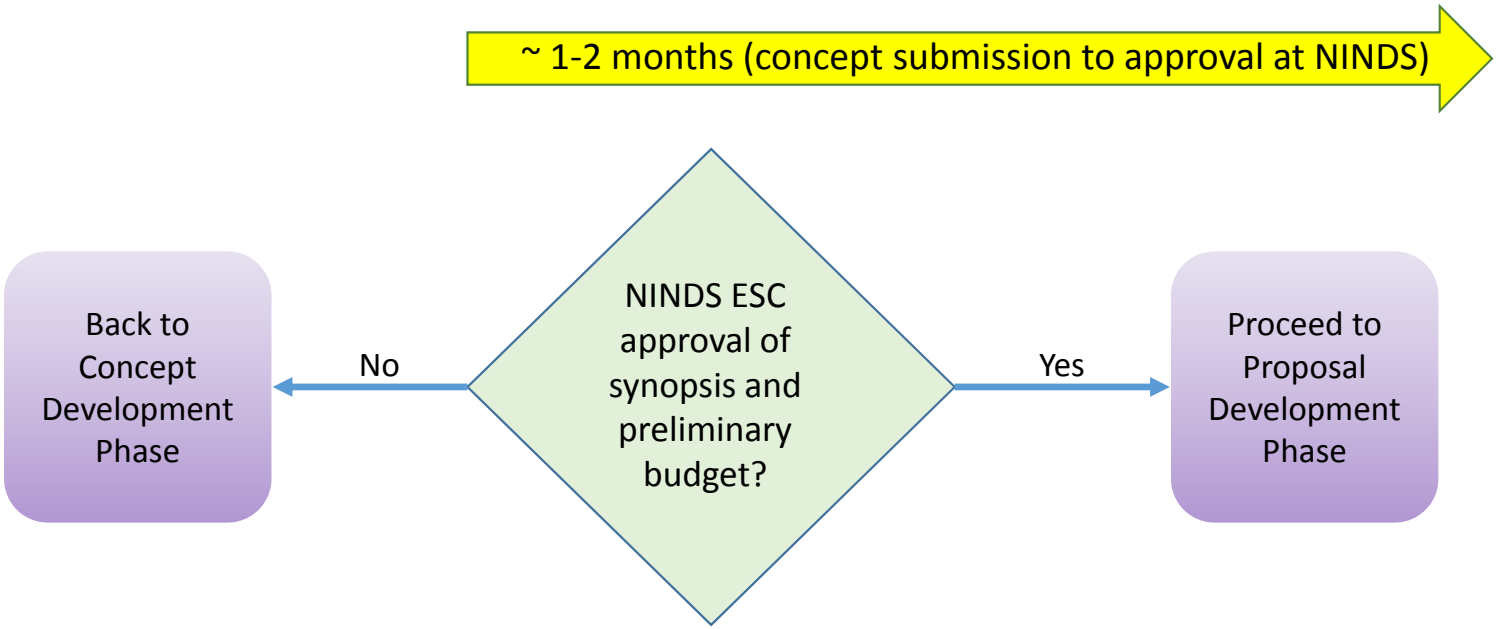


* Contact at NINDS: StrokeNetInquiry@mail.nih.gov; # Contact at NCC: Rose Beckmann (BECKMARE@ucmail.uc.edu); § See WG composition (last slide)

STROKENET: PROPOSAL DEVELOPMENT PHASE – **Steps for the PI**



CONCEPT APPROVAL PHASE



NIH StrokeNet Trials Update

- TeleRehab (Recovery) - Completed
- DEFUSE-3 (Acute) - Completed
- ARCADIA (Prevention)
- MOST (Acute)
- Sleep SMART (Prevention)
- TRANSPORT 2 (Recovery)
- SATURN (Prevention)

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Final Comments

Questions and Discussion

http://nihstrokenet.org/

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