

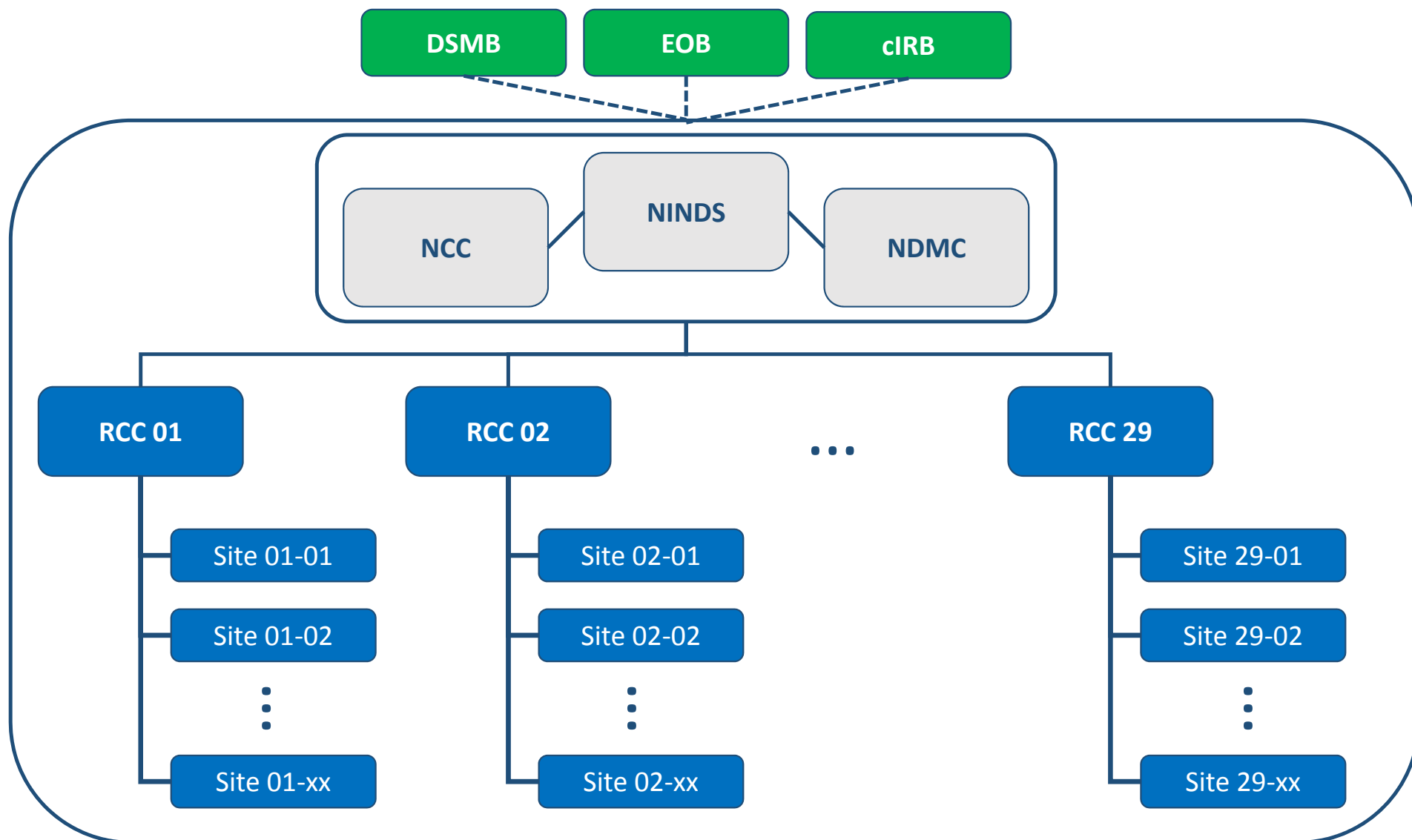


NIH StrokeNet Montreal Meeting

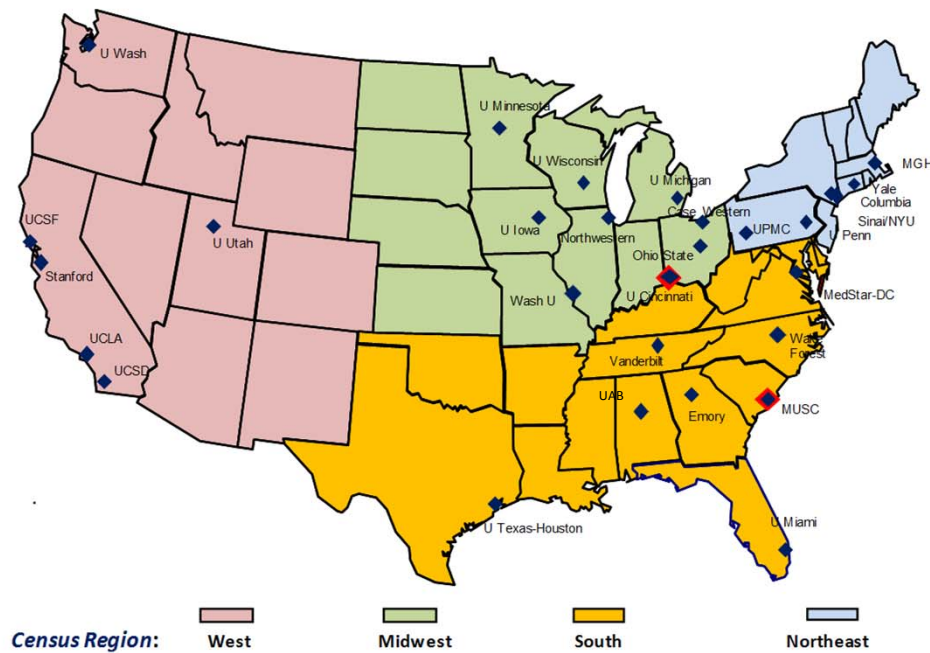


NIH StrokeNet Infrastructure

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



National and Regional Coordinating Centers

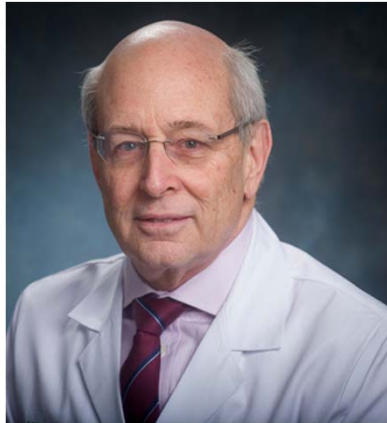


Regional Coordinating Center (R26)

Awarded Institution – University of Alabama Birmingham



Toby I. Gropen, MD (MPI)



Ronald M. Lazar, PhD (MPI)



Mark R. Harrigan, MD (MPI)

Coordinator Tammy Davis



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)

Coordinator Mysha Sissine, MPH

Regional Coordinating Center (R28)

Awarded Institution – Washington University (MARCC)



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)



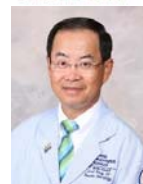
St. Luke's Hospital North (MO)
 St. Luke's Hospital East (MO)
 Western Missouri Medical Center (MO)
 Hedrick Medical Center (MO)
 St. Luke's Crushing Hospital (KS)
 Wright Memorial Hospital (MO)
 Golden Valley Memorial Hospital (MO)
 Shawnee Mission Medical Center (KS)
 Cameron Regional Medical Center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



Jin-Moo Lee, MD, PhD (MPI)



Peter Panagos, MD (MPI)



David Wang, DO (Site PI)



Randall Edgell, MD (Site PI)



Karin Olds, MD (Site PI)



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)



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)

Coordinator Jill Newgent

Regional Coordinating Center (R29)

Awarded Institution – Yale University (Southern NE - SPIRIT)



Kevin N. Sheth, MD (MPI)



Karen L. Furie, MD, MPH (MPI)



Mark Alberts, MD (MPI)



Coordinators Sara Jasek, Ashley Schomer, Laura Greiner

NIH StrokeNet Central Institutional Review Board (CIRB)

NIH StrokeNet CIRB Infrastructure Leadership at the University of Cincinnati

- 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

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

StrokeNet Central Pharmacy

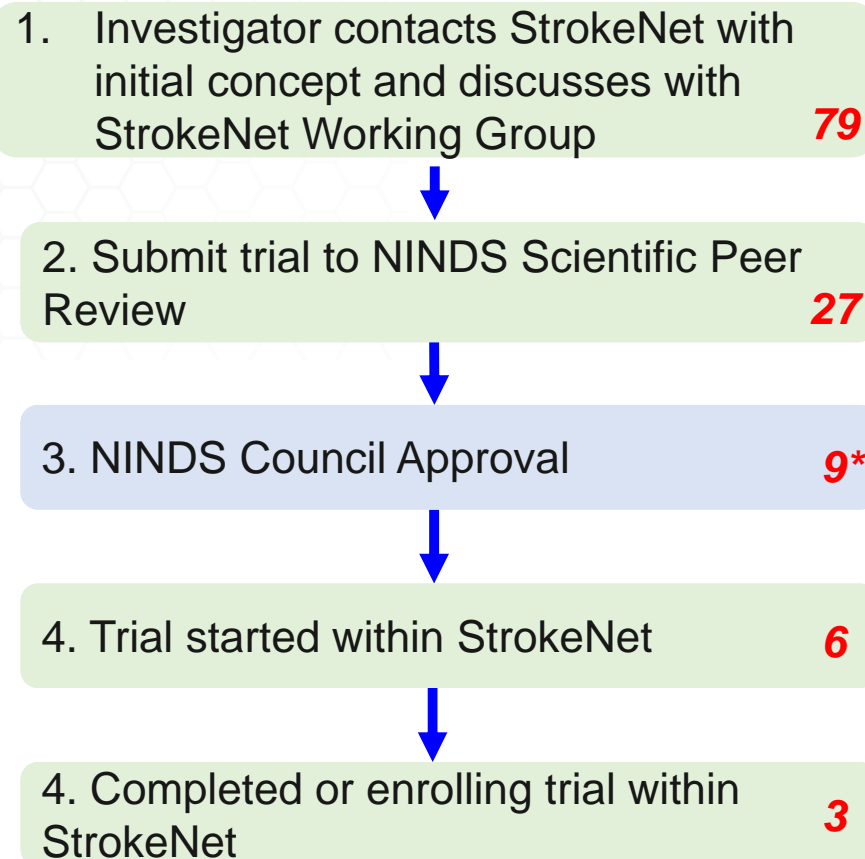
- Works with trial team to get pharmacy quotes for budgets
- Assists with planning the blinding if needed
- Plans the shipping logistics and frequency
- Central distribution pharmacy for StrokeNet Trials involving Study Drug

Regional Coordinating Centers (RCCs)

RCC Responsibilities

- Establishing a Master Agreement with the NCC
- Complying with Central IRB requests in a timely manner
- Implementation and supervision of any approved protocol at RCC, satellite sites, and other performance sites.

StrokeNet Trial Development Process



*5 submissions still pending first review

NINDS Trials Funded Prior to StrokeNet

Trial	Category	Outcome
POINT	Acute Prevention	Stopped early by DSMB and NINDS. Published NEJM 5/2018: Change in practice
Rhapsody	Acute	Enrollment completed and presented. Publication pending.
MISTIE 3	Acute	Enrollment completed. Results to be presented at 2019 ISC
i-DEF	Acute	Enrollment completed. Results to be presented at 2019 ISC.
SHINE	Acute	Stopped early by DSMB and NINDS. Results to be presented at 2019 ISC
CREST - 2	Prevention	Enrollment ongoing. 1184 of 2480 as of 10/2018
CREST - H	Prevention	Ancillary Study for CREST – 2 funded after StrokeNet started. Enrollment ongoing.

StrokeNet Trials Completed

Trial	Category	Outcome
DEFUSE 3	Acute	Published NEJM – change clinical practice and guidelines
TeleRehab	Recovery/Rehabilitation	Completed, presented, and manuscript nearing completion.

NIH Approved Ongoing NIH StrokeNet Trials = 7

Current Trials	Domain	PIs	Sample Size	Number of sites	Actively enrolling
ARCADIA	Prevention	Mitch Elkind , Hooman Kamel, Dave Tirschwell, Will Longstreth	1100	120	Yes N = 101
MOST	Acute	Ope Adeoye Andrew Barretto James Grotta Joe Broderick	Adaptive design, Max. 1200	110	Early 2019
SLEEP-SMART	Prevention /Recovery	Devin Brown Ron Chervin	3062	110	Early 2019
TRANSPORT 2	Recovery	Wayne Feng Gottfried Schlaug	129	12	Early-Mid 2019
Saturn	Prevention	Magdy Selim	1456	140	Late 2019
ASPIRE	Prevention	Kevin Sheth , Hooman Kamel	550	125	Late 2019
I-ACQUIRE	Recovery	Sharon Ramey , Warren Lo	240	12	Late 2019

Global Alliance of Independent Stroke Networks (GAINS)

- Network of national stroke networks
- Meeting by phone quarterly and in person 2-3 times a year
- How to facilitate/coordinate global trials, educational efforts
- <https://www.globalstroketrials.org/> : listing of contacts and people.

NCC and NDMC – Activities since Last Meeting

- Web-DCU interface with CIRB documents and financial invoicing
- CIRB approval prior to trial award – work closely with PIs
- Increased and ongoing CIRB webinars
- Web-DCU webinars
- Redesign of MTA process
- Enhanced process between NDMC and StrokeNet Research Pharmacy
- Movement of CIRB database to new Huron system (January, 2019)
- Ongoing expansion of NCC and NDMC personnel to reflect growth to one ongoing and 6 trials just starting or soon to start (5 with > 100 sites).
 - New trial managers, regulatory people, pharmacy personnel, payment personnel, database programmers, etc.