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# Industry Disclosures

- UC Dept of Neurology received funds from Genentech (PRISMS Trial PI) and Lumosa (consultation, DSMB) for my research effort
- Payment from Biogen (DSMB) and Novartis (coinvestigator)
- Travel support from Neuravi (academic workshop attendance)

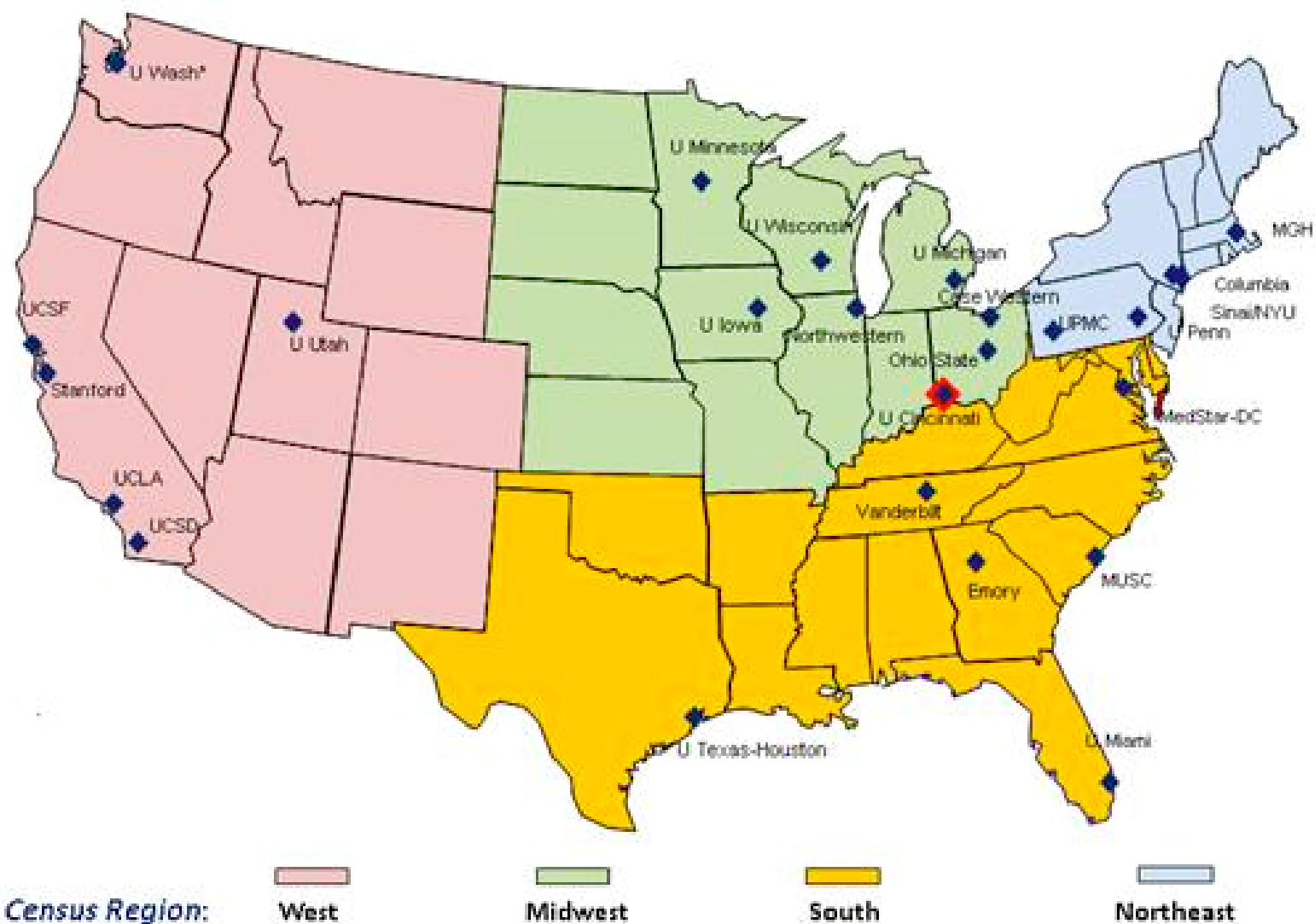
# NIH Trial Networks In Context

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- NETT
    - Phase III trials in emergency neurology
  - NeuroNEXT
    - Pilot trials in the neurosciences
  - StrokeNET
    - All phases in stroke (treatment, prevention, recovery)
  - SIREN
    - All phases in emergency neurology (except stroke), cardiovascular, respiratory, and trauma

# StrokeNET Infrastructure

- **NCC (National Coordinating Center)**
  - University of Cincinnati
  - PI: Joe Broderick, MD
  - “Co-PIs”
    - Acute: Pooja Khatri MD
    - Prevention: Marc Chimowitz, MD
    - Recovery: Steve Cramer, MD
- **NDMC (National Data Management Center)**
  - Medical University of South Carolina (MUSC)
  - Multiple PIs: Yuko Palesch, PhD and Wenle Zhao, PhD
- **RCCs (Regional Coordinating Centers)**
  - 25 RCCs with 316 clinical performance sites

# National and Regional Coordinating Centers



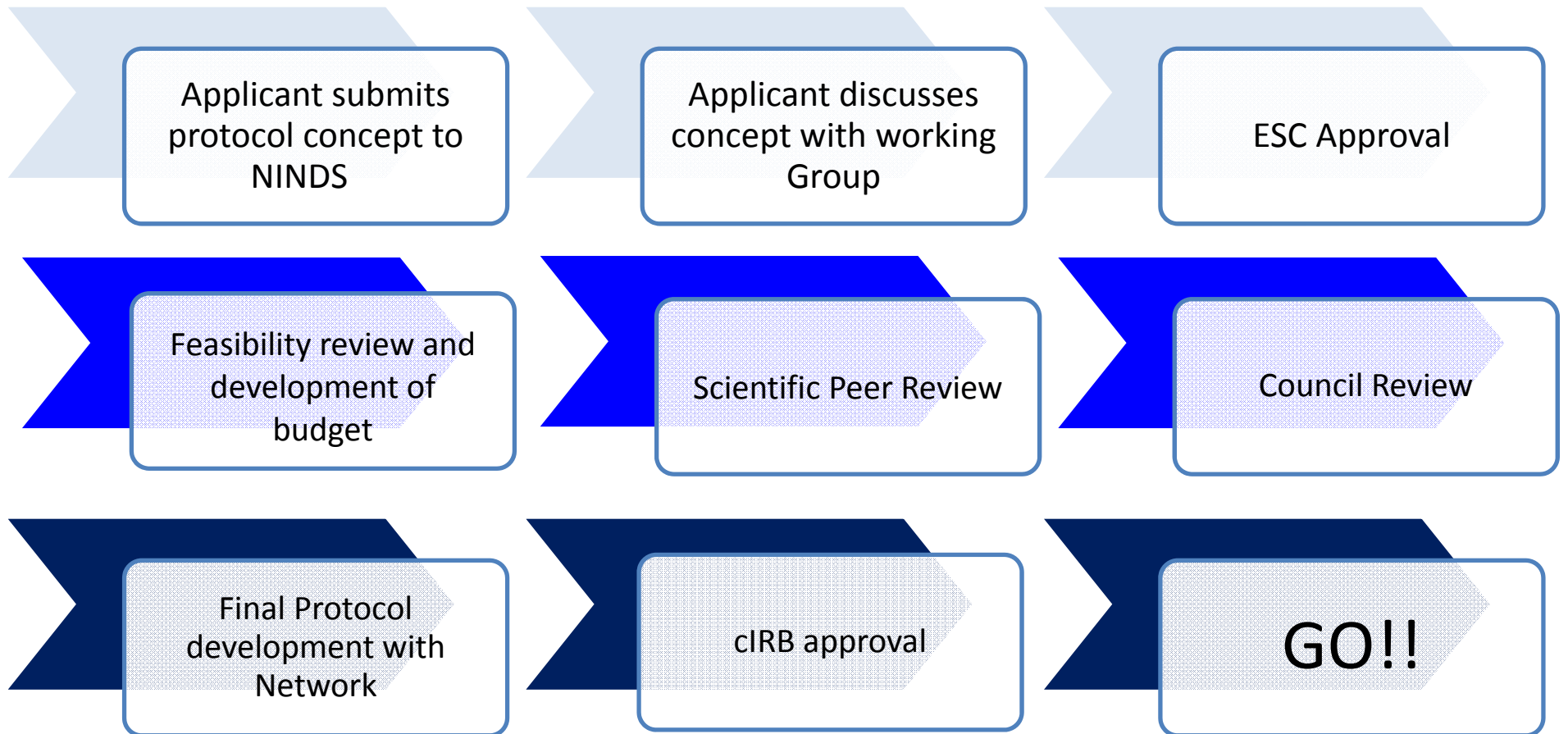
# Key Elements for RCCs

- Funds for program manager
- Funds for trainee
- Master trial agreement requirement
- Central IRB requirement

# Trial Concepts

- Arise from within or outside StrokeNet
- Process involves interaction with scientific input (not review) and trial feasibility within the network

# Trial Development Process





# Working Groups

Acute Stroke	Primary and Secondary Prevention	Recovery and Rehabilitation
<ul style="list-style-type: none"> <li>• <b>Chair: Pooja Khatri University of Cincinnati</b></li> <li>• <b>Co-chair: Jeff Saver UCLA</b></li> <li>• Renee' Martin NDMC</li> <li>• Greg Albers Imaging Core</li> <li>• David Liebeskind Imaging Core</li> <li>• TBD Minority Recruitment and Retention</li> <li>• Bill Barsan University of Michigan (ad hoc NETT member)</li> <li>• Lee Schwamm Massachusetts General Hospital</li> <li>• Ed Jauch Medical University of South Carolina</li> <li>• Brett Meyer UC San Diego</li> <li>• Phil Scott University of Michigan</li> <li>• Jay Mocco Mt. Sinai School of Medicine – (#2)</li> <li>• Cathy Sila Case Western Reserve University School of Medicine</li> <li>• Wade Smith UC San Francisco</li> <li>• Azam Ahmed University of Wisconsin</li> <li>• Michel Torbey The Ohio State University</li> <li>• Coordinator: Kiva Schindler Emory University</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Chair: Marc Chimowitz Medical University of South Carolina</b></li> <li>• <b>Co-Chair: Ralph Sacco University of Miami School of Medicine</b></li> <li>• Sharon Yeatts NDMC</li> <li>• Colin Derdeyn Imaging Core</li> <li>• Steve Warach Imaging Core</li> <li>• Bernadette Boden-Albala PhD. Mt. Sinai School of Medicine/New York City Collaborative Minority Recruitment and Retention</li> <li>• Amy Towfighi USC/UCLA</li> <li>• Scott Kasner University of Pennsylvania</li> <li>• Kamakshi Lakshminarayan University of Minnesota</li> <li>• David Tirschwell University of Washington</li> <li>• Shyam Prabhakaran Northwestern University</li> <li>• Enrique Leira University of Iowa</li> <li>• Natalia Rost Massachusetts General Hospital</li> <li>• Coordinator: Glenn Schubert University of Washington</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Chair: Steve Cramer UC Irvine</b></li> <li>• <b>Co-chair: Steve Wolf PhD Emory University</b></li> <li>• NINDS representative: Daofen Chen, PhD</li> <li>• Caitlyn Ellerbe NDMC</li> <li>• Max Wintermark Imaging Core</li> <li>• TBD Minority Recruitment and Retention</li> <li>• Ron Lazar Columbia University</li> <li>• Alex Dromerick The MedStar Research Institute</li> <li>• Larry Wechsler University of Pittsburgh</li> <li>• Sean Savitz University of Texas at Houston</li> <li>• Lorie Gage Richards University of Utah</li> <li>• Maarten Lansberg Stanford University</li> <li>• Andrew Grande University of Minnesota</li> <li>• Elliot Roth Northwestern University</li> <li>• Harold Adams University of Iowa</li> <li>• Kari Dunning University of Cincinnati (ad hoc)</li> <li>• Coordinator: Mary Pautler University of Utah</li> </ul>

# Cores and Advisory Committees

< StrokeNet Cores >		
<Imaging Core>	<p>Membership:</p> <p>Chair: Dr. Max Wintermark, Dr. Gregory W. Albers, Dr. Colin Derdeyn, Dr. Steve Warach, Dr. David Liebeskind, Dr. Arthur Toga, TBN (DMC representative), and RCC representatives TBN</p>	<p>Core Group Function- Oversees the imaging component of StrokeNet trials. This group will provide feedback regarding imaging training at RCCs and will facilitate the organization, central reading processes, and storage for imaging studies required for StrokeNet network trials.</p>
< Educational Core >	<p>Membership:</p> <p>Chair: Dr. Dawn Kleindorfer, Co-chair Dr. Randolph Marshall, TBN (DMC representative) , RCC representatives (faculty, fellows, and coordinators)</p>	<p>Core Group Function- implements Network-wide educational activities and mentoring programs for RCC fellows, faculty and coordinators in collaboration with NETT and Neuronext Networks.</p>

- 1) Ethics and Competing Trials Committee (Jennifer Majersik)
- 2) The Minority Recruitment and Retention Advisory Committee (B. Boden Albala and Dawn Kleindorfer)
- 3) The Interventional Advisory Committee (Colin Derdeyn and Sam Zaidat)
- 4) Pediatric Stroke Committee (Heather Fullerton and Catherine Amlie-Lefond)

# Education Core

- Activities
  - Supervision of the RCC Training Programs
  - Feedback to trainees about research projects
  - Didactic and professional development webinars
    - <https://www.nihstrokenet.org/webinars>

# 2015-2016 Didactic Webinars

Date	Topic	Speaker	Institution	Moderator
July 30	Ethics in Acute Research and Emergency Medicine	Michelle Biros	UMinn	Liebeskind
Aug 27	BP and Cognition - Impact of Blood Pressure and Hypertension on Cognitive Function	Clinton Wright	Miami	Marshall
Sept 24	Consent in Clinical Trials Remote Enrollment by Telemedicine	Jennifer Majersik Teddy Wu	Utah Texas	Liebeskind
Oct 29	Treatment of Carotid Stenosis	Seemant Chaturvedi	Miami	Marshall
Nov 19	Rehab in Acute Stroke/Neuroplasticity	Lorie Richards	Utah	Marshall
Jan 28	Imaging Selection Approaches in Endovascular Trials	David Liebeskind	UCLA	Tirschwell
Feb 25	Brain Computer Interface for Rehab	Elliott Roth	Northwestern	Liebeskind
Mar 24	Gloves Off for Acute Stroke Management; Fellow Case Presentations to two Stroke Experts	Jay P Mohr	Columbia	Kleindorfer
April 28	Neuroprotection – STAIR Criteria and the Future	Louise McCullough	Texas	Marshall
May 26	ICH Secondary Prevention	Magdy Selim	Beth Israel	Tirschwell

# Professional Development Webinars 2015-16

Date	Topic	Speaker	Time	Institution	Moderator
July 27 Mon	Writing your CV & Biosketch (updated with new format)	Dawn Kleindorfer	4:00	Cincinnati	Kleindorfer
Aug 20 Thursday	Approval Process for Medical Devices in Stroke	Wade Smith	2:00	UCSF	Tirschwell
Sept 30 Wed	How to Present your Data	Enrique Leira	3:00	Iowa	Kleindorfer
Oct 20 Tues	Creating a Study Budget	Joe Broderick Judy Spilker	1:30	Cincinnati	Kleindorfer
Nov 12 Thurs	Grant Writing	Steve Greenberg	1:00	MGH	Marshall

# StrokeNET Trials

<b>Current Trials (n=5)</b>	<b>Domain</b>	<b>PI</b>	<b>Actively enrolling</b>
CREST 2	Prevention	Tom Brott, MD	Yes
MISTIE III	Acute	Daniel Hanley, MD	Yes
iDEF	Acute	Magdy Selim, MD	Yes
TeleRehab*	Recovery	Steve Cramer, MD	Yes
DEFUSE III*	Acute	Greg Albers, MD	Done
ARCADIA*	Acute	Mitch Elkind, Hooman Kamel, Dave Tirschwell, Will Longstreth	Soon
<i>SN also contributes to enrollment in SHINE, POINT, and Rhapsody</i>			

\*Managed entirely by StrokeNET

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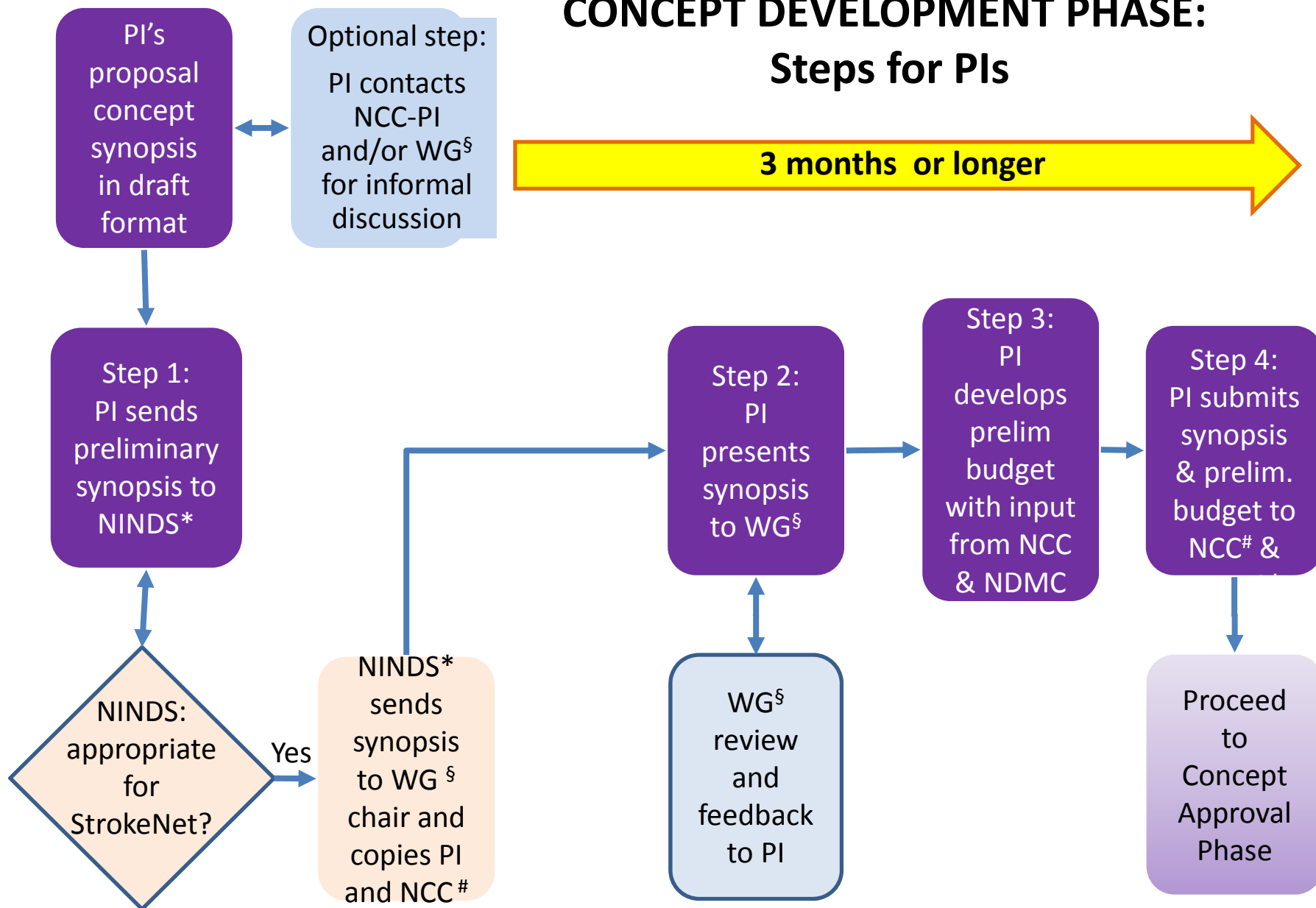
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***Hoping for MOST trial and IPAP trial in next round!***

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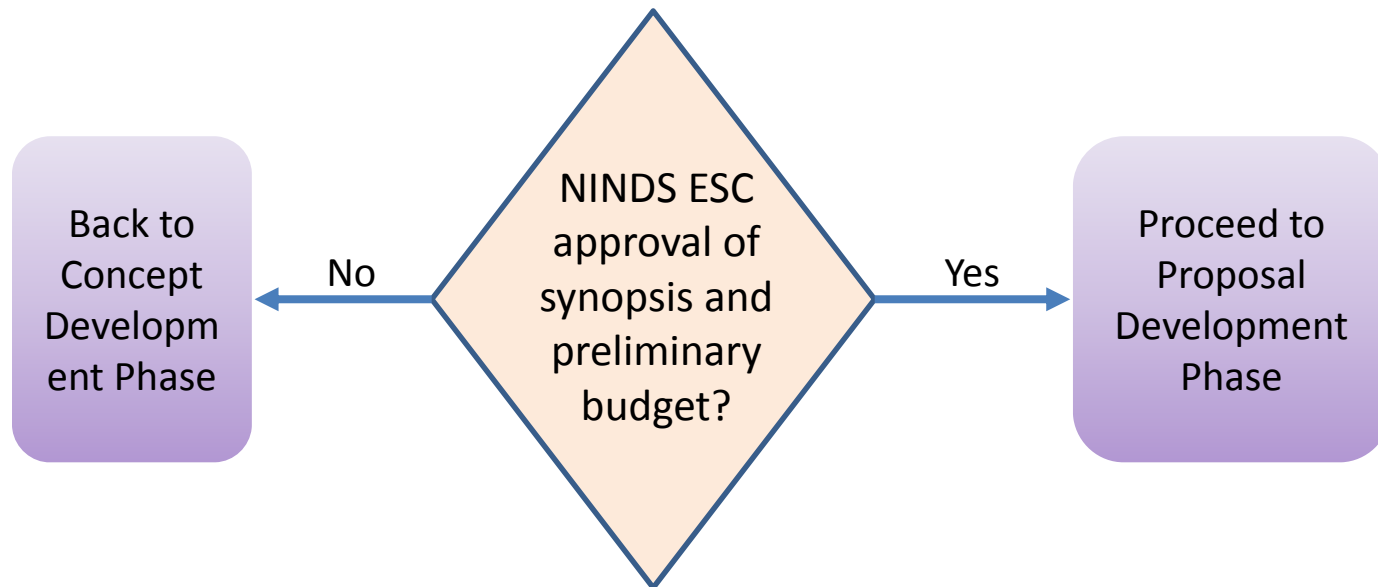
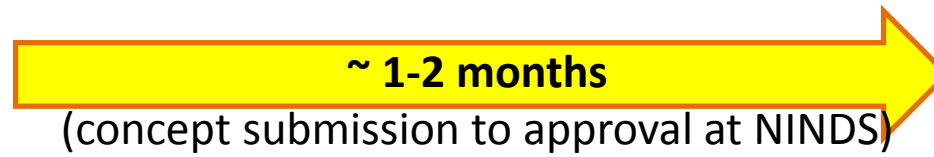


# CONCEPT DEVELOPMENT PHASE: Steps for PIs



\* Contact at NINDS: Lupe Aquino ([lupe.aquino@nih.gov](mailto:lupe.aquino@nih.gov)); # Contact at NCC: Rose Beckmann ([BECKMARE@ucmail.uc.edu](mailto:BECKMARE@ucmail.uc.edu)); § See WG composition (last slide)

# CONCEPT APPROVAL PHASE



# STROKENET: PROPOSAL DEVELOPMENT PHASE –

## Steps for the PI

~ 3 months

