

Welcome to the
NETT
Neurological Emergencies
Treatment Trials

Neurological Emergency Treatment Trials Network



Overview of the network

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nett.umich.edu



Mission



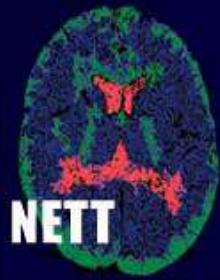
The mission of the Neurological Emergencies Treatment Trials (NETT) Network is to improve outcomes of patients with acute neurological problems through innovative research focused on the emergent phase of patient care.

Vision



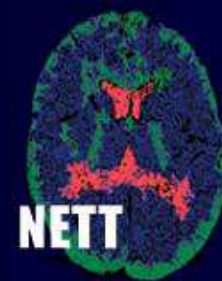
NETT will engage clinicians and providers at the front lines of emergency care to conduct large, simple multi-center clinical trials to answer research questions of clinical importance.

The NETT structure will be utilized to achieve economies of scale enabling cost effective, high quality research.



Overall Network Concept

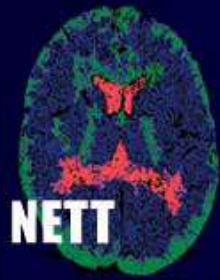
- Phase 3 clinical trials only
- Hub and Spoke Network
- Separate awards for:
 - CCC
 - SDMC
 - Hubs
- NINDS funding only for infrastructure
- Specific study funding must be secured
- NETT is an “open” network



Design for the future

Large simple trial designs

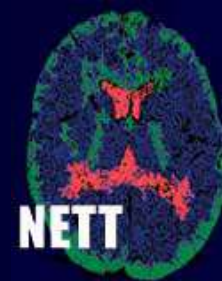
- Streamlined protocols
- Collect only essential data (short case report forms)
- High enrollment – lower per-patient costs



Design for the future

Emphasis on intervention

- Focus on phase III intervention trials
- Patient-oriented readily-applicable results
- Diverse enrollment (patients & practice environments)

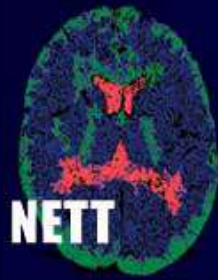


Design for the future

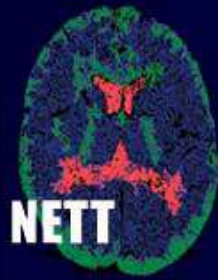
Consent issues

- Exception to informed consent for emergency research
- Optimize methods that respect human subjects
- Dedicate network resources to facilitate local efforts
- Help develop centralized IRB review

Guidelines for NETT Trials



- Study an emergent condition best conducted in the emergency care setting with the primary intervention being delivered in the prehospital or emergency phase of treatment.
- The study should have a patient oriented primary outcome.
- The study should be “simple” in design with clearly defined endpoints and gather only essential data to answer the scientific question.
- The study should not be pilot study
- Have sample sizes amenable to being conducted in a system of eleven hubs and their spokes (if needed)
- Be phase III or late phase II interventional treatment or health services trials.
- Be designed such that the results are easily translated into clinical practice.

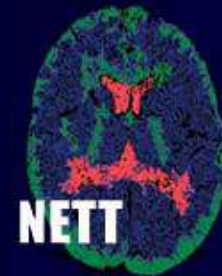


Study Selection

Investigator Initiated Studies

- Investigator Initiated Studies
 - Incentives and Limitations
 - Application Process

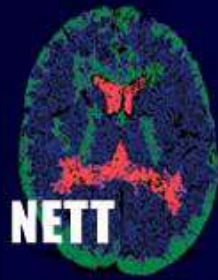
- Industry Sponsored Studies
 - Network / Investigator Design



Study Selection

Investigator Initiated Studies

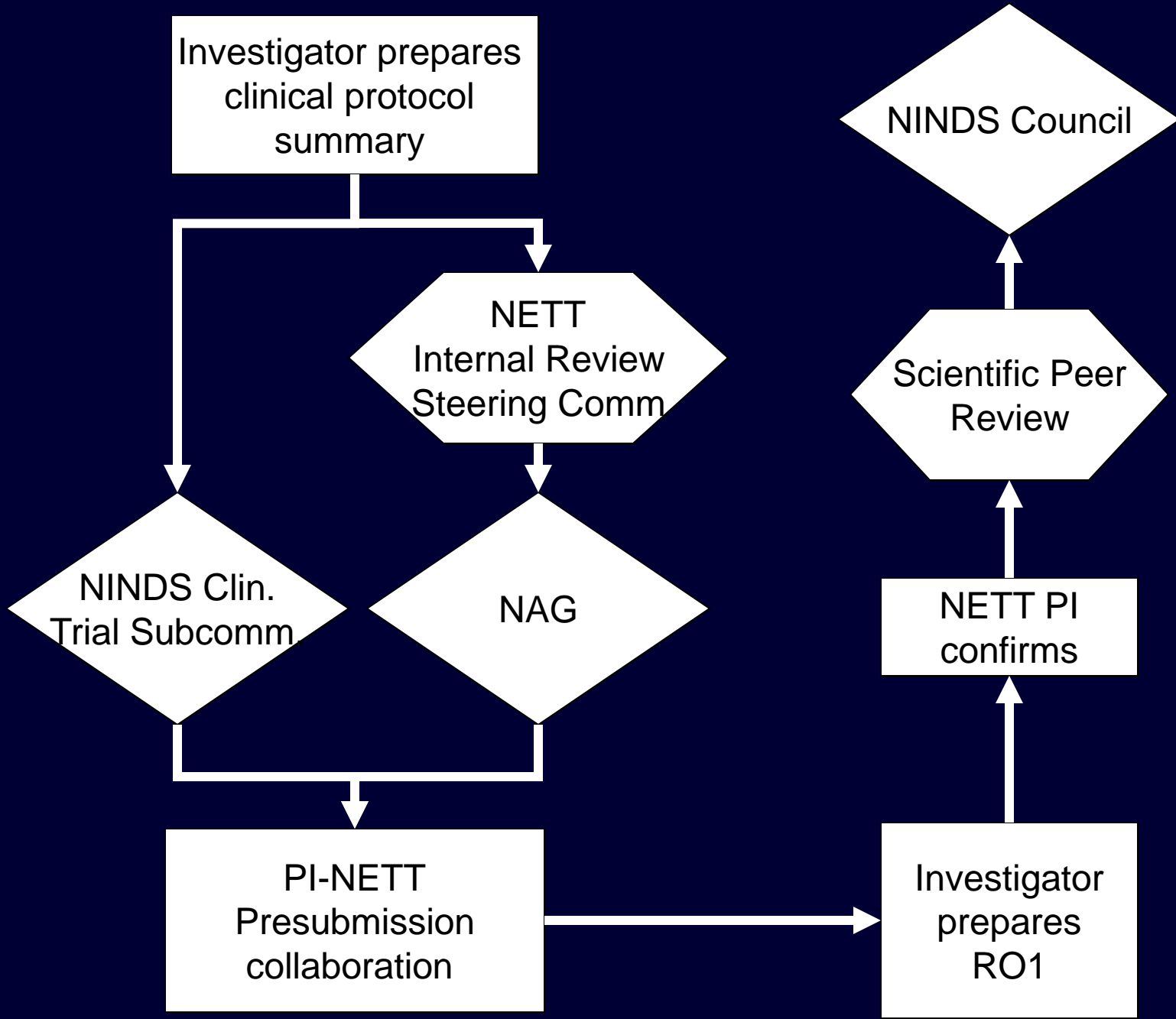
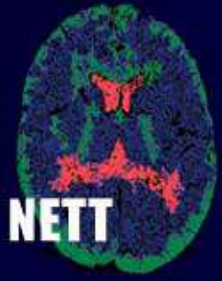
- Incentives
 - Investigator receives the trial award
 - Scientific control, credit, authorship preserved
 - Infrastructure already established
- Limitations
 - Fewer funds stay at investigators institution
 - Commitment to stay within the network

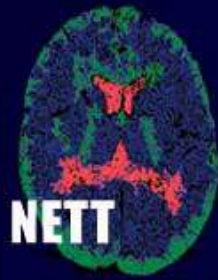


Study Selection

Investigator Initiated Studies

- Process
 - NETT Trial Guidelines
 - Clinical Trial Subcommittee & NETT-AG
 - Administrative Consultation
 - Submission for Scientific Review



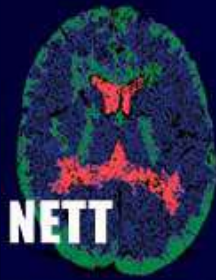


Study Selection

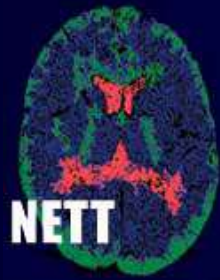
Industry Sponsored Studies

- Network / Investigator Design
 - Scientific Control
 - Shared Economies of Scale
 - No Direct Subsidy
 - NETT-AG solicits scientific review

Grant Review process



- Special Emphasis Panel
 - Have continuity of review process
 - Familiar with NETT guidelines
 - Add experts in content area
 - Sometimes leads to longer process



Publications

- Overall NETT Publications committee
 - Exec Committee
 - For publications not associated with a trial
- Publications committee for each trial
 - Chaired by the trial PI
 - Members from EC, Hubs, SDMC
 - All publications related to the clinical trial
 - Includes substudies or ancillary projects

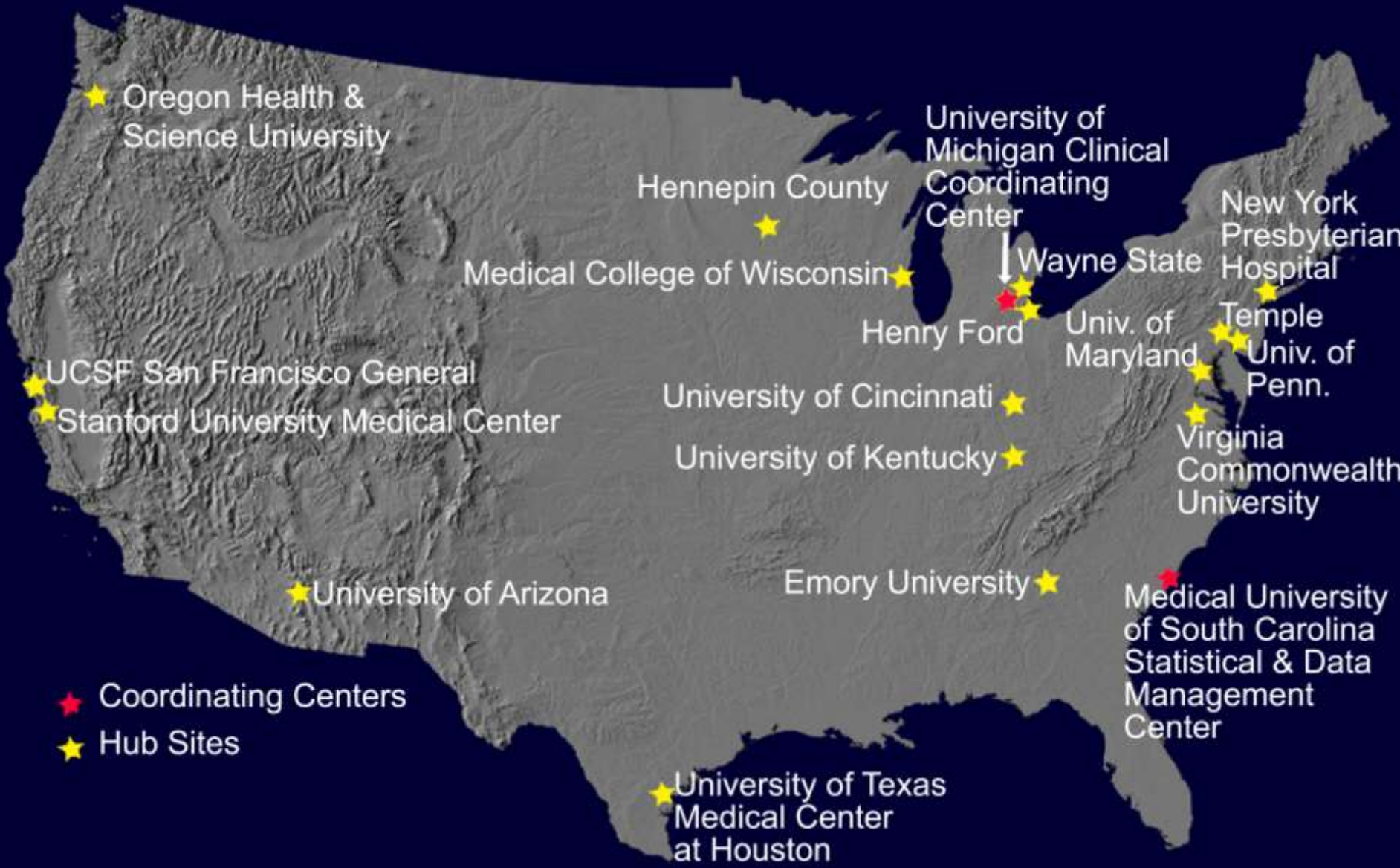
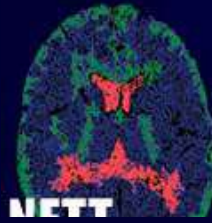


NETT

Organizational

Structure

NETT Coordinating and Hub Sites



A small brain scan image in the top right corner, showing a cross-section of a brain with red and green highlights. The text "NETT" is overlaid on the image in white, bold, sans-serif font.

NETT

Hubs

NINDS

CCC

SDMC

CCC



Leadership Administration

Barsan
Lowenstein

Bylaws, Contracts, Budgets, Compliance, Reports, Coordination of Units, Promotion of network within EM and Neurology communities

Liaison to NAG & Scientific Program Director

Trial Management

Morgenstern

Trial Solicitation, Scientific Review, Publications, Clinical Translation Unit.

Liaison to Trial Investigators and NSD-K

CCC Internal Advisory Committee

Site Management

Pancioli

Recruitment, Training, Certification, Screening, Enrollment, Monitoring,

Liaison to Hub investigators

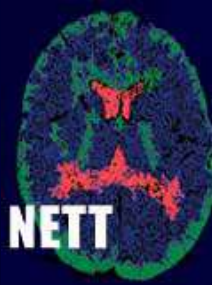
Study Operations

Silbergleit

MOP, Human Subjects Protection, Outcome Assessment, Centralized Data, Telemedicine,

Liaison to SDMC and DSMB

SDMC



Data Management

V. Durkalski, C. Dillon

Data processing

Data query generation
and monitoring

Data validation

Site contact

Training

Report generation

Archiving

WebDCU™

W. Zhao

Database development

PM tools development

Central randomization

Maintenance

Statistics

Y. Palesch, V. Durkalski

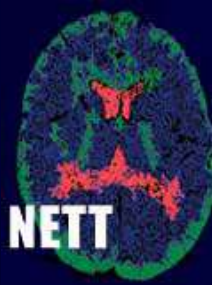
Protocol design

SAP development

DSMB report generation

Analyses

NINDS



Scientific Guidance

Robin Conwit, MD
Scientific Program Director

Peter Gilbert, PhD
Scientific Guidance-SDMC

Scientific leadership
Promote the mission of the NINDS
Identify needs & develop new initiatives

Administrative

Scott Janis, PhD
Administrative Program Director

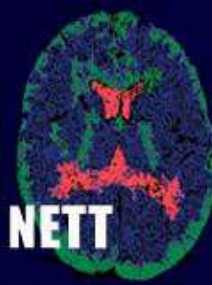
Gavin Wilkom
Funding Management

Coordinate Funding
Grants Management

Liaison

NINDS Leadership
NETT-Advisory Group
NETT DSMB

HUB COMPLEXES

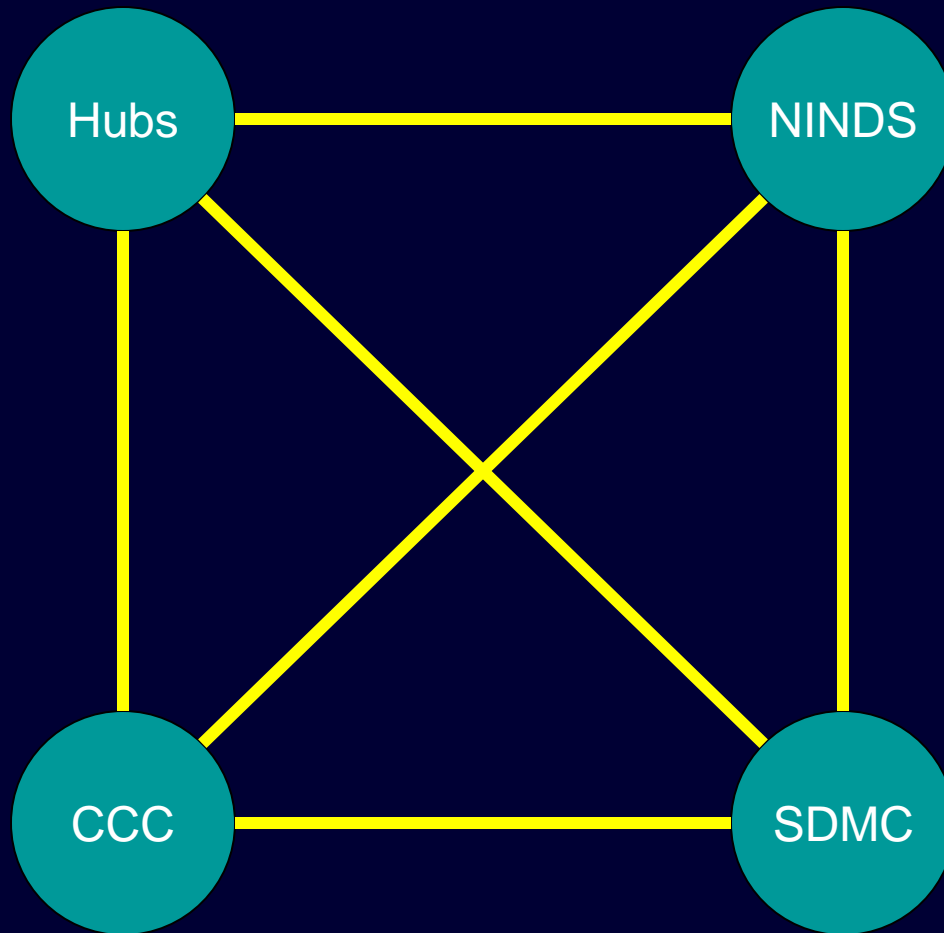
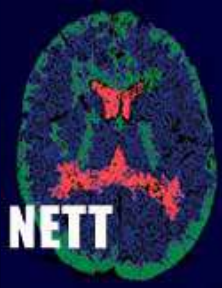


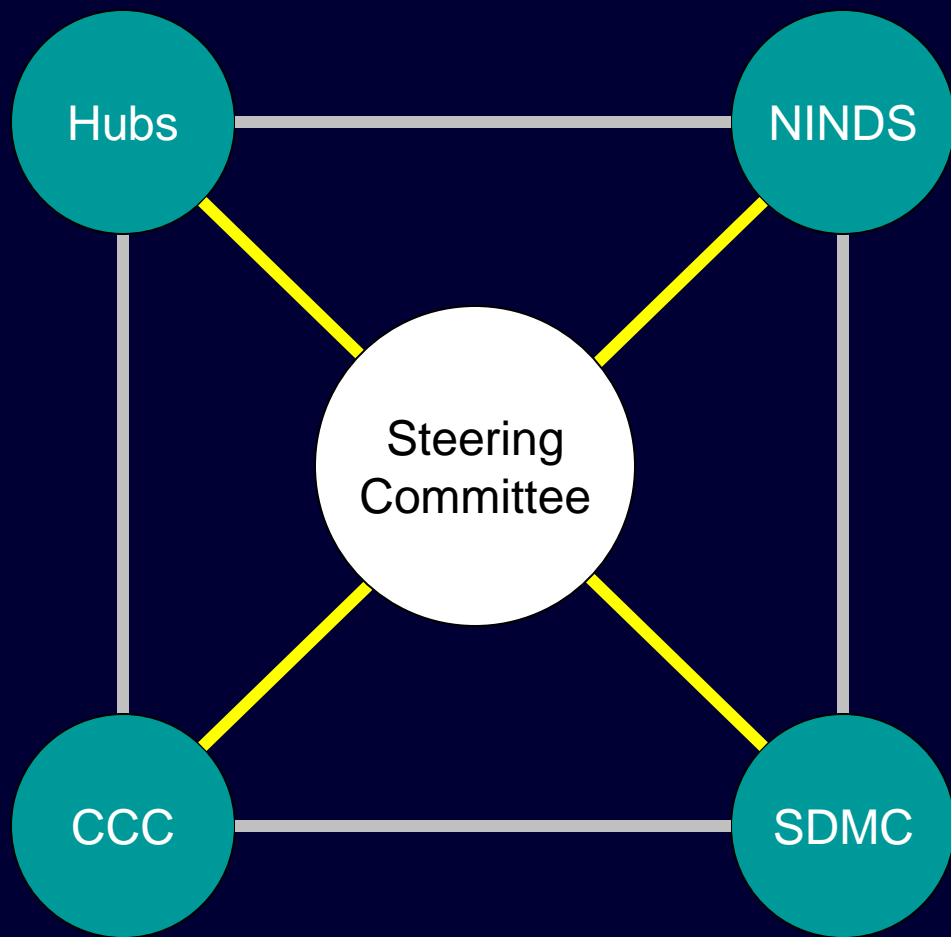
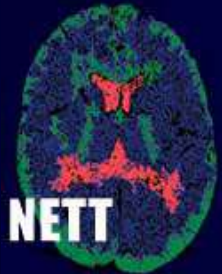
Hubs

- Develop operational plans
- Patient recruitment, treatment, and follow-up
- Complete and accurate data collection
- Participate in writing manuscripts
- Adhere to a common study protocol for each trial
- Attend training and investigator meetings
- Protect human subjects
- Ensure adequate representation
- Assist data audits and other quality control procedures
- Provide research infrastructure & monitoring of spokes

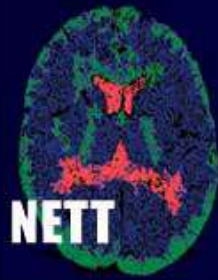
Spokes

- Participate in studies requiring larger sample size

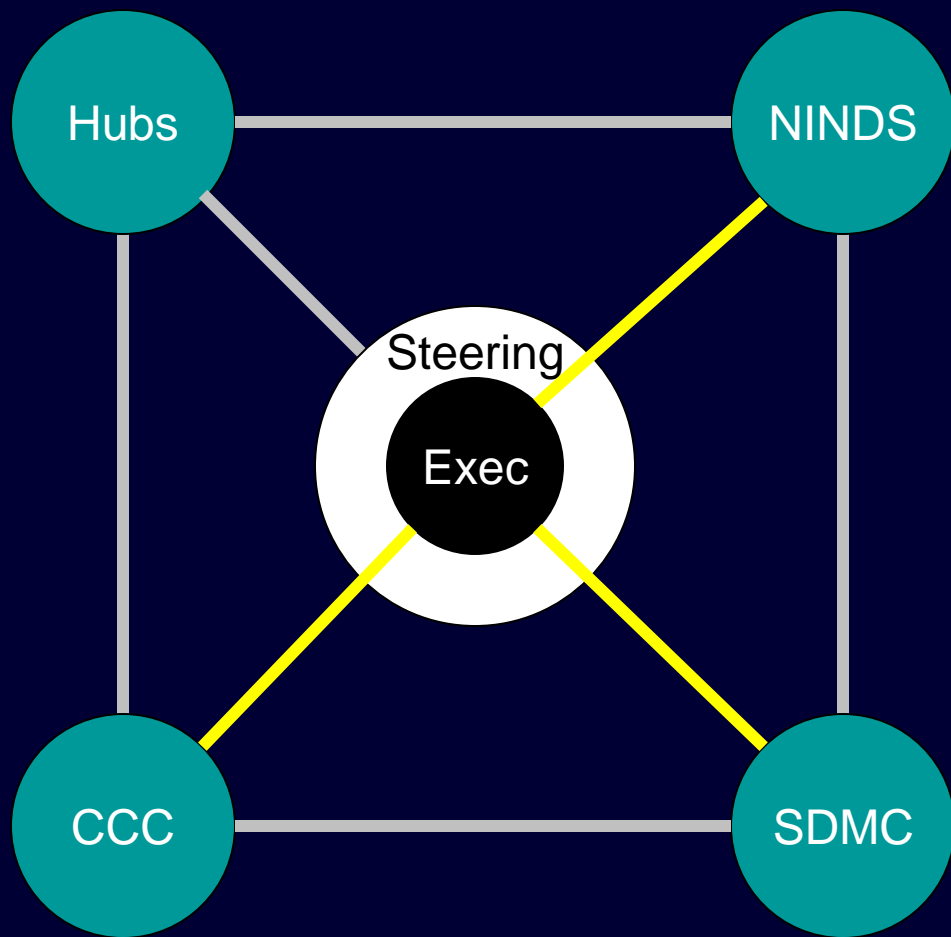
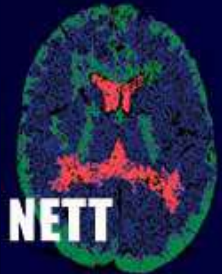




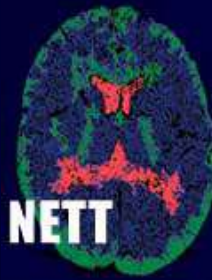
Steering Committee



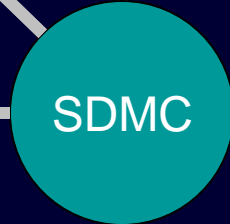
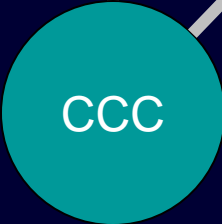
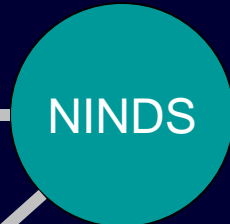
- Activities
 - Consider modifications and approve final versions of protocols and operations
 - Supervise overall execution of the trial
 - Provide input on generating and approving study policies
 - Plan and draft study-related publications
- Members
 - Members of the Executive Committee
 - Hub Principal Investigators

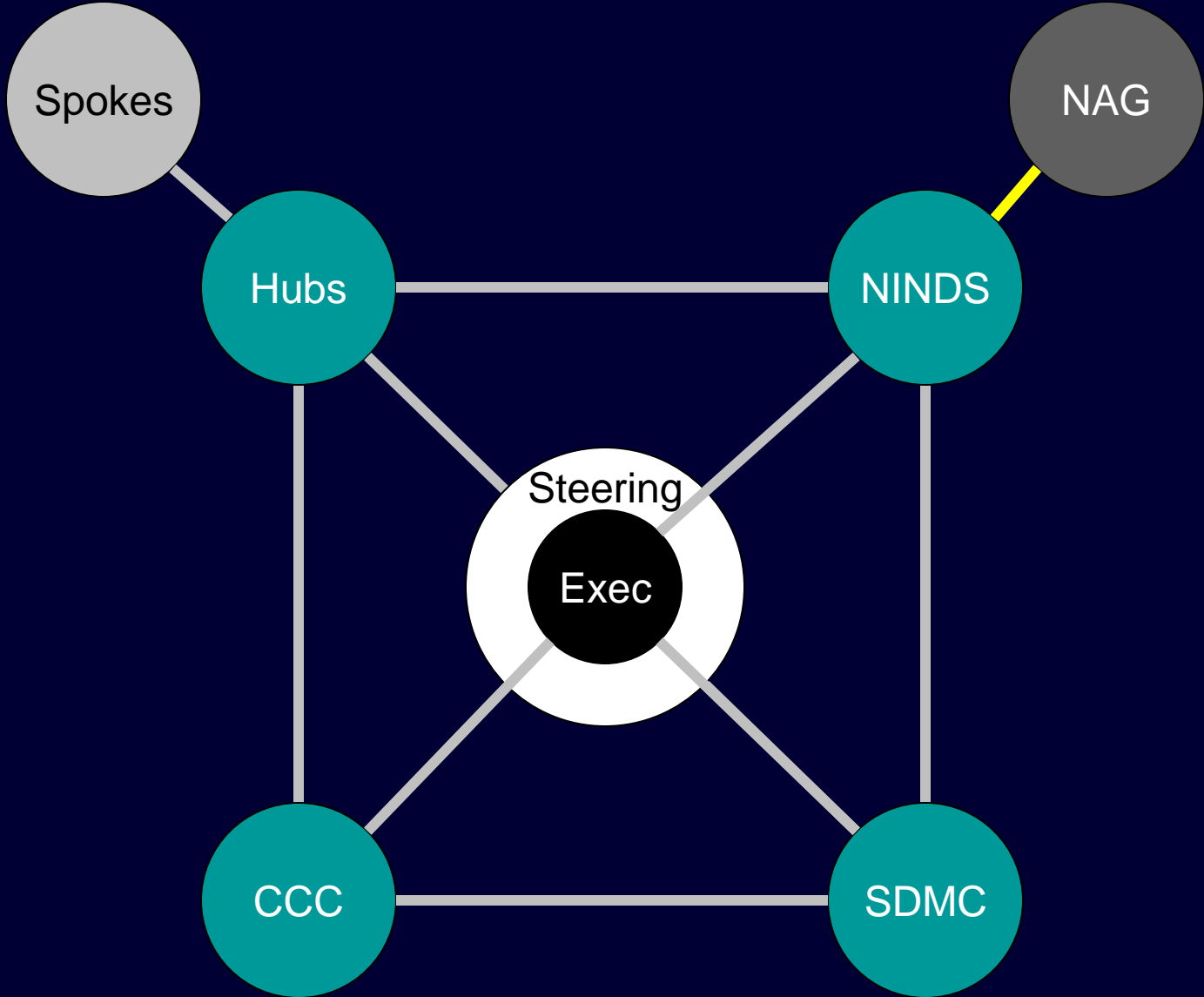


Executive Committee

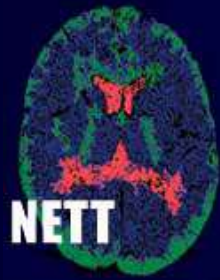


- Activities
 - Oversee administrative functions
 - Ensure effective communication and collaboration among Hubs
 - Formulate and maintain standards for the network
 - Responsible for integration of all elements of the network, including all regulatory compliance
 - Advocates, represents, and promotes mission of the network
- Members
 - William Barsan (Chair), Robin Conwit, Catherine Dillon, Valerie Durkalski, Dan Lowenstein, Lewis Morgenstern, Yuko Palesch, Art Pancioli, Robert Silbergleit, Valerie Stevenson

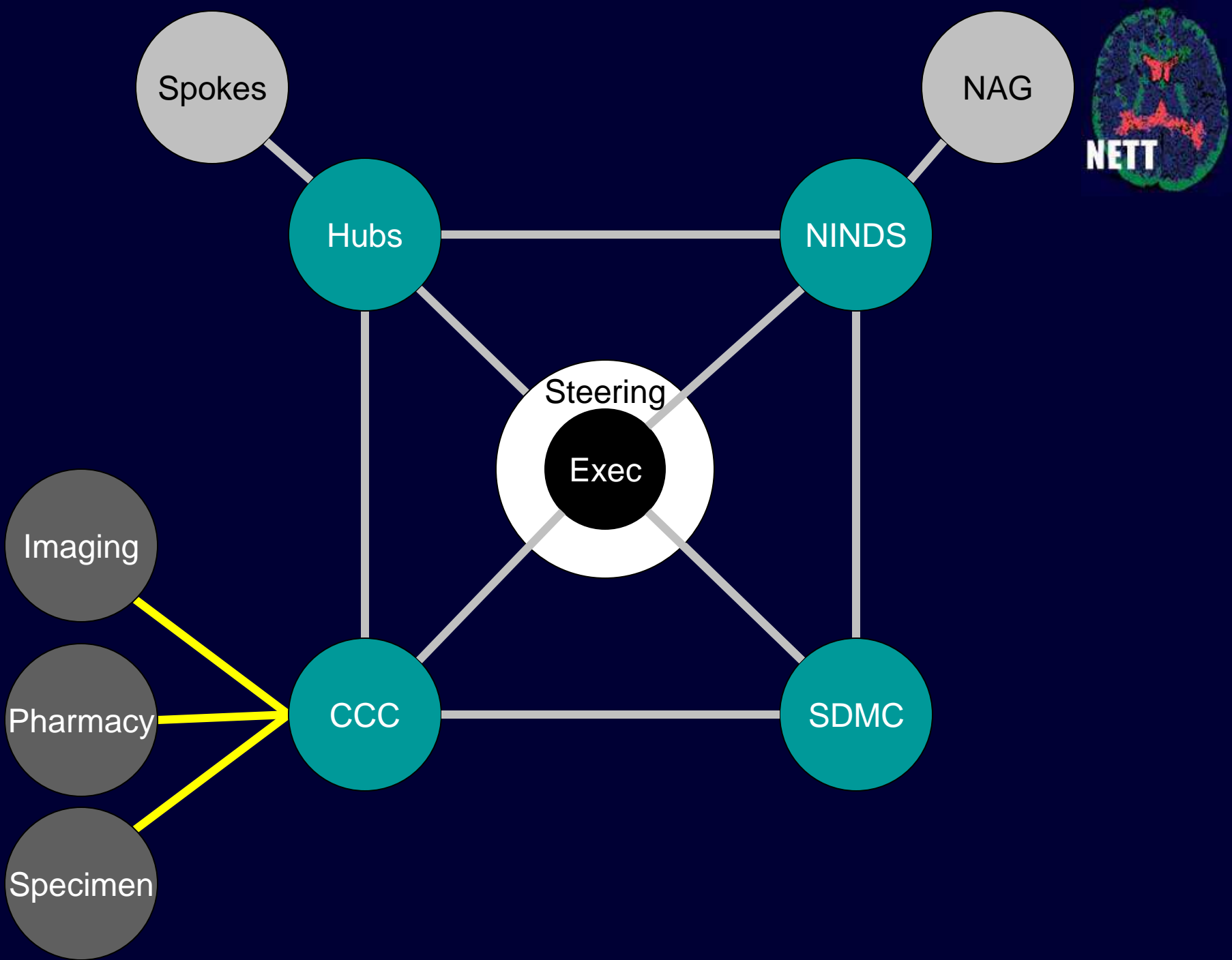


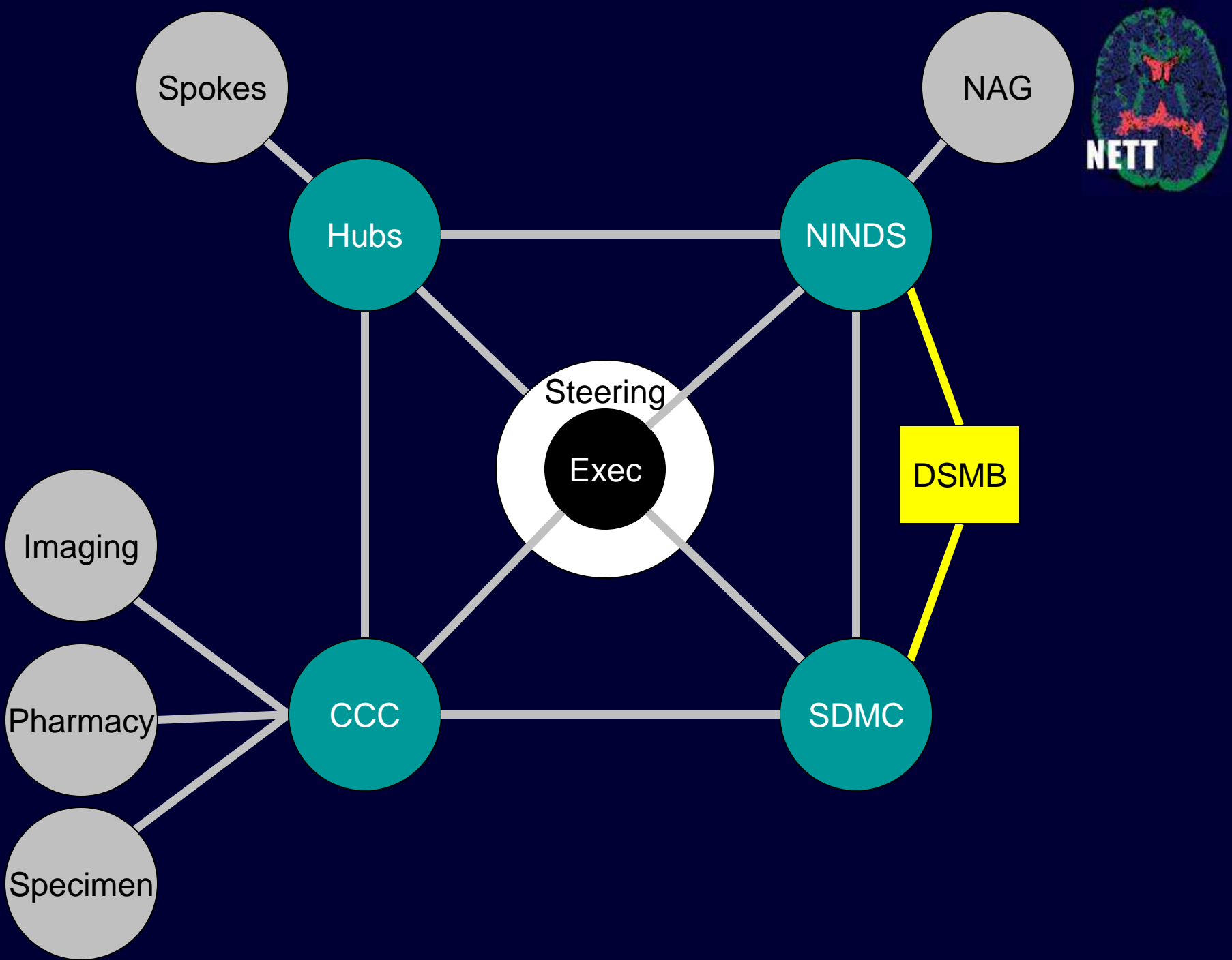


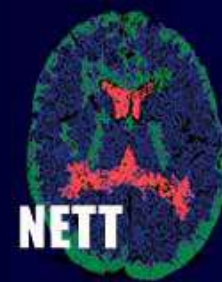
Network Advisory Group



- Activities
 - Oversight of the network
 - Give final approval to
 - trial protocols
 - modifications to the protocols
 - the overall budget
 - plans for analysis
- Members
 - Appointed and organized by NINDS
 - Experts in Emergency Medicine and Neurology
 - NINDS officials with expertise in clinical trials
- Forwards reports and recommendations to NINDS

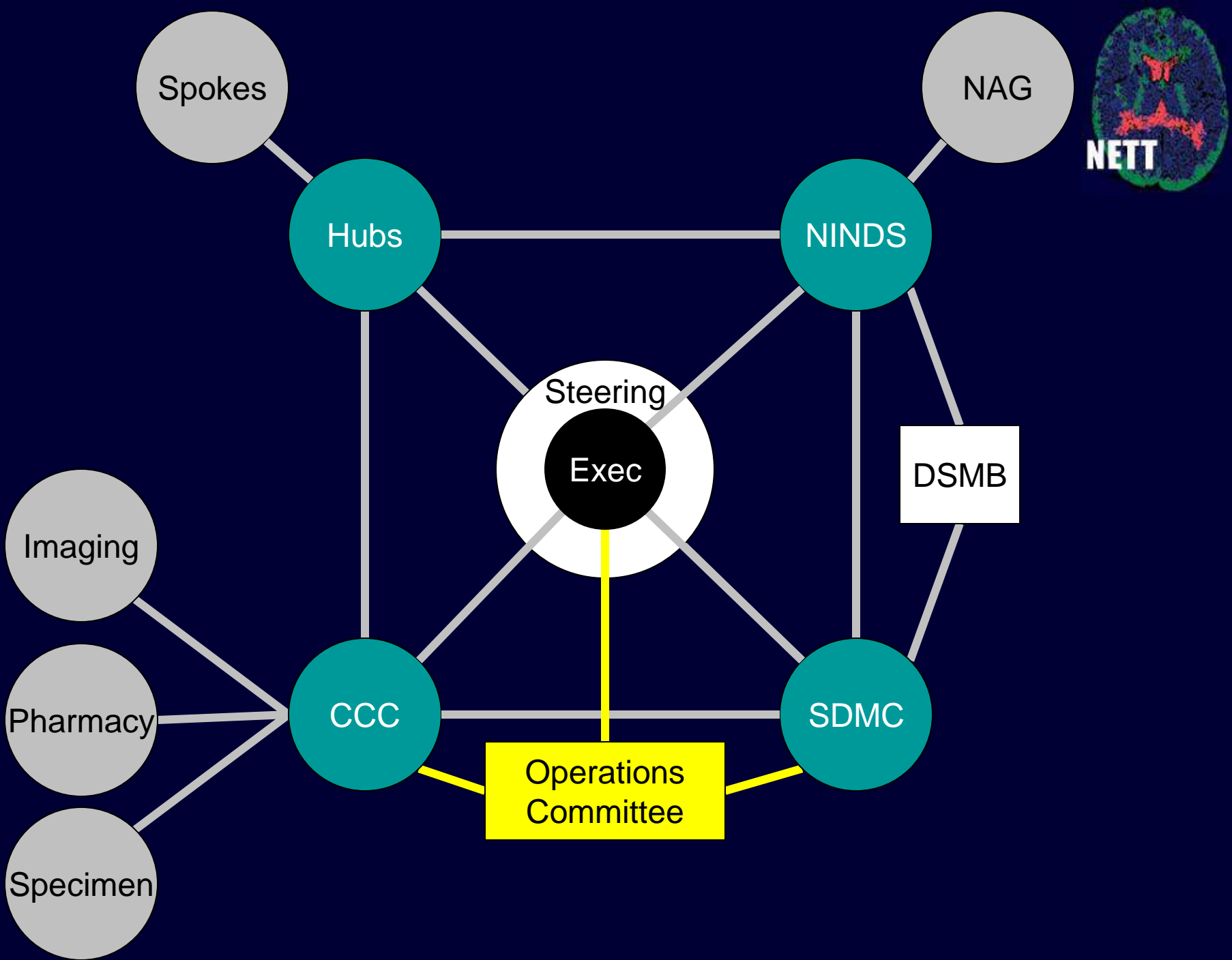




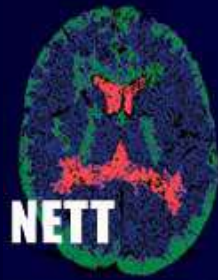


Data and Safety Monitoring Board (DSMB)

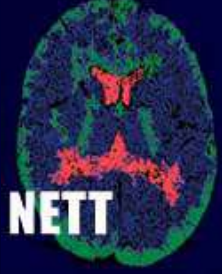
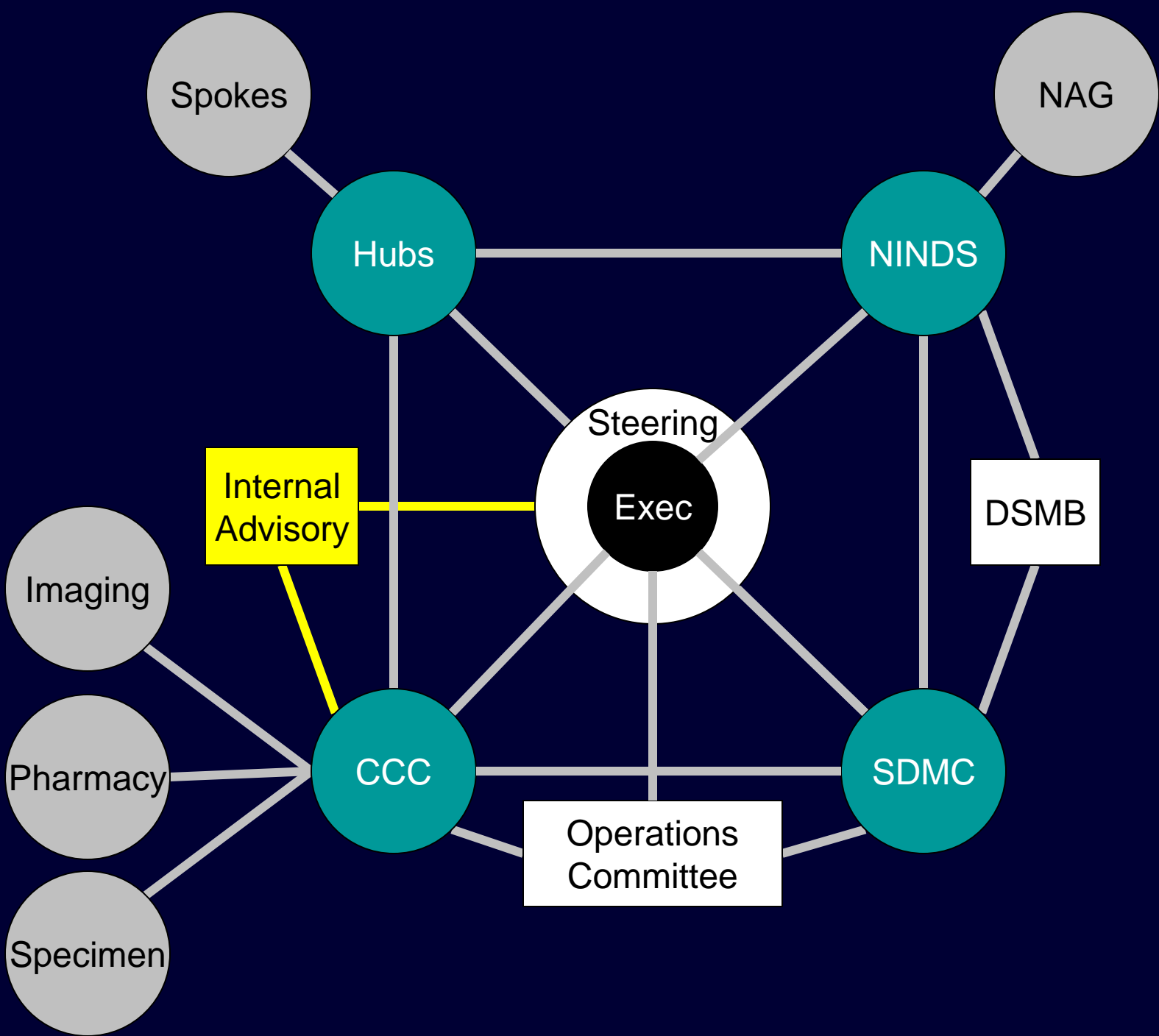
- Members
 - Appointed by NINDS
- Activities
 - Monitor safety and performance and to review interim analyses in the NETT Network clinical trials
- Depending on the specific trials selected, more than one DSMB may be required

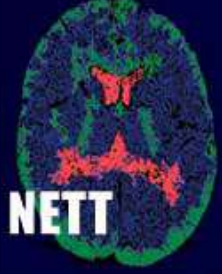
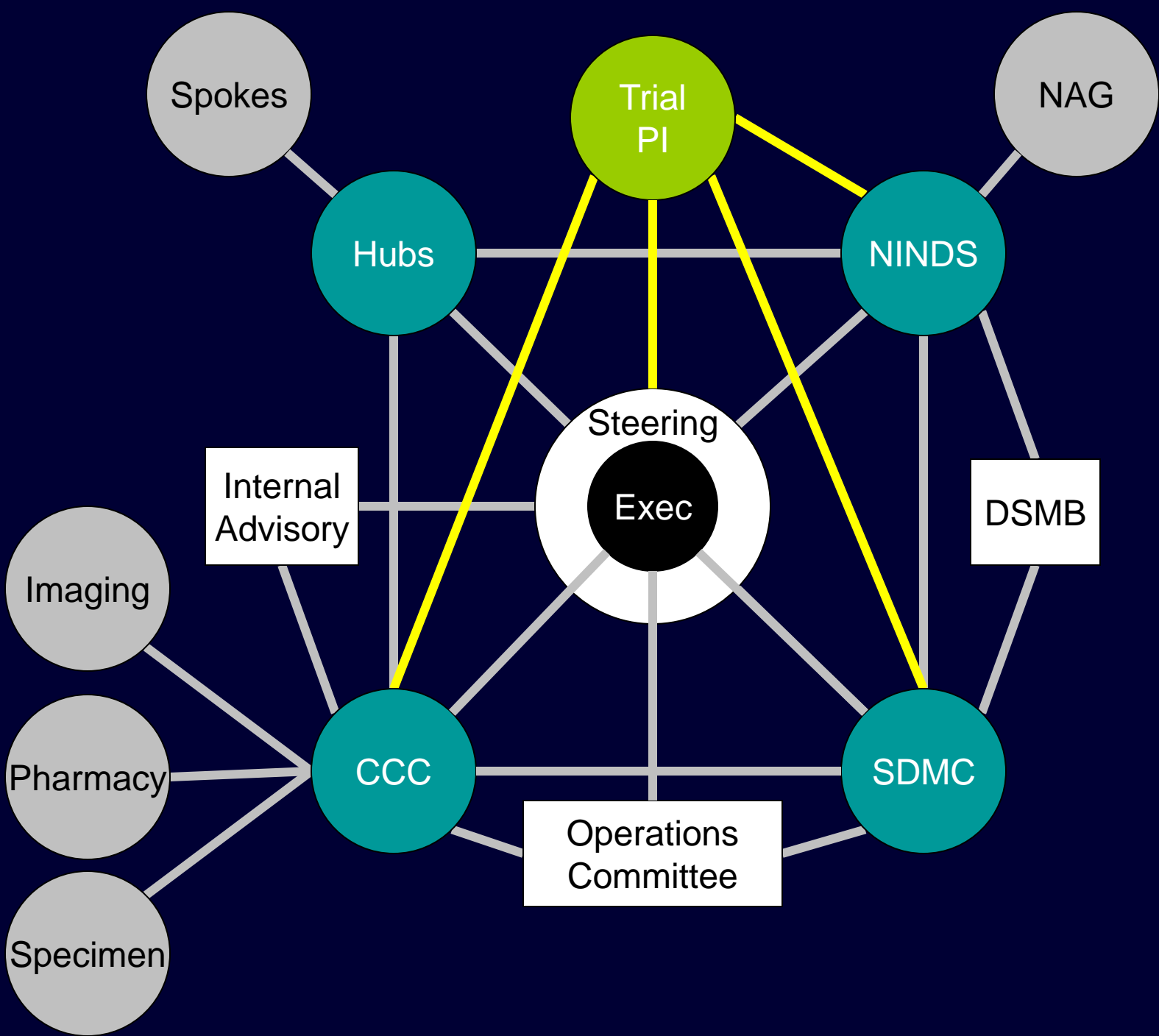


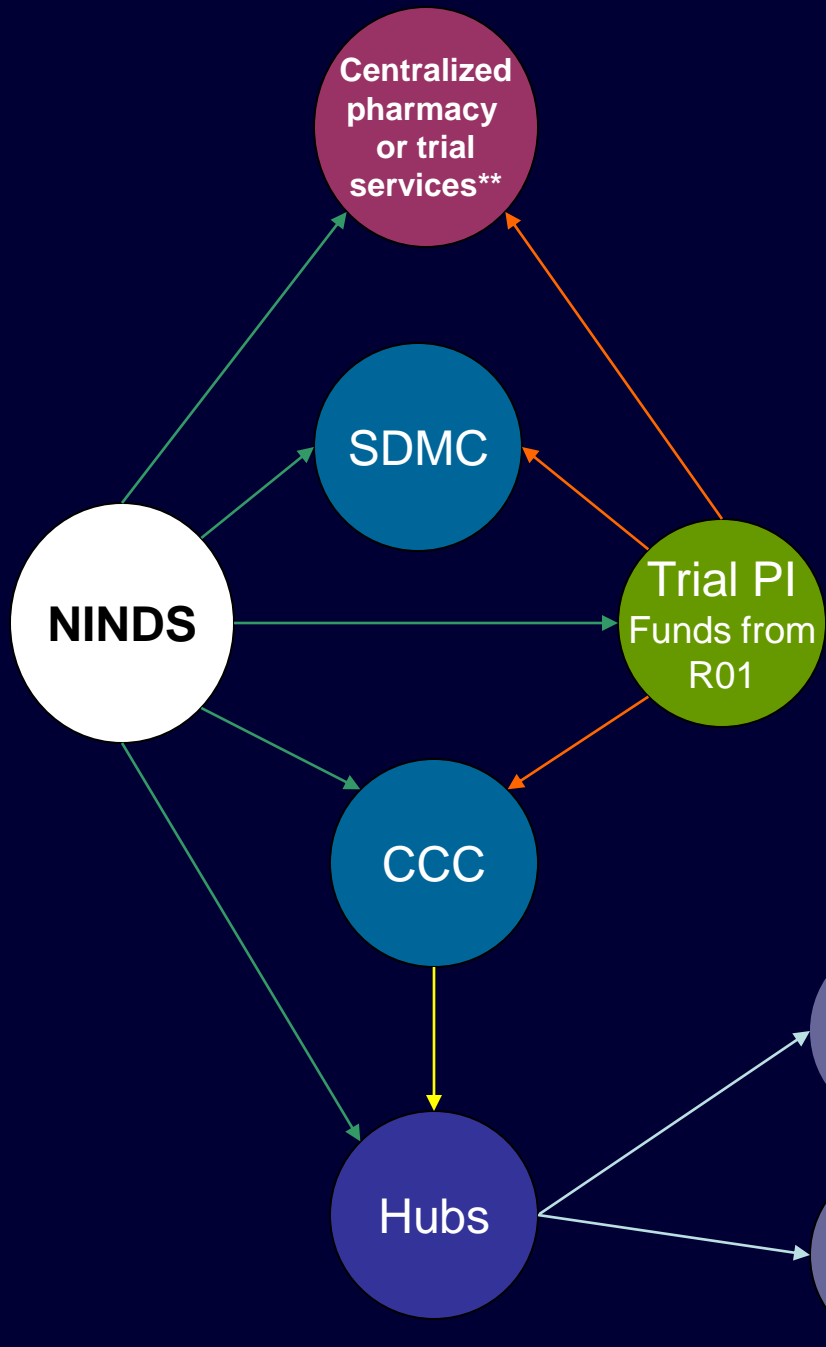
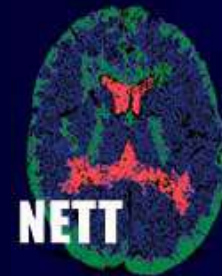
Network Operations Committee



- Activities
 - Oversees the day-to-day operational issues of both study management and site management
 - Responsible for the operational aspects of the individual trials such as regulatory compliance, monitoring and maximizing recruitment
 - Responsible for the integration of the Hub and Spoke System by providing education, guidance and feedback to Network personnel
- Members
 - Catherine Dillon, Valerie Durkalski, Irene Ewing, Erin Zaleski, Donna Harsh, Deneil Kolk, Yuko Palesch, Art Pancioli, Joy Pinkerton, Robert Silbergleit, Valerie Stevenson







Color Key for Flow Of Funds

Infrastructure awards directly from NINDS

Subcontracts with Trial PI

Subcontract with NETT CCC

Subcontract with Hub

** Source of funding depends on type of agency providing the service



Questions?