

Building a Strong Data Management Center for the National Institutes of Health's Stroke Trials Network

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MEDICAL UNIVERSITY
of SOUTH CAROLINA

Society for Clinical Trials

36th Annual Meeting

May 18-20, 2015

Crystal City, MD

Acknowledgements

*** National Institute of
Neurological Disorders and
Stroke**

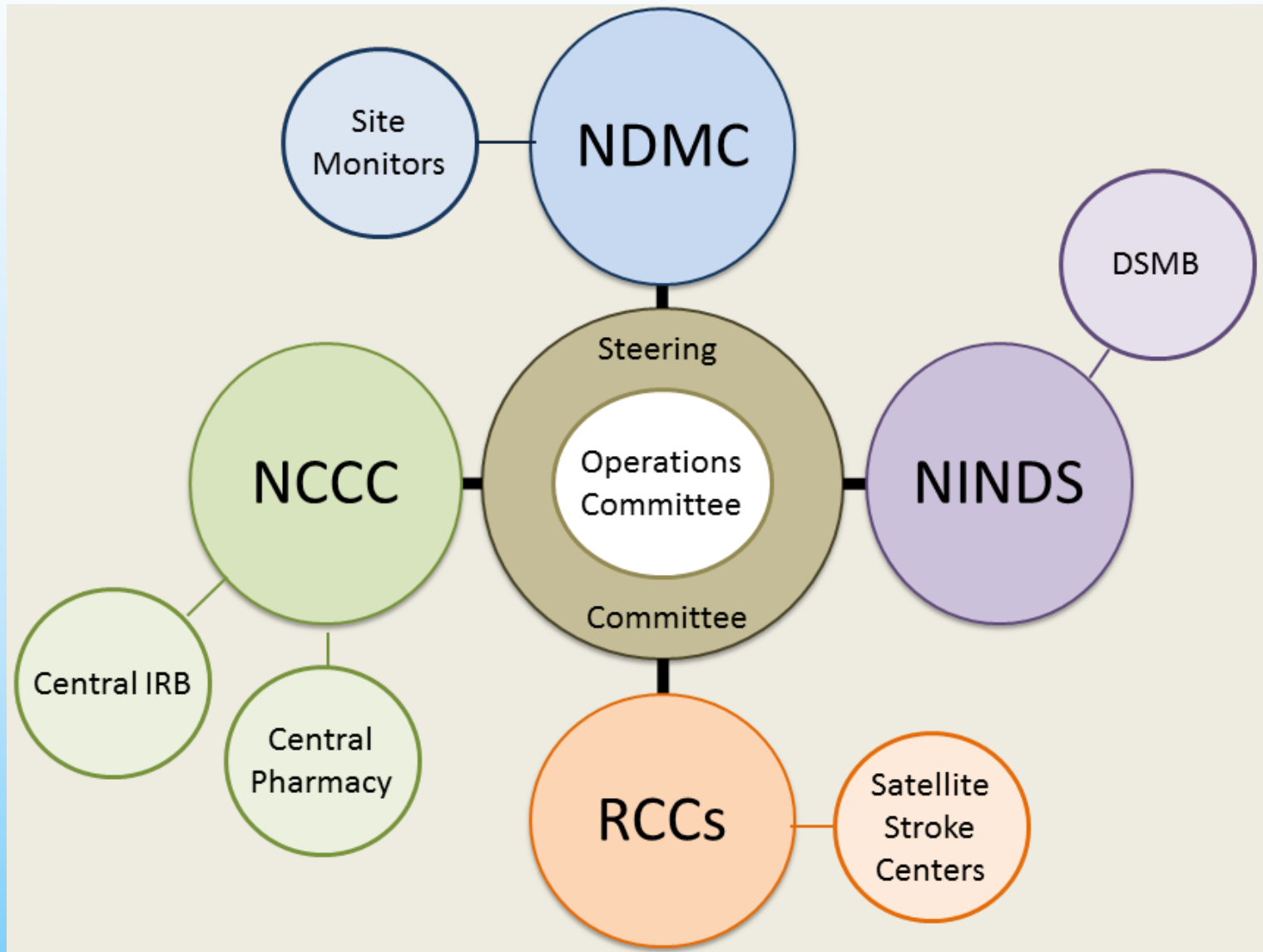
***1U01NS087748-01**





- * Funded by NINDS, 2014
- * Stroke Prevention, Treatment, Recovery
- * Workscope
 - Exploratory clinical trials
 - Confirmatory clinical trial
 - Biomarker-validation studies

StrokeNet Organization



StrokeNet Organization



DMC Workscope

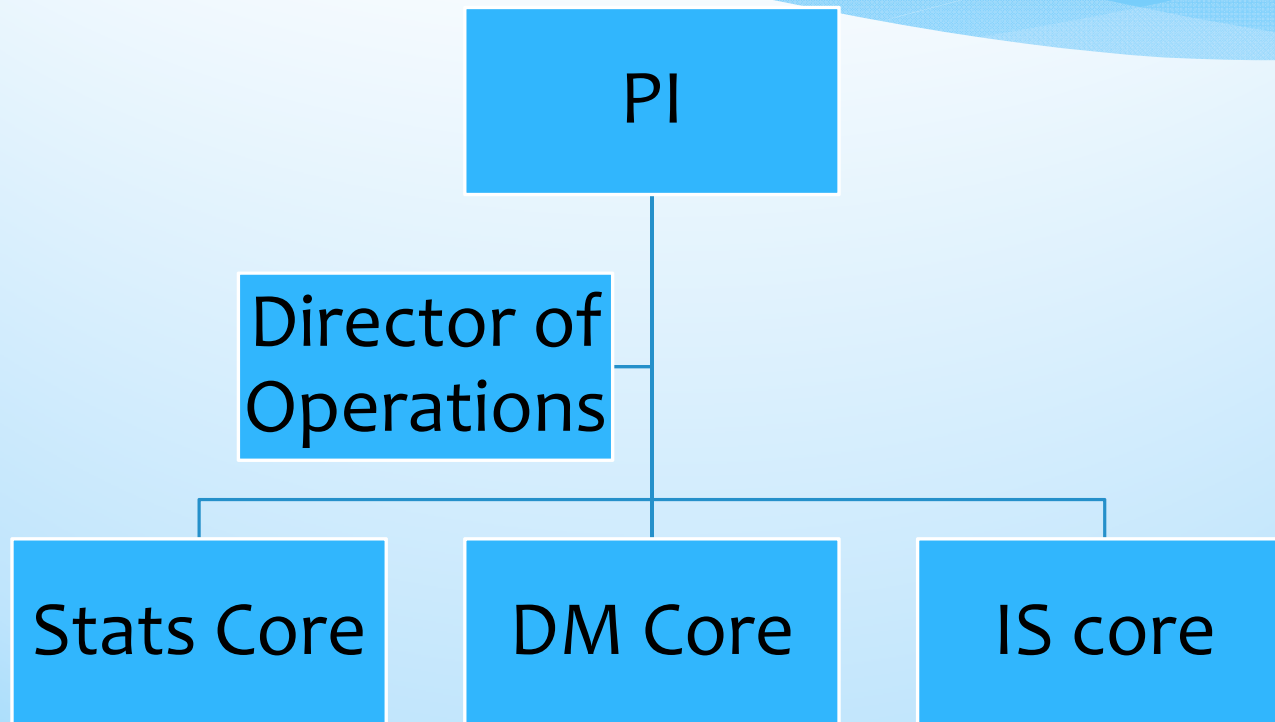
- * Trial design
- * Trial operations
- * Data management
- * Data monitoring
- * Data analysis

Strategic Approach

- * Experienced personnel
- * CTMS
- * Database template

Experienced Personnel

DMC Organization



Director of Operations: Qualifications

- * Senior level
- * Full time
- * Experience in NIH and industry-funded research multi-center trials
- * Knowledge of FDA regulation, GCP-ICH

Director of Operations: Qualifications

- * Understand network structure
- * Knowledge in therapeutic area
- * Understand each trial
- * Strong communication and organizational skills

Director of Operations: Work

- * Provide guidance during the design, execution, and reporting of clinical studies
- * Liaise b/t sponsor, study PIs, programmers, statisticians, other networks
- * Manage/mentor junior staff members

CTMS

CTMS

CCC

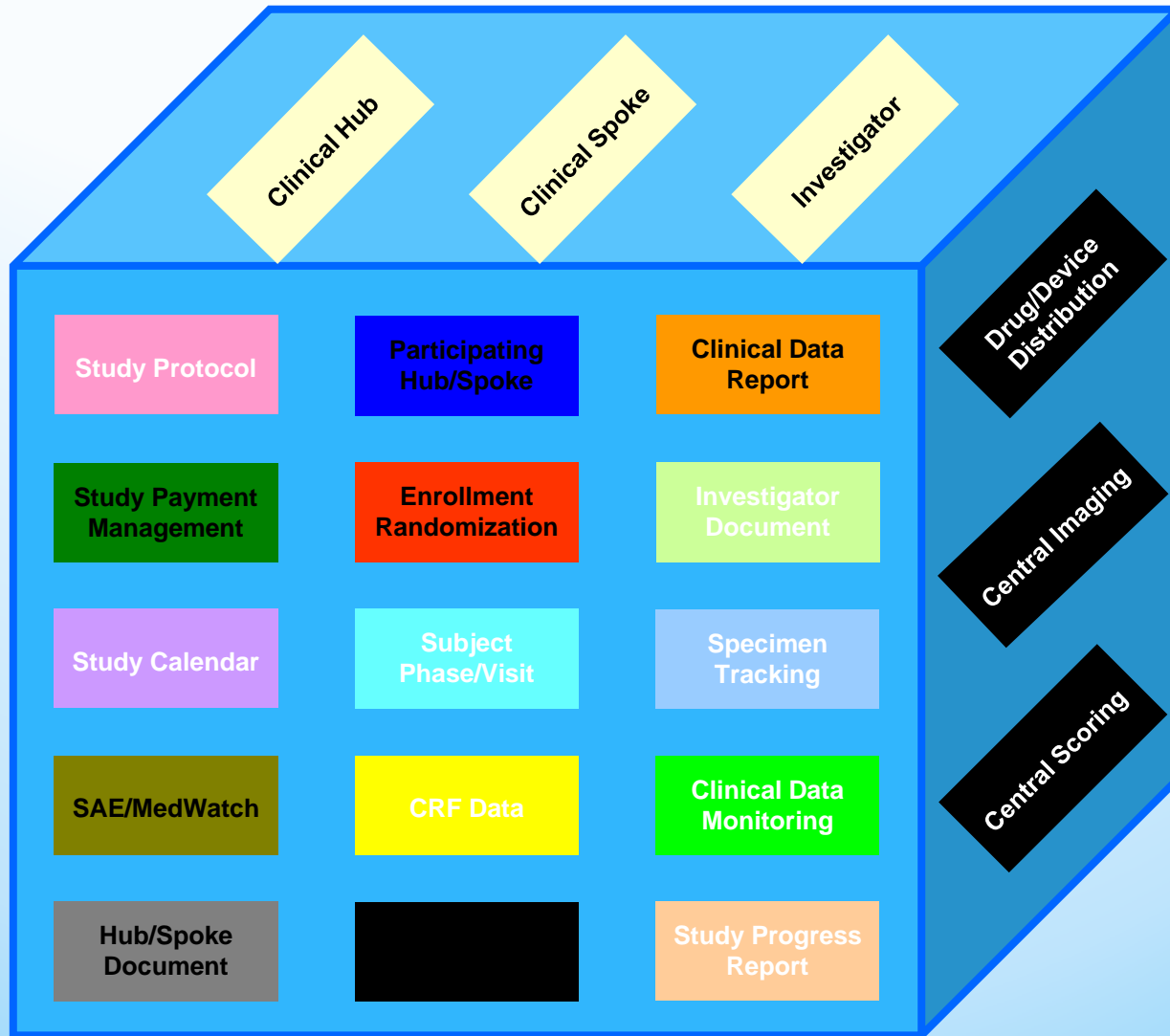
NINDS

Steering Committee

Executive Committee

MSM

DSMB



Hub/Spoke Staff

Central Pharmacy

Central Lab

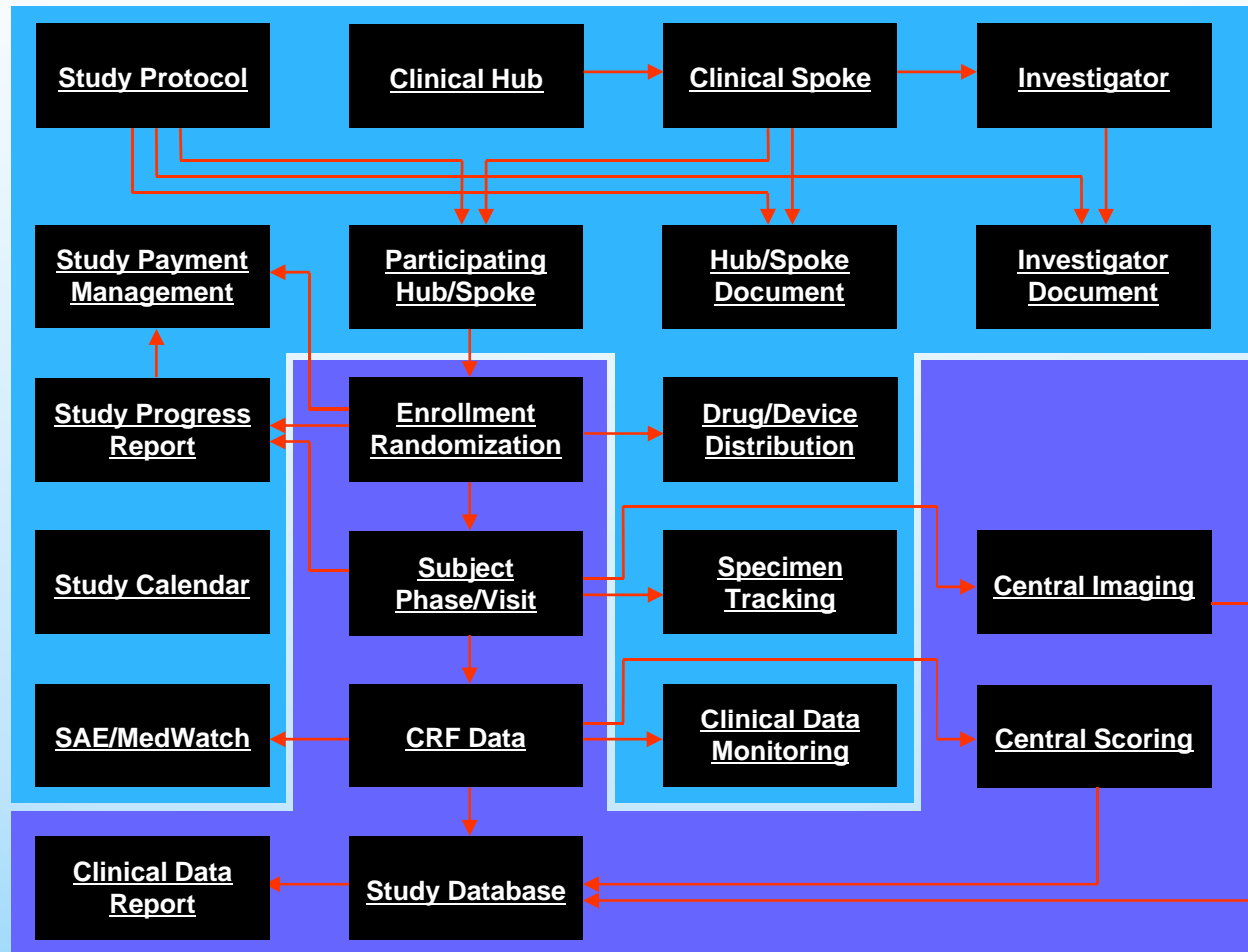
Image Reader

Score Expert

SDMC

CTMS

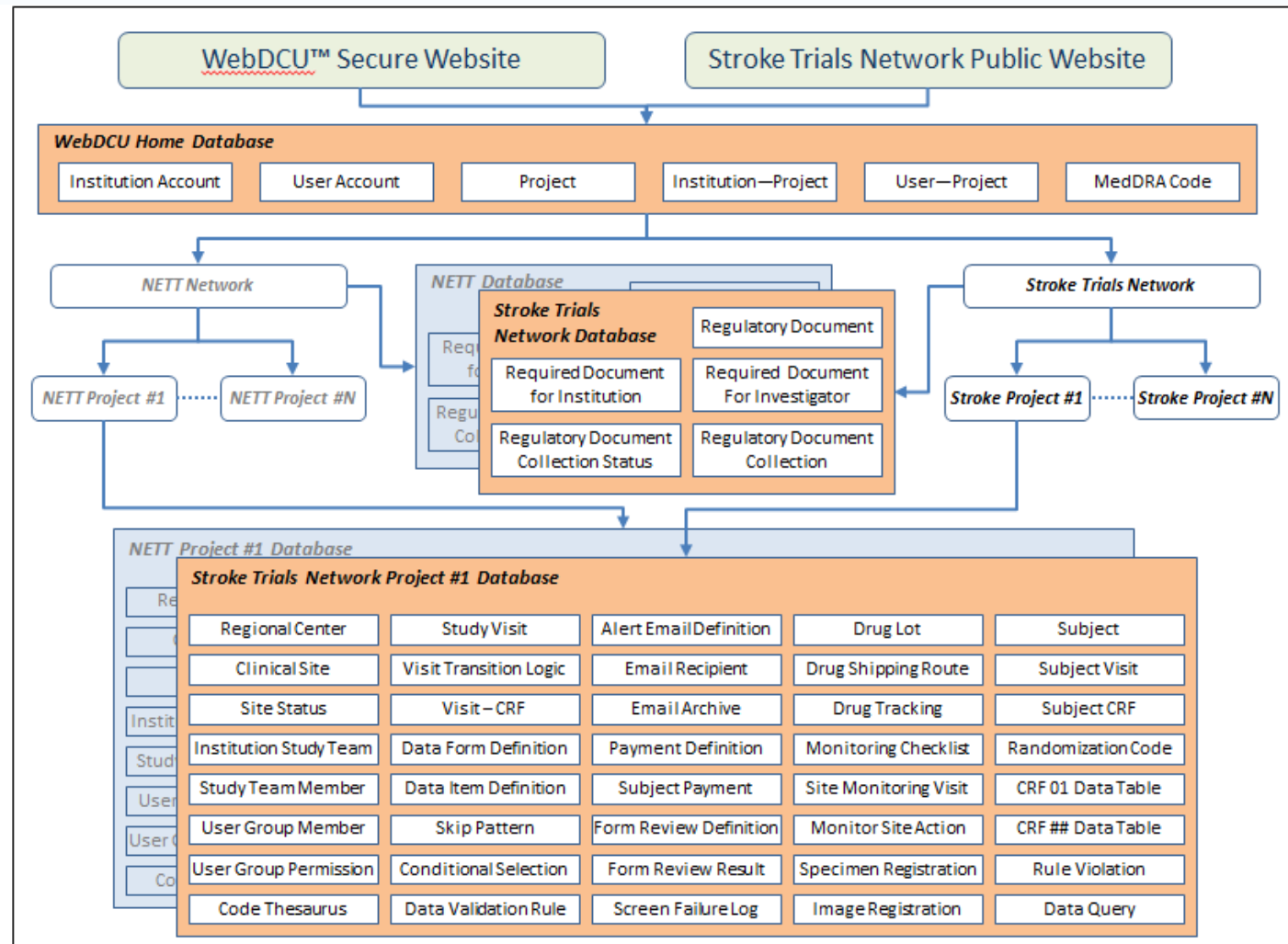
Project Management



Data Management

Database Template


Database Template



Common Data Elements

Annotated: F05 NIH Stroke Scale

Form ID: 506 DB Table Name: F05 DB View Name: vF05

| | |
|---|---|
| Data Collected DB Name: [zDataCollected] | <input type="radio"/> 0 - No <input type="radio"/> 1 - Yes |
| Date/time of assessment DB Name: [Q01] | dd ▾ mmm ▾ yyyy ▾  hh ▾ : mm ▾ <input type="radio"/> AM <input type="radio"/> PM |
| Alert at the time of assessment? DB Name: [Q02] | <input type="radio"/> 0 - No <input type="radio"/> 1 - Yes |
| Alerts at the time of assessment? DB Name: [Q03] | <input type="radio"/> 0 - No <input type="radio"/> 1 - Yes |
| Substituted at the time of assessment? DB Name: [Q04] | <input type="radio"/> 0 - No <input type="radio"/> 1 - Yes |
| (1a) Level of Consciousness DB Name: [Q05] CDE Name: [C13232] | <input type="radio"/> 0 - 0=Alert; keenly responsive <input type="radio"/> 1 - 1=Not alert, but arousable by minor stimulation to obey, and oriented (3=Not alert, requires repeated stimulation to attend, or is oriented only to a single stimulus) <input type="radio"/> 2 - 2=Not alert, requires repeated stimulation to attend, or is oriented only to a single stimulus <input type="radio"/> 3 - 3=Responds only with reflex motor or autonomic effects or no response |
| (1b) LOC Questions DB Name: [Q06] CDE Name: [C13233] | <input type="radio"/> 0 - 0=Answers both questions correctly <input type="radio"/> 1 - 1=Answers one question correctly <input type="radio"/> 2 - 2=Answers neither question correctly |
| (1c) LOC Commands DB Name: [Q07] CDE Name: [C13234] | <input type="radio"/> 0 - 0=Performs both tasks correctly <input type="radio"/> 1 - 1=Performs one task correctly <input type="radio"/> 2 - 2=Performs neither task correctly |

Questions?

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