

STAIR VIII

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Presentation by

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NINDS

Why do we need a stroke network?



What could a stroke network do, that we don't already do?

NINDS is the lead institute for Stroke research at NIH

\$317 M/NIH

\$217 M/NINDS in FY 2010

\$13 M

Translational program and SBIR/STTR

\$7 M

Training and career development

\$97 M

other basic and translational research

\$64 M

Phase 3 trials

\$24 M

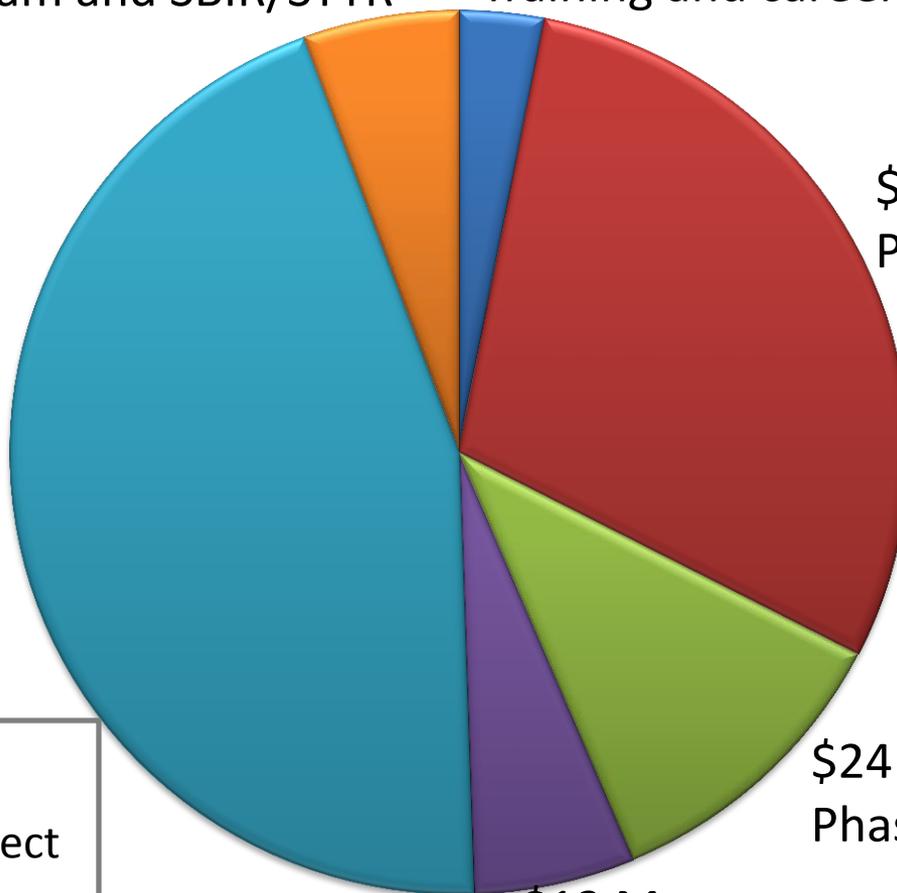
Phase 1/2 trials

\$13 M

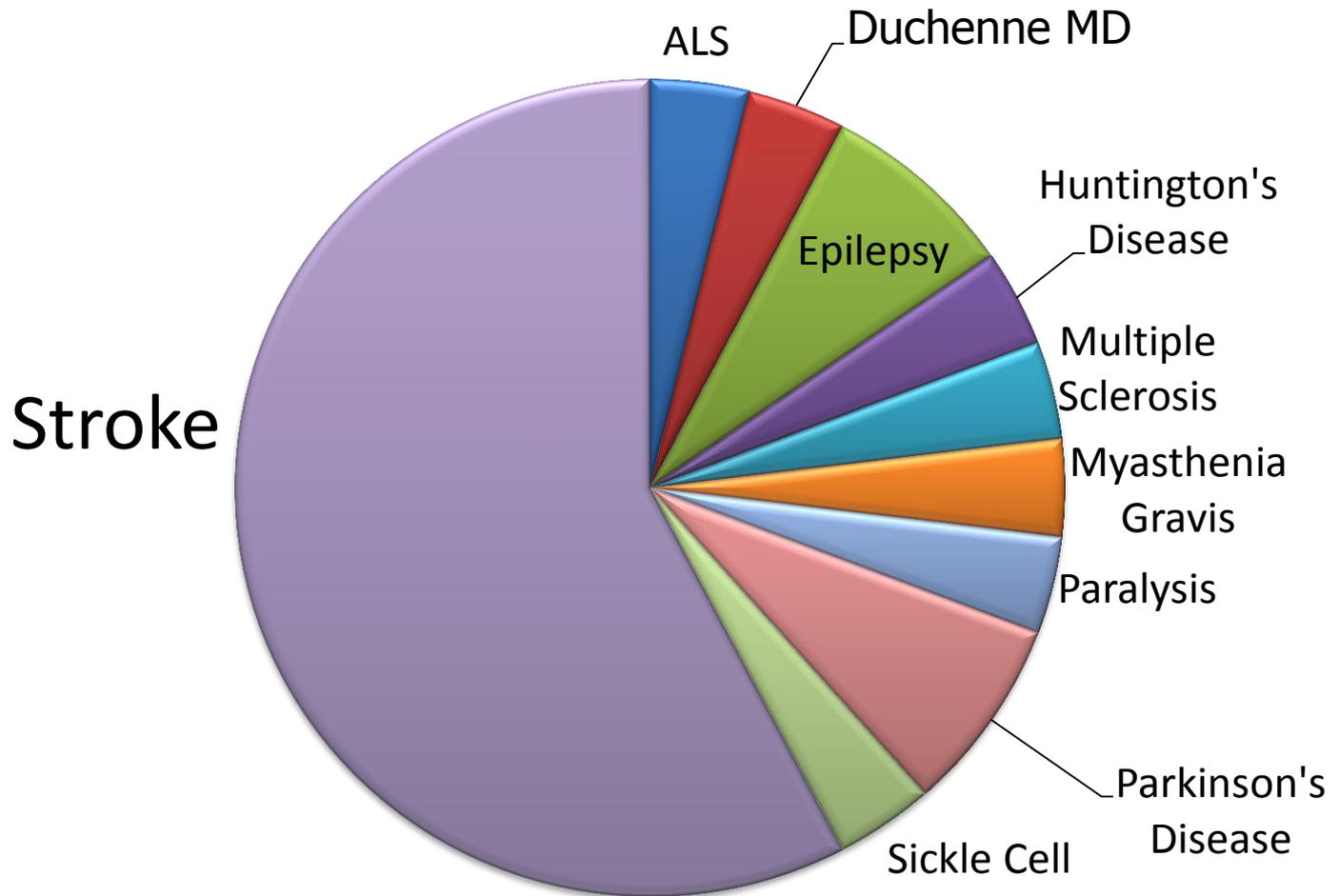
Epidemiology and genetics U01s

~ 17% NINDS solicited

~ \$30 M program project and center grants



NINDS Phase 3 trials



Why do we need a stroke network?

- Current system is inefficient.
 - Long start up times to enrollment (1-2 years)
 - Once trial completed the system shuts down
 - Infrastructure, duplicated but not enhanced over time.
 - Redundancy
 - Enrollment often slow
 - Require more funding to complete, some fail.
 - Questions not as relevant as when started
 - Some questions need to be answered in stepwise manner
 - Current system doesn't optimally utilize intellectual capital, manpower, systems, or funds.



What could a stroke network do?

Streamline trial start-up

- Centralize IRB and master contracts
- Build off central infrastructure and enhance capabilities over time.
- Decrease system redundancy
 - Central data center
- Incentivize enrollment

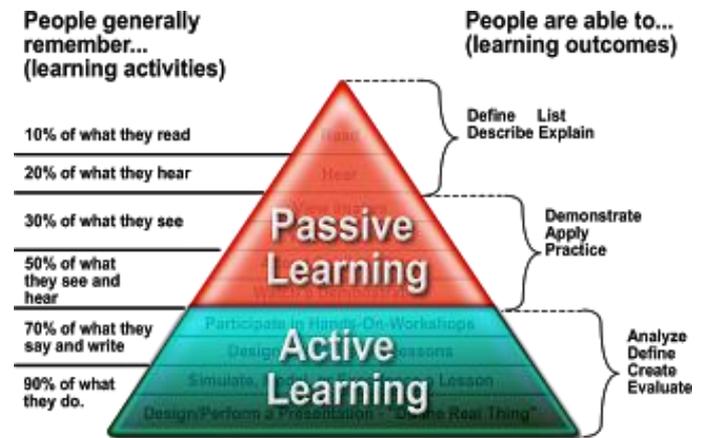
Improve cost effectiveness of research dollars

Engage preclinical and clinical stroke leaders in advancing stroke treatment



Why do we need a stroke network?

- Current system lacks strong institutional memory; slows the learning process
 - Systematic problems get partial solutions
 - Lessons learned in one trial don't move smoothly to inform successive trials.
- Clinical research tool development often stalls in the pre-validation stage: decreases utility for RCTs.



Institute a culture of continuous system improvement & innovation.

- Identify systematic problems
 - Address as a national network
 - Persistent problem-solving over time
 - Leverage NIH resources: NETT, NeuroNext, CTSA
- Coordinate/Standardize tool development to advance clinical trial success.

Why do we need a stroke network?

- Prioritizing stroke trials is imperfect.
 - What gets funded depends on what comes in for review, and difficult to know whether the scientific community is committed to the trial.
 - Generally fund one potential solution to an important question without identifying the best of multiple solutions.
 - Multiple trials competing for same patient group slows or threatens completion.
- Data not comparable among trials or easily accessible



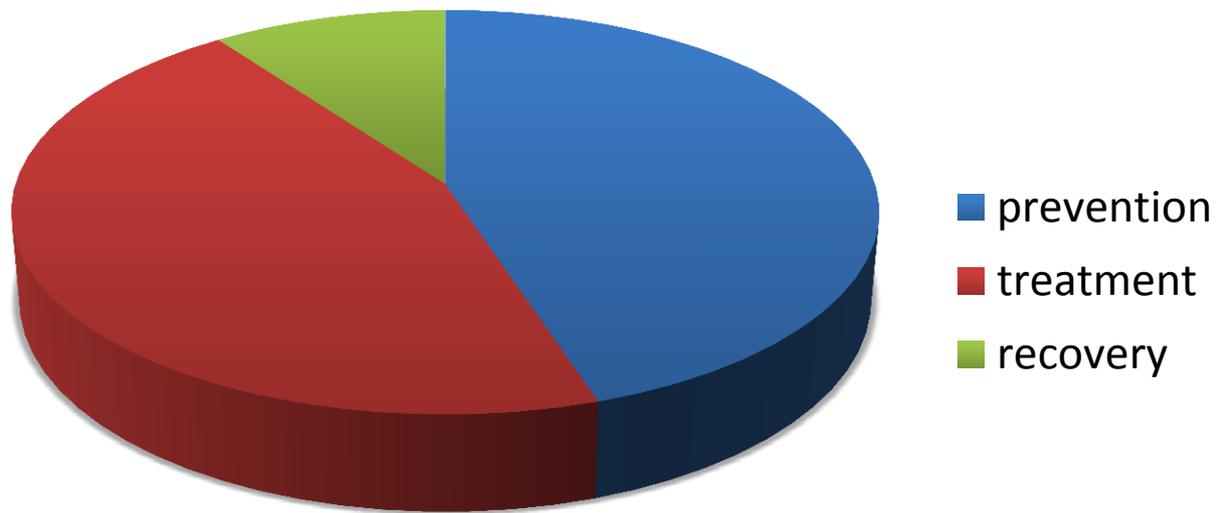
- Model the network capability for trials that compete for same patient group.
- Establish path for phase 2 moving to phase 3.
- Logical ordering of trial entry into network
- Comparison of multiple potential solutions to an important problem, either simultaneously or sequentially.

Use CDEs and make primary data widely accessible

Why do we need a stroke network?

- Stroke research portfolio is not balanced

Stroke Research



Why do we need a stroke network?

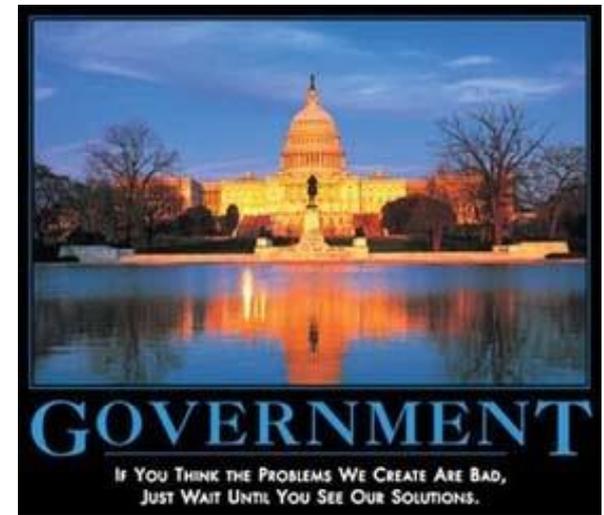


- Current system makes it difficult to coordinate with non-NINDS partners
 - Other NIH Institutes: NHLBI, NIA
 - Other governmental agencies
 - FDA, CMS
 - International partners
 - Co-prioritize/design/CDEs/analyze
 - Co-fund with international funding agencies
 - Industry
 - Protect IP, Co-fund

- NINDS discusses stroke priorities with other ICs, HHS agencies, International Funding Agencies.
- Industry submits proposals for the network under CRADA.
- Network investigators explore cooperation with other partners.



What a stroke network should not do!



Need to be very careful not to stifle innovation.

- Network needs to be OPEN:
 - to investigator initiated studies
 - to industry initiated studies
- All network sites need to provide intellectual capital, both preclinical and clinical

