U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Institute of Neurological Disorders and Stroke

NeuroNEXT

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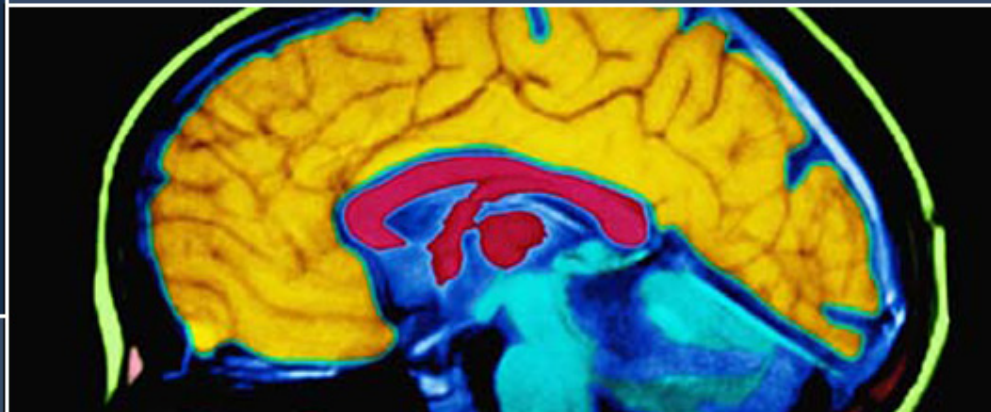
Webinar for advocacy

October 14, 2011



- NINDS has a diverse disease portfolio
- NINDS has extensive clinical trials experience
- NINDS has preexisting relationships with academic investigators and advocacy groups
- Utilizing these strengths NINDS has created an infrastructure, NeuroNEXT, to efficiently conduct Phase II trials targeted towards potential marketing applications

NeuroNEXT goals

- Test highly promising therapies in phase II clinical trials potentially increasing the impact of NINDS funded clinical research.
- Accelerate drug development through an established clinical trials infrastructure
- Decrease the time/cost between trial design and trial completion
- Coordinate public/private sector efforts by leveraging NINDS' existing relationships with academic investigators and patient advocacy groups

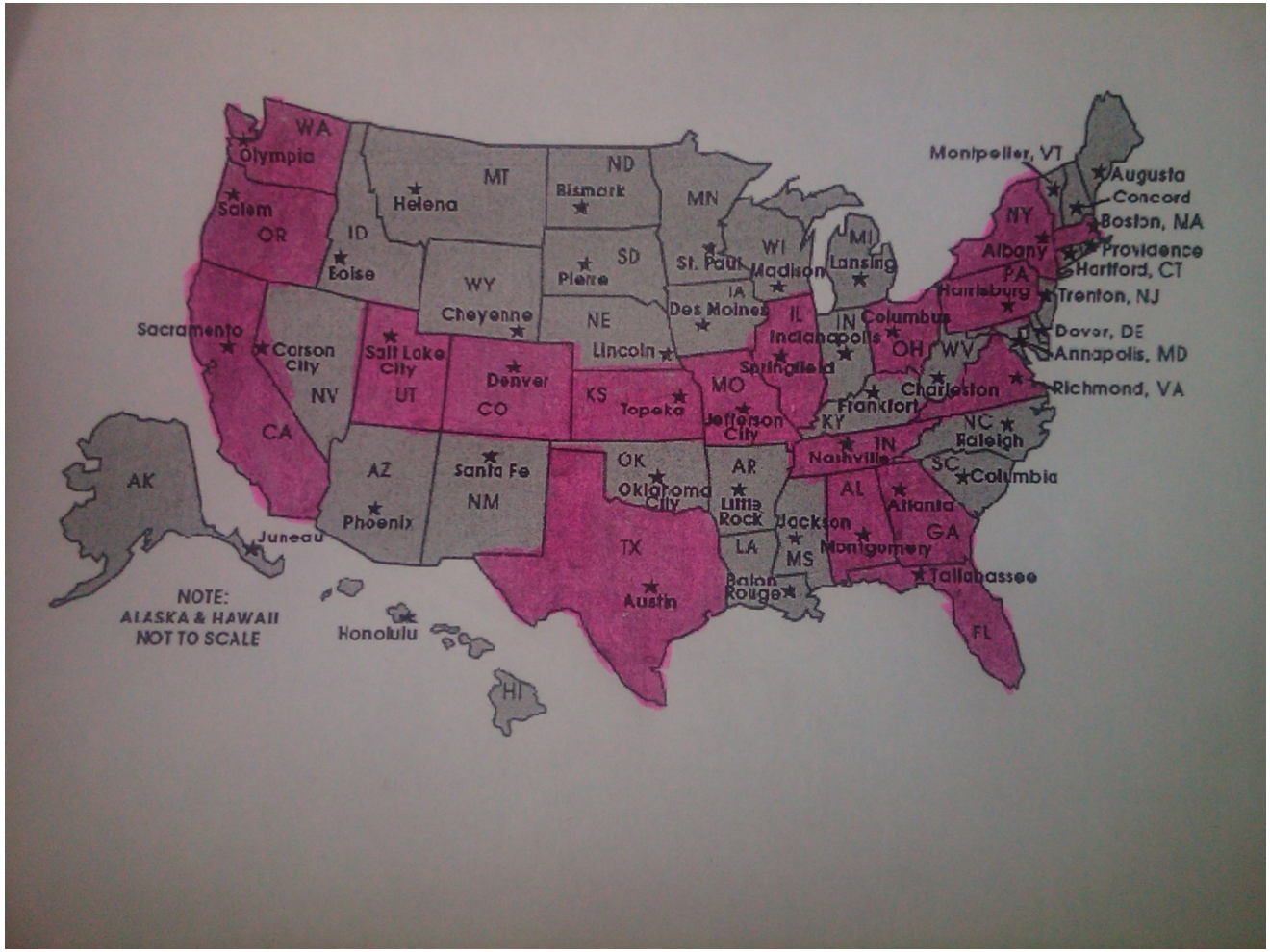
NeuroNEXT Sites

- Clinical Coordinating Center
  - Massachusetts General Hospital
- Data Coordinating Center
  - University of Iowa
- 2 Children's Hospitals
  - Children's Hospital of Boston
  - Children's National Medical Center (DC)

Clinical sites (Adult/Pediatrics)

- Albert Einstein College of Medicine-Yeshiva
- Columbia-Cornell
- Emory
- Massachusetts General Hospital
- Northwestern University
- Ohio State University
- Oregon Health and Science University
- Swedish Health Services (Seattle)
- SUNY (Buffalo, Downstate, Upstate, and Stony Brook)
- University of Alabama, Birmingham
- University of California, Davis
- UCLA
- University of Cincinnati
- University of Colorado, Denver
- University of Kansas
- University of Miami
- University of Pittsburgh
- University of Rochester
- University of Utah
- University of Virginia
- University of Texas, Dallas
- Vanderbilt
- Washington University in St. Louis

Distribution of NeuroNEXT clinical sites



A few words on geographic distribution

- We realize that there are some states with no NeuroNEXT sites. However, if a given patient wants to participate in a trial—we hope that he/she could find a site within a reasonable travel distance.
- Additionally, if there is a contingent of patients who all want to travel to a given site—a site which may be vacillating on participation due to recruitment fears—the advocacy group could communicate directly with the site to encourage participation.

As advocacy groups, we want to play an earlier role in developing clinical trials—how may we work with NeuroNEXT?

- We plan to ask advocacy groups to consider providing a contact willing to assist in protocol development-with the understanding that all grants go through review so NINDS funding of any particular submission is not guaranteed.

We work with Drs X and Y- how would they apply to NeuroNEXT?

- Three possible mechanisms-all are accepting applications now
  - Traditional U01-standard timelines
  - Small business grant-standard timelines
  - Resource Access Award (X01)
    - Allows access to NeuroNEXT infrastructure
    - Pre-existing master trial agreements for all 25 sites
    - Central IRB review administered through NeuroNEXT CCC
    - Expedited review-submission dates every two months
    - NINDS provides infrastructure/partner provides funding

How are sites selected to conduct the trials?

- NINDS does not select sites.
- The sites self-select. Each of the 25 sites is offered the opportunity to accept or decline participation in any NeuroNEXT approved protocol.

We have a consortium-may we add our sites as participants in the protocol?

- It depends.
- The application would have to provide a compelling reason (e.g specialized expertise, equipment) that the *ad hoc* sites should be funded in addition to the existing 25 sites.
- Having said that, if the PI of an accepted protocol is not at a NeuroNEXT site, his/her site would be allowed to collaborate with the network for the given trial. The protocol PI would not have to relinquish his/her role.

We are a foundation rich in financial resources. May we apply for an X01 grant?

- Yes, you may.
- As per PAR-11-344, cost-sharing arrangements are handled through a cooperative agreement.
- You would need to speak with Heather Gunas regarding those arrangements: GunasH@ninds.nih.gov

NeuroNEXT-Contacts

- Elizabeth McNeil (general information on NeuroNEXT)
  - mcneilde@ninds.nih.gov
- Heather Gunas (information on CRADAs, materials transfer agreements)
  - GunasH@ninds.nih.gov

One stop shopping:

- www.ninds.nih.gov/NeuroNEXT