

NeuroNEXT NEWSLETTER

CUMC-WCMC

Quarterly-Issue 1-July 2012

The need to independently develop infrastructure for each trial is one of the impediments to efficiently implement phase 2 trials. To improve efficiency, the National Institute of Neurological Disorders and Stroke (NINDS) initiated the Network for Excellence in Neuroscience Clinical Trials (NeuroNEXT) in the fall of 2011. Our accomplishments this year included the following: 1) NeuroNEXT established Standard Operating Procedures (SOPs) for the Data Coordinating Center (DCC) and the Clinical Coordinating Center (CCC); 2) the SOP committee completed a draft of individual site SOPs; and, 3) our site successfully finalized the Master Trial Agreements (CUMC, WCMC, NYPH) and Reliance Agreements between the Central Institutional Review Board (IRB) at Massachusetts General Hospital (MGH) and IRBs at Columbia and Weill Cornell. In addition, Protocol Working Groups (PWGs) have been formed to work with the CCC, the DCC, and academic, industry and advocacy partners to design and finalize high quality protocols and grant applications. NeuroNEXT will develop and implement at least five clinical trials over the next seven years. This innovative approach to improving efficiency in phase 2 clinical trials may lead to more rapid development of therapies for adults and children with neurological disorders. Our first NeuroNEXT trial, *Spinal Muscular Atrophy (SMA) Biomarkers in the Immediate Postnatal Period of Development, National PI, Stephen Kolb, MD*, will start in the fall 2012. We were selected as one of 15 sites.

Goals of the Network

- Provide a robust standardized and accessible infrastructure to facilitate rapid development and implementation of protocols in neurological disorders affecting adult and/or pediatric populations.
- Support scientifically sound, biomarker-informed, phase 2 clinical trials that provide data for clear go/no-go decisions.
- Energize and mobilize federal, industry, foundations and patient advocacy partners by leveraging existing relationships between NINDS and NeuroNEXT to organize high impact phase 2 clinical trials for neurological disorders.
- Expand the pool of experienced clinical investigators and research staff who are prepared to be leaders of multicenter clinical research trials.

Meet Our Team

Karen Marder, M.D., MPH – Co-Principal Investigator

Claudia Chiriboga, M.D., MPH – Co-Principal Investigator

Claire Henchcliffe, M.D., DPhil – Site PI at Weill Cornell

Rachael Yoo, MA – CUMC-WCMC Project Manager

Highlights

- Rachael Yoo was hired in December 2011 as the CUMC-WCMC Project Manager to oversee all NeuroNEXT activities.
- Our team members and George Gasparis, CU's IRB Director attended the investigator meeting at NIH in November 2011.
- Master Trial Agreement and the Reliance Agreement from both sites have been finalized.
- Public website went live on January 30, 2012 (www.neuronext.org)
- Ms. Yoo met with 20 CUMC coordinators and collected information about their active studies, educational needs, and areas that could be strengthened. In April 2012, the co-PIs and Ms. Yoo held two informational sessions to discuss NeuroNEXT, what Ms. Yoo learned from meeting with the coordinators, and how to bolster our infrastructure. It was also an opportunity for investigators to learn about NeuroNEXT and how to submit a proposal. She has also met with four coordinators at WCMC.

Highlights

- Two protocols from Columbia-Weill Cornell have been approved for grant submission
-Treatment of Neuropathy Associated with anti-MAG Antibodies and Non-malignant IgM Monoclonal Gammopathy by PI-Norman Latov, MD and CoPI-Thomas Brannagan, MD, scheduled to submit in August 2012
-Immunomodulation and Aggressive Fever Control After Subarachnoid Hemorrhage with intravenous Ibuprofen by PI-Neeraj Badjatia, MD and CoPI-Sander Connolly, MD, scheduled to submit in December 2012
- Three of our team members are on four NeuroNEXT committees: Dr. Marder (NeuroNEXT Executive Committee), Dr. Henchcliffe (Recruitment and Retention), and Ms. Yoo (SOP Committee). Ms. Yoo is also a member of the PWG for Dr. Badjatia's NeuroNEXT proposal.
- We have encouraged junior investigators to be mentored by senior investigators at both campuses. New assistant professor at WCMC, Dr. Grinspan, will work with Dr. Chiriboga on the SMA biomarker trial.
- First progress report was submitted in July 2012.

Grant Proposals

- 49 proposals submitted to NINDS for concept approval
- After NINDS review, 29 proposals were submitted to NeuroNEXT Executive Committee for approval
- 28 Site Feasibility Questionnaires were distributed to all sites for proposals
- Ten Protocol Working Groups formed
- Two new grant proposals were submitted for peer review (April and June)
- SMA Biomarker funded on February 2012
- First SMA subject enrolled anticipated in September of 2012

Ambulatory Care Network Collaboration

As part of our mission to streamline recruitment resources, we have begun a project with the NYPH Ambulatory Care Network (ACN). The NYPH ACN serves 400,000 ethnically-diverse residents in 13 primary care clinics, seven school-based health centers, and 65 subspecialty care clinics throughout Washington Heights-Inwood and Harlem with over 750,000 visits per year. In our initial meeting with the ACN, we discovered there were no SOPs in place for investigators interested in research collaboration with the ACN. We agreed to meet on a regular basis to develop SOPs for research collaboration to be implemented at the ACN. Since our first meeting in January 2012, we had three additional meetings with attendees from ACN at both campuses, bioinformatics, public relations, the clinical trials office, and sponsored projects.

Special Thanks

Our team thanks everyone that contributed to the success of our NeuroNEXT site completing 28 protocol feasibility (PF) questionnaires on time. We are especially thankful to Drs. Claire Riley, Dale Lange, Dana Leifer, Jai Perumal, Joshua Cappell, Neeraj Badjatia, Norman Latov, Susan Gauthier, Thomas Brannagan, Zach Grinspan and Kerri Natkiel, the Neurology Billing Manager who assisted us with numerous PFs. Thank you for your support!

Upcoming Events

- Dr. Chiriboga will be giving a talk at the CTSA's Columbia Community Partnership for Health Center on Pediatrics Clinical Research. The talk will be for parents and community leaders to encourage participation of Spanish speaking children for research.
- We will schedule a Recruitment/Retention and Advisory Committee meeting after the SMA Biomarker protocol has been finalized.
- SMA Biomarker investigator meeting is on September 6 and 7, 2012.

To learn more about NeuroNEXT, go to www.neuronext.org.

For questions, contact Rachael Yoo, ry2203@columbia.edu or (212) 305-8367.