

Newly established neuroscience clinical trials center could bring treatments to patients faster

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In a development that could pave the way for treatment for rare neurological diseases and clues to more common ones, physician-scientists at Albert Einstein College of Medicine of Yeshiva University and Montefiore Medical Center, the University Hospital for Einstein, have secured a grant to establish a clinical site for the Network for Excellence in Neuroscience Clinical Trials (NeuroNEXT). One of only 25 such federally-funded centers in the country, the Einstein-Montefiore site was created in partnership with Einstein affiliates Beth Israel Medical Center in Manhattan and the North Shore-Long Island Jewish Health System. The NeuroNEXT network and its centers were established with grants from the National Institute of Neurological Disorders and Stroke (NINDS), part of the National Institutes of Health.

NeuroNEXT was created to facilitate Phase II clinical trials for rare neurological diseases, which face significant challenges securing funding from industry, as well as with recruiting and retaining participants. (Phase II trials are conducted to assess how well and at what frequency and dosage a drug delivers effective results.) Should a promising drug be identified, enrolling enough participants with these rare disorders requires identifying and enlisting multiple sites around the country – each of which can only contribute a few patients. Additionally, each has its own rigorous process in place to oversee such research.

These hurdles often prove insurmountable. By establishing a pre-existing

network of sites and streamlining cumbersome logistics, the NeuroNEXT network and their centers aim to change that. "We'll basically be a S.W.A.T. team," said Shlomo Shinnar, M.D., Ph.D., co-principal investigator on the grant. "Researchers – and interested physicians with no research experience – will be able to tap into an existing infrastructure that can provide the research and regulatory expertise to participate in these clinical trials. Normally, when you build a multi-center study, it can take a year or two to get the trial going. We hope to get this down to a few months." Dr. Shinnar is professor in the Saul R. Korey Department of Neurology and of pediatrics at Einstein and an attending physician at Montefiore.

Despite the difficulties in initiating these studies, significant advances have been made in recent years in the understanding and treatment of unusual neurological disorders.

"While common diseases like Alzheimer's and Parkinson's have been slow to give up their secrets, real progress has been made in discovering the origins of – and therapies for – rare neurological diseases," said Mark Mehler, M.D., professor and chair of the Saul R. Korey Department of Neurology at Einstein and chair of neurology at Montefiore. "While this initiative offers us an opportunity to dramatically change the lives of patients with these rare diseases, the findings are also likely to provide insight into more common neurological disorders, like migraine and stroke, which affect millions of people." Dr. Mehler also holds the Alpern Family Foundation Chair in Cerebral Palsy Research at Einstein.

The Einstein-NeuroNEXT includes over 150 adult neurologists and 25 pediatric neurologists who serve an unusually diverse population base of over 8 million. Einstein's clinical affiliates have neurological expertise across all age groups – children, adults and geriatrics. Each year, these affiliates assess over 35,000 individual neurology patients, including

more than 10,000 pediatric neurology patients. Each clinical site boasts special clinical expertise, including the Sleep-Wake Center and Rett Syndrome Center at Montefiore, Beth Israel's Bachman-Strauss Dystonia Center of Excellence and North Shore-LIJ's work with Huntington's Disease at the Cushing Movement Disorders Institute.

"In addition to the breadth and strength of our center's expertise in rare neurological disorders, the success of our application was aided by the existence of the NIH-funded Einstein-Montefiore Institute for Clinical and Translational Research and the newly established Office of Clinical Trials," said Richard Lipton, M.D., co-principal investigator on the grant. "Both centers were established to promote and facilitate clinical research and trials and together they represent Einstein and Montefiore's commitment, knowledge and skill in the area." Dr. Lipton is professor and vice chair of the Saul R. Korey Department of Neurology, the Edwin S. Lowe Chair of Neurology, and professor of psychiatry and behavioral sciences at Einstein. He is also director of the Montefiore Headache Center.

NeuroNEXT centers are encouraged to submit their proposals for [clinical trials](#) to the network for evaluation. The inaugural study will focus on spinal muscular atrophy and recruitment will begin this year.

Provided by Albert Einstein College of Medicine

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