

Graduation Medical Education (GME): Clinical Trial Methodology and Regulatory Science

Robin Conwit, MD, Dietrich Haubenberger, MD, Billy Dunn, MD, John Marler, MD, Heather Fitter, MD

Overview

The Division of Neurology Products (DNP), Food and Drug Administration (FDA), and the National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH), are pleased to announce a fellowship opportunity offering training in clinical trial methodology and regulatory science.

The rapid pace of discovery in the basic neurosciences has created opportunities to translate some of these advances into improved therapeutics for people burdened by neurological disorders. To accelerate this process we need investigators with comprehensive expertise in all facets of the conduct of clinical research. Advanced knowledge of both clinical trial methodology and the regulatory pathways leading to approval of new treatments for patients is essential for successful human research. Education in these distinct yet closely related and highly overlapping fields is invaluable but often arrived at informally rather than in a structured setting. Neurologists and neurosurgeons who are working on clinical trials in academia or government now increasingly receive formal training in clinical research methodology, but typically receive little, if any, formal training in the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of drugs and medical devices.

We therefore aim to build capacity in Neurology and Neurosurgery therapeutics development through training a clinical research workforce with competencies in clinical trial conception, design, implementation, and analysis arrived at through formal education in research methodology and regulatory science.

Program Description

The two-year NIH/FDA fellowship will include hands-on participation both in neurology clinical research conducted at the NIH Clinical Center in Bethesda, Maryland, and in neurology clinical research regulatory review on the FDA Main Campus at the Federal Research Center in Silver Spring, Maryland. Expanding the opportunities from early-stage clinical trials to large, multi-center trials, the fellows will participate in activities related to the planning, implementation, conduct, data and safety monitoring, and regulation of trials either conducted or funded by the NINDS and regulated by the FDA. During the two-year fellowship-period, the emphases will be:

- Acquiring the skills necessary for the conduct of clinical trials research through immersion in the NINDS clinical trial methodology activities taking

place at the NINDS Intramural Research Program and the NINDS Office of Clinical Research.

- Intensive participation in the full spectrum of activities at FDA within DNP, ranging from pre-investigational discussions with clinical investigators about first-in-human drug trials to analysis of multi-center trials leading to possible approval of new medical products.
- In addition, a research project oriented towards clinical trial methodology and regulatory science will be completed during the fellowship.

Application Information

Applicants should be planning careers in the clinical neurosciences (Neurology or Neurosurgery) and therapeutics development, including but not limited to academic medicine or government service. All Neurology or Neurosurgery residents, or post doctoral clinical fellows in Neurology or Neurosurgery are eligible to apply. Priority will be given to applicants who have already identified an area of clinical interest in a given subspecialty or disease area, and who have already developed plans or pilot studies for potential clinical research projects. Fellowships are available annually. Applications now are being accepted for 2015 fellowship start dates. Applications may be submitted to Drs. Dietrich Haubenberger haubenbergerd@ninds.nih.gov and Robin Conwit conwitr@ninds.nih.gov at the National Institute of Neurological Disorders and Stroke, NIH, or Drs. Billy Dunn billy.dunn@fda.hhs.gov and Heather Fitter heather.fitter@fda.hhs.gov, at the Food and Drug Administration.

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