Anne B. Young, MD, PhD,
Neuroscience Translational Medicine Fellowship

Unique fellowships, endless opportunities
Biogen, in collaboration with the Mass General Neurology Department, Neurological Clinical Research Institute (NCRI) and the Mass General Bio Statistics Center, has established The Anne B. Young Neuroscience Translational Medicine Fellowship. The long-term objective of the Biogen-Mass General initiative is to train clinician-scientists to rapidly and efficiently translate advances in neuroscience into life improving treatments for people with neurological disorders. Acute and chronic neurological disorders impose a massive burden on patients and society. This burden may be ameliorated by translating recent major discoveries in basic neuroscience into meaningful treatments. Challenges to the effective and efficient development of treatments for neurological disorders include a shortage of individuals trained and prepared to be the leaders of multicenter clinical research in academia and industry. For clinicians, entry into industry is most often a ‘second career’ in their later professional stages. This early career fellowship aims to highlight the common focus of academia and industry on translational sciences. In doing so it aspires to breakdown traditional career path biases and create new professional opportunities for gifted clinician scientists.

Each Fellow will develop a research project under the guidance of a mentoring committee that includes at least one Biogen and one Mass General mentor. The mentoring committee will meet quarterly with the Fellow to discuss project development and educational progress. Fellows are expected to present their work in meetings and to publish results of their research in peer-reviewed journals. Presentation on a specific topic at the American Society for Experimental NeuroTherapeutics (ASENT) meeting at the completion of the fellowship is expected.

Fellows will be involved and instructed in clinical trial design, execution, monitoring, data analysis and presentation/publication. They will have firsthand exposure to key aspects of drug development at Biogen including early drug development course, attendance at specific Biogen drug development program team meetings, FDA meetings, protocol review processes and in-licensing due diligence exercises. Fellows will have the opportunity to take didactic courses at the Harvard School for Public Health, Mass General Clinical Research Program, Harvard Medical School Catalyst program or any other affiliated institutions. Fellows will also attend appropriate training provided by Biogen based on their role and scope of projects.

Fellows will participate in Chief’s Rounds and shadow clinical trials on rounds that review clinical trial conduct at Mass General. Fellows would likewise shadow senior leaders at Biogen for exposure across the various disciplines.

Caring Deeply.
Changing Lives.
Biogen

Corporate Overview
Biogen is committed to discovering, developing and delivering innovative therapies that improve the lives of patients with serious neurodegenerative diseases, hematologic conditions and autoimmune disorders. We are a leader in the development of treatments for multiple sclerosis (MS) and have recently introduced new treatment advances for hemophilia.

Our Science
Our research efforts are focused on better understanding the underlying biology of disease so we can discover and deliver innovative treatments in areas of high unmet medical need. Our pipeline includes candidates for diseases including Alzheimer’s disease, MS, spinal muscular atrophy, neuropathic pain, lupus nephritis and fibrotic disorders.

Today, Biogen provides important therapies such as AVONEX®, PLEGRIDY®, TECFIDERA®, TYSABRI®, and FAMPYRA® for people living with MS, as well as ALPROLIX® for hemophilia B and ELOCTATE® for hemophilia A.

Our Corporate Citizenship
Biogen is committed to being a responsible corporate citizen and conducting business in a manner that is consistent with the company mission. Our commitment extends to patient education and support programs, giving back to the communities in which we operate, promoting and advancing science education, and operating in a sustainable manner.

In 2015, Biogen was named the biotechnology industry leader on the Dow Jones Sustainability World Index for the second year in a row, after becoming the first U.S.-based biotech company to make the list in 2013. The company was also named to the Dow Jones Sustainability Index North America for the sixth consecutive year, one of only three biotech companies included.

Locations
Biogen is headquartered in Cambridge, Massachusetts, which is also home to our research operations. Our world-class large- and small-scale manufacturing facilities are located in Cambridge, North Carolina and Denmark. Biogen’s international headquarters is based in Zug, Switzerland. We offer our therapies to patients globally, with offices in 30 countries and a network of distribution partners in over 50 additional countries.

Massachusetts General Hospital and Harvard Medical School
Massachusetts General Hospital (www.massgeneral.org), founded in 1811, is the original and largest teaching hospital of Harvard Medical School. Massachusetts General Hospital conducts the largest hospital-based research program in the United States, with major research centers in AIDS, cardiovascular research, cancer, computational and integrative biology, cutaneous biology, human genetics, medical imaging, neurodegenerative disorders, regenerative medicine, reproductive biology, systems biology, transplantation biology and photomedicine.

Since 1872, The Neurology Department at Mass General has helped map out the intricacies of the brain and nervous system and shaped what neurology care is today. Consistently ranked among the top three neurology departments in the country, according to U.S. News & World Report, ours is also one of the nation’s largest hospital-based neuroscience research programs, focused on all phases of the discovery continuum including: basic research in the genetic and biochemical basis of brain function, translational studies linking lab findings with potential drug therapies and clinical trials testing the safety and effectiveness of new treatments through our Neurological Clinical Research Institute (NCRI). Major milestones include developing the first functional MRI machine and discovering numerous genes that contribute to neurological diseases. Our more than 230 physicians and scientists, many of whom have gained national and international recognition for their clinical and/or research efforts, conduct approximately 35,000 outpatient visits annually and are united by a common purpose: finding new treatments and cures that will reduce and ultimately eliminate the devastating impact of neurological disorders.
The Neurological Clinical Research Institute at Mass General (NCRI) was co-founded in 1994 by Dr. Merit Cudkowicz and Dr. Steven Greenberg to accelerate translational research in neurological disorders through initiating and testing novel therapies. Since the NCRI’s inception, it has been committed to the training and mentoring of future international leaders in the fields of clinical research, science, and medicine. Opportunities within the NCRI provide advanced, in-depth clinical education and practical, hands-on instruction needed to manage multi-center clinical research studies, from discussion with the FDA to the submission of a grant. Training within the NCRI includes: Overall Principal Investigator Responsibilities; Study Team and Protocol Development; Study Management and Infrastructure; and Electronic Data Capture and Data Management Systems. Further training is given in all facets of study conduct from initial recruitment to study closeout, data analysis and trial reporting.

The NCRI’s impressive list of accomplishments establishes it as a leading organization where future researchers can explore neurological therapeutic development. In collaboration with the Mass General Biostatistics Center, the NCRI has an extensive record of rapidly and efficiently organizing, overseeing, and conducting innovative observational and large, multi-center clinical trials for neurological disorders. Since 1995, the NCRI and the Northeast ALS Consortium (NEALS), a non-profit group of over 100 clinical centers across the globe, have completed 27 clinical research studies in ALS. This collaboration has also yielded not only ALS outcome measures to improve clinical trial design and efficiency, but also the launch of shared data and biological sample resources, a crucial means for accelerating ALS discovery. In 2011, the NCRI was appointed as the Clinical Coordination Center of NeuroNEXT, a National Institute of Health (NIH) supported network to expedite therapy development for neurological disorders in phase II trials. Two unique features of the NeuroNEXT Network include the Mass General central Institutional Review Board and the establishment of standardized master clinical trial agreements.

Mass General Biostatistics Center serves as the statistical center for national and international clinical studies. The center provides statistical support to investigators who are planning clinical studies, consults with investigators on data analysis problems, and conducts research in statistical methodology, which focuses on interval censored data, the relationship between longitudinal and survival data, and the design of clinical trials including sample size estimation. The Biostatistics Center has been involved with the coordination of six major national and international programs, including NEALS. Because of the Biostatistics Center’s extensive experience, their use of data management systems can be customized for each specific project.

“I am incredibly thrilled about this great opportunity and I am confident that the Biogen experience will have a transformative impact on the trainee’s career.” – Nazem Atassi, MD
Ajay Verma, MD, PhD

Dr. Ajay Verma is a Vice President in the Global Biomarkers Discovery and Development group at Biogen and head of Experimental Medicine. His efforts are aimed at building capabilities to select, create, and use novel clinical biomarkers, enhance drug delivery, and better understand disease pathophysiology in man. The cutting edge research performed by the Experimental Medicine group facilitates drug development across all of Biogen's therapeutic areas, including Neurology.

Prior to joining Biogen, Dr. Verma pursued neuroscience and ophthalmology drug development at Novartis Pharmaceuticals and Merck & Co., Inc. Dr. Verma served in the U.S. Army for 12 years, leaving as a Lt. Colonel. He remains an adjunct professor of Neurology at the Uniformed Services University of the Health Sciences (USUHS), the U.S. Military’s Medical School. Dr. Verma was previously director of basic research for the department of Neurology at USUHS, where he trained more than 20 graduate students, post docs, and research fellows in his lab. He completed his residency in Neurology at the Walter Reed Army Medical Center and received his MD and PhD from Johns Hopkins University.

Alfred W. Sandrock Jr., MD, PhD

Dr. Alfred Sandrock is Chief Medical Officer and Group Senior Vice President of Development Sciences at Biogen, overseeing global medical affairs, clinical development, global regulatory affairs, global safety and benefit risk management, global clinical development operations, biometrics, early program leadership, and discovery sciences.

Dr. Sandrock is a board-certified neurologist and is Assistant Clinical Professor of Neurology at Harvard Medical School. His contributions to the literature include peer-reviewed articles on axonal regeneration, synapse formation, neurophysiology, and multiple sclerosis.

Dr. Sandrock received an MD from Harvard Medical School in Boston, and a PhD in Neurobiology from Harvard University in Cambridge. He completed an internship in Medicine, a residency and chief residency in Neurology, and a Clinical Fellowship in Neuromuscular Disease and Clinical Neurophysiology (electromyography) at Massachusetts General Hospital.
Merit Cudkowicz, MD, MSc

Dr. Merit Cudkowicz, Chief of Neurology at Mass General Hospital, is also the Julieanne Dorn Professor of Neurology at both Mass General Hospital and Harvard Medical School. Dr. Cudkowicz completed medical training at the Health Science and Technology program of Harvard Medical School, and she was a resident in Neurology at Mass General. She obtained a Master’s degree in Clinical Epidemiology from the Harvard School of Public Health in June, 1996.

Dr. Cudkowicz directs the Mass General Amyotrophic Lateral Sclerosis (ALS) Multidisciplinary Clinic and the Neurological Clinical Research Institute at Mass General. She is one of the founders and co-directors of the Northeast ALS Consortium, a group of more than 100 clinical sites in the United States and Canada dedicated to performing collaborative, academic led clinical trials in ALS. She is the Principal Investigator for the Clinical Coordinating Center of the new NINDS NeuroNEXT initiative for early phase clinical trials in neurological disorders.

Anne Young, MD, PhD

Dr. Anne Young and her late husband (John B. Penney, Jr.) provided the most widely cited model of basal ganglia function. The model has provided the springboard for testing novel interventions in Huntington’s disease (HD), Parkinson’s disease (PD) and related disorders. Dr. Young established the MassGeneral Institute for Neurodegenerative Disease (MIND). MIND brings together scientists at Mass General concentrating on studies of Alzheimer’s, PD, HD and amyotrophic lateral sclerosis. Dr. Young spearheaded the comprehensive drug discovery efforts at MIND and has been successful in identifying drug targets for PD, HD and other neurodegenerative diseases.

Dr. Young received an MD and a PhD in Pharmacology from Johns Hopkins University and then completed residency training in neurology at the University of California, San Francisco. After 13 years on the neurology faculty at the University of Michigan, she was recruited to Mass General as its first female chief at the hospital. Dr. Young holds membership in the Institute of Medicine, the American Academy of Arts and Sciences. She is also the only person (male or female) to have been president of both the International Society for Neuroscience and the American Neurological Association.

Eric A. Macklin, PhD

Dr. Eric A. Macklin is an instructor at the Harvard Medical School and a biostatistician at the Massachusetts General Hospital Biostatistics Center with a focus on neurodegenerative and neurodevelopmental diseases. He is currently the study statistician for four ALS clinical trials studying pharmacologic, nutritional, and physical interventions, a multicenter trial in Parkinson’s disease evaluating the safety of urate elevation, three trials run by the Autism Treatment Network studying stress reactivity and interventions for sleep dysregulation and atypical anti-psychotic associated over-weight, and a study seeking predictors of sleep apnea among patients with Down Syndrome.

Dr. Macklin is also an Executive Committee member for the Parkinson’s Study Group, a senior statistician with the Harvard NeuroDiscovery Center, and a statistical reviewer for Cochrane Library neuromuscular disease section. His previous work in neurology and neuro-oncology includes studies of brain infarction in sickle cell disease, acupuncture for treatment of chronic stroke symptoms, imaging of intracranial aneurysms, design of phase I/II multiple sclerosis trials, and treatment and prognostics of glioblastoma. Outside of neurology, Dr. Macklin was Co-PI of the data coordinating center for an international research network studying thalassemia, PI of a study of acupuncture for treatment of hypertension, and currently supports clinical trials and genetic studies of schizophrenia, leads methodologic research to improve ovarian cancer screening, and collaborates on clinical trials and observational studies in psychiatry, hematology, cardiology, and gynecology.
Massachusetts General Hospital Faculty

Nazem Atassi, MD

Nazem Atassi, MD, MMSc, is Associate Director of the Neurological Clinical Research Institute (NCRI) at Massachusetts General Hospital (MGH) in Boston, Massachusetts, Assistant Professor of Neurology at Harvard Medical School. He completed Neurology training at Boston University Medical Center and Fellowship in Neuromuscular Disorders and Clinical Trials at MGH. He received his Masters of Medical Science in 2010 from Harvard Medical School. Dr. Atassi is Co- Chair of the Upper Motor Neuron Task Force, Co-Chair of the Imaging committee at the Northeast ALS Consortium (NEALS), and board member of the ALS Research Group (ALSRG). Dr. Atassi received several awards including the MIT 100K Life Science Award from Massachusetts Institute of Technology (MIT), the Anne B. Young Translational Neuroscience Fellowship, and NIH K23 Career Development Award. He has hands-on industry experience in running multi-center clinical trials through his work as a Medical Monitor for Pfizer and Fellow at Biogen. He is the Primary Investigator for several research projects focusing on Amyotrophic Lateral Sclerosis (ALS) and Primary Lateral Sclerosis (PLS) clinical trials, and neuroimaging.

Current Fellows

Elena Ratti, MD

Dr. Elena Ratti is a Clinical Research Fellow in Amyotrophic Lateral Sclerosis (ALS) and Neurodegenerative Diseases within the Neurological Clinical Research Institute at Massachusetts General Hospital (MGH). She completed her Neurology residency at Emory University in Atlanta, GA, where, in addition to her clinical training, she continued basic research projects investigating molecular mechanisms of Alzheimer’s disease that she had previously initiated as a post-doc scientist in the Neurology Department at Duke University in Durham, NC.

Dr. Ratti is currently pursuing formal training in clinical investigation through the Master’s Program in Clinical and Translational Investigation at Harvard Medical School and she is transitioning into a junior faculty position within the Neurology Department at MGH where she attends both the MGH ALS Multidisciplinary Clinic and Frontotemporal Dementia (FTD) Clinic.

While gaining experience as a clinical investigator in clinical trials in ALS, Dr. Ratti is leading multiple projects to discern ALS heterogeneity, predictors of disease progression and the scientifically intriguing overlap of ALS and FTD. Under the mentorship of Drs. Merit Cudkowicz and Bradford Dickerson, she is leading a project aimed at improving the understanding of the FTD-ALS spectrum longitudinally with clinical and neuroimaging assessments.

Katharine Nicholson, MD

Dr. Katharine Nicholson is an Assistant in Neurology at Massachusetts General Hospital (MGH) and Instructor of Neurology at Harvard Medical School. She completed a fellowship in Neuromuscular Disorders at MGH and Brigham and Women’s Hospital (BWH), followed by additional training as a clinical research fellow in neurodegenerative disorders at MGH. She performed her Neurology residency at Dartmouth-Hitchcock Medical Center. Her current clinical activities relate to her subspecialty interests in neuromuscular medicine and Amyotrophic Lateral Sclerosis (ALS).

Dr. Nicholson is actively engaged in clinical research. Her research activities strive to improve the diagnostic delay in ALS, explore the role of the microbiome in ALS, and characterize clinical interventions and associated outcomes in people with ALS. Additionally, she is interested in identifying diagnostic and prognostic biomarkers in ALS.
Three key domains will be covered during the Fellowship. The exact project, coursework, and set of Biogen meetings will be tailored to the individual Fellow’s interests.

1. **Project and translational/development work**: this will be the core of the Fellow’s experience and will be chosen in consultation with the mentoring committee
   
   a. Active participation in a translational or clinical development program
   b. Individual project: projects or key parts of multi-stage projects are expected to be completed within the 2 year time frame and subsequently presented and published as appropriate

2. **Course work and guided readings**: coursework may be completed at Harvard University or another participating academic center. Some Fellows may have completed these prior to fellowship. No more than 1 course should be taken at a time in conjunction with the Fellowship. Suggested course work and reading for Fellows working in clinical development is shown below; this may be replaced with imaging or other translational courses
   
   a. Coursework
      i. Introduction to biostatistics (year 1)
      ii. Introduction to epidemiology (year 2)
   
   b. Guided readings from Clinical Trials in Neurology
      i. Biostatistics and clinical measurement chapters (1 hour biweekly, Fall-Winter year 1)
      ii. Clinical trial designs, ethics, regulation, operations (1 hour biweekly, Spring and Summer year 1)

3. **Biogen meetings and lectures**: participation in internal meetings is an important part of the overall experience. This will give the Fellow exposure to a variety of disciplines and programs within Biogen. Fellows should plan to actively participate and present, when appropriate, on behalf of their program or project team. Sample meetings are included below and will be tailored to the Fellow
   
   a. Onboarding/orientation programs
      i. Introduction to clinical development
      ii. Relevant trainings/SOPs
   
   b. Clinical Development Plan Review Meetings
   
   c. Case studies in neurology clinical development
   
   d. Journal Club
   
   e. Project review forums
   
   f. Translational Neurology Interface
   
   g. Clinical development sciences
Program Design

Anne B. Young, MD, PHD Neuroscience Translational Medicine Fellowship

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<tr>
<th>DURATION</th>
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<th>START DATE</th>
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<td>2 YEARS</td>
<td>TWO</td>
<td>JULY 1, 2016 &amp; JULY 1, 2017</td>
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Compensation
The Biogen-Mass General Clinician Scientist Fellowships provide two years of salary support plus fringe and indirect costs.

Certificate of Completion
MGH and Biogen will award a professional certificate upon successful completion of the fellowship program.

Eligibility
- Physician scientist pursuing a career path in neuroscience translational research.
- Fellow or junior faculty in Neurology.
- Identified a mentor at Mass General with whom applicant will develop a research project during the program.
- Availability of 60-80% effort.

Application Must Include the Following:
- Anne B. Young, MD, PhD Neuroscience Program application form. (To obtain, contact Andrea Evans: acevans@partners.org)
- Current Curriculum Vitae (CV).
- Letter of interest outlining career goals and why and how the program would advance these career goals (2 pages maximum).
- Letter of support from mentor confirming mentorship with the applicant, space and resources.
- Two additional letters of reference.
- Other support report—Current and pending grant support information.
- Non-US Citizens must include proof of Visa status.
- Candidates will be selected by a joint selection committee comprised of members from both MGH and Biogen.
- Applications for position starting July 1, 2016 and position starting July 1, 2017 due by November 30, 2015.
- Please submit applications in PDF format to: Andrea Evans at acevans@partners.org
- Applications will be treated as confidential documents. Questions about the program can be directed towards:

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