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 more than 30 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
Sarah I. Sheikh, MD, MSc, MRCP

Dr. Sarah Sheikh is a Senior Medical Director in Late Stage Clinical Development at Biogen. Her current focus is on developing therapies for multiple sclerosis/neuroinflammation, remyelination and neuro-repair.

Prior to Biogen, Dr. Sheikh was an attending in Neurology at Brigham and Women’s Hospital. She completed her internship at Massachusetts General Hospital and residency in Neurology and Neuromuscular fellowship at Massachusetts General Hospital and Brigham and Women’s Hospital. She received her medical degree from Oxford University Medical School, and a Masters in Cell Physiology from Oxford University, Corpus Christi College. She is a member of the Royal College of Physicians, London.

Alfred W. Sandrock Jr., MD, PhD

Dr. Alfred Sandrock is our Executive Vice President, and Chief Medical Officer and has served in this position since November 2015. Dr. Sandrock has served as Group Senior Vice President from May 2014 to October 2015 as well as Chief Medical Officer since February 2012. Since joining us in 1998, Dr. Sandrock has held several senior executive positions, including Senior Vice President of Development Sciences, Senior Vice President of Neurology Research and Development, and Vice President of Clinical Development, Neurology. Dr. Sandrock oversees global medical affairs, clinical development, global regulatory affairs, global safety and benefit risk management, global clinical development operations, bio- metrics, early program leadership, and discovery sciences at Biogen.

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 his BA in human biology from Stanford University, 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.
Nazem Atassi, MD MMSc (Program Director)

Nazem Atassi, MD, MMSc, is Associate Director of the Neurological Clinical Research Institute (NCRI) at Massachusetts General Hospital (MGH) in Boston, Massachusetts, Associate 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 serves on the executive committee of the Northeast ALS Consortium (NEALS), and he is the founder and Co-chair of the Upper Motor Neuron and Imaging committees at NEALS.

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.

Dr. Atassi is the Primary Investigator for several research projects focusing on Amyotrophic Lateral Sclerosis (ALS) and Primary Lateral Sclerosis (PLS) clinical trials, and neuroimaging.

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 Mass General 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.

Current Fellows

Olga Rosenvold, MD

During residency Dr. Olga Rosenvold developed an interest in Neuro-ophthalmology and especially in its overlap with autoimmune disorders, such as multiple sclerosis. After she finished Neurology at the Partners program, she pursued a one year clinical fellowship in Neuro-ophthalmology. When searching for options for further training in MS, a mentor recommended her the ABY fellowship, with the unique opportunity to combine MS with drug development learning at Biogen. While joining this fellowship happened serendipitously, it was the perfect opportunity for her. The academic pathway offers no exposure to industry, but using her skills as a Neuro-ophthalmologist in multiple sclerosis clinical trial design is the ideal way to combine her interests.

Julia Ciampa Shirvan, MD

Dr. Julia Ciampa Shirvan has been interested in clinical research from the earliest stages of her career. While an undergraduate at Harvard College, she worked on clinical trials in the Neuroendocrine Unit of MGH. The experience motivated her to integrate medicine and statistics in her graduate training. She earned an MSc in Applied Statistics with Honors from the University of Oxford, completing her dissertation on serial neuroimaging in Alzheimer’s diagnosis. She completed her DPhil in Statistics through the NIH-Oxford Scholars program, based at the National Cancer Institute, Division of Cancer Epidemiology and Genetics. Her dissertation focused on methods to identify genetic interactions in genome-wide association studies with applications to prostate cancer. For her medical training she earned an MD from the University of Massachusetts and completed both her medicine internship and neurology residency at Columbia University - New York Presbyterian Hospital. She was awarded an R25 by the National Institute of Neurological Disorders and Stroke during her residency to conduct pathway-based analyses of genetic risk factors in Alzheimer’s Disease. She considers the Anne B. Young Fellowship the perfect extension of her training.

Massachusetts General Hospital Faculty and Fellows
Curriculum and Training

The fellowship provides an active exposure to high standards of clinical research and therapeutic development at both Biogen and the Department of Neurology, Massachusetts General Hospital (MGH), offering a unique perspective on the academic and industry approaches to disease.

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<th>Biogen</th>
<th>MGH</th>
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<tr>
<td>Leading an individual project</td>
<td>Carry out specific study protocols</td>
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<td>Team incorporation</td>
<td>Clinical or basic research unit involvement</td>
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<tr>
<td>POD curriculum</td>
<td>Harvard Catalyst or HSPH coursework</td>
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<tr>
<td>Decision-making forums</td>
<td>Grand rounds and unit specific conferences</td>
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**Biogen Involvement:**

Fellowship activities at Biogen provide both a broad introduction to a therapeutic development career in industry, and more focused exposure through the Fellow’s individual project and as part of a Biogen team.

At the beginning of the fellowship, participants will discuss areas of interest and potential project ideas with the fellowship directors. Based on their interests, fellows will be introduced to the team structure and dynamics in various therapeutic programs at Biogen, and will be offered a hands-on exposure to therapeutic development. Participants are expected to carry out an individual project from inception to completion during the course of the fellowship, with relevant tasks including protocol development, execution, data analysis, publication, and presentation. Fellows will become involved in multiple projects and contribute to drug development programs with their expertise.

Anne B. Young fellows participate in a 9 month-long, half day per week course at Biogen, the Physician Onboarding and Development (POD) program, designed to provide training in clinical development to physicians transitioning to industry. The POD program curriculum covers the following areas:

- Introduction to functional areas in drug development
- Principles of clinical drug development from Phase 1-4
- Protocol design
- Study conduct and good clinical practices
- Regulatory framework for conducting clinical trials
- Drug approval process in the US and EU
- Drug safety and benefit-risk management
- Case studies in drug development
- Personality type and teamwork
- Presentation training

In addition to formal coursework, fellows regularly attend decision-making forums in biomarker and clinical development, to observe discussion of a variety of therapeutic programs at different stages of development at Biogen. When appropriate, fellows are welcome to present in these platforms on behalf of their program or project team.
**MGH Involvement:**

During the fellowship time spent at MGH, he or she may engage in basic or clinical research and patient care applicable to their area of expertise. Didactic activities at MGH include weekly Neurology grand rounds and research unit specific conferences, such as monthly lecture series and translational research meetings. Participants are encouraged to take advantage of coursework offered by various institutions across the Harvard Medical and Partners Healthcare System, including the T. Chan Harvard School of Public Health and Harvard Catalyst. Fellows will become involved in specific study protocols at MGH, learning the institutional regulatory process and working with principal investigators, project managers, biostatisticians, nurses, and research coordinators as applicable to their research unit.
Program Design

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

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<th>DURATION</th>
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<th>STARTDATE</th>
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<tr>
<td>2 YEARS</td>
<td>ONE</td>
<td>July 1, 2018</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
n Physician-scientist pursuing a career path in neuroscience translational research.

n Fellow or junior faculty in Neurology.

n Identified a mentor at Mass General with whom applicant will develop a research project during the program.

n Availability of 60-80% effort to dedicate for the Fellowship

Application Must Include the Following:

n Anne B. Young, MD, PhD Neuroscience Program application form. (To obtain, contact Jill Cafaro: jcafaro@mgh.harvard.edu)

n Current Curriculum Vitae (CV).

n Letter of interest outlining career goals, an overview of the proposed project, and how the Fellowship would advance these career goals (2 pages maximum).

n Letter of support from the MGH mentor confirming the availability of mentorship, space and resources.

n Two additional letters of reference.

n Other support report—Current and pending grant support information.

n Non-US Citizens must have a green card or include proof of valid Visa status.

* Candidates will be selected by a joint selection committee comprised of members from both MGH and Biogen.

* Applications for the position starting July 1, 2018 due by November 1, 2017

* Please submit applications in PDF format to: Jill Cafaro at JCAFARO@mgh.harvard.edu

* Applications will be treated as confidential documents. Questions about the program can be directed towards:

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Front right photo courtesy of Elkus Manfredi Architects.