

Anne B. Young, MD, PhD,
Neuroscience Translational Medicine Fellowship
Unique fellowships, endless opportunities



MASSACHUSETTS
GENERAL HOSPITAL

NEUROLOGY



Biogen™

The Anne B. Young Neuroscience Translational Medicine Fellowship

Biogen, in collaboration with the Massachusetts General Hospital Department of Neurology, the MGH 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 studies 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 an 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 Harvard-affiliated institutions such as the Harvard School of Public Health, the Mass General Clinical Research Program, and the Harvard Medical School Catalyst Program. Fellows will also receive appropriate training programs at Biogen based on their role and scope of projects.

Fellows will participate in Chief's Rounds and Clinical Trials Rounds that review clinical trial conduct at Mass General. Fellows will likewise shadow senior leaders at Biogen for exposure across the various disciplines.

Caring Deeply.

Changing Lives.

Biogen

At Biogen, our mission is clear; we are pioneers in neuroscience.

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 introduced the first treatment for Spinal Muscular Atrophy.

Since our founding in 1978 as one of the world's first global biotechnology companies by Charles Weissmann, Heinz Schaller, Kenneth Murray and Nobel Prize winners Walter Gilbert and Phillip Sharp, Biogen has led innovative scientific research with the goal over the last decade to defeat devastating neurological diseases.

We believe that no other disease area holds as much need or as much promise for medical breakthroughs as neuroscience.

Biogen has some of the world's best neurologists and neuroscientists. We engage with physicians and scientific leaders around the world with the aim to further medical research. Our focus on neuroscience, our deep scientific expertise and our courage to take risks make us leaders in the research and development of medicines to transform neuroscience to benefit society.

Our technology and engineering capabilities create novel ways to seamlessly transition products from development to manufacturing with the intent of bringing our high-quality medicines to market faster.

We respect the contributions of health care providers caring for people living with neurological diseases. We honor the important role of caregivers, families and friends who care about them.

Biogen is committed to working with advocacy and patient organizations as they serve the communities they represent.

Recognizing the challenges facing health care systems today, we collaborate with regulatory authorities and customers such as health care providers and payers, so that those in need can access our medicines.

Professional, ethical, and compliant, we hold ourselves accountable to deliver value to our shareholders.

Biogen contributes to the communities where we live. We are committed to our employees, diversity and inclusion, and environmental sustainability.

We care deeply about making a difference. We work fearlessly. We do not give up even when challenged, pursuing innovation in all that we do. We are humbled by the opportunity to change lives.

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 are 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, neuroscience and neurological 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 neurology departments in the country according to News & World Report, MGH Neurology houses 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.

The 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 delighted to direct this Translational Fellowship at MGH and I am confident that the Biogen experience will have a transformative impact on the Biogen-MGH fellows' trainee's careers."

–Andrew J. Cole, MD

Toby A. Ferguson, MD, PhD (Co-Program Director)

Toby Ferguson, MD, PhD is Vice President, Head of the Neuromuscular Development Unit at Biogen. He joined Biogen in October of 2013 to work on thoughtfully restarting ALS efforts at Biogen following the failure of Dexamipexole. He has partnered with neurology research colleagues at Biogen and Ionis, and the external ALS community to develop a pipeline of therapies for both genetic and sporadic forms of ALS. The most advanced molecule in the ALS pipeline is in phase 3 testing for SOD1 ALS. His group's mission is to develop transformative therapies for ALS, SMA, and muscle disease. In addition to support of clinical programs, his group works actively to develop novel biomarkers and outcome measures in support of more efficient early stage drug development. He is the Biogen leader for the Anne B. Young Neuroscience Translational Medicine Fellowship at MGH and Biogen.



Prior to Biogen, Dr. Ferguson had a clinical neuromuscular neurology practice and a lab focused on peripheral axon injury and regeneration at Shriners Research Center and Temple University in Philadelphia. He trained in neurology and neuromuscular disease at the University of Pennsylvania. He obtained an MD and PhD (Neuroscience) at the University of Florida and maintains an interest in axon regeneration and degeneration.

Alfred W. Sandrock Jr., MD, PhD

Alfred W. Sandrock Jr. is the Executive Vice President, Research and Development at Biogen. He has served on the executive committee since 2015 and was named Head of R&D in October 2019. He was Chief Medical Officer from 2012 until January 2020. Since joining Biogen in 1998, Dr. Sandrock has held several senior executive positions including Group Senior Vice President of Development Sciences, Senior Vice President of Neurology Research and Development, and Vice President of Clinical Development, Neurology. Prior to joining Biogen, Dr. Sandrock was Assistant Professor of Neurology at Harvard Medical School and an Assistant in Neurology at Massachusetts General Hospital.



Dr. Sandrock received a B.A. in Human Biology from Stanford University, an M.D. from Harvard Medical School, and a Ph.D. in Neurobiology from Harvard University. 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 in Boston, MA.



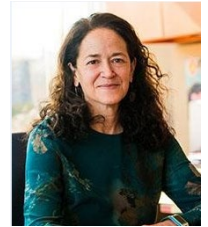
Andrew J. Cole, MD (Co-Program Director)

Andrew J. Cole, MD, FRCP(C), is Professor of Neurology at Harvard Medical School, and Vice Chair of the Department of Neurology, Director of the MGH Epilepsy Service and Chief of the Division of Clinical Neurophysiology at Massachusetts General Hospital in Boston. He served as Assistant Professor of Neurology at Johns Hopkins in Baltimore before moving to Massachusetts General Hospital where he has been since 1992. At MGH he oversees a large Epilepsy Clinic, a busy Epilepsy Surgery Program, and an Epilepsy and Clinical Neurophysiology Fellowship Program that has trained over 75 fellows under his directorship. He has had NIH funding to support basic research on the consequences of abnormal neuronal activity, and he has been a Principal Investigator on numerous NIH and industry supported clinical trials of drugs and devices in epilepsy. He is the Founding Chair of the Translational Research Committee of American Epilepsy Society. Previously he chaired the American Epilepsy Society's Annual Course Committee and was Director of the AES Annual Course from 2002 through 2004. He is the Founding Associate Editor of *Annals Clinical and Translational Neurology* and has been a member of the Editorial Boards of *Epilepsia* and *Neurology and Clinical Neurophysiology*. He serves as an ad hoc reviewer for many journals, including *Science*, *Neurology*, the *New England Journal of Medicine*, *Annals of Neurology*, *Archives of Neurology*, *Neuropharmacology* and the *Journal of Neuroscience*. He has authored over 150 papers, chapters and abstracts on epilepsy and cellular and molecular correlates of neuronal activity and has been an organizer, discussant or invited speaker at many national and international meetings. In the field of epilepsy, he is considered an expert in the evaluation and surgical treatment of patients with refractory epilepsy. He is credited with focusing attention on the role of immediate early gene expression after seizures and in association with synaptic plasticity, developing the "two-hit" hypothesis of epileptogenesis, identifying a role for Nerve Growth Factor Receptor-bearing neurons in protecting against seizure-induced neuronal injury during development, improving the application of modern neuroimaging tools, including high field strength anatomic scanning and perictal imaging, in patient care, and advancing the surgical treatment of highly refractory focal status epilepticus. Most recently, he has pioneered use of responsive neurostimulation in refractory idiopathic generalized epilepsy, provided proof of principle supporting development of a novel drug for status epilepticus that is now in Phase III clinical trial, and demonstrated the occurrence of cryptic seizures in mesial temporal structures of patients with Alzheimer's Disease.



Merit Cudkowicz, MD, MSc

Dr. Merit Cudkowicz is the Director of the Sean M. Healey & AMG Center for ALS, Chief of Neurology at Mass General, Director and the Julieanne Dorn Professor of Neurology at Harvard Medical School. Dr. Cudkowicz's research and clinical activities are dedicated to the study and treatment of people with Amyotrophic Lateral Sclerosis (ALS). Dr. Cudkowicz is one of the founders and past Co-Chairs of the Northeast ALS Consortium (NEALS), a group of over 134 clinical sites in the United States, Canada, Europe and the Middle East dedicated to performing collaborative clinical trials and research in ALS. She has brought innovations to accelerate the development of treatments for people with ALS, including a senior role in first antisense oligonucleotide treatment for a neurological disorder (SOD1 ALS), adaptive trial designs, central IRB - all with a goal to bring the best treatments rapidly. Dr. Cudkowicz is the Principal Investigator of the Clinical Coordination Center for the National Institute of Neurological Disorders and Stroke's Neurology Network of Excellence in Clinical Trials (NeuroNEXT). Dr. Cudkowicz is launching the first platform trial initiative in ALS, the HEALEY ALS Platform Trial, a program that will greatly accelerate therapy development in ALS.



Dr. Cudkowicz received the American Academy of Neurology 2009 Sheila Essay ALS award, the 2017 Forbes Norris Award from the International MND Alliance, the 2017 Pinnacle Award from the Boston Chamber of Commerce and the 2019 Ray Adams American completed Neurological Association Award. A dedicated educator, Dr. Cudkowicz mentors many young neurologists in clinical investigation of ALS and related neurodegenerative disorders. Dr. Cudkowicz her undergraduate degree in chemical engineering at Massachusetts Institute of Technology and obtained a medical degree in the Health Science and Technology program of Harvard Medical School. She served her internship at Beth Israel Hospital in New York and her neurology residency and fellowship at MGH. She also obtained a master's degree in Clinical Epidemiology from the Harvard School of Public Health.

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.

Massachusetts General Hospital Faculty and Fellows

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 overweight, 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

Ilena George, MD

Dr. Ilena George has been involved in translational neuroimaging research in multiple sclerosis (MS). What started as a summer research experience grew into the basis for her career in medicine, leading her to a neurology residency and then on her current fellowship in Harvard MS at Mount Sinai. Her intention is to continue in both academia and clinical research and the Anne B. Young fellowship has helped continue her development in a new area of therapeutic development.



Leeann Burton, MD

Dr. Leeann Burton is a neurologist with subspecialty training in neuromuscular and electrodiagnostic medicine. She did her undergraduate studies Hamilton College, where she majored in neuroscience. She then attended medical school and trained in the Partners Neurology Residency Program at Massachusetts General and Brigham and Women's Hospitals. She recently completed the Harvard Neuromuscular Medicine Fellowship. Leeann's clinical and research interests include autoimmune neuromuscular disease and disorders of muscle and the neuromuscular junction. She is very interested in emerging therapeutics for neuromuscular diseases and is thrilled to be starting the Anne B. Young Fellowship at Biogen to advance her career goals in translational and clinical research.



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.

Biogen	MGH
Leading an individual project	Carry out specific study protocols
Team incorporation	Clinical or basic research unit involvement
POD curriculum	Harvard Catalyst or HSPH coursework
Decision-making forums	Grand rounds and unit specific conferences

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

DURATION	NUMBER OF POSITIONS	START DATE
2 YEARS	ONE	July 1, 2021

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 who is or will be a BC/BE Neurologist by July 1, 2021
- Fellow or Junior faculty in Neurology
- Ability to commit 50% of time to Biogen and 50% of time to MGH

Application Must Include the Following:

- Anna B. Young, MD, PhD Neuroscience Program application form
- Current Curriculum Vitae (CV).
- Letter of support from the MGH mentor confirming the availability of mentorship, space and resources.
- One additional letter for reference.
- Other support report – current and pending NIH or other grant support information.
- Non-US citizens must have a green card or include proof of valid visa status.

Please submit applications in PDF format to program coordinator Bo (Carol) Qian at Bo.Qian@mgh.harvard.edu from July 1, 2020 to November 30, 2020.

All application materials will be treated as confidential documents.

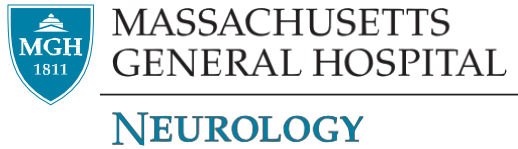
Candidates will be selected by a joint selection committee composed of members from both MGH and Biogen.

Andrew J. Cole, MD

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Bo (Carol) Qian, MBA

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