2025

Northeastern University

FELLOWSHIP PROGRAM

in collaboration with BridgeBio Pharma

bridgebio

Northeastern University
Pharmaceutical Industry Fellowships

ABOUT BRIDGEBIO

BridgeBio Pharma Inc. (BridgeBio) is a biopharmaceutical company founded to discover, create, test and deliver transformative medicines to treat patients who suffer from genetic diseases. BridgeBio's pipeline of development programs ranges from early science to advanced clinical trials. BridgeBio was founded in 2015 and its team of experienced drug discoverers, developers, and innovators are committed to applying advances in genetic medicine to help patients as quickly as possible.

BridgeBio exists to bring meaningful medicines to patients as quickly and as safely as possible. We're passionate about fostering open and transparent relationships with patients and their families by staying connected, listening to their experiences, and applying their insights into our work. We hope that by developing these relationships with patients, families, and patient advocacy organizations early in the development phase of our therapies that we can also craft our clinical trial protocols with the patient experience at the forefront.

For more information visit bridgebio.com and follow us on LinkedIn, X and Facebook.

www.bridgebio.com x.com/bridgebiopharma linkedin.com/company/bridgebio

OUR MISSION

To **discover, create, test and deliver** transformative medicines to treat patients who suffer from genetic diseases and cancers with clear genetic drivers.

Check out our research pipeline

OUR VALUES

Put Patients First

BridgeBio ultimately exists to help patients. Millions worldwide are afflicted with genetic diseases, but small patient populations and industry reluctance to conduct early-stage development mean that for many, treatments have not been forthcoming. We are committed to bridging this gap: between business case and scientific possibility, between patient and hope. This starts with our first core value: put patients first.

Think Independently

Our goal is to not simply accept the ideas and opinions of others as fact, but instead to ask “why?” and “why not?” We endeavor to bring a rigorous, first-principles mindset to each problem that we take on.

Be Radically Transparent

A commitment to independent thinking requires us to consider the ideas of others and to adopt them if they prove best. We strive to maintain a culture where any idea is worthy of both consideration and testing.

Every Minute Counts

Our decentralized model strives to deliver treatments from discovery to patients as fast as humanly possible by utilizing focused teams of experts for each asset. Big decisions can be taken by people best-equipped to understand them, without wasting time on unnecessary cycles.

Let Science Speak

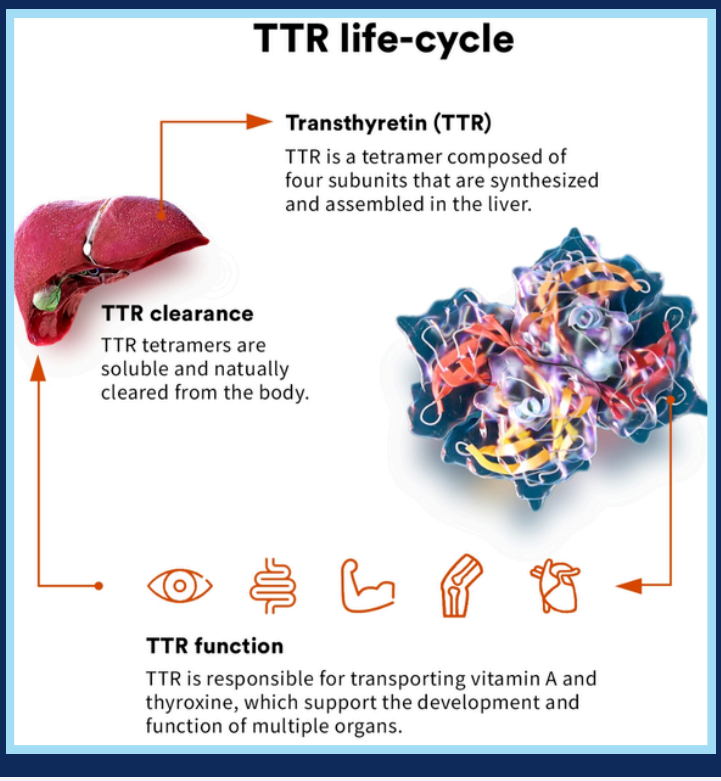
Our model was designed to promote the rational assessment of our programs. Decisions about a program’s fate are driven by its performance against a set of objective criteria, giving each potential medicine’s scientific merits the last word.

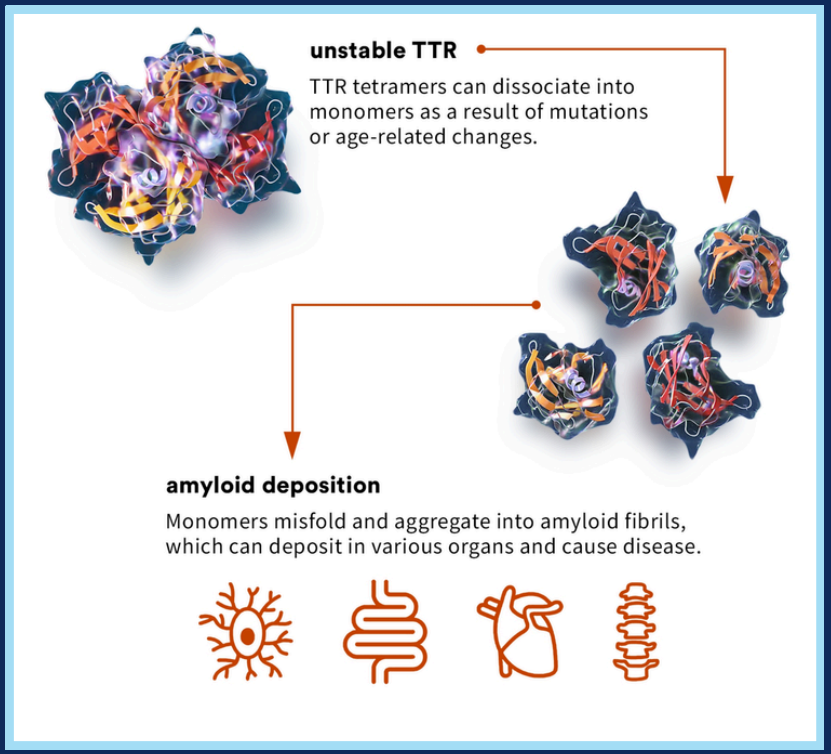
PROGRAM OVERVIEW

In partnership with Northeastern University, Eidos Therapeutics is offering a two-year Regulatory Affairs PharmD fellowship based in **San Francisco, California**. The program consists of a **2-year assignment** within the Regulatory Affairs team and may be eligible for elective rotations within Clinical Development, Clinical Operations, and Medical Affairs. The PharmD Fellow will work both remotely and on-site at the BridgeBio office location in San Francisco, CA.

ABOUT EIDOS

Transthyretin (TTR) amyloidosis (ATTR) is a rare, underdiagnosed, and life-threatening disease with limited treatment options that can damage the heart and/or nervous system. BridgeBio's mission is to improve the morbidity and mortality of patients with ATTR through the discovery and development of a novel therapeutic through its affiliate, Eidos Therapeutics.





OUR GROWING FELLOWSHIP PROGRAM

We at BridgeBio are excited to be able to collaborate with Northeastern University for our 4th fellowship cohort cycle. Our growing fellowship program seeks to provide Doctor of Pharmacy (PharmD) graduates with hands-on and well-rounded academic and industry experiences that will help prepare them for a successful career in the pharmaceutical industry. Upon completion of this 2-year fellowship, BridgeBio fellows will be equipped with the technical skills necessary to navigate the unique and ever-changing landscape of Regulatory Affairs in a biopharmaceutical company. Additionally, fellows will have the opportunity to work in cross-functional teams and expand their professional network.

Stuart Heminway, MS
Senior Vice President, Regulatory Affairs, Cardiorenal Program Director, BridgeBio - Northeastern Fellowship Program

Elisa Tsuji, PharmD
Senior Manager, Regulatory Affairs, Calcilytix
Fellowship Preceptor, BridgeBio - Northeastern Fellowship Program

"The BridgeBio Regulatory Affairs Fellowship was a transformative experience that not only deepened my understanding of global regulatory frameworks but also gave me direct involvement in high-impact projects. The hands-on training and close mentorship allowed me to develop critical skills and insights that are essential for navigating the complexities of regulatory affairs." - Elisa Tsuji, PharmD

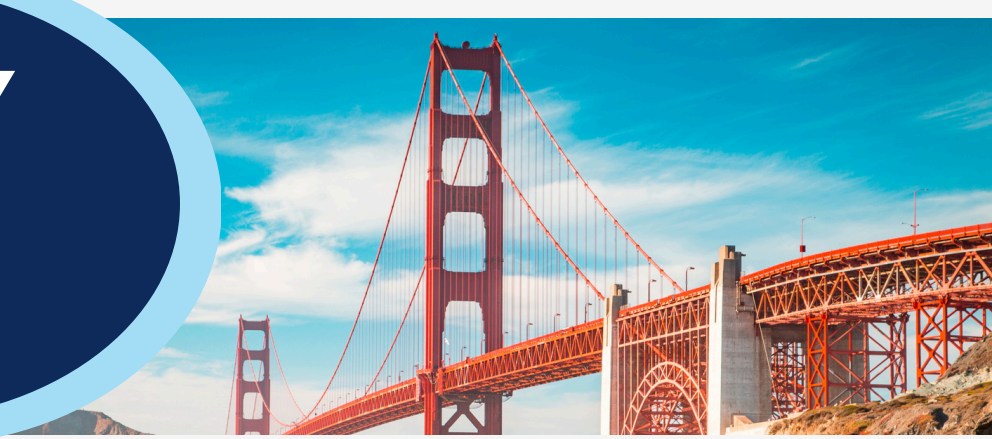
"What initially sparked my interest in pursuing this fellowship was BridgeBio's patient-focused method of bridging the therapeutic gaps for patients dealing with genetic diseases with unmet needs. As a post-doctoral fellow with BridgeBio and Northeastern University, I've had the opportunity to gain a diverse set of experiences across different functional areas. The team-centric environment, along with the support from my mentors have allowed me to gain and develop the skills needed to prepare me for a successful career in the pharmaceutical industry." - Yohanna Berhanu, PharmD

Yohanna Berhanu, PharmD
First Year Regulatory Affairs/Clinical Development Fellow

bridgebio
hope through rigorous science

REGULATORY AFFAIRS FELLOWSHIP

Recruting **1 Fellow** for 2025-2027



OBJECTIVES

REGULATORY STRATEGY

- Manage, develop, and implement regulatory strategy in support of Eidos development programs.
- Support the planning, preparation and execution of high-quality regulatory submissions (e.g. Clinical Trial Application (CTA)/Investigational New Drug (IND) application and amendments, annual reports, initial license applications (New Drug Application (NDA)/Marketing Authorization Application (MAA), etc.) and supplements/variations).
- Develop and maintain knowledge of International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), Good Clinical Practice (GCP), Good Manufacturing Practice (GMP), and other relevant global guidelines to ensure compliance of regulatory strategies and submissions.
- Work in cross-functional teams including Clinical, Statistics, Medical Affairs, Commercial, and Nonclinical groups to help operationalize regulatory strategy.
- Support regulatory interactions with regulatory bodies including preparation of meeting requests and briefing documents.

GLOBAL LABELING

- Gain in-depth knowledge of labeling regulations regarding Company Core Data Sheet (CCDS), US Package Insert (USPI), Summary of Product Characteristics (SmPC), and Structured Product Labeling (SPL).
- Support development of regulatory labeling strategy and the negotiation and maintenance of competitive labeling with global health authorities.
- Maintain core labeling documents.
- Provide strategic guidance on labeling regulations, competitor labeling, and labeling trends and work with cross-functional team to ensure that the regulatory labeling strategy is aligned with the global regulatory strategy.
- Assist in preparation of responses to labeling-related queries from health authorities.

ADVERTISING AND PROMOTION

- Support regulatory review of promotional and non-promotional materials in accordance with business goals and objectives, health authority regulations, ICH guidelines, Pharmaceutical Research & Manufacturers of Americans (PhRMA) guidelines, company policies and established precedents and recommend revisions/actions that achieve fair balance.
- Support the review and approval of promotional and non-promotional materials in a cross-functional promotional review committee that includes Commercial, Medical Affairs, and Legal.
- Coordinate timely and accurate review of materials for submission to the United States Food and Drug Administration (FDA).

Northeastern University
Pharmaceutical Industry Fellowships

ABOUT OUR PROGRAM

OVERVIEW

Northeastern University Pharmaceutical Industry Fellowships Program is a two-year experiential program designed to advance lifelong learning and the education and training of PharmD graduates. Critical to the success of the program is our ability to prepare fellows to meet the ongoing workforce needs in various areas of industry.

Our program provides fellows an opportunity to work with our innovative biopharmaceutical industry partners while collaborating with Northeastern University faculty in the areas of professional and career development, service, scholarship, and teaching.

OUR MISSION

Our mission is to provide the highest quality training for future biopharmaceutical industry professionals by combining industry expertise with Northeastern University's renowned tradition of lifelong and experiential learning.

CORE VALUES

- Innovation
- Lifelong Learning
- Social Impact Through Drug Development
- Quality Industry Pharmacy Training

FOCUS AREAS

LEARN

Pursue graduate degrees or certificates in Regulatory Affairs, Business, Public Health, and more through tuition reimbursement.

TEACH

Teach pharmacy students in various small and large group classes. Earn a Teaching Certificate of achievement.

RESEARCH

Perform research with faculty and students. Present data at conferences. Publish your findings. Generate literature.

NETWORK

Boston has a lot to offer, both socially and professionally. Our program takes advantage of it all!

> "Thanks to the collaboration and dedication of our industry partners over the course of nearly 10 years, our program is now the 3rd largest industry fellowship program in the nation."

OUR PROGRAM PILLARS

TEACHING & SCHOLARSHIP

Teaching and Learning Seminar Series provides contextual activities and reflection on adult education and pedology outcomes.

PROFESSIONAL & CAREER TRAINING

Professional Development and Career Training Series is customized to engage fellows in appropriate and professional conduct for success.

SERVICE

Through their service on committees, fellows have an active connection within the community and program. This allows an opportunity to demonstrate leadership development and skills.

Northeastern University Pharmaceutical Industry Fellowships Program provides a dynamic academic environment offering fellows the opportunity for a wide breadth of experiences.

PROGRAM OPPORTUNITIES

Develop teaching skills through participation in our Teaching and Learning Seminar Series

Utilize a layered learning model in experiential education by co-precepting students on pharmacy practice experiences including Northeastern's unique co-op program

Facilitate small and large group didactic education in partnership with a faculty mentor

Create, present, and publish scholarly research through collaborative industry and university relationships

Engage with faculty who participate in various interdisciplinary graduate programs including biotechnology, nanomedicine, immunology, health informatics, and drug discovery

Network with local residents and other Northeastern fellows via professional development programs, teaching seminars, and participation on fellowship committees

OUR PARTNER COMPANIES

SINCE 2015

Through these exciting partnerships, Northeastern fellows collaborate and learn from each other, further positioning them to be successful in both academic and industry settings. Fellows are empowered to shape their experience, as well as the future of the program, through leadership on the Professional Development & Networking and Recruitment committees.

24	73	119	99%
Industry Partnerships	Active Fellows	Fellowship Alunmi	Employment in Industry within 90 days of Fellowship Completion

Abbott
Alnylam PHARMACEUTICALS
AMRYT PHARMA
Apellis
ARVINAS
BAUSCH Health
blueprint MEDICINES
bridgebio
Chiesi global rare diseases
CSL Seqirus
flatiron
GSK
IPSEN Innovation for patient care
Ironwood IRONWOOD PHARMACEUTICALS
Karyopharm Therapeutics
PACIRA BIOSCIENCES, INC.
PRAXIS
SAREPTA THERAPEUTICS
Takeda
VERTEX

OUR TEAM

Andrew Orr-Skirvin
Faculty Director

Sherisse Mayala-Nelson
Program Manager

Sophia Sawtelle
Senior Program Coordinator

Karen Stanley
Bouvé Director of Finance and Administration

Julia Van
Director of Corporate and Foundation Relations

Milini Rambukwella
Human Resources Associate

Dayna D'Angelo
Budget Coordinator

CONNECT WITH US!

Instagram
@nufellowship

LinkedIn
Northeastern Pharmaceutical Industry Fellowships

Jenny Van Amburgh
Clinical Professor
Fellowship Faculty Manager

Debra Copeland
Clinical Professor
Fellowship Faculty Manager

Joseph Elijah
Clinical Professor
Fellowship Faculty Manager

Michael Gonyeau
Clinical Professor
Fellowship Faculty Manager

Jason Lancaster
Clinical Professor
Fellowship Faculty Manager

Adam Wooley
Clinical Professor
Fellowship Faculty Manager

BOSTON, MA:

Northeastern University is in the heart of Boston, steps away from the famous Fenway Park and downtown Boston. Surrounded by top tier academic and research institutions, the area is home to pioneers of innovation who are committed to intellectual curiosity and scientific advancement. The greater Boston area is a cultural hub, offering world-class attractions and rich history.

NORTHEASTERN FELLOWS















YEAR 1 FELLOWS

Druti Shukla, PharmD, MHA
Abbott
Global Medical Affairs

Nathan Gruenke, PharmD
Alnylam
Clinical Development

Nicholas Saad, PharmD, RPh
Abbott
Global Medical Affairs

Pavlos Papamanolis, PharmD
Apellis
Medical Affairs

Alice Fan, PharmD
Alnylam
Medical Communications
and Publications

Kaitlin Greco, PharmD
Arvinas
Medical Affairs

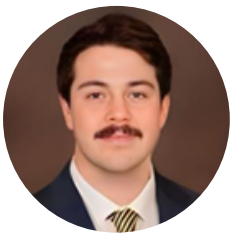
Eva Houser, PharmD
Alnylam
US Medical Affairs

Yohanna Berhanu, PharmD
BridgeBio
Regulatory Affairs /
Clinical Development

Hina Patel, PharmD, RPh
Alnylam
Global Medical Information

Jonathan Lu, PharmD
Chiesi
North America Medical Affairs

Hirra Zaidi, PharmD
Alnylam
Global Patient Safety
and Risk Management



Thomas Senneff, PharmD, RPh
CSL Seqirus
Medical Affairs

YEAR 1 FELLOWS

Ali Al Juboori, PharmD, MBA
IPSEN
Medical/Regulatory Affairs

Palmer McNally, PharmD
Sarepta
Global Scientific Communications

Alison Bechwati, PharmD
IPSEN
Commercial Rare Disease
Operations and Marketing

Abhishek Alagaratnam, PharmD, MS DRA
Takeda
Global Regulatory Affairs

Deborah Nikolla, PharmD, MPH
IPSEN
Epidemiology and
Real World Evidence

Brandi McKnight, PhD
Takeda
Global Medical Affairs

Nasim Malakoti Negad, PharmD
IPSEN
Commercial Oncology

Cathy Cheng, PharmD
Takeda
Global Medical Affairs

Mildred Asamoah, PharmD, MBS
Ironwood
Clinical Development /
Medical Scientific Affairs

Kathryn DeStefano, PharmD
Takeda
Clinical Science

Yasser Ibrahim, PharmD
Ironwood
Global Patient Safety /
Regulatory Affairs

Michael Nome, PharmD
Takeda
Clinical Science

YEAR 1 FELLOWS

Raymond Jubrail, PharmD
Takeda
Global Medical Affairs

Michael McShan, PharmD
Vertex
Global Regulatory Affairs

Danielle Mauro, PharmD
Vertex
Global Medical Affairs

Naafiah Raidah, PharmD, MBA
Vertex
Global Regulatory Affairs

Eunice Lee, PharmD
Vertex
Global Regulatory Affairs

Olivia Laprade, PharmD
Vertex
Clinical and Quantitative Pharmacology

Julieta Rossi Fortunati, PharmD
Vertex
Clinical Scientist

Ryan Ha, PharmD
Vertex
Clinical and Quantitative Pharmacology

Kailey Davies, PharmD
Vertex
North America Commercial – Marketing

Samin Malek Marzban, PharmD
Vertex
North America Commercial – Market Access

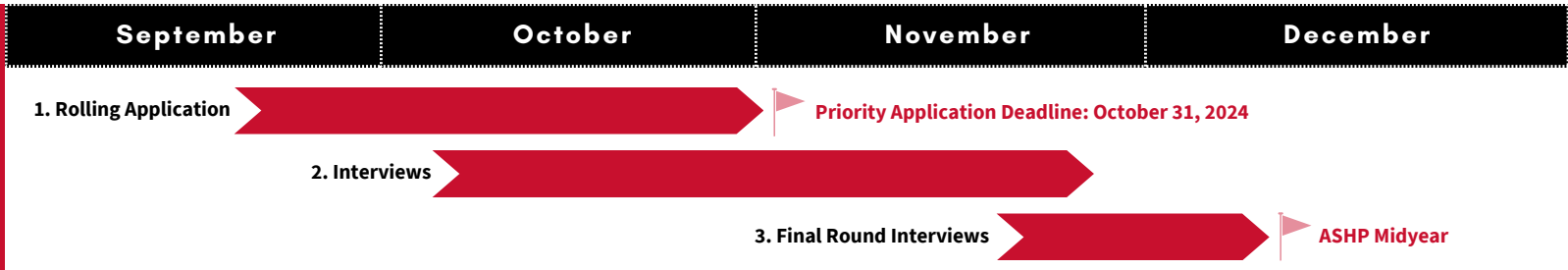
Loren Sampson, PharmD, MBA
Vertex
North America Commercial – Guidance and Patient Support

Sarah Casella, PharmD
Vertex
Global Medical Affairs

Northeastern University
Pharmaceutical Industry Fellowships

APPLICATION REQUIREMENTS

Fellows are selected on a nationally competitive basis. Unless otherwise noted in the position description, candidates must have a Doctor of Pharmacy degree from an ACPE-accredited college of pharmacy by June 30, 2025. Candidates must apply through Northeastern's career portal and are encouraged to do so by the priority application deadline of October 31, 2024.



Step 1: Application

- Fellowship position postings go live on **September 16, 2024**. We will cross-post positions on ASHP's PPS website.
- Complete the application by **October 31, 2024**, for priority consideration for first-round interviews.

Step 2: Interviews

- Phone screenings and initial interviews will be conducted with eligible candidates starting in early October into November.
- After the priority deadline, interviews will be conducted with both the sponsor company and Northeastern University.

Step 3: Final Round Interviews & Offers

- Final round interviews will take place **virtually or in person** during ASHP Midyear in New Orleans, LA. Visit midyear.ashp.org for event details.
- Northeastern University, in conjunction with the Alliance of Industry Fellowship Associates (AIFA), has agreed to extend offers for fellowships no earlier than **December 16, 2024.**

Applications are reviewed on a rolling basis - apply early!

Application Materials:

- Curriculum Vitae (CV)
- Unofficial PharmD Transcript
- Cover Letter

3 Letters of Recommendation:

- Highly encouraged to submit by **October 31, 2024**
- Official Deadline: **November 22, 2024**
- Email: PharmDFellowships@northeastern.edu
- Letter writers should submit one letter per candidate and indicate the companies of interest in the subject or body of the email

ADDRESS YOUR COVER LETTER AND 3 LETTERS OF RECOMMENDATION TO:

J. Andrew Orr-Skirvin, PharmD, BCOP
Clinical Professor, School of Pharmacy
Chair, Department of Pharmacy & Health System Sciences
Director of Pharmaceutical Industry Fellowship Program
360 Huntington Ave, 140TF R218
Boston, MA 02115

For more information and fellowship resources:

Visit: a27p.com

Visit: bouve.northeastern.edu/pharmacy/fellowships

Email: PharmDfellowships@northeastern.edu