







# Alnylam PharmD Fellowship Program

• 2 Alnylam® IN PARTNERSHIP WITH Northeastern University Bouvé College of Health Sciences

# A Message from Alnylam's Leadership

The Alnylam Fellowship Program offers a unique experience that, I believe, is unrivaled in our industry. Alnylam's broad pipeline, continued growth, and open culture allows fellows to take on meaningful projects and roles and explore interests in multiple expertise areas across the company. The opportunities for an Alnylam fellow are limited only by their interests.



The fellowship program is rewarding for Alnylam as well as it allows our organization to develop a pipeline of top talent capable of tackling the complex challenges we face in our mission to bring groundbreaking medicines to patients around the world. We have had a strong track record of recruiting those fellows who complete the program into positions across the company. Seeing our past fellows continue to succeed in various roles within Alnylam, and across the industry, is personally rewarding to me and our preceptors and reflects the breadth of possibilities the Alnylam Fellowship Program offers.

Andrew Slugg, MS, MBA

Senior Vice President, Regulatory Affairs Executive Sponsor of the Alnylam/Northeastern Fellowship Program



# A Message from Alnylam's Fellowship Program Director

Commitment to People, Fiercely Innovative, Purposeful Urgency, Open Culture, and Passion for Excellence. These are Alnylam's core company values, and these qualities are found in everything we do here at Alnylam, including the Alnylam Fellowship Program. This is a truly unique program that provides unparalleled, hands-on experiences that allow a fellow to develop valuable skills that will contribute to their future success in the biotech and pharmaceutical industry.



I have been involved with the Alnylam Fellowship Program for several years now, and every year, I am incredibly impressed with the talent and enthusiasm that each fellow brings to the company. They are valuable assets to Alnylam and are recognized for their significant contributions. As Program Director and mentor to the fellows, I am exceedingly proud of what they have all accomplished and will continue to accomplish in the future.

### Heather Sun, PharmD

Senior Director, Medical Information & Review Alnylam Fellowship Program Director



## **TABLE OF CONTENTS**

About Alnylam	
Company OverviewScience and RNAi Platform	
The Alnylam Fellowship Program	
Fellowship Program Overview  Fellowship Opportunities  US Medical Affairs  Global Medical Information  Global Medical Publications  US Marketing  Global Market Access  Regulatory Affairs  Global Patient Safety and Risk Management  Clinical Development	
Past Fellows	16-18
Northeastern University	
Northeastern Fellowship  Fellow Network/Life in Boston	
Application Information	
Application Process	21



## | Alnylam Pharmaceuticals

### Company Overview

Founded in 2002 by a team of distinguished life sciences leaders, Alnylam's vision is to harness the potential of RNAi therapeutics to transform the lives of people living with diseases for which there are limited or inadequate treatment options. Alnylam led the translation of RNAi to an innovative class of approved and investigational medicines used to treat a wide range of diseases using its powerful, clinically validated approach. In the summer of 2018, Alnylam established a new class of medicines, pioneering

To those who say "impossible, impractical, unrealistic," we say:

#### CHALLENGE ACCEPTED

We are relentless in our pursuit of new treatments. Because patients shouldn't have to wait for hope.

the delivery of RNAi therapeutics to patients through the FDA and EMA approval of ONPATTRO® (patisiran). Alnylam has since had 4 additional products approved with many more in the pipeline. This is just the beginning as we enter into our goals antipated in the "Alnylam P<sup>5</sup>x25" guidance for the advancement and commercialization of RNAi therapeutics. The passionate and dedicated employees at Alnylam look forward to delivering its medicines to patients who need them around the world.

#### AN AWARD WINNING COMPANY RECOGNIZED IN LEADERSHIP AND INNOVATION









WE HAVE BEEN NAMED A TOP PLACE TO WORK 8X IN A ROW

## The Boston Globe

## TOP PLACES TO WORK

2015-2022



"RNAi has been heralded as a major scientific breakthrough that happens once every decade or so."

Phillip Sharp, Ph.D.

Noble Laureate & Founder of Alnylam



# | Alnylam's Science and RNAi Platform

RNAi was first discovered in the purple petunia flower and later translated into worms by biologists Andrew Fire and Craig Mello, marking a major scientific breakthrough while establishing a new frontier in drug development. Alnylam's mission is to build a top-tier biopharmaceutical company founded on RNAi. Rather than treating symptoms, Alnylam's approved and pipeline of investigational therapies work upstream of today's medicines by silencing the messenger RNA (mRNA) that is transcribed into disease-causing or disease-contributing proteins. Through RNAi, patients are treated in a fundamentally new way.

#### **FROM POSSIBILITIES TO PATIENTS**



#### **ABOUT RNAi**



#### **NEW CLASS OF MEDICINES**



#### ALNYLAM CLINICAL DEVELOPMENT PIPELINE

#### Focused in 4 Strategic Therapeutic Areas (STArs):

Genetic Medicines	Cardio-Metabolic Diseas	s Infectious Diseases		CNS/Ocu	CNS/Ocular Diseases	
		EARLY/MID STAGE (IND or CTA Filed-Phase 2)	LATE STAGE (Phase 2-Phase 3)	REGISTRATION/ COMMERCIAL <sup>2</sup> (OLE/Phase 4/IIS/registries)	COMMERCIAL RIGHTS	
ONPATTRO® (patisiran) <sup>3</sup>	hATTR Amyloidosis-PN			•	Global	
AMVUTTRA® (vutrisiran)⁴	hATTR Amyloidosis-PN				Global	
GIVLAARI® (givosiran)5	Acute Hepatic Porphyria			•	Global	
OXLUMO® (lumasiran)6	Primary Hyperoxaluria Type 1			•	Global	
Leqvio® (inclisiran) <sup>7</sup>	Hypercholesterolemia			•	Milestones & up to 20% Royalties <sup>8</sup>	
Patisiran	ATTR Amyloidosis-CM Label Expansion			•	Global	
Vutrisiran	ATTR Amyloidosis-CM		•		Global	
Fitusiran	Hemophilia				15-30% Royalties	
Cemdisiran (+/- Pozelimab) <sup>9</sup>	Complement-Mediated Diseases		•		Global Milestone/Royalty	
ALN-TTRsc04	ATTR Amyloidosis				Global	
Belcesiran <sup>10</sup>	Alpha-1 Liver Disease				Ex-U.S. option post-Phase 3	
ALN-HBV02 (VIR-2218) <sup>11</sup>	Hepatitis B Virus Infection	•			50-50 option post-Phase 2	
Zilebesiran (ALN-AGT)	Hypertension	•			U.S. 50-50; Ex-U.S. Royalties	
ALN-HSD <sup>12</sup>	NASH				Royalty	
ALN-APP	Alzheimer's Disease; Cerebral Amyloid Angiopathy	•			50-50	
ALN-PNP	NASH	•			50-50	
ALN-KHK	Type 2 Diabetes	•			Global	

POC, proof of concept - defined as having demonstrated target gene knockdown and/or additional evidence of activity in clinical studies

As of August 2023



Includes marketing application submissions
Approved in the U.S. and Canada for the polyneuropathy (PN) of hATTR amyloidosis in adults, and in the EU, Japan and other countries for the treatment of hATTR amyloidosis in adults with stage 1 or stage 2 PN

Approved in the U.S. for the polyneuropathy (PN) of hATTR amyloidosis in adults, and in the EU and Japan for the treatment of hATTR amyloidosis with stage 1 or 2 polyneuropathy

Approved in the U.S., Brazil and Canada for the treatment of adults with acute hepatic porphyria (AHP), and in the EU and Japan for the treatment of AHP in adults and adolescents aged 12 years and older

Approved in the U.S. for the treatment of primary hyperoxaluria type 1 to lower urinary and plasma oxalate levels in children and adults, and in the EU and Brazil for the treatment of primary hyperoxaluria

type 1 in all age groups Novartis has obtained global rights to develop, manufacture and commercialize inclisirar

<sup>\*50%</sup> of inclisiran royalty revenue from Novartis will be payable to Blackstone by Alnylam
Alnylam and Regeneron are evaluating potential combinations of the investigational therapeutics cemdisiran and pozelimab

Novo Norodisk is leading and funding development of Belcesiran
 Vir is leading and funding development of ALN-HBVO2
 Regeneron is leading and funding development of ALN-HSD

## | Fellowship Program

#### Overview

In 2015, Alnylam Pharmaceuticals partnered with Northeastern University to offer a unique fellowship opportunity in the heart of Boston. The program set out to equip postdoctoral PharmDs with the skills necessary to develop the advanced medicines of the future, like RNAi. The goal was and remains the same: to cultivate the future leaders of biotechnology and allow fellows to pioneer new therapies for patients. Alnylam fellows are grounded in their core expertise area but utilize the fellowship's flexibility to branch out and discover other opportunities throughout the organization. Part of the backbone of the fellowship program is the Northeastern University teaching opportunities which allow fellows to share their knowledge in an educational setting.

#### WHAT SETS THE ALNYLAM/NORTHEASTERN FELLOWSHIP APART?

- 1. Ability to work in multiple therapeutic areas across pre-commercial, launch, and post-approval activities
- 2. Vested interest and individualized mentoring from leading professionals in their field
- 3. Opportunities to engage in immersive, personalized experiences inside and out of one's expertise area
- 4. Ability to conduct academic research aligned with your interests under the mentorship of engaged Northeastern faculty members
- 5. Located in the heart of the world's biotech hub, Cambridge, MA



Heather Sun, PharmD

Alnylam Fellowship Program

Director & Senior Director, Medical
Information & Review



Jenny A. Van Amburgh, BS, PharmD, RPh, FAPhA, FNAP, BCACP, CDCES Northeastern Faculty Fellowship Manager



**Michael Gonyeau, PharmD, MEd, RPh** Northeastern Faculty Fellowship Manager

## **US Medical Affairs**

#### **ACTIVELY RECRUITING: 1 FELLOW**

US Medical Affairs translates and implements the disease and product strategy set at the global level and adapts it to the US healthcare landscape. US Medical works within a cross-functional and strategic matrix team building

#### **ROTATIONAL OPPORTUNITIES**

- Field Medical
- Medical Outcomes Science Liaison/ Health System Directors Support
- Medical Publications
- Value and Evidence Strategy/HEOR
- US Medical Operations

tactical alignment with internal partners (Clinical Operations, Commercial, Legal, Regulatory, Compliance, Global Medical Excellence, Publications, Patient Advocacy) and delivers on the medical plan. With a deep understanding of the treatment landscape, disease landscape and provider mindset, US Medical directors play a key role in informing global product development and data generation strategies with perspective of US Region. The team also provides disease and product education to both internal stakeholders (Commercial, sales, new employees) as well as the external healthcare community. Field medical teams within US Medical engage in scientific discussions with both HCPs and payers to collect and disseminate evolving insights on the external treatment landscape, Alnylam's clinical trial programs, and Alnylam data to inform Alnylam strategy.

The US Medical Fellow will support the development and pull through of scientific presentations to support upcoming launch activities. The fellow will also have a chance to shadow MSLs and understand the principles of engagement with HCPs, gathering insights and leading scientific discussions. Working closely with the Senior Medical Director of US Medical, the Fellow will have the opportunity to develop, lead, and implement projects to support medical excellence and value metrics across the whole department.

#### **ROLES AND RESPONSIBILITIES**

- Contribute to the tactical planning and execution of US Medical Affairs plans
- Understand patient pathways, care gaps, and HCP education needs in different US geographies and support development of regional field medical plans across specified rare and TTR disease areas and programs
- Support the medical plan for the ongoing evolution of Alnylam and its products (patisiran and vutrisiran) in the ATTR amyloidosis space
- Support the development and/or pull-through of US-specific medical communications, publications, and training of materials including slide decks, infographics, abstracts, digital assets, posters, and articles
- Support, as needed, other key US-specific Medical Affairs projects or initiatives
- Develop other new opportunities within Medical Affairs to expand to additional experiences tailored to your career goals



#### Why did you choose Alnylam?

"During pharmacy school, I realized very early a desire to work "upstream" of 1:1 patient care to broaden my impact in the pharmaceutical sciences. Alnylam's Nobel Prize-winning breakthrough technology of RNAi redefines what it means to work upstream. I am experiencing firsthand how Alnylam is changing the way we treat diseases, from rare, genetic diseases in small patient populations to cardio-metabolic conditions that impact a vast majority of the population. In addition to the revolutionary scientific platform on which Alnylam was founded, I chose Alnylam because it supports the personal and professional wellbeing of its employees. I often reflect on the quote, "If you love what you do, you'll never work a day in your life." Because of Alnylam's steadfast commitment to science, patients, and its employees, it was my top choice for a fellowship."

Rachel Hawley, PharmD, 1st Year US Medical Affairs Fellow

#### What learning opportunities and impact can a US Medical fellow have?

"Alnylam's mission is to harness the potential of RNAi therapeutics to transform the lives of people living with diseases for which there are limited or inadequate treatment options. US medical affairs is a vanguard in forwarding this mission. A fellow deeply embedded within our department will have an incredible opportunity to learn and provide measurable impact. I have personally observed the work of keen past and current fellows directly impacting strategic and tactical decisions and outputs that ultimately translated into improved patient care. Not only does this work provide a profound sense of accomplishment, but these tangible examples can also be pulled-through into a career-launching portfolio."



Steven Roblin, PhD, Preceptor & Senior Medical Director, US TTR Lead

Alnylam

## | Global Medical Information

#### **ACTIVELY RECRUITING: 1 FELLOW**

The Global Medical Information team serves to provide healthcare professionals, patients, and caregivers with balanced, accurate, and current medical information about Alnylam's products. Medical Information engages cross functionally with other expertise areas such as Pharmacovigilance/Safety, Quality, Legal, Regulatory Affairs, Commercial, Clinical Operations, Clinical Development, and Information Technology, to ensure the safe, effective, and appropriate use of our therapies. Fellows

#### **ROTATIONAL OPPORTUNITIES**

- Medical Training
- Medical Communications
- Medical Publications
- Field Medical (e.g. Medical Science Liaisons)
- Medical Operations
- Pharmacovigilance and Safety

in this program will partake in the development and launch of Medical Information services across the globe supporting multiple products. Furthermore, fellows sharpen their ability to read, interpret, and develop medical content accurately and fairly. While helping build the global medical information infrastructure to support Alnylam's robust pipeline, the fellow will learn key project management skills as well.

#### **ROLES AND RESPONSIBILITIES**

- Global management of requests for medical information
- Medical Information content development, including standard response letters, custom response letters, and FAQs
- Adverse event and product quality complaint reporting
- Data analytics and insights collection and reporting
- Global product launch preparation and execution pertaining to medical information activities
- Support of medical congress and information booth



#### What inspires you about Alnylam?

"I am inspired by Alnylam's constant drive to develop groundbreaking medicines for patients by leveraging the potential of RNAi therapeutics. It's exciting to work at a company that has pioneered the use of RNAi to transform the treatment landscape for certain rare diseases and expand its scope to target more prevalent diseases as well."

Charlene Guo, PharmD, 1st Year Global Medical Information Fellow

#### What is something that has surprised you about working at Alnylam?

"What surprised me about working at Alnylam was that, upon starting the fellowship, the fellows become an integral part of the company to help the organization to deliver their ambitions. They are highly valued in their teams and are provided with a wealth of resources and tailored mentorships across the company who guide and support fellows towards successful careers in biopharmaceutical industry. I am very excited to contribute to the advancement and potential launch of transformative medications in both rare and common diseases."



 $\textbf{Hayoung Chang, PharmD, } 2^{\text{nd}} \, \textbf{Year Global Medical Information Fellow}$ 



## How do you believe the fellowship will drive your fellow's future career path and help them achieve their career goals?

"The Global Medical Information Fellow will be fully integrated into the team and have the opportunity to learn the role by gaining real-world experience. Working hands-on with the team, the fellow will develop a strong platform of knowledge and skills that will serve as the basis of their professional career. At the completion of the fellowship, the fellow will be fully prepared to launch into their career path in the pharmaceutical or biotech industry."

Alana McGill, PharmD, RPh, BCGP, Preceptor & Associate Director, Medical Information & Review



## | Global Medical Publications

#### **ACTIVELY RECRUITING: 1 FELLOW**

The core responsibility of Global Medical Affairs at Alnylam is to advance medicines for patients who have limited or inadequate treatment options. Global Medical Publications achieves this through stakeholder engagement and strategic dissemination of data, enabling scientific exchange and ultimately improving the care of patients. Fellows can expect to drive Global Medical Publications strategy through engaging in cross-functional collaborations to advance RNAi therapeutics. This position is ideal for determined and adaptable individuals seeking unique experiences and professional growth within Global Medical Affairs.

#### **ROTATIONAL OPPORTUNITIES**

- Medical Communications
- Medical Strategy
- Medical Information and Review
- Medical Training
- Patient Advocacy
- Value and Evidence Strategy/HEOR

#### **ROLES AND RESPONSIBILITIES**

- Contribute to the tactical planning and execution of global publications plans
- Create medical congress materials, including abstracts, posters, and presentations
- Lead and support the development of peer-reviewed manuscripts
- Engage with key opinion leaders to develop various medical publication deliverables
- Execute scientific communication strategy from development to commercialization
- Opportunities to expand to additional experiences tailored to your career goals



#### Why did you choose Global Medical Publications at Alnylam?

"The Global Medical Publications fellowship at Alnylam provides me with the amazing opportunity to work with a cross-functional team of motivated and talented individuals in a cutting-edge environment. As a fellow, I am excited to contribute to a variety of impactful deliverables as Alnylam's pipeline continues to grow and the company pushes the boundaries of RNAi."

Alba Ilia, PharmD, RPh, 1st Year Global Medical Publications Fellow

#### What excites you about Alnylam's pipeline?

"At the forefront of RNAi, Alnylam has made its mark by developing innovative medicines for rare and even ultra-rare diseases. I'm excited to be involved in this work as we continue to expand indications and increase treatment options for patients. Beyond this, Alnylam's ventures into more prevalent disease states allows for the potential to leverage its novel RNAi platform towards impacting a significantly greater number of patients."



Bhavna Jois, PharmD, MS, Medical Communications & Publications Manager & Fellowship Alumnus 2021-23



#### What does being a mentor mean to you?

"I've devoted my career to science and to educating healthcare professionals as well as those interested in the pharmaceutical industry. As a mentor, I develop trusted relationships with individuals, help guide their journey, and act as an advisor and sounding board for new ideas. In this manner, I support fellows to make important decisions that will define their career path."

Thierry Aupérin, PhD, Preceptor & Vice President, Medical Communications and Training



# | US Marketing

#### **ACTIVELY RECRUITING: 1 FELLOW**

#### **ROTATIONAL OPPORTUNITIES**

- Commercial Operations
- Market Insights
- Market Access
- Launch Excellence

US marketing strategy for Alnylam's RNAi therapeutics. Marketing achieves this through cross-functional collaboration with Medical Affairs, Regulatory Affairs, Clinical Development, and others. The US Marketing Fellow will engage in the development and execution of strategic brand plans and key marketing initiatives, product launches, and the generation of commercial insights. This fellowship is for individuals who are entrepreneurial, biased for action, and enjoy working in a dynamic business environment. The fellow will gain key experiences and skills in communication, commercial execution, marketing and strategic planning.

#### **ROLES AND RESPONSIBILITIES**

- Execution of personal promotion and targeted non-personal promotion tactics
- Creation of product value messaging and disease awareness materials to support field personnel
- Development of strategic and tactical plans for the Alnylam TTR franchise

The US Marketing team is responsible for developing and executing the

- Cross-functional collaboration with Patient Services, Data & Analytics, Market Insights, Competitive Intelligence, and US commercial field teams to support launch activities
- Commercial activities at key conferences, including booth development, product theaters, and sponsorships
- Assessment of commercial opportunity and strategic fit of early pipeline assets including market sizing, competitive landscape scanning, target product concept development, and revenue forecasts



#### What is the environment like in the office?

"My team fostered a welcoming and supportive environment right at the start of my fellowship where I was encouraged to ask questions, seek guidance, and collaborate with more experienced individuals. The willingness of my team members to share their knowledge and expertise not only accelerated my learning, but also instilled a sense of confidence and belonging. Through weekly meetings and one-on-one mentorship, I felt empowered to contribute my ideas and perspectives. My time with this exceptional team inspires me to embrace a more innovative mindset and challenges me to think outside the box to deliver RNAi therapeutics to patients."

Andrew Do, PharmD, 1st Year US Marketing Fellow

#### How has the Alnylam fellowship helped you grow and succeed?

"I've been in involved in a multitude of projects across the US TTR franchise including patient marketing, HCP marketing, digital marketing, and launch experience. Further along my first year, the team entrusted me to lead several initiatives, which helped push me beyond my comfort zone. Moving into my second year, I feel more confident in the projects I lead, and have learned to dive in and take initiative when working with our cross-functional partners. Overall, my experiences at Alnylam will serve as a strong foundation as I prepare for a full-time role."



Faith Goan, PharmD, 2<sup>nd</sup> Year US Marketing Fellow



#### What learning opportunities will the US Marketing fellow have?

"The next US Marketing fellow will be joining the company at a very exciting time – our TTR and rare disease franchises continue to grow with data read-outs and potential launches in the years to come. This growth presents various opportunities across the marketing continuum, including digital marketing projects (websites, social), personal promotion (developing materials for field teams to use in 1:1 interactions), disease awareness initiatives, direct-to-consumer marketing, and more. Throughout the two-year program, fellows will have the chance to immerse themselves in all aspects of marketing. This comprehensive experience will offer valuable insights into the dynamic world of marketing."

Christina Zhao, PharmD, Preceptor & Senior Director, US TTR Marketing



## | Global Market Access

#### **NOT RECRUITING 2024-2026**

The purpose of the Global Market Access (GMA) team at Alnylam is to lead the development of the overall access strategy and pricing philosophy for inline and pipeline products across the company's portfolio through cross-

#### **ROTATIONAL OPPORTUNITIES**

- Value and Evidence Strategy/ HEOR
- New Product Commercialization
- US Commercial
- International / Regional Affiliates

functional collaboration with New Product Commercialization, Value and Evidence Strategy (VESt), US / International / Partner and Emerging Markets, Clinical Development, Regulatory, Market Insights, and other expertise areas. GMA's goal is to ensure excellence in getting approved medicines broadly reimbursed and into patients' hands. The fellow will develop a thorough understanding of and gain hands-on experience in working with and communicating the value of our products to payers on the global and local levels, navigating national / regional pricing and reimbursement processes across all major markets and developing sustainable pricing models, including pioneering new and innovative ways such as financial, performance- and outcomesbased models to ensure patient access to our medicines. The experience gained throughout this fellowship will allow the GMA fellow to develop a deep understanding of global market strategy from Phase 1 through perilaunch, commercialization, and beyond.

#### **ROLES AND RESPONSIBILITIES**

- Support Global Market Access leads, regions and key markets (US, EU, UK, Japan and Brazil), in developing and executing on strategic pricing and market access strategy for inline and pipeline assets
- Contribute to the development of strategic pricing and value framework decisions for ultra-rare, specialty and prevalent disease assets through highly integrated global, regional and local commercial teams
- Work with regional partners to monitor global pricing and market access trends and pricing decisions across countries to ensure alignment with global pricing strategy and identify opportunities for novel payer engagement
- Lead a Global Market Access product sub-team and participate in cross-functional working groups



#### Why did you choose Market Access at Alnylam?

"When I was applying to fellowships, I exclusively chose programs that were highly focused on global market access. Alnylam has provided me the opportunity to explore different parts of access across the globe, while simultaneously exposing me to all assets from Phase 1 through our launched products. Being the first fellow in the broader Global Commercial Organization has allowed me to shape the fellowship to my interests, while holistically developing me as a professional."

**Jung Seo, PharmD,** 1<sup>st</sup> Year Global Market Access Fellow

#### What learning opportunities will the Global Market Access fellow have?

"This program will provide an opportunity to work closely with a broad swath of cross-functional colleagues, from New Product Commercialization, to our International and Regional affiliates and beyond and gain a deep understanding of the demands and needs of payers across the world. While on the surface this may sound daunting, my goal is for the fellow to learn a framework in which to assess and communicate the value of new pharmaceutical products in this complex and ever changing healthcare landscape and ultimately walk away as the go-to country access expert. The fellow will get hands on experience working closely with global public and private payers and health systems, developing access and pricing strategies, testing new asset business cases, and obtain familiarity with all of Alnylam's assets, from Phase 1 through our launched products."

Steven Sligh, PharmD, MBA, Preceptor & Associate Director, Global Market Access



# | Regulatory Affairs

#### **NOT RECRUITING 2024-2026**

Regulatory Affairs at Alnylam is a group with diverse scientific, technical, and clinical expertise. The team is responsible for creating and implementing innovative global strategies for expedited drug development and approval of Alnylam's products. All stages of drug development are dependent on

#### **ROTATIONAL OPPORTUNITIES**

- Global Regulatory Affairs Strategy
- Advertising and Promotional Review
- Global Labeling Strategy
- Chemistry, Manufacturing, and Controls

effective regulatory support and management, including the generation and filing of investigational new drug applications, clinical trial applications, and marketing applications, continuing throughout Alnylam's product life-cycle.

#### **ROLES AND RESPONSIBILITIES**

- Support, prepare, and submit a wide range of regulatory filings such as investigational new drug applications, new drug applications, international marketing authorization applications, and clinical trial applications
- Collaborate with Clinical, Commercial, and Medical teams in US and EU to achieve regulatory milestones and support new product launches
- Conduct guidance and precedent research to support regulatory strategy and regulatory chemistry, manufacturing, & controls (CMC)
- Actively participate in creation and implementation of product prescribing information
- Support the development and maintenance of regional labeling and advertising & promotion across programs



#### How is the Alnylam Fellowship unique from your perspective?

"The Alnylam Fellowship enables fellows to partake in impactful projects and experiences, while also fostering meaningful relationships within and outside your expertise area. At Alnylam, fellows have the opportunity to work with RNAi therapeutics, providing an exciting perspective that help elevate one's career in the biopharmaceutical industry. All of these factors show how truly unparalleled the Alnylam Fellowship is."

Allison Kotas, PharmD, 1st Year Regulatory Affairs Fellow

#### What inspires you about Alnylam?

"Alnylam's commitment to develop top-tier solutions to improve patient's lives is what inspires me. As a company with a wide variety of pipeline products utilizing RNAi technology, there's an opportunity to be exposed to various innovative technologies and creative regulatory processes. Alnylam's dedication to transforming the lives of patients impacted by debilitating diseases is demonstrated by the P<sup>5</sup>x25 strategy plan of marketing 6 products by 2025. I believe Alnylam's willingness to accept challenges will provide me with an unmatched experience that will propel my career towards success."



Katrina Tate, PharmD, MBA, 2<sup>nd</sup> Year Regulatory Affairs Fellow



#### What characteristics do you believe define an Alnylam fellow?

"One is 'insatiable curiosity'. This characteristic emanates throughout Alnylam and has helped the company make many scientific breakthroughs for patients. An Alnylam fellow should be insatiably curious about drug development, innovative science, and how all of this comes together in our submissions and interactions with Health Agencies. Another is being 'team oriented'. One of our core values is Commitment to People, including the diverse set of team members we work with daily from across different expertise areas. Drug development is a highly collaborative endeavor, and an Alnylam fellow will need to engage globally. This will provide skills and experiences to help in any career path they choose."

Andrew Slugg, MS, MBA, Preceptor & Senior Vice President, Regulatory Affairs



# | Global Patient Safety and Risk Management

#### **ACTIVELY RECRUITING: 1 FELLOW**

Global Patient Safety and Risk Management (GPSRM) oversees all activities related to the detection, assessment, understanding, and prevention of

ROTATIONAL OPPORTUNITIES

- PV Science
- Safety Operations
- Safety in Clinical Development
- Safety in Post Marketing
- Global Medical Information
- Clinical Development
- Regulatory Affairs

adverse effects or other medicine-related safety concerns to ensure safe use of medicines and to safeguard health of patients. The fellow can expect to gain a thorough understanding of pharmacovigilance (PV) activities and actively participate in the development and maintenance of the drug safety profiles for our revolutionary RNAi platform.

#### **ROLES AND RESPONSIBILITIES**

- Provide scientific and strategic assistance to safety product leads to support Alnylam products
- Participate in the collection, interpretation, and presentation of safety data in internal forums
- Support signal detection and management activities with lead safety physicians and PV scientists
- Engage in safety data review, analysis, and reporting of safety data to internal and external stakeholders by planning, managing, and authoring safety aggregate reports (PBRERs, DSURs)
- Participate in the development and management of Risk Management Plans



#### What makes Alnylam stand out to you?

"Alnylam's commitment to its patients and employees is what stands out to me. Bringing 5 products to market in 4 years with a new drug class targeting patients with limited treatment options is a testament to their innovation and dedication to improving human health. Alnylam's inclusive work culture creates an environment that inspires its employees and creates endless opportunities for growth and learning."

Nina Teo, PharmD, 1st Year Global Patient Safety & Risk Management Fellow

#### Why did you choose Alnylam?

"I chose Alnylam because I was eager for a well-rounded PV experience that would translate across disease states. This program will expose you to all Alnylam products at a variety of life cycle stages and through multiple functional area perspectives. PV science really is a process with core principles; the GPSRM team here genuinely works to build that foundation in an exciting, dynamic way."



Amira Yusuf, PharmD, 2nd Year Global Patient Safety & Risk Management Fellow



#### What is the commitment to professional development at Alnylam?

"At Alnylam, we are driven by a desire and passion to do work that matters. The GPSRM group works to ensure that the safety profiles of all products are continually monitored and assessed. Through the Fellowship Program, we enable professional development and offer the opportunity to apply clinical knowledge in an industry setting to ensure that the right patients are receiving the right therapies."

 $\textbf{Lois\,Ahn, PharmD,} \ \mathsf{Preceptor\,\&\,Associate\,Director,} \ \mathsf{Pharmacovigilance\,Science}$ 

#### What learning opportunities will the GPSRM fellow have?

"This program provides an opportunity to work closely with safety physicians and PV scientists in collaboration with other departments. The GPSRM Fellow will be exposed to the broad spectrum of PV activities that span over a product's lifecycle and will gain skills on signal detection, risk management, and other crucial aspects of patients' safety in clinical trials as well as the post-marketing area."

Elena Yureneva, MD, MHA, Preceptor & Executive Director, Head of Medical Safety and Risk Management



## | Clinical Development

#### **ACTIVELY RECRUITING: 1 FELLOW**

Clinical Development is the cornerstone of data generation in delivering novel medicines to patients. The Clinical Development fellowship at Alnylam will engage the fellow in work that is a fusion of scientific knowledge and operations of trial management to support clinical trial excellence. The fellow

#### **ROTATIONAL OPPORTUNITIES**

- Regulatory Affairs
- Patient Recruitment & Retention
- Clinical Oversight and Systems
- Data Science & Statistics
- Pharmacovigilance/Patient Safety
- Pharmacokinetics/ Pharmacodynamics

will work in Clinical Operations and collaborate closely with Clinical Research, while also working alongside other expertise areas involved in the day-to-day of the trials. The intent of this program is to train fellows in comprehensive Clinical Development activities to build a foundation for roles as a clinical drug developer.

#### **ROLES AND RESPONSIBILITIES**

- Operational, technical, and scientific aspects of generating clinical development plans and clinical trial execution from startup through closeout, including management of contract research organizations (CROs) and vendors
- Development of key study documents, including protocol concepts and protocols (Phase I-III, natural history), data capture tools such as case report forms, procedure manuals, study operation plans, informed consent forms, clinical study reports, and IND/NDA submission documents
- Engagement in ongoing medical data review, analysis, and reporting of clinical information in materials for sites, investigators, and other stakeholders
- Planning and execution of investigator meetings and congresses to provide key messages about clinical trial data and study execution
- Participate in the development of effective working relationships with key investigators to optimize scientific quality/innovation of clinical study design, execution, reporting, and publication
- Process evaluation to ensure that all studies are conducted with the highest level of ethical and safety standards and in compliance with ICH/GCP guidelines and all applicable regulatory policies



#### How do you believe this fellowship will drive the fellow's career path?

"Becoming an expert in your role requires more than understanding how your part of the process works, but rather, how it interacts with all the surrounding parts. For example, this fellowship provided excellent opportunities to work on both early and late-stage projects and to collaborate closely with Medical Affairs, Medical Writing, Regulatory, and Finance. Getting this breadth of experience early in one's career opens many opportunities going forward."

Ben Waddell, PharmD, Clinical Trial Manager & Fellowship Alumnus 2021-23

#### What characteristics do you believe define an Alnylam Fellow?

"Work in clinical development is multi-faceted, requiring an Alnylam fellow to be comfortable and familiar with the research and business side of clinical trials. Two characteristics that really define an Alnylam fellow are a passion for learning and a commitment to people, one of Alnylam's key core values. This refers to the patients, who are at the heart of everything we do and also our team members across the many functions within Alnylam, that we work with on a daily basis. Individuals need to be highly collaborative and able to converse and liaise with key opinion leaders and external business partners, which requires strong communication and influencing skills. This unique opportunity offers an invaluable experience and insight into the drug development process and the career paths available."



Elisa Prior, Preceptor & Director, Clinical Operations



## | Past Fellows

The Alnylam Fellowship Program is proud to be able to watch our fellowship alumni continue their professional development in key roles within the industry. The experiences and skills they gained during their fellowship tenure have become a launching pad for continued success and learning.



Alex Wei, PharmD 2015-2017 Medical Affairs Fellow Current Role: Regional Director, MSLs at Blueprint Medicines



Dayna LeSueur, PharmD
2016-2018 Regulatory Affairs Fellow
Current Role: Associate Director,
Regulatory Affairs at Verve Therapeutics



Anastasia McManus, PharmD, RPh 2016-2018 Medical Affairs Fellow Current Role: Director, US Medical Communications at Takeda



Ruthvik Malladi, PharmD 2017-2019 Medical Affairs Fellow Current Role: Senior MSL at Blueprint Medicines



Madeline Merkel, PharmD
2017-2019 Value and Evidence
Strategy Fellow
Current Role: Associate Director, MSL
at Alnylam



Sarah Scott, PharmD 2017-2019 Regulatory Affairs Fellow Current Role: Regulatory Affairs at Immunovant



Caitlin Skenyon, PharmD, RPh 2018-2020 Regulatory Affairs Fellow Current Role: Senior Manager, Regulatory Affairs at Alnylam



Jit Sheth, PharmD, RPh 2018-2020 Medical Affairs Fellow Current Role: Regional Medical Director at Horizon Therapeutics



Stephen Meninger, PharmD, MS, MBA 2018-2020 Value & Evidence Strategy Fellow Current Role: Associate Director, Medical Outcomes Science Liaison at Alnylam



Ralph Reyes, PharmD, RPh 2018-2020 Medical Information Fellow Current Role: Associate Director, MSL at Alnylam



Jessica Baldwin, PharmD
2019-2021 Value and Evidence Strategy
Fellow
Current Role: Senior Manager, Global
Health Economics and Outcomes
Research at Vertex



Katie Alfond, PharmD
2019-2021 Medical Affairs Fellow
Current Role: Associate Director,
Scientific Communications at Sarepta
Therapeutics



## | Past Fellows (cont.)



Farida Azizova-Such, PharmD, RPh 2019-2021 Regulatory Affairs Fellow Current Role: Associate Director, Regulatory Affairs at Argenx



May Le, PharmD 2019-2021 Medical Information Fellow Current Role: Senior Manager, Medical Information at Alnylam



Joshua Emerson, PharmD, RPh 2019-2021 Clinical Development Fellow Current Role: Associate Director, Senior Clinical Scientist at Bristol Myers Squibb



David long, PharmD
2019-2021 US Marketing Fellow
Current Role: Senior Product Manager,
Marketing at Ipsen



Caitlin Albrecht, PharmD 2020-2022 Regulatory Affairs Fellow Current Role: Associate Director, Regulatory Affairs at IDRx



Andrew Karaki, PharmD 2020-2022 Marketing Fellow Current Role: Senior Manager, US Marketing at Alnylam



Lauren Elfman, PharmD 2020-2022 Medical Publications Fellow Current Role: Associate Director, Scientific Communications at Ionis



Siddharth Jain, PharmD
2020-2022 Value and Evidence
Strategy Fellow
Current Role: Senior Manager, Health
Economics and Outcomes Research



Basia Reed, PharmD, RPh 2020-2022 Medical Information Fellow Current Role: Manager, Medical Information at Alnylam



Thomas Solomon, PharmD, RPh 2020-2022 Clinical Development Fellow Current Role: Clinical Scientist at Bristol Myers Squibb



Andres Bermudez, PharmD 2021-2023 Regulatory Affairs Fellow Current Role: Manager, Regulatory Affairs at Alnylam



Bhavna Jois, PharmD, MS 2021-2023 Medical Publications Fellow Current Role: Manager, Medical Communications and Publications at Alnylam



# | Past Fellows (cont.)



Henry Wu, PharmD, RPh 2021-2023 Medical Information Fellow Current Role: Manager, Medical Information and Review at Takeda



Jake Kohley, PharmD 2021-2023 Marketing Fellow Current Role: Manager, US Marketing at Alnylam



Ben Waddell, PharmD
2021-2023 Clinical Development Fellow
Current Role: Clinical Trial Manager
at Alnylam



Thao Luu, PharmD 2022-2024 Medical Publications Fellow Current Role: Senior Manager, Medical Publications at Deciphera

Northeastern University is a global, experiential, research university built on a tradition of engagement with the world, creating a distinctive approach to education and research. At Northeastern, students are encouraged to become engaged, confident, and resourceful global citizens who realize their knowledge and actions have a farreaching impact.

The Northeastern University Pharmaceutical Industry Fellowship Program provides a dynamic academic environment offering fellows the opportunity for a wide breadth of experiences, such as:

- Developing teaching skills through participation in our Teaching and Learning Seminar series
- Facilitate small and large group didactic education in partnership with a faculty mentors
- Utilize a layered learning model in experiential education by co-precepting students on pharmacy practice experiences including Northeastern's unique co-op program
- 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



Andrew Orr-Skirvin Clinical Professor Fellowship Program Director



Jason Lancaster Clinical Professor Fellowship Faculty Manager



Debra Copeland Clinical Professor Fellowship Faculty Manager



Sherisse Mayala-Nelson Fellowship Program Manager



Michael Gonyeau Clinical Professor Fellowship Faculty Manager



Sophia Sawtelle Fellowship Program Coordinator



Jenny Van Amburgh Clinical Professor Interim Fellowship Faculty Manager

#### INDUSTRY PARTNERS OF THE NORTHESTERN UNIVERSITY FELLOWSHIP PROGRAM





































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.

#### Life in Boston

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.







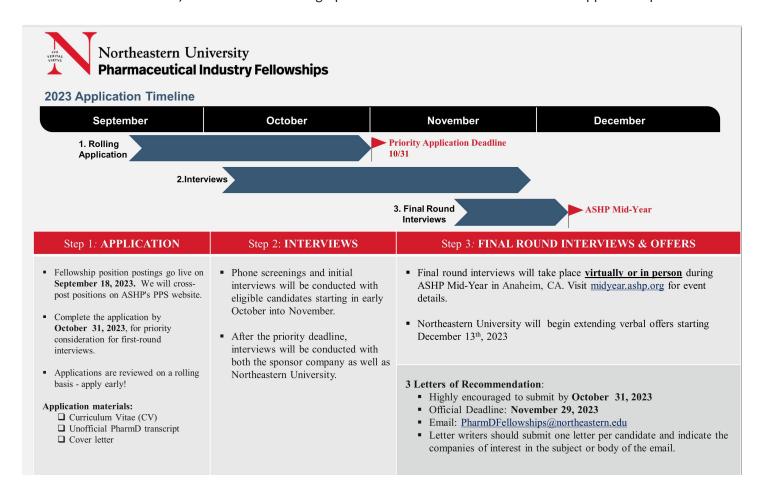


# **Application Process**

### Launch your post-graduate career. Apply Now!

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, 2024.

Candidates must apply through Northeastern's career portal and are encouraged to do so by the priority application deadline of **October 31st, 2023**. Please see the graphic below for more information on the application process.



#### Questions?

#### For more information and to apply:

Visit: bouve.northeastern.edu/pharmacy/fellowships

Email: PharmDfellowships@northeastern.edu

#### Address your cover letter and three letters of recommendation to:

J. Andrew Orr-Skirvin, Pharm.D., BCOP

Clinical Professor & Chair, Department of Pharmacy & Health System Sciences

Bouvé College of Health Sciences

360 Huntington Ave; 140 The Fenway, R218

Boston, MA 02115

Send letters of recommendation to PharmDFellowships@northeastern.edu