

MEDICAL AFFAIRS FELLOWSHIP PROGRAM

One Two-Year Global Medical Affairs Position 2024-2025



In partnership with

RUTGERS

Institute for Pharmaceutical Industry Fellowships

A Word From Our Executive Sponsors

The Exelixis Medical Affairs Fellowship Program provides an opportunity for a fellow to become immersed in strategy and tactical execution of deliverables critical to achieving our patient-focused corporate mission. Our fellow will work alongside experienced professionals within the various Medical Affairs subfunctions and will gain exposure to critical cross-functional collaborations across the organization. My colleagues and I are excited to play an important role in helping the fellow establish a strong foundation for launching a rewarding career within the biotech/ pharmaceutical industry.

— Sandra Wiejowski, Pharm.D.
 Executive Sponsor
 Vice President, Medical Affairs—Information

The Exelixis Medical Affairs field team is proud to bring our cutting-edge science to our oncology community with an overall mission of helping patients recover stronger and live longer.
Renee Schmutte, RN, MSN, NP Executive Spansor

Executive Sponsor Vice President, MSL Team & Training



About Exelixis

A History of Science and Discovery Exelixis is on a mission to help cancer patients recover stronger and live longer

Exelixis is a globally ambitious oncology company innovating next-generation medicines and regimens at the forefront of cancer care. Powered by bicoastal centers of discovery and development excellence, we are rapidly evolving our product portfolio to target an expanding range of tumor types and indications with our clinically differentiated pipeline of small molecules, antibody-drug conjugates, and other biotherapeutics.

Our discovery efforts have resulted in over 100 clinical trials across 4 commercially available products.* We have entered partnerships with leading pharmaceutical companies to bring these important medicines to patients worldwide.

*Includes trials sponsored by collaborations with the National Cancer Institute's Cancer Therapy Evaluation Program, the European Organization for Research and Treatment of Cancer (EORTC), investigator sponsored trials, and those conducted by our pharmaceutical partners.



HISTORY OF RESEARCH

3

About Exelixis



Our Mission, Core Values, and Credo

Exelixis is on a mission to help cancer patients recover stronger and live longer

Our Values

5557
~~~

← o →

## Be Exceptional

Take the right action and lead others to do the right thing at the right time in the right way

### **Excel for Patients**

Innovate to design solutions and remove barriers to show how much we care

#### Exceed Together

Apply rigor, resourcefulness, and respect to maximize opportunities and deliver impactful results



We drive for results, so patients can survive and thrive. We are resilient in the face of adversity and tireless in advancing our science. We celebrate our long history of prolific drug discovery and rigorous drug development. We unite to launch innovative medicines for difficult-to-treat cancers. We exist to give people hope—one drug, one patient at a time.

## We are Exelixis.



# **About Exelixis**

## **Medical Affairs Vision**

# Purpose: Improve patient outcomes through scientific innovation, education, communication, and research

#### Mission

- Be recognized as an expert resource for medical and scientific knowledge of Exelixis products and associated disease states
- Harness insights from the clinical community and provide actionable recommendations to the organization
- Expand strategic and tactical publication capabilities to maximize the impact of our research
- Maximize our external research programs to advance our pipeline, leading to the potential approval of multiple new indications
- Assure a collaborative, intellectual, entrepreneurial, and fun environment that fosters team and individual growth

#### Strategy

- We fulfill our vision by delivering high-quality results while maintaining highly collaborative relationships with our teammates, colleagues, partners, and vendors
- We build and enhance organizational processes, technologies, and systems that will enable us to be more efficient and scale commensurate with our growth
- We anticipate change and implement a dynamic and strategic response plan
- Our values guide us in all that we do to improve the lives of patients living with cancer







## **Exelixis Markets Two FDA-Approved Products**

## CABOMETYX[®] (cabozantinib tablets) is indicated for the treatment of¹

- Patients with advanced renal cell carcinoma (RCC)
- Patients with advanced RCC, as a first-line treatment in combination with nivolumab
- Patients with hepatocellular carcinoma who have been previously treated with sorafenib
- Adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible

Please see full Prescribing Information available at cabometyx.com

#### Single agent:

#### Warnings and precautions:

hemorrhage, perforations and fistulas, thrombotic events, hypertension and hypertensive crisis, diarrhea, PPE, proteinuria, ONJ, impaired wound healing, RPLS, thyroid dysfunction, hypocalcemia, and embryo-fetal toxicity.

## In combination with nivolumab:

#### Warnings and precautions:

hemorrhage, perforations and fistulas, thrombotic events, hypertension and hypertensive crisis, diarrhea, PPE, hepatotoxicity, adrenal insufficiency, proteinuria, ONJ, impaired wound healing, RPLS, thyroid dysfunction, hypocalcemia, and embryo-fetal toxicity.

#### Most common (≥20%) adverse reactions:

diarrhea, fatigue, PPE, decreased appetite, hypertension, nausea, vomiting, weight decreased, and constipation.

#### Most common (≥20%) adverse reactions:

diarrhea, fatigue, hepatotoxicity, PPE, stomatitis, rash, hypertension, hypothyroidism, musculoskeletal pain, decreased appetite, nausea, dysgeusia, abdominal pain, cough, and upper respiratory tract infection.

## **COMETRIQ[®]** (cabozantinib capsules) is indicated for the treatment of²

 Patients with progressive, metastatic medullary thyroid cancer

Please see full Prescribing Information available at cometriq.com

#### Warnings and precautions:

perforations and fistulas, hemorrhage, thrombotic events, impaired wound healing, hypertension and hypertensive crisis, ONJ, diarrhea, PPE, proteinuria, RPLS, and embryo-fetal toxicity.

#### Most common adverse reactions (≥25%):

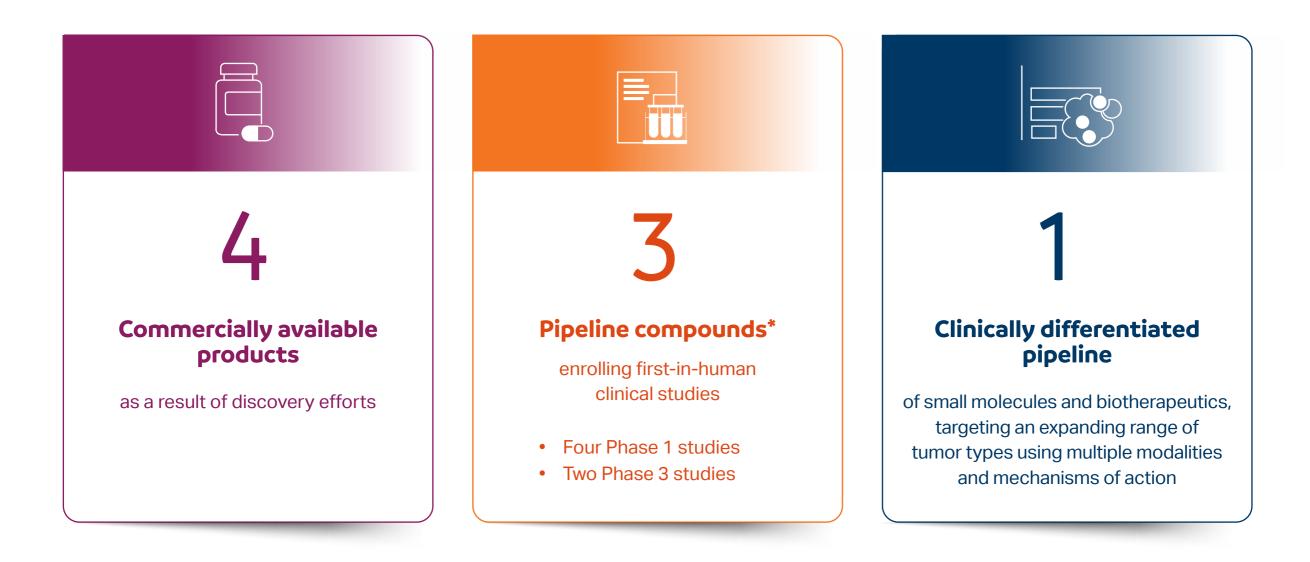
diarrhea, stomatitis, PPE, decreased weight, decreased appetite, nausea, fatigue, oral pain, hair color changes, dysgeusia, hypertension, abdominal pain, and constipation.

ONJ = osteonecrosis of the jaw; PPE = palmar-plantar erythrodysesthesia; RPLS = reversible posterior leukoencephalopathy syndrome. **1.** CABOMETYX[®] (cabozantinib) [prescribing information]. Alameda, CA: Exelixis Inc; 2022. **2.** COMETRIQ[®] (cabozantinib) [prescribing information]. Alameda, CA: Exelixis, Inc.; 2020.





## **Expansive Research Program**



*Not included are two partner programs: 1) CBX-12 (Cybrexa Therapeutics), currently enrolling a Phase 1 study, and 2) ADU-1805 (Sairopa), which recently cleared IND application.





## **Robust Pipeline Beyond Cabozantinib**

Exelixis has a diverse pipeline of small molecules and biologics that cover a broad range of targets and therapeutic modalities.

We recently expanded the development program for our next-generation oral tyrosine kinase inhibitor, XL092, and enrollment has been ongoing for our Phase 1 studies with XB002 and XL102.

Program Name	Mechanism	Discovery / Preclinical	IND	Phase 1a	Phase 1b	Phase 2 / 3
Zanzalintinib (XL092)	TKI targeting MET/VEGFR/AXL/MER					
XB002	TF-targeting ADC					
XL102	Orally bioavailable	e CDK7 inhibitor				
CBX-12 (Cybrexa)	Exatecan peptide	e-drug conjugate				
ADU-1805 (Sairopa)	SIRPα-targeting r	nAb				
XB010	5T4-targeting AD	C				
XB014	Bispecific antiboo targeting PD-L1 +	dy ⊦ CD47			 	
XB628	Bispecific antiboo targeting PD-L1 +	dy + NKG2A				
XB371	TF-topoisomeras	e ADC				

ADC = antibody-drug conjugate; CD47 = cluster of differentiation 47; CDK7 = cyclin-dependent kinase 7; IND = Investigational New Drug status; mAb = monoclonal antibody; NKG2A = natural killer cell receptor group 2A; PD-L1 = programmed death-ligand 1; TF = tissue factor; TKI = tyrosine kinase inhibitor; SIRPα = signal-regulatory protein alpha.





## **Expansive Research**

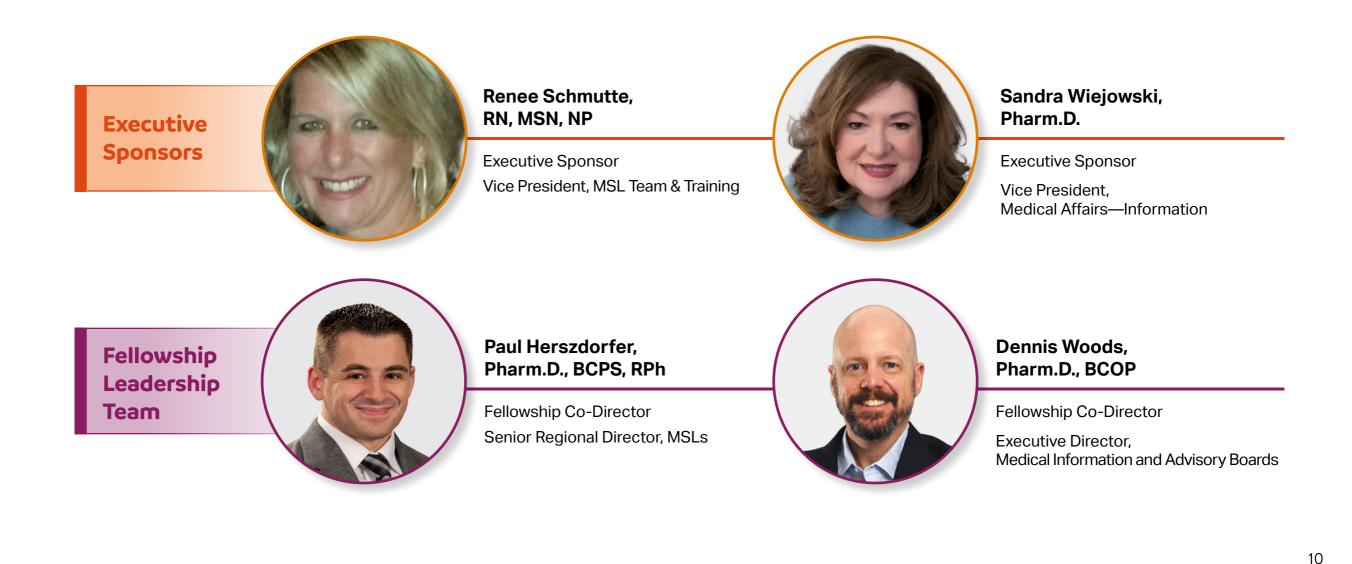
## Valued partnerships and collaborations





## At Exelixis, We Believe That Leadership Is Important Across All Levels

We lead by example, and fostering shared purpose and a heartfelt passion for giving patients hope are core drivers of our business performance. Together, we are resilient in the face of adversity, relentless in delivering results, and unwavering in our commitment to excel for patients through the work we do and medicines we bring to market. We strive to create sustained value by translating science and opportunity into impact.





## **Inaugural Fellow**

Gage McInturff is a 2023 Pharm.D. graduate from The University of North Texas Health and Science Center. She is from a small town outside Ada, Oklahoma, and completed a bachelor's degree at The University of Oklahoma. She is heavily involved as a leader in APhA, Rho Chi, Phi Lambda Sigma, Pharmacy Student Government, and NCODA. In her free time, Gage enjoys traveling, reading, and spending time with her husband and friends. She is excited to be a fellow for a fantastic company like Exelixis and can't wait to make her big move from Texas to California!

2023-2025 Fellow



While researching fellowships, I was inspired by Exelixis' drive to continuously push boundaries in research to give hope to patients with life-threatening oncologic diseases. I became passionate about the field of oncology during my pharmacy school journey and felt that Exelixis aligned with my goals to help others. During the interviews, everyone was so welcoming and encouraging; they made me feel like I could be a part of a family, not just a company!





## **Components of the two-year Medical Affairs Fellowship**

## Exelixis will recruit one fellow for the 2024-2026 Medical Affairs Fellowship program

For the appointed fellow, the fellowship program offers mentorship, networking, and professional development, among other opportunities. Our Scientific Education and Training team has an established, comprehensive onboarding program that provides disease state education and employee socialization for new Medical Affairs colleagues.

In addition to varied activities and responsibilities, the fellow will have the opportunity for cross-functional work with other teams. The Medical Affairs department commonly interfaces with other functional groups across the company, including numerous Pharm.D.s, and is regularly involved in interdepartmental meetings. **The fellow will be based out of our Alameda campus.** 



*Elective rotation can be completed prior to a 6-month MSL/Scientific Education rotation and a 6-month Training rotation.





## YEAR Medical Information (MI)

## 1

## **Roles and responsibilities**

- Create and deliver timely, scientifically accurate, and fair-balanced responses to unsolicited medical information inquiries through the development of standard response letters and frequently asked questions
- Develop literature-searching expertise and provide routine surveillance of the medical literature
- Assist with the management of call center activities and monitor the quality of responses to medical inquiries received from healthcare professionals, patients, and managed care organizations
- Serve as a medical expert and provide product and disease state training for the call center
- Aid in the triaging of product complaints and adverse events according to company policy
- Assist in the development of and updates to product Academy of Managed Care Pharmacy dossiers
- Perform gap analyses and develop data submission packages for oncology guidelines and pathways

- Attend scientific congresses to enhance therapeutic knowledge and provide staffing for the Medical Affairs booth
- Participate and present in inter-/intradepartmental meetings
- Provide presentations on MI metrics/insights at Medical Affairs strategy team meetings
- Support prelaunch preparations for potential new molecules and/or label expansions
- Collect, analyze, and develop comprehensive MI metrics reports on a regular basis that are communicated to senior leadership companywide
- Develop product and disease state expertise, maintain awareness of best practices in industry-based MI practice, and adhere to Compliance standards
- Collaborate cross-functionally with other teams, as appropriate, including Regulatory, Legal, Compliance, Clinical Development, Pharmacovigilance, Public Affairs, and Market Access

## Preceptors



**Dennis Woods, Pharm.D., BCOP** Executive Director, Medical Information and Advisory Boards



# **YEAR Medical Science Liaison (MSL)** & Scientific Education and Training

## **Roles and responsibilities**

2

- Develop scientific training resources, such as slide decks, interactive e-modules, or podcasts
- Create and present content to a crossfunctional audience following major medical congresses
- Provide strategic and operational support through field insight analysis
- Participate in cross-functional and larger Medical Affairs discussions as a member of the Scientific Education & Training team

- Shadow an MSL when engaging with key national and regional thought leaders/healthcare professionals
- Understand novel clinical and scientific areas of interest for external sponsored research, and assist with the site recommendation process of company-sponsored trials
- Participate in scientific reviews/presentation preparation of unsolicited IST proposals
- Represent Exelixis at medical conferences, provide data summaries, and obtain insights





Paul Herszdorfer, Pharm.D., BCPS, RPh Senior Regional Director, MSLs



Rashmi Morani, Pharm.D., MS, RPh **Executive MSL** 



Anh-ton Dang, Pharm.D., Senior Manager, Scientific Education and Training



Kylie Josefiak, Pharm.D. Senior Manager of Scientific Education and Training

Preceptor

## **Elective** Investigator-Sponsored Trials (ISTs)

## **Roles and responsibilities**

- Activate and support planned and ongoing ISTs
- Develop program-level tools and metrics to understand the breadth of tumor types, treatments, study designs, and data outputs in the IST program
- Collaborate with Medical Directors and MSLs to review concepts and protocols
- Participate in meetings with Principal Investigators to triage research-related questions



**Kimberly Natividad, MPH** Associate Medical Affairs **Operations Director** 





## Elective

# Publications/Medical Communications

## **Roles and responsibilities**

- Develop strategic publication plans related to marketed or pipeline compounds
- Determine key scientific concepts
- Develop strategic abstract and manuscript plans
- Develop and execute post hoc analyses using primary clinical data
- Execute abstract, presentation, primary manuscript development, and reviews

### Elective

## **Medical Strategy**

## **Roles and responsibilities**

- Along with the Medical Affairs Director (MAD), research an area of interest for Exelixis products and present findings to the Medical Strategy team
- Follow the review process of Medical Affairs materials through development and review by the medical review committee, and then observe the utilization of materials in the field. Learn the nuances of materials developed for use by the Commercial, Managed Access, and Medical Affairs teams

- Develop congress plans and novel educational materials for deployment at congresses, and design and deploy congress exhibits
- Develop educational materials used by the field team
- Assist with the Medical Affairs Grants and Sponsorships program

Along with the MAD, develop a strategy for

upcoming conferences covering Exelixis

engagement, gathering insights, and analysis

medical strategy. Participate along with the

MAD in cross-functional planning for

Collaborate with the MAD and Executive

of the impact of new data on the tumor-specific

Medical Director on the development of slides to be presented at a national advisory board meeting and observe how the material is

products/pipeline and competitor data presentations. Activities include KOL

## Preceptor



**Douglas Clary, Ph.D.** Vice President, Medical Affairs

## Preceptor



Tasha Hall, Ph.D., RN Executive Medical Affairs Director

〈 🏫 〉

launch activities

implemented



Ernest Mario School of Pharmacy Soaring Ever Higher

**Pharmaceutical Industry Fellowship Program** 

## **Rutgers Pharmaceutical Industry Fellowship Program**

Ernest Mario School of Pharmacy Rutgers, The State University of New Jersey

#### **Program History**

In 1984, at Rutgers, The State University of New Jersey, the Ernest Mario School of Pharmacy and two pharmaceutical companies began a first-of-its-kind collaborative pilot program to evaluate the potential contributions of clinically-trained pharmacists within a pharmaceutical industry practice setting. Following the successful pilot, the Rutgers Pharmaceutical Industry Fellowship (RPIF) Program grew significantly and expanded to include 27 companies within the pharmaceutical and biopharmaceutical industry and approximately 350 Fellows.

In 2002, Dr. Ernest Mario generously provided an endowment to establish the *Institute for Pharmaceutical Industry Fellowships* to enhance and promote the role of pharmacists in industry through the RPIF Program. The Institute staff members:

- provide leadership and administrative support
- promote quality, communication, scholarly activity, and professional development
- arrange specialized Fellowship training opportunities within the pharmaceutical and biopharmaceutical industry.

In 2018, our Program expanded to offer interdisciplinary Fellows' training by adding select physician Fellowship opportunities to our well-established program.

The RPIF Program has thrived under the leadership of the founder, Dr. Joseph A. Barone, Dean and Professor II of the Ernest Mario School of Pharmacy, Dr. Carolyn Seyss, the Director for the Institute for Pharmaceutical Industry Fellowships, and Dr. Michael Toscani as the Director Emeritus.

The RPIF Program Certificate is now associated with special credentials so our alumni can now proudly identify themselves as **RUCIF (Rutgers University Certified Industry Fellow)**. Well over 1,500 Post-Doctoral Fellows have completed the RPIF Program, most of whom are experiencing influential and rewarding careers in the pharmaceutical and biopharmaceutical industry throughout the US and abroad. The RPIF Program has Preceptors and Mentors from industry who share their knowledge and experiences with the Fellows through an intense but closely-guided training program. Assignments and projects are challenging, meaningful, and designed to enhance understanding of the pharmaceutical and biopharmaceutical industry and the Fellow's functional area(s). Our goal is to provide the environment for Fellows to build the foundations to fuel their careers as future leaders in the industry.



Connect with us on social media: @RutgersFellow



Joseph A. Barone, Pharm.D., F.C.C.P.

Dean and Professor II Ernest Mario School of Pharmacy Rutgers University



Carolyn Seyss, Pharm.D., RUCIF

Fellowship Director Institute for Pharmaceutical Industry Fellowships Ernest Mario School of Pharmacy



Michael Toscani, Pharm.D.

Research Professor, Fellowship Director Emeritus Institute for Pharmaceutical Industry Fellowships

RUTGERS Institute for Pharmaceutical Industry Fellowships

ABOUT EXELIXIS

**HISTORY OF RESEARCH** 

FELLOWSHIP PROGRAM OVERVIEW

16

## RUTGERS Ernest Mario School

of Pharmacy

# Soaring Ever Higher Pharmaceutical Industry Fellowship Program

#### Key Program Features

The Rutgers Pharmaceutical Industry Fellowship Program **FOSTER**s the growth and development of future pharmaceutical and biopharmaceutical industry professionals and leaders through key program features:

F O S

E

**Family of Leading Companies** — Partners include several of the top global pharmaceutical and biopharmaceutical companies and offer large to small company environments.

**Outstanding Alumni Track Record** — Well over 1,500 alumni hold prominent positions at many leading companies, including VP and C-suite levels.

**Strong Network** — Fellows develop valuable, lasting connections with each other, alumni, Preceptors, and Rutgers EMSOP faculty.

**Trusted and Proven Since 1984** — the Rutgers Fellowship Program is nationally recognized, trusted, and proven as the key pathway to industry for pharmacists as future leaders.

**Enhanced Career Development** — Breadth of experiences informs career path choices, increasingly challenging assignments build depth of experience, and visibility creates opportunities — enhancing the potential for accelerated career paths.

**Rigorous Academic Component** — Rutgers affiliation provides academic and professional development opportunities.

Rutgers, The State University of New Jersey, with over 67,000 students in its three campuses, is one of the major state university systems in the United States. The New Jersey College of Pharmacy was founded in 1892 and was incorporated into the University in 1927. The <u>Ernest</u> <u>Mario School of Pharmacy (EMSOP)</u> is part of Rutgers Biomedical and Health Sciences (RBHS), the only state school of pharmacy in New Jersey, with approximately 1,350 students in its Doctor of Pharmacy degree program. The Rutgers EMSOP is located on the University's main science and technology campus in Piscataway, New Jersey. Because of its relationship with and close proximity to most of the nation's leading pharmaceutical and biopharmaceutical companies, the EMSOP and the RPIF Program are uniquely capable of providing Fellows with advanced training in the pharmaceutical and biopharmaceutical industry.

#### Professional Development Series

All Fellows gather once monthly as a group to participate in the Professional Development Day (PDD) series, an important component of their training that complements the hands-on experience provided at the partner companies. The PDDs are steered by a committee of Fellows and are designed to enhance the Fellows' leadership skills such as emotional intelligence, communication, critical decision making, and presentation skills. Fellows develop skill sets under the guidance of external trainers and accomplished RPIF alumni. PDDs also provide general knowledge about various aspects of drug development/commercialization and issues facing the pharmaceutical and biopharmaceutical industry, and promote connectivity and a sense of community among Fellows and alumni from different companies and disciplines.

The Fellows can learn from each other through individual and group presentations on topics and issues related to the pharmaceutical and biopharmaceutical industry. The dynamic forum of PDD provides an opportunity for open discussion and debate among Fellows, Rutgers faculty, and company Preceptors. In addition, outside experts provide training and professional development in a variety of areas (e.g., tools for corporate success, professional writing, presentations, meeting facilitation, negotiating, influencing, networking, conflict resolution, giving and receiving feedback, and business etiquette). Other PDD guest speakers include senior industry executives, including our successful RPIF Program alumni, who share their career paths, insights, and experiences. Importantly, PDDs provide an excellent opportunity for Fellows to interact with each other and develop lasting personal friendships and a strong professional network of Fellows, faculty, alumni, and other industry executives.





Connect with us on social media: @RutgersFellow

**ABOUT EXELIXIS** 

# RUTGERS

Ernest Mario School of Pharmacy

# Soaring Ever Higher Pharmaceutical Industry Fellowship Program

#### **Application Process and Eligibility Requirements:**

Pharmacy Fellows for the Rutgers Pharmaceutical Industry Fellowship Program are selected on a nationally competitive basis. Candidates must have completed a Doctor of Pharmacy degree from an ACPE-accredited institution before July 1 of the fellowship term.

#### How to Apply:

The RPIF Program is highly competitive. Candidates will be selected for interviews on a rolling basis, so we strongly encourage you to submit your application as soon as possible.

Interested candidates may submit their application with short-answer questions and supporting materials (letter of intent, curriculum vitae, and 3 letters of recommendation) as soon as October 6, 2023 by visiting our website at: https://pharmafellows.rutgers.edu/how-to-apply/

All application materials **must be submitted electronically to the RPIF Website** per instructions on the site.

#### Your Letter of Intent & Letters of Recommendation should be addressed to:

Joseph A. Barone, Pharm.D., F.C.C.P. Dean and Professor II Ernest Mario School of Pharmacy Rutgers, The State University of New Jersey 160 Frelinghuysen Road Piscataway, NJ 08854-8020

#### Alliance of Industry Fellowship Associates Fellowship Offers

Recognizing that the choice of a Post-Doctoral Industry Fellowship is an important decision, AIFA exists to promote a common aspect of each of our program's cultures by supporting a consensus first offer date of December 13, 2023 for all fellowship candidates.

We hope that other academic and non-academic Fellowship Programs will respect this timeline to allow for best program fit for candidates.

Required Items	Submit by
Application with short-answer questions	October 13th
Letter of Intent (LOI)	October 13th
Curriculum Vitae (CV)	October 13th
Letters of Recommendation (LORs)	December 1st



AIIIance of Industry Fellowship Associates

Institute for Pharmaceutical Industry Fellowships



Connect with us on social media: @RutgersFellow

**ABOUT EXELIXIS** 

HISTORY OF RESEARCH

FELLOWSHIP PROGRAM OVERVIEW

RPIF PROGRAM

# We look forward to meeting you!





RUTGERS Institute for Pharmaceutical Industry Fellowships



**ABOUT EXELIXIS** 

**HISTORY OF RESEARCH** 

FELLOWSHIP PROGRAM OVERVIEW

**RPIF PROGRAM**