Post-Doctoral Fellowship Program in Early Clinical Development 2019

Sponsored in conjunction with

MedImmune
A member of the AstraZeneca Group

UNIVERSITY of MARYLAND
THE FOUNDING CAMPUS
ABOUT MEDIMMUNE

MedImmune is the global biologics research and development arm of AstraZeneca, a global, innovation-driven biopharmaceutical business that focuses on the discovery, development, and commercialization of small molecule and biologic prescription medicines. MedImmune is pioneering innovative research and exploring novel pathways across key therapeutic areas, including oncology; respiratory; cardiovascular, renal, and metabolic disease (CVRM); and infectious disease and vaccines (ID/Vax).

MedImmune was founded by Dr. Wayne T. Hockmeyer in 1988 as Molecular Vaccines Inc., subsequently becoming MedImmune in 1990. AstraZeneca acquired MedImmune in 2007, and it now accounts for nearly half of AstraZeneca’s Research and Development portfolio. MedImmune currently has ~130 ongoing research projects – possessing one of the most robust pipelines in the industry.

MedImmune is headquartered in Gaithersburg, Maryland (30 miles from Washington, DC) one of AstraZeneca’s three global R&D centers, with additional sites in Cambridge, United Kingdom and Gothenberg, Sweden. With a drive to follow the science, MedImmune employs some of the best scientific minds in the industry who continually push the boundaries of science to deliver life-changing medicine.
The MedImmune Clinical Development Fellowship is intended to bridge the gap between earning a Doctor of Pharmacy degree and being an effective drug developer. This two-year experience embeds the fellows into the drug development process and allows them to work within the cross-functional teams that are advancing new medicines through clinical evaluation. The fellowship is a hands-on program where fellows learn by fulfilling the role of a clinical scientist on clinical study teams. In the first year, the fellows are assigned to a team in one of MedImmune’s main therapeutic area (oncology, cardiovascular/metabolic, respiratory, infectious disease/vaccine). During the second year, the fellows select a different therapeutic area to broaden their experience and obtain insights into how medicines are developed for different indications. Because MedImmune is the biotech arm of AstraZeneca, all medicines are manufactured within living organisms. This means the experience gained through the fellowship is specialized and uniquely valuable within the biopharmaceutical industry. Exposure to cutting edge research and experience working on novel biotech medicines have helped all the previous fellows compete successfully for positions within the biopharmaceutical industry.

Filip Dubovsky, MD, MPH
Fellowship Program Director
Vice President, Infectious Disease and Vaccine
MedImmune, LLC

The University of Maryland School of Pharmacy partnership with MedImmune makes available a unique clinical development fellowship to new graduates who are interested in pursuing careers in the pharmaceutical and biotechnology industries. This fellowship not only provides a wonderful training opportunity for outstanding graduates but also creates a pipeline for the development of highly-qualified scientists who will be on the forefront of creating new medicines for the treatment of a variety of diseases. This innovative educational and research opportunity allows fellows to experience firsthand the work environment and challenges of the pharmaceutical industry. Furthermore, the fellowship allows students to leverage their PharmD education and apply it to real-world applications. As evidenced by the success of former fellows, MedImmune Clinical Development Fellows are uniquely positioned to compete in the highly competitive pharmaceutical and biotechnology industry. Thus, this opportunity provides an exciting springboard for a highly successful career at MedImmune and beyond.

Peter Swaan, PhD, MS
Fellowship Program Director
Associate Dean and Professor
University of Maryland School of Pharmacy
OVERVIEW

The MedImmune-University of Maryland Clinical Development Fellowship is an exclusive 2-year program geared for University of Maryland School of Pharmacy graduates with a penchant for clinical research in the pharmaceutical and biotechnology industries. Established in 2009, the fellowship has paved the career path for numerous University of Maryland School of Pharmacy graduates.

Fellows in the program will be involved in two different therapeutic areas during the first and second year of the fellowship. These areas may include oncology, cardiovascular/metabolic, respiratory/autoimmunity, and infectious disease/vaccine. The key learning objectives of the fellowship program are to understand:

- The organizational approach to drug development and the roles of various departments/functions.
- Components of an integrated product development plan (iPDP) & clinical development plan (CDP), investigational new drug (IND) filing process – including preclinical, toxicology, and PK/PD requirements.
- Regulatory requirements and interactions between FDA and industry.
- The purpose of Phase I, II, and, III research.
- Biologic license application (BLA) filing process.
- Post-marketing commitments, pharmacovigilance and risk management plans.
- The role of health economics and patient-reported outcomes in clinical development activities.
- Approach to commercial and business assessment of pharmaceutical products.
- The process of lifecycle management of pharmaceutical products.
- The importance of biomedical ethics and protection of human subjects in clinical research.
- Didactic and experiential forms of instruction through preceptorship of fourth-year student pharmacists.
FELLOWSHIP OBJECTIVES

At the end of the fellowship, the fellow will have developed competency in the following areas:

- Scientific research process (including hypothesis generation and development)
- Study design
- Protocol development
- Study coordination
- Data collection activities
- Data analysis and interpretation
- Presentation of results to internal and external personals (includes team meetings, conferences, and publications)
The MedImmune Clinical Development Fellowship has provided me with a wonderful and unique opportunity to learn different aspects of drug development and to participate in clinical development efforts in designing and conducting clinical trials. This program offers a hands-on training opportunity which allowed me to utilize my clinical knowledge, gained through my PharmD education, in a very interactive and stimulating scientific environment and contribute to developing novel medications for patients that currently do not have effective therapeutic agents.

Fatemeh (Mitra) Tavakkoli, MD, PharmD  
Medical Monitor  
BioMarin Pharmaceutical  
Former Fellow

Through the clinical drug development post-doctoral program at MedImmune, I was able to learn invaluable skills such as understanding clinical trial design, protocol development, the scientific research process and much more. Through this opportunity, I was also able to apply the clinical science I had learned in school to help assess patient profiles for safety as well as efficacy of the investigational drugs we work on here at MedImmune.

Natasha Angra, PharmD  
Associate Director, Clinical Development (Oncology)  
AstraZeneca, PLC  
Former Fellow

The MedImmune Clinical Development Fellowship was an invaluable experience in my career development. The fellowship’s flexibility allowed me to shape my experience and achieve my personal goals along with those of the program. Most importantly, I learned how to thrive within a matrixed group of industry professionals working towards the shared goal of creating new treatment options for patients.

Ibrahim Qazi, PharmD, MS  
Clinical Scientist  
Beigene  
Former Fellow
The fellowship offered an exceptional opportunity for me to gain first-hand experience in drug development. Through the fellowship, I was able to gain experience in early phase immuno-oncology and late phase autoimmune clinical trials. I was also fortunate to work with a number of amazing mentors that prepared me for a career in cancer drug development. The fellowship really opened up doors for me, and I am very grateful for the experience. Any pharmacy student with an interest in biotechnology and drug development should strongly consider applying.

Robert Gharavi, PharmD, MS
Senior Clinical Research Scientist
Boston Biomedical
Former Fellow

Starting the fellowship, I knew that my professional growth would be successful because I was assigned a fantastic mentor, Dr. Jacob Wesley (a former fellow). The flexibility of the fellowship is what excited me the most; I could define my career path with the assistance of a MedImmune mentor. MedImmune’s open door policy and emphasis on collaboration continually prepares me for a role as a clinical scientist. That is why my response to anyone who asks me how my fellowship is going thus far is as such; “It is the best decision I made in pharmacy school.”

Andong Nkobena, PharmD
Senior Manager Clinical Scientist (Immuno-Oncology)
Beigene
Former Fellow

From the pharmacologist who identifies a receptor, to the regulatory affairs personnel who facilitates the approval of the drug, each individual in the drug development process plays a pivotal role in the outcome – creating a treatment. This cross-functional approach to meeting a clinical need is what led me to pursue a career in drug development. The fellowship has exposed me to this collaborative nature of drug development and the opportunity to work with a diverse group of clinicians and researchers.

Abdulafeez (Deji) Oluyadi, PharmD
Clinical Research Scientist
Karyopharm Therapeutics
Former Fellow
This fellowship offers an unparalleled opportunity to train for the role of a clinical scientist with experts in the industry. The experience in two therapeutic areas is an important asset of this fellowship that endows us with the skills to agilely take on new development programs in any disease state. In addition, we frequently work with our AstraZeneca colleagues on combination studies with small molecules which helps broaden our exposure to various therapeutic mechanisms that present different challenges. MedImmune has one of the most impressive pipelines of drugs with novel mechanisms, and being on the forefront of science means that we have the benefit of learning about new theories in medicine while also contributing to the development of life-changing drugs.

Jonathan Meyer, PharmD
Second Year Clinical Development Fellow
Cardiovascular, Renal, and Metabolic Diseases (CVRM)
MedImmune LLC

This fellowship is a unique opportunity to immerse oneself in the dynamic role a clinical scientist plays in the drug development process. It arms fellows with the skills needed to act as contributing members to the clinical development team, working towards curating novel therapies and combination treatments for populations with high unmet need. A spirit of innovation and collaboration thrives at MedImmune, fostering an open environment for ample learning and creativity. The fellowship opens the door to training opportunities that adequately prepare its fellows for a career in industry.

Stephanie Anyanwu, PharmD
First Year Clinical Development Fellow
Oncology
MedImmune LLC
REQUIREMENTS

1. Applicant has achieved a grade point average of ≥ 3.0 (on 4.0 scale) during pharmacy school.

2. Applicant has conducted research in relevant scientific fields (includes: toxicology, pharmacokinetics/pharmacodynamics, analytical chemistry, health services or pre-clinical/clinical).

3. Applicant demonstrates sufficient communication (written and oral) skills as per prior curriculum requirements or presentation of prior research.

4. Applicant has been conferred a PharmD by the start of the fellowship program (fellowship starts on the first week of July 2019).

APPLICATION PROCESS

Students will be evaluated by the Executive Committee composed of MedImmune and University of Maryland School of Pharmacy staff and are required to submit the following documents:

1. A one-page statement explaining career goals, research experiences, and interest in clinical research.

2. A curriculum vitae that highlights clinical, research, and work experience.

3. Maximum of two (2) optional professional letters of recommendations (either prior employer and or faculty) submitted confidentially via email. Letter of recommendation writers should email the letters of recommendation to the Office of the Associate Dean of Research & Graduate Education and Jonathan Meyer, PharmD using the instructions below.

APPLICATION DEADLINES

• All materials must be submitted by Friday, October 19, 2018

Please send all required documents via email to BOTH:

• Office of the Associate Dean of Research & Graduate Education at research@rx.umaryland.edu

• Jonathan Meyer, PharmD at meyerjo@medimmune.com

All letters of recommendation must be sent from an institution or corporate email address. For all email correspondence, include in subject line — 2018 MedImmune Clinical Development Fellowship Application

For additional information on the program, please contact:

Peter Swaan, PhD (pswaan@rx.umaryland.edu)