

PPD[®]

 **UNC** | **ESHELMAN SCHOOL OF PHARMACY**



2021-2023

PPD Clinical Research and Drug Development Fellowship

Partnership **Solid Foundation. Top-tier Results.**

PPD

PPD is a leading global contract research organization (CRO) providing comprehensive, integrated drug development, laboratory and lifecycle management services. Our clients and partners include pharmaceutical, biotechnology, medical device, academic and government organizations. With offices in 46 countries and approximately ~23,000 professionals worldwide, PPD applies innovative technologies, therapeutic expertise and a firm commitment to quality to help clients and partners bend the cost and time curve of drug development and optimize value in delivering life-changing therapies to improve health.

DAVID SIMMONS

CHAIRMAN AND CHIEF EXECUTIVE OFFICER

“We measure our success by customers who are pleased partners, employees who are driven and engaged, and patients who are getting quality therapies faster. Our passion and drive for excellence are strong, and we are optimistic about the future of our company and the industry.”

UNC Eshelman School of Pharmacy

The UNC Eshelman School of Pharmacy is located on the University of North Carolina campus in Chapel Hill. The school is one of five health science schools in the Division of Health Affairs at UNC. The school has a long and respected history of successful collaborative clinical and research accomplishments. Fellowships have been offered since 1980, thereby ensuring an experienced environment for program participants. UNC Hospitals, the University’s teaching hospitals, provide primary and tertiary care and serve as one of the state’s principle referral, diagnostic and treatment centers.

Diversity, Equity & Inclusion

We aspire to be a diverse and inclusive community of people to accelerate new thinking and ideas in education, research and practice that have a positive impact on human health worldwide. We envision a school that reflects, in all its dimensions, the population it serves.

Year ONE

The fellow will spend the first year at the University of North Carolina at Chapel Hill, and will have the opportunity to:

- + Participate in an original clinical research project under the direction of a clinical faculty member
- + Develop a protocol, recruit and monitor patients or subjects, coordinate clinical studies, collect and analyze data, and prepare a manuscript
- + Gain experience with analytical methodologies, drug disposition and metabolism, and PK/PD/PG
- + Fellows may also participate in selected coursework in: clinical research methods, clinical study design, biostatistics, advanced PK and PD, genomics, data management, advanced therapeutics, drug metabolism and molecular biology
- + Fellows may opt for teaching opportunities to students within the pharmacy curriculum in pharmacotherapy and related courses

Year Two

The fellow will spend the second year in PPD offices, primarily at the Morrisville (RTP), N.C., campus. Based on our company model, the second year of the fellowship will take into account the fellow's strengths and skills to maximize his or her experiences with current and future company needs.

The fellow will have a broad experience and will be exposed to many departments during several rotations (either sequential or parallel) that will be customized and adaptable based on the fellow's interest areas. The duration of each rotation is flexible and may be longitudinal depending on the fellow's area of focus. An introductory rotation will allow fellows to gain a basic understanding of PPD's core business.



OUR PURPOSE

Improve Health



OUR MISSION

Help Our Customers Deliver Life-Changing Therapies



OUR STRATEGY

Bend the Cost and Time Curve of Drug Development and Optimize Value for Our Customers

Introductory Rotation: CRO Orientation/Operations

OBJECTIVES:

- + Orient the fellow to all aspects of this full service CRO, including services provided (e.g., IND to NDA to post market projects)
- + Experience all aspects of proposal development and contract preparation, including surveying the request or proposal (RFP), writing the proposal, development of the budget and possible attendance at presentation of proposal to sponsor
- + Expose the fellow to monthly project team and senior management budget meetings
- + Complete Clinical Foundation Training or equivalent training necessary to complete projects successfully
- + Meet with different departments within PPD

EXPECTATIONS/EXPERIENCES:

- + Gain familiarity with PPD's corporate environment and general operations of a CRO
- + Become familiar with PPD's different departments and their role within the organization
- + Obtain basic understanding of business development process within PPD

Departmental Rotations

PROPOSED GROUPS/ROTATIONS:

- + Clinical development/project management
- + Global product development
- + Global regulatory affairs
- + Global strategic proposal development
- + Pharmacovigilance (safety)
- + Pharmacokinetics
- + Medical writing
- + Strategic development
- + Marketing
- + Business Development
- + Global Strategic Feasibility

OBJECTIVES:

- + Gain broad exposure to many departments within PPD potentially in a therapeutic area of interest
- + Work on an interdisciplinary team to consult on client development programs from Phase I to Phase IV
- + Provide medical support and drug information to global product development physicians and pharmacists or regulatory affairs professionals
- + Conduct market analysis and competitive intelligence
- + Complete a clinical trial landscape analysis of a disease state and/or drug class
- + To experience all aspects of being a member of a clinical project team dedicated to clinical study within a therapeutic area of interest
- + To assist in the project-specific training activities for the clinical project team (e.g., seminars)
- + Work independently as associate/co-project manager and lead activities of the clinical development team
- + Determine investigator recruitment strategies and feasibility planning
- + Participate in regulatory document review and processing including (Case Report Form (CRF) design/protocol review, investigator grant development and negotiation exposure to IRB issues)
- + Witness site monitoring visits for multiple sites according to FDA regulations and PPD SOPs
- + Become trained as a clinical pharmacologist in the pharmaceutical industry setting

Fellowship Eligibility Requirements:

Ideal candidates will have obtained a PharmD, PhD, or MD. The fellowship is a two-year program that **begins July 1**. The fellowship offers a competitive stipend and provides health insurance, paid vacation, and compensation for travel and ancillary expenses to one professional meeting each year.

How To Apply:

Please refer to the UNC fellowship website for details on how to submit the materials listed below.

<http://pharmacydpetfellowships.web.unc.edu/>

Electronic submission is preferred (opens Sept. 8th). If electronicsubmission is not possible, you can mail your application materials to:



Fellowship Application – Dr. Bob Dupuis
fellowships@unc.edu

311 Pharmacy Lane, 3213 Kerr Hall, CB# 7569
Chapel Hill, NC 27599-7569

SUBMISSION MATERIALS:

- + A personal interest statement and how an appointment would affect your personal and professional growth
- + A curriculum vitae
- + Complete unofficial transcripts
- + Three professional letters of recommendation
- + Early consideration deadline: October 15, 2020
- + **The application deadline is December 15, 2020**

Interviews:

Informational interviews with PPD, UNC faculty and/or program alumni may be arranged at IPhO, ACCP and ASHP Midyear Meetings. Interviews will be conducted by phone and online.

Next Steps:

Following interviews and review of application materials, you may be invited to interview “on-site,” which will be conducted digitally this cycle.

FOR ADDITIONAL INFORMATION REGARDING THE FELLOWSHIP PLEASE CONTACT:



Fellowship Director:
Austin Combest, PharmD, BCOP, MBA
Sr. Director, Clinical Information and Science
by phone: 910-541-0067 (office)
or 201-213-9851 (mobile)
or via email: Austin.Combest@ppdi.com

Visit:

PPD Clinical Research and Drug Development Fellowship

<https://pharmacy.unc.edu/education/fellowships/ppd-clinical-research-and-drug-development-fellowship/>

General UNC Fellowship information, Current Fellows, and Fellowship Alumni

<https://pharmacy.unc.edu/education/fellowships/>



UNC/PPD Drug Development Fellows: *Where Are They Now?*

Angela Donahue, PharmD
1997 – 1999 Fellow
Sr. Director, Global Project
Management, Ophthalmology
*PPD

**Stephanie Faucette, PharmD,
PhD**
1998 – 2000 Fellow
Clinical Scientist, Strategic
Solutions
PRA Health Sciences

Naumann Chaudry, PharmD
1999 – 2001 Fellow
Executive Director, Global RA
Strategy Head for Inflammation;
Head, RA Advertising and
Promotion
Gilead Sciences

**Aliou Ousmanou, PharmD,
MBA***
2001 – 2003 Fellow
Senior Director, Clinical
Operations
United Therapeutics

Pinal Shah, PharmD
2002 – 2004 Fellow
Associate Director of Project
Management
PPD

Nabil Uddin, PharmD, RAC
2003 – 2005 Fellow
Vice President, Corporate
Development
Concert Pharmaceuticals

Michael Kardas, PharmD, RAC*
2005 – 2007 Fellow
Innovation Vice President, Design
& Delivery
IQVIA

Thomas Cho, PharmD*
2006 – 2008 Fellow
Safety Risk Management Scientist
United Therapeutics

Tedi Soule, PharmD, RAC*
2006 – 2008 Fellow
Scientific Director, Medical Affairs
GSK

Shriya Bhushan, PharmD
2007 – 2009 Fellow
Executive Director, Worldwide
Hematology Myeloid Marketing
Bristol-Myer Squibb

Dustan Byrd, PharmD*
2008 – 2010 Fellow
Pharmacy Manager
Walgreens

John An, PharmD, PhD*
2008 – 2010 Fellow
Associate Director, Global
Regulatory Lead
Allergan

**Austin Combest, PharmD,
BCOP, MBA**
2009 – 2011 Fellow
Sr. Director of Clinical Science and
Information, Global Product
Development, Drug Development
Fellowship Director
PPD

Jill Parris, PharmD
2010 – 2012 Fellow
Clinical Scientist Director, Global
Product Development
PPD

Savanna Steele, PharmD
2010 – 2012 Fellow
Director, Feasibility Strategy
Site and Patient Access
*PPD

Ben Greener, PharmD, MS
2011 – 2013 Fellow
Clinical Scientist Director, Global
Product Development
PPD

Brian Simmons, PharmD, MS
2011 – 2013 Fellow
Senior Clinical Scientist, Oncology
Genentech

Ashley Simmons, PharmD*
2012 – 2014 Fellow
Director Clinical Development
Dova Pharmaceuticals

**Paulina Zelenay McAtee,
PharmD**
2013 – 2015 Fellow
Associate Director, Feasibility
Strategy
Site and Patient Access
PPD

John Andrew Lee, PharmD
2013 – 2015 Fellow
Regional Field Medical MSL
Associate Director, Immuno-
Oncology
Bristol-Myer Squibb

Elizabeth Shearin, PharmD
2014 – 2016 Fellow
Junior Director, Clinical Scientist
Janssen

Richard Tran, PharmD
2015 – 2017 Fellow
AD Feasibility Strategist
Site and Patient Access
PPD

Robert Pope, PharmD
2016 – 2018 Fellow
Feasibility Strategist
PPD

Judy Hsu, PharmD
2016 – 2018 Fellow
Clinical Scientist I, Global Product
Development
*PPD

Daijha Anderson, PharmD
2018 – 2020 Fellow
Associate Clinical Scientist
Director
PPD

Megan Gower, PharmD
2019 – 2021 Fellow
Current UNC/PPD 2nd-yr Fellow

Sheel Patel, PharmD
2019 – 2021 Fellow
Current UNC/PPD 2nd-yr Fellow

Ian Mulrenin
2020-2022 Fellow
Current UNC/PPD 1st-yr Fellow

Preetika Sharma
2020-2022 Fellow
Current UNC/PPD 1st-yr Fellow