

- Document accountability, stability and storage conditions of clinical trial materials
- Site management
- Assist a project manager in pharmacovigilance with serious adverse event processing and reporting
- Query generation and resolution
- Investigator study file maintenance
- Report generation
- Project/executive review meeting attendance

### 3rd Quarter (January 1 – March 31)

#### Concept: Data Management, Biostatistics and Medical Writing

##### Objectives:

- ◇ Experience preclinical and clinical review of CRFs
- ◇ Become familiar with and participate in clinical trial data entry into database(s), data validation, data transfer, auditing and database lock
- ◇ Become familiar with and participate in data analysis, the generation of tables and listings, analysis plan and a clinical statistical report
- ◇ Participate in preparation of protocols (design and development) and integrated clinical and statistical reports

##### Proposed Rotations:

- Data Management
- Biostatistics
- Medical Writing
- Health Outcomes

### 4th Quarter (April 1 – June 30)

#### Concept: Elective

##### Fellowship Eligibility Requirements:

The fellowship is a two-year program, beginning July 1. Applicants must have completed an accredited PharmD program. The fellowship offers a competitive stipend, health insurance, paid vacation, and compensation for travel and ancillary expenses to one professional meeting each year.

## How to Apply

For complete details on submitting an application, see: <http://pharmacy.unc.edu/programs/fellowships/how-to-apply>

Preliminary interviews will be conducted at the American Society of Health System Pharmacists Midyear Clinical Meeting through the personal placement service. Fellows will be selected on a nationally competitive basis.



## Questions?

For answers to common questions, see <http://pharmacy.unc.edu/programs/fellowships/fellowships-faq>, or contact

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# Drug Development & Clinical Research Fellowship Program



Sponsored by the  
**UNC Eshelman School of Pharmacy**  
 at the  
**University of North Carolina at Chapel Hill**  
 and  
**PPD**

## PPD

PPD is a leading global contract research organization (CRO) providing discovery and development services, market development expertise and compound partnering programs to biopharmaceutical, device, academic and government organizations. With a global infrastructure, PPD applies innovative technologies, therapeutic expertise and a commitment to quality to help its clients and partners maximize returns on their R&D investments while also accelerating the delivery of safe and effective therapeutics to patients. PPD has offices in the Americas, Europe, the Middle East, Africa, Asia and the Pacific Rim. PPD has sponsored the Drug Development & Clinical Research Fellowship since 1997, and has provided extensive training opportunities in different arenas of clinical research.

## UNC Eshelman School of Pharmacy

Located on the UNC campus, the School is one of five health science schools in the Division of Health Affairs. The School boasts a long, respected history of 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 hospital, provides primary and tertiary care and serve as the state's principle referral, diagnostic and treatment center.

### Year 1:

Fellows will spend the first appointment year at the University of North Carolina at Chapel Hill, where they will have the opportunity to:

- Participate in original clinical research projects under the direction of a clinical faculty member at the UNC Eshelman School of Pharmacy
- Develop a protocol, obtain appropriate approvals and funding, recruit and monitor study subjects, collect and analyze data, and prepare abstracts and manuscripts
- Gain experience with drug assay methodologies (HPLC, RIA), *in vitro* drug metabolism models, pharmacodynamic monitoring techniques, and methods of managing and analyzing data

- Enroll in courses that supplement training and personal interests. Topics may include biostatistics, laboratory drug analysis, advanced pharmacokinetics, study design methodology and epidemiology

### Year 2:

Fellows will spend their second year at the offices of PPD, primarily at the Morrisville, NC location. Under the direction of Dr. Angela Donahue, the second fellowship year will be split into four quarters. Objectives for the first three quarters are outlined below. The fourth quarter will be conceptualized (analogous to electives) by the fellow based on individual goals and objectives.

### 1<sup>st</sup> Quarter (July 1-September 30)

#### Concept: Orientation/Business Development

#### Objectives:

- ◇ Orient to all aspects of this full service CRO, including services provided (e.g., IND to NDA to post market)
- ◇ Experience all aspects of proposal development and contract preparation, including surveying the request for proposal (RFP), writing the proposal, development of the budget, possible attendance at presentation of proposal to sponsor, and inspection of the letter of intent and contract
- ◇ Gain exposure to monthly project team and senior management budget meetings
- ◇ Further develop the fellow's ability to create and present seminars via scientific training for various functions or presentation at investigator meetings
- ◇ Complete Clinical Foundation Training
- ◇ Meet with different departments within PPD

#### Proposed Rotations:

- Orientation/Selective-Training
- Business Development
- Bids and Contracts/Proposal Development
- Phase I Clinic

### 2nd Quarter (October 1 – December 31)

#### Concept: Clinical Project Team

#### Objectives:

- ◇ Experience all aspects of being a member of a clinical project team dedicated to a Phase II-IV study within one of the therapeutic units in the Morrisville, NC office
- ◇ Assist in the project-specific training activities for the clinical project team (e.g., seminars)

#### Proposed Rotations:

- Clinical Project Team
- Regulatory Affairs
- Pharmacovigilance (Safety)
- Program Management
- Centralized Professional Call Center
- Medical Communications

#### Proposed Co-Responsibilities as a Member of the Project Team:

- Investigator recruitment
- Regulatory document review and processing
- Case report form (CRF) design/protocol review
- Investigator grant development and negotiation
- Exposure to IRB issues
- Exposure to central lab issues
- Attendance at investigator meetings
- Attendance to pre-study (qualification), initiation, and close-out site visits
- Monitoring of visits for multiple sites throughout the fellowship year according to FDA regulations and PPD