Advances in Medical Education and Practice

Dovepress
open access to scientific and medical research

Open Access Full Text Article

PERSPECTIVES

Establishing a clinical pharmacology fellowship program for physicians, pharmacists, and pharmacologists: a newly accredited interdisciplinary training program at the Ohio State University

This article was published in the following Dove Press journal:
Advances in Medical Education and Practice
23 June 2014
Number of times this article has been viewed

Joseph P Kitzmiller[1,4]
Mitch A Phelps[2]
Marjorie V Neidecker[3]
Glen Apseloff[4]

[1]Center for Pharmacogenomics, Colleges of Medicine and of Engineering, The Ohio State University Medical Center, [2]Colleges of Pharmacy and Medicine, Pharmacoanalytic Shared Resources Laboratory, The Ohio State University, [3]Colleges of Medicine, Nursing, and Pharmacy, The Ohio State University, [4]Department of Pharmacology, The Ohio State University College of Medicine, Columbus, OH, USA

Abstract: Studying the effect of drugs on humans, clinical pharmacologists play an essential role in many academic medical and research teams, within the pharmaceutical industry and as members of government regulatory entities. Clinical pharmacology fellowship training programs should be multidisciplinary and adaptable, and should combine didactics, applied learning, independent study, and one-on-one instruction. This article describes a recently developed 2 year clinical pharmacology fellowship program – one of only nine accredited by the American Board of Clinical Pharmacology – that is an integrative, multi faceted, adaptable method for training physicians, pharmacists, and scientists for leadership roles in the pharmaceutical industry, in academia, or with regulatory or accreditation agencies. The purpose of this article is to provide information for academic clinicians and researchers interested in designing a similar program, for professionals in the field of clinical pharmacology who are already affiliated with a fellowship program and may benefit from supplemental information, and for clinical researchers interested in clinical pharmacology who may not be aware that such training opportunities exist. This article provides the details of a recently accredited program, including design, implementation, accreditation, trainee success, and future directions.

Keywords: clinical pharmacology education, clinical pharmacology fellowship

Introduction

The American College of Clinical Pharmacology defines clinical pharmacology as the promotion of the rational use of medications in humans, innovative research, development and regulation of medications, and the education of health care professionals and patients on the optimal utilization of medications.[1] Established in 1991, the American Board of Clinical Pharmacology (ABCP) promotes the discipline of clinical pharmacology, accredits clinical pharmacology training programs, and certifies individual clinical pharmacologists.[2–4] The ABCP awards certification in either Clinical Pharmacology (MD or DO candidates) or Applied Pharmacology (PhD or PharmD candidates) to individuals who have successfully completed rigorous postdoctoral training, and who have met requirements for experience in the field, and who have passed the ABCP examination in clinical pharmacology. Their official website, http://www.abcp.net, details the specific requirements for board eligibility and lists the primary areas of emphasis for the board examinations.[5] The ABCP also registers and accredits clinical pharmacology training programs[6] (currently accredited programs are listed in Table 1).

Correspondence: Joseph P Kitzmiller
Center for Pharmacogenomics, Colleges of Medicine and of Engineering, The Ohio State University Medical Center, 5072B Graves Hall, 333 West Tenth Avenue, Columbus, OH 43210, USA
Tel +1 614 292 8438
Email joseph.kitzmiller@osumc.edu

submit your manuscript | www.dovepress.com
Dovepress
http://dx.doi.org/10.2147/AMEP.S60986

Table 1 Clinical pharmacology fellowship training programs with ABCP-accreditation

Program, location	Year accreditation granted by ABCP	Website, program highlights
Baylor College of Medicine Houston, TX, USA	2003	https://www.bcm.edu/departments/medicine/sections-divisions-centers/hypertension-and-clinical-pharmacology/education/hypertension-and-clinical-pharmacology • Research program focuses on regulation of vascular function in health and disease • Clinical rotations include Clinical Pharmacology Research and Diagnostic Clinic, Hypertension and Clinical Pharmacology Consultation Service, and Clinical Pharmacokinetics Core Laboratory at Baylor College of Medicine or Texas Children's Hospital • Trainee, in conjunction with the faculty in one of several departments or internal medicine divisions within the College, determines an area of interest
Children's Mercy Hospitals and Clinics Kansas City, MO, USA	2008	https://www.childrensmercy.org/ClinPharmFellowship/ • The only pediatric clinical pharmacology program accredited by the ABCP in the US • Opportunity to conduct research alongside pediatric subspecialist physicians and biomedical scientists committed to the evaluation of pediatric pharmacotherapies • New (2012) pediatric clinical research unit with state-of-the-art facilities for research and clinical trials
Dartmouth-Hitchcock Medical Center Lebanon, NH, USA	2006	No external website, contact Lionel.Lewis@Dartmouth.edu • Extensive training in oncology drug development • Research strengths in pharmacokinetic and bioanalytic methodology • Opportunity to participate on Clinical Pharmacology and Toxicology consult services
Indiana University, School of Medicine Indianapolis, IN, USA	2003	http://medicine.iupui.edu/clinpharm/fellowship • Pediatric, obstetric, and general clinical pharmacology specializations • Research strengths in personalized medicine and pharmacogenetics for cancer, HIV, and cardiovascular disease • Seven NIH-funded fellowship positions
The Ohio State University, College of Medicine Columbus, OH, USA	2009	http://www.medicine.osu.edu/pharmacology/graduate-programs/pages/fellowship-programs.aspx • Associated with the Center of Pharmacogenomics, OSU College of Medicine • Instruction, clinical experience, and research are tailored to trainee's experience and interests • Master's degree in Pharmacology incorporated into fellowship
Thomas Jefferson Medical College, Department of Pharmacology and Experimental Therapeutics Philadelphia, PA, USA	2006	http://www.jefferson.edu/jmc/departments/pharmacology/education/fellowship.html • Training within a dedicated academic phase I unit • Training experience with a pharmaceutical company, with the editorial board of the Annals of Internal Medicine journal, and with the US Food and Drug Administration • Opportunity to concentrate in adult or pediatric clinical pharmacology
Uniformed Services University of the Health Sciences and Walter Reed Army Institute of Research School of Medicine Silver Spring, MD, USA	2004	http://wrair-www.army.mil/OtherServices_ClinicalPharmacology.aspx • Available to US Army active-duty PhDs/PharmDs and US Army physicians who are board eligible/certified in a primary specialty; civilians can be considered but must join the US Army and successfully compete for their fellowship position • Conduct laboratory, animal, and clinical research under the supervision of a mentor • 3 month rotation at the FDA
University of California at Los Angeles David Geffen School of Medicine Los Angeles, CA, USA	2005	http://icptp.k30.ucla.edu • Broad, interdisciplinary, program focused on clinical pharmacology and experimental therapeutics • Salary support provided through the National Institute of General Medical Sciences (NIGMS) T32 Clinical Pharmacology Postdoctoral Training Program grant • Emphasis is placed on conducting research in special populations, including women, children, geriatrics, and members of ethnic minorities • Clinical research curriculum available as an auditing-only track, a 2 year certificate program in clinical research, or a Master of Science (MS) degree in Clinical Research
University of Chicago, Division of Biological Sciences Chicago, IL, USA	2002	http://ccpp.bsd.uchicago.edu • Clinical and basic research projects in pharmacogenomics, drug development, clinical pharmacology, genetics of drug abuse, and clinical trial design • Core curriculum includes courses in Pharmacogenomics, Personalized Medicine, Advanced Clinical Pharmacology, and Patient-Oriented Research • Experience serving on the University's Biological Sciences Division Institutional Review Board, Pharmacy and Therapeutics Committee, and Clinical Pharmacology Consultation Service • Three training tracks: Clinical Therapeutics, Clinical Therapeutics in Oncology, and Clinical Therapeutics in Industry

Abbreviations: ABCP, American Board of Clinical Pharmacology; FDA, US Food and Drug Administration; HIV, human immunodeficiency virus; NIH, National Institutes of Health; OSU, the Ohio State University.

Fellowship programs in clinical pharmacology should offer a multidisciplinary training experience combining didactics, applied learning, independent study, and one-on-one instruction in pharmaceutical science, personalized medicine, general pharmacology, drug development, toxicology, pharmacogenomics, special-populations (including women, children, geriatrics, and members of ethnic minorities) pharmacology, and clinical trial design and regulation. Designed to meet those requirements, the 2 year clinical pharmacology fellowship program at the Ohio State University (OSU) provides an example of a successful, recently established, accredited training program for physicians, pharmacists, pharmacologists, and those with doctoral degrees in other pharmacology-related disciplines. Variety exists among clinical pharmacology fellowship training programs. The program at OSU, however, effectively illustrates the general training components of a 2 year ABCP-accredited clinical pharmacology fellowship program. It provides an adaptable framework for shaping an entirely new program or for enhancing an existing program. Likewise, the program description may be of particular interest to individuals interested in clinical pharmacology and to those considering fellowship training in clinical pharmacology.

Fellowship training year 1

The first year of fellowship training at OSU is composed mostly of didactic learning; fellows are required to obtain a Master of Science (MS) degree in Pharmacology. Courses are taught by faculty members from the Colleges of Medicine, Pharmacy, and Public Health. The required courses in biostatistics, pharmacokinetics, general pharmacology, ethics, and clinical-trial science are described in Table 2. First year fellows are also required to complete additional assessments, certifications, online tutorials, and training in early-phase clinical trials. These additional learning components, listed in Table 3, complement the formal course work and provide comprehensive training in clinical pharmacology.

Trainees also participate in the National Institutes of Health (NIH)'s online teleconference course, Principles

Table 2 Coursework required to complete the OSU Clinical Pharmacology Fellowship

Course	Credit hours[a]	Course description	Text
Pharmacology 5600, Introduction to General Pharmacology	3	Online instruction; organ systems approach; focuses on drug mechanisms of action	*Lippincott's Illustrated Reviews: Pharmacology,* R Harvey (Lippincott Williams & Wilkins),[10] required
Pharmacology 7250, Pharmacogenomics[c]	2	Discussion- and presentation-based; focuses on basic-science approaches for biomarker development and clinical implications	
Pharmacology 8250, Clinical Trials I	7	Lecture and discussion based; focuses on clinical trial design and federal regulations	*Principles and Practice of Clinical Research* by J Galin and F Ognibene (Academic Press),[11] required
Pharmacology 8260, Clinical Trials II	7	Lecture and hands-on-experience based; focuses on clinical trial document preparation and implementation strategies	
Pharmacology 7510, Professional and Ethical Issues in Biomedical Sciences[b]	2	Lecture and discussion based; focuses on developing and evaluating professional behaviors in biomedical science	
Pharmacy 6220, Drug Delivery II[c]	3	Lecture based; focuses on pharmaceutical dosage forms, ionization, solubility, and stability	
Pharmacy 7310, Clinical Pharmacokinetics I	3	Lecture based; focuses on modeling absorption, distribution, metabolism, and elimination of pharmaceutics and on inter- and intra-patient variability in pharmacokinetics	*Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications* by M Rowland and T Tozer (Lippincott Williams & Wilkins)[12] and *Applied Biopharmaceutics and Pharmacokinetics* by L Shargel, A Yu, and S Wu-Pong (McGraw-Hill Medical),[13] recommended
Pharmacy 7320, Clinical Pharmacokinetics II	3	Lecture based; focuses on the pharmacokinetic–pharmacodynamic relationship of pharmaceutics	
Public Health: Biostatistics 6210, Design and Analysis of Studies in the Health Sciences I	3	Lecture based; focuses on basic data-summary methods, estimation, and hypothesis testing	*Fundamentals of Biostatistics* by B Rosner (Cengage Learning),[14] required
Public Health: Biostatistics 6211, Design and Analysis of Studies in the Health Sciences II	3	Lecture based; focuses on analysis of variance methods and computer-based statistical methodology	

Notes: [a]A minimum of 30 credit hours is required for the Master's degree; [b]pharmacology 7510 is not required for the Master's degree but is a requirement of the fellowship program; [c]students are required to select one of these courses.
Abbreviation: OSU, the Ohio State University.

Table 3 Additional training requirements of first year fellows in the OSU Clinical Pharmacology Fellowship

American Heart Association Basic Life Support (BLS) certification; case simulation and written examination
American Heart Association Advanced Cardiac Life Support (ACLS) certification; case simulation and written examination[a]
American Heart Association Pediatric Advanced Life Support (PALS) certification; case simulation and written examination[a]
Standard Operating Procedures (SOP) for Clinical Trial Implementation; written examination
Good Clinical Practice (GCP); written examination
Collaborative Institutional Training Initiative (CITI) course in the protection of human subjects; computer-based examination
Good Laboratory Practice (GLP); written examination
Code of Federal Regulations (CFR); written examination
Environmental Health and Safety Certificate of Completion for Blood-Borne Pathogens; written examination
Health Insurance Portability and Accountability Act (HIPPA) training; computer-based examination
Environmental Health and Safety Certificate of Completion for Lab Standards – 29 CFR; written examination

Note: [a]Required of physicians only.
Abbreviation: OSU, the Ohio State University.

of Clinical Pharmacology. Covering the fundamentals of clinical pharmacology as a translational scientific discipline focused on rational drug development and utilization in therapeutics, the course comprises a series of approximately 30 weekly lectures, complementing the primary text by Atkinson[6] and reinforcing the participant's basis of knowledge for successful completion of a training program in Clinical Pharmacology and potential ABCP certification. Courses are taught by faculty members from the NIH, the US Food and Drug Administration, the pharmaceutical industry, and several academic institutions from across the US.[7]

Fellowship training year 2

The second year of fellowship training involves mostly hands-on learning. Fellows assist in the design, implementation, and direction of a variety of early- and late-phase pharmaceutical trials at OSU's Comprehensive Cancer Center, pediatric clinical trials at OSU-affiliated Nationwide Children's Hospital, and lifestyle- and nutritional-intervention clinical trials at OSU's NIH-sponsored Center for Clinical and Translational Science Research Center. Clinical-experience objectives to be completed during the fellowship are listed in Table 4. Fellows broaden their basis of knowledge in pharmacology while gaining teaching experience as they assist in the instruction of graduate courses in clinical-trial science (Pharmacology 8250 and 8260) and give lectures and workshops to OSU medical students. Learning experiences in pharmacoanalytic methodology and pediatric pharmacology include didactic and independent instruction as well as clinical learning, and these complete the required training of the final year of the fellowship.

Pediatric clinical pharmacology rotation

This 1 month full-time rotation, led by the pediatrics residency director, incorporates didactic lectures, core reading, and clinical experience at Nationwide Children's Hospital

Table 4 Clinical-experience objectives for the Clinical Pharmacology Fellowship at OSU

Witness and conduct[a] dosing of investigational pharmaceuticals
Support the design and submission of clinical study protocols for review by the Institutional Review Board
Obtain medical and medication histories from adult and pediatric subjects and patients
Perform[a] physical examinations for determining participant eligibility
Interpret[a] electrocardiograms and real-time cardiac telemetry
Obtain informed consent (adults) and assent (children and adolescents) from potential clinical-trial participants
Supervise research staff in the implementation of clinical-trial activities
Collect, process, and store biological samples
Assess, document, and treat[a] adverse events; assist with assigning causality of adverse events
Collect and document data as well as assist with data query resolution
Perform quality assurance checks of source documents and case report forms
Design and implement strategies to recruit patients
Interact and develop professional relationships with representatives from pharmaceutical companies and regulatory agencies
Perform drug preparation, dispensing, and accountability
Supervise and implement laboratory analysis of biological samples
Perform analysis and modeling of pharmacokinetic and pharmacodynamic data
Evaluate standardized study-specific meals ensuring specific caloric and nutritional requirements

Note: [a]Restricted to licensed physicians.
Abbreviation: OSU, the Ohio State University.

Table 5 Additional expectations during the clinical pharmacology fellowship

Write commentaries, abstracts, or manuscripts suitable for publication in peer-reviewed journals
Write investigator-initiated protocols and study-related documents
Write original grant proposals suitable for submission to the National Institutes of Health or private foundations
Attend Institutional Review Board meetings (for both Biomedical Sciences and Behavioral Sciences)
Attend an institutional Health Insurance Portability and Accountability Act privacy board meeting
Participate in monthly journal clubs, presenting and critiquing research relevant to clinical pharmacology
Establish an interactive multidisciplinary network of research and professional collaborators
Explore potential career pathways in academia, the pharmaceutical industry, clinical research organizations, and regulatory agencies

in Columbus, Ohio. Didactic lectures and core reading assignments focus on the following topics: history of pediatric regulations and legislation; assent and consent in pediatric trials; management of adverse events in pediatric trials; balancing risks and benefits in pediatric trials; current trends in pediatric therapeutics, vaccines, and counterterrorism measures; benchmarks in pediatric drug development; physiologic and enzymatic differences between pediatric and adult populations; regulatory differences between pediatric and adult clinical trials; scientific issues relating to the pediatric population, including pharmacokinetics, extrapolation, bridging, safety studies, endpoint analysis and validation; and child growth and developmental issues related to clinical trials. Additional topics addressed during this rotation include pediatric-specific concerns regarding informed consent, protocol requirements, recruitment strategies, scheduling, advertising, coercion, special accommodations, and payment procedures. Clinical experiences during the pediatric rotation focus on current laboratory techniques for pediatric clinical trials, and direct interactions with pediatric patients and their families.

Pharmacoanalytical methodology rotation

This 6 month part-time rotation is supervised by the technical director of the OSU Pharmacoanalytical Shared Resource (PhASR) laboratory. The PhASR laboratory provides investigators with pharmacokinetic and bioanalytical services for preclinical and clinical drug development, and PhASR laboratory activities in experimental design and data analysis primarily support clinical research in the Experimental Therapeutics program at OSU's Comprehensive Cancer Center. During this rotation, fellows receive training and gain hands-on experience in the design and analysis of clinical pharmacokinetic and pharmacodynamic correlative studies. They become directly involved in various phases of multiple clinical trials in order to gain experience in the following areas: pharmacokinetic study design, drug disposition, pharmacodynamic study design, bioanalytical assay development and validation, supply of drug and metabolite standard materials, individual and population pharmacokinetic–pharmacodynamic modeling, and comparison of preclinical real-time and post-trial data.

During the second year, fellows also attend monthly Pharmacology and Therapeutics Committee meetings at OSU's College of Pharmacy, weekly Oncology Phase Clinical Trial meetings at OSU's Comprehensive Cancer Center, and weekly Internal Medicine Grand Rounds lectures at the OSU medical center. Fellows also participate in clinical pharmacology and pharmacy consultations pertaining to drug-dosage adjustments in organ dysfunction and drug–drug interactions. Table 5 provides a list of additional expectations during the Clinical Pharmacology Fellowship.

The final component of the Clinical Pharmacology Fellowship is one-on-one instruction focusing on board-preparation for the ABCP certification examination. Major areas which are reviewed include biostatistics, pharmacokinetics, pharmacodynamics, pharmacogenomics, adverse drug reactions, drug interactions, toxicology, therapeutic drug monitoring, clinical trial design and regulation, drug metabolism and receptors, bioanalytical assays, and therapeutics in pediatric and geriatric populations. Goodman & Gilman's *The Pharmacological Basis of Therapeutics*[9] is the primary reference text for both the fellowship training program and board examination preparation.

Conclusion

The fellowship program at OSU exemplifies a multidisciplinary learning experience that prepares clinical pharmacologists for careers in academic medicine, the pharmaceutical industry, or with regulatory or accreditation agencies. Graduates should be board eligible in Applied Pharmacology (PharmDs and PhDs) or Clinical Pharmacology (MDs and DOs) with the ABCP. In addition, physician graduates should be eligible to become Certified Physician Investigators with the Association of Clinical Research Professionals.[8]

The OSU Clinical Pharmacology Fellowship program is continually exploring additional collaborations to provide further experience-based learning opportunities for fellowship trainees. Optional rotations are being considered in nonclinical research at the OSU College of Veterinary Medicine, basic-science research at the OSU Center for Pharmacogenomics, regulatory training by the US Food and Drug Administration, and industry training/partnership with pharmaceutical companies.

Acknowledgments

The authors express gratitude to Eduard Mikulik, MD for his assistance in the instruction provided in our clinical pharmacology fellowship training program. Funding provided by the National Institutes of Health K23 GM100372 helped to support the development of this manuscript.

Disclosure

The authors have no disclosures or conflicts of interest to declare.

References

1. ACCP [homepage on the Internet]. The American College of Clinical Pharmacology. Available from: http://www.accp1.org/history_objectives.shtml. Accessed February 3, 2014.
2. Lewis LD, Nierenberg DW. American Board of Clinical Pharmacology fellowship training and certification in clinical pharmacology: educational value and future needs for the discipline. *Clin Pharmacol Ther*. 2007;81(1):134–137.
3. Shepherd AMM, Weidler DJ. The American Board of Clinical Pharmacology, Inc. *Clin Pharmacol Ther*. 1993;54(2):117–122.
4. Shepherd AM, Atkinson AJ Jr. Report from American Board of Clinical Pharmacology. *Clin Pharmacol Ther*. 1999;65(4):355–356.
5. ABCP.net [homepage on the Internet]. The American Board of Clinical Pharmacology, Inc.; [updated December 9, 2013]. Available from: http://www.abcp.net. Accessed February 3, 2014.
6. Atkinson AJ, Abernathy DR, Daniels CE, Dedrick RL, Markey SP, editors. *Principles of Clinical Pharmacology*. 2nd ed. San Diego: Academic Press; 2007.
7. NIH.gov [homepage on the Internet]. Principles of Clinical Pharmacology: General Information. The National Institutes of Health; 2014. Available from: http://cc.nih.gov/training/training/principles/info.html. Accessed February 3, 2014.
8. ACRPNET.org [homepage on the Internet]. The Association of Clinical Research Professionals; 2014. Available from: http://www.acrpnet.org/. Accessed February 3, 2014.
9. Parker KL, Brunton LL, Lazo JS. *Goodman & Gilman's The Pharmacological Basis of Therapeutics*. 12th ed. New York: McGraw-Hill; 2011.
10. Harvey RA, Clark MA, Finkel R. *Lippincott's Illustrated Reviews: Pharmacology*. 5th ed. Baltimore: Lippincott Williams & Wilkins; 2011.
11. Gallin J, Ognibene F. *Principles and Practice of Clinical Research*. 2nd ed. New York: Academic Press; 2007.
12. Rowland M, Tozer T. *Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications*. Baltimore: Lippincott Williams & Wilkins; 2010.
13. Shargel L, Wu-Pong S, Yu A. *Applied Biopharmaceutics and Pharmacokinetics*. 5th ed. New York: McGraw-Hill; 2004.
14. Rosner B. *Fundamentals of Biostatistics*. 7th ed. Independance: Cengage Learning; 2010.