

Division of Clinical Pharmacology

DIVISION PROFILE

Number of Faculty	6
Number of Other Students (full and part-time)	1
Number of Support Personnel	2
Annual Total Grant Support (direct)	\$50,120
Annual Total Industry Contracts (direct)	\$98,709
Number of Peer Reviewed Publications	2

FACULTY LISTING

Philip D. Walson, MD, Professor, Division Director, Clinical Pharmacology and Medical Director of the Clinical Trials Office and CCCR

Alexander A. Vinks, PharmD, PhD, Research Professor, Fellowship Director, Clinical Pharmacology

Tracy Glauser, MD, Professor of Pediatrics, Neurology Division

Dan Nebert, MD, Professor, UC Department of Environmental Health

Charles H. Pierce, MD, PhD, UC College of Pharmacy

R. Sallee, MD, PhD, UC Department of Psychiatry

OVERVIEW

The Division of Clinical Pharmacology is involved in clinical, research, and training activities dedicated to improving the care of children through an increase in both the quality and quantity of funded, important and ethically acceptable clinical and basic research. Major progress has been made towards this goal despite the tremendous growth in the complexity of federal requirements for pediatric clinical research, as well as the lack of adequate numbers of trained investigators and clinical support staff, faculty time, and funding. The Division has been moved from the main campus to the Oak Campus as part of the 53,500 sq. ft. Cincinnati Center for Clinical Research (CCCR). This facility, located five minutes by shuttle bus from the main campus, houses the entire Division, as well as the Clinical Trials Office (CTO), the Pediatric Pharmacology Research Unit (PPRU), the Laboratory of Applied Pharmacokinetics and Therapeutic Drug Management (LAP-TDM), Good Laboratory Practice (GLP) compliant laboratories, the Gamble Program for Clinical Studies, a 38-subject, Phase I adult study unit and a 20-room outpatient facility that includes a CRC satellite Dexa-unit.



P. Walson

HIGHLIGHTS

Dr. Walson assumed the position as Division Head of Clinical Pharmacology when Dr. Jennifer Loggie became Emeritus. Additional active faculty members included Drs. Glauser, Nebert, Pierce, Sallee, and Vinks. Dr. Walson's support comes both from the CCRF overhead (as Medical Director, CTO/CCCR) as well as grant, contract, and consulting revenue. He is PI or co-Investigator on a number of industry and federal grants. Dr. Vinks receives salary support from the Department of Laboratory Medicine and is also well funded as an investigator or co-investigator on several NIH and industry grants.

CTO faculty and staff have collaborated with faculty from many divisions to obtain external industry, foundation and federal funding. Division members, especially Drs. Vinks and Glauser have helped establish the first pharmacokinetics/pharmacogenetics consultation service with the Divisions of Neurology (Dr.

Glauser) and Medical Genetics (Dr. Wenstrup). The division's clinical and research laboratories are involved in a number of funded projects.

CLINICAL TRIALS OFFICE (CTO) AND THE CINCINNATI CENTER FOR CLINICAL RESEARCH (CCCR)

In early 2004 the CCCR and CTO management structure merged to provide a solid infrastructure and comprehensive research program which encompasses support services to all of CCRF researchers and facilities to conduct research. The Clinical Pharmacology Division Director (Dr. Walson) became Medical Director of the CCCR. Dr. Vinks became Director of the LAP-TDM laboratory in CCCR and replaced Dr. Sallee, as Principal Investigator of the NICHD funded PPRU. Dr. Walson became a Co-Investigator and the Physician Pediatric Clinical Pharmacologist for the PPRU (see below).

The CTO continues to provide support on a voluntary basis to a number of investigators and divisions that are conducting industry, NIH or investigator initiated clinical trials. Budgetary support is provided by the CTO Budget and Contracts Specialist, Sarah Kleiner, BS, MBA, with help from Dr. Walson and Mindy Muenich, RN, MBA. Ms. Muenich is the Business Director for the CCCR/CTO, Clinical Pharmacology Division and PPRU. The CTO helps prepare many, and reviews all, clinical trial budgets. IRB and other regulatory support is provided by the CTO Regulatory Affairs Coordinator, Jackie Hullfish. The Clinical Research Manager, Melanie Houchell, BS, CCCR supervises the CTO coordinator float pool consisting of nurse and non-nurse clinical trial coordinators who are available to staff CCHMC trials. The CTO also maintains reliable, retrievable off-site storage for clinical trial files. The office produces or helps investigators produce both general and trial specific recruitment materials. High quality, effective, internal and external marketing brochures and displays have been developed. The CTO marketing and recruiting manager, Mr. Mark Schuller, MA, provides support to a growing number of investigators and coordinators who request CTO assistance. Effective and professional internal and external study recruitment marketing tools, provided through cooperation with the Marketing and Communications Department, include print information, public relations activities, and print and broadcast advertising. The CTO also maintains adult and pediatric subject databases that are used to identify subjects for studies. Ms. Houchell has also developed a clinical coordinator training program for use by the CTO. In collaboration with the E-Health and Information Services, Mr. Schuller redesigned and greatly improved the CTO and CCHMC webpages to better support clinical trial information and subject identification.

TRAINING

Ivana Kacirova, MD		Ostrava, Czech Republic
Leslie A. Stalker	Year III	University of Cincinnati College of Medicine
Timothy P. Welch	Year IV	University of Cincinnati College of Medicine

GRANTS, CONTRACTS AND INDUSTRY AGREEMENTS

Grant and Contract Awards

Annual Direct/Project Period Direct

Walson, P

Rational Therapeutics for the Pediatric Population

Agency for Healthcare Research and Quality (University of North Carolina subcontract)

U18 HS GM 10397

09/30/02 – 09/29/05

\$50,120/\$152,503

Current Year Direct

\$50,120

Industry Contracts

Walson, P

Aventis Pharmaceuticals	\$15,161
Johnson & Johnson	\$13,834
Mallinckrodt	\$11,297

Merck & Co., Inc.	\$5,247
Omnicare	\$2,695
SmithKlineBeecham	\$33,105
Wyeth Ayerst	\$17,370

Current Year Direct Receipts	\$98,709
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TOTAL	\$148,829
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PUBLICATIONS

1. **Walson PD**. Interpreting medical research results. Clin Ther 2004;26(5):779.
2. **Walson PD**, Cox S, Utkin I, Gerber N, Crim L, Brady M, Koranyi K. Clinical use of a simultaneous HPLC assay for indinavir, saquinavir, ritonavir and nelfinavir in children and adults. Ther Drug Monit 2003;25(6):650-6.