### APPENDICES

<table>
<thead>
<tr>
<th>Appendix</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appendix A</td>
<td>Disease Oriented Publications</td>
</tr>
<tr>
<td>Appendix B</td>
<td>Listing of PPRU Publications in POPPK</td>
</tr>
<tr>
<td>Appendix C</td>
<td>Traditional PK/PD Modeling Listing of Studies</td>
</tr>
<tr>
<td>Appendix D</td>
<td>Analytical Pharmacology Core Library Assays</td>
</tr>
<tr>
<td>Appendix E</td>
<td>PG Publications Emanating from the PPRU Network</td>
</tr>
<tr>
<td>Appendix F</td>
<td>PPRU Data Repository White Paper</td>
</tr>
<tr>
<td>Appendix G</td>
<td>List of Patient Oriented Publications</td>
</tr>
<tr>
<td>Appendix H</td>
<td>List of Publications in Neonatology</td>
</tr>
<tr>
<td>Appendix I</td>
<td>Trainee Publications and Career Progression</td>
</tr>
<tr>
<td>Appendix J</td>
<td>List of Publications with Multi Disciplinary Investigators</td>
</tr>
</tbody>
</table>
Appendix A

*Disease Oriented Publications*
Disease Oriented Publications

**ADHD**


**Asthma**


Appendix A: Disease Oriented Publications


Vanden Burgt JA, Busse WW, Martin RJ, **Szefler SJ**, Donnell D. Efficacy and safety overview of a new inhaled corticosteroid, QVAR (hydrofluoroalkane-beclomethasone extrafine inhalation aerosol) in asthma. *Journal of Allergy and Clinical Immunology*. Dec; 106(6):1209-26.


**Atopic Dermatitis**


**Autism**


**Childhood Cancer**


Appendix A: Disease Oriented Publications


Papers of interest identified between 2004 and 2006:


**Cystic Fibrosis**


**Diabetes**


**Heart Disease**


**HIV**


Appendix A: Disease Oriented Publications


**Hypertension**


Appendix A: Disease Oriented Publications


**Infectious Diseases**


Inflammatory Bowel Disease


Pain Management


Lehr VT, Cepeda E, Frattarelli DA, Thomas R, LaMothe J, Aranda JV. Lidocaine 4% cream compared with lidocaine 2.5% and prilocaine 2.5% or dorsal penile block for circumcision. *American Journal of Perinatology.* July 2005; 22(5): 231-237. **PPRU Protocol # 10522.**


**Psychiatric Disorders**


**Respiratory Failure**


**Seizure Disorders**


**Toxicology/Overdoses**


Appendix B

Listing of PPRU Publications in Population Pharmacokinetics
Listing of PPRU Publications in Population Pharmacokinetics


Appendix C

Traditional PK/PD Modeling
Listing of Studies
Examples of PPRU Pharmacometric Study Activity

I. Traditional PK/PD studies - In vitro, in silico, in vitro and animal studies-used directly for PPRU study design
   - Actinomycin PK - physiologic based modeling
   - Azithromycin in mouse model for BPD - both pre-clinical PK and PD
   - Cisapride - metabolism studies performed to determine pathway for metabolite formation
   - Codeine /Morphine CSF penetration - primate modeling for pain initiative
   - Dextromethorphan – in vitro expression and characterization (kinetic) of functional consequences of newly discovered allelic variants
   - Fluticasone - reaction phenotyping used to characterize role of CYP3A4 isoforms in biotransformation
   - Lamisil – in vitro and in vivo characterization of inhibition of CYP2D6 in humans

II. Modeling and Simulation (MS) Used in PPRU Study Design
   - Absence Epilepsy – MS used to develop dosing strategies – including compiling clinical data from to develop preliminary models. Integrated model to revise company dosing algorithm.
   - Acetaminophen protein adducts – Modeling of preliminary data used to determine sampling scheme for ADR grant application.
   - Actinomycin – PBPK modeling used with MS used to developing dosing strategies.
   - Azithromycin – MS based pediatric data to develop model for BAL concentrations and intracellular accumulation. Dosing and PK study design based on these activities.
   - Daptomycin – MS performed (PK/PD) as the basis for projection of dosing regimens for phase III pediatric program.
   - Fexofenadine – MS performed as the basis to develop design for Pop PK studies.
   - Fluconazole – MS used to determine dose. Re-analyzed data from literature. Incorporated newborn PK data and models from PK studies in simulations
   - Ibuprofen for PDA – MS used to determine dosing and sampling strategy – incorporated prior data collected outside PPRU. Used to justify study design change to FDA.
   - Inositol – ongoing MS to develop dosing for collaboration with Neonatal Network studies. Non-linear reabsorption capacity and endogenous production confounders in this model.
   - Lorazepam for Sedation – MS to determine dosing strategy with adaptive design. Initial target concentration achieved by bolus maintained by continuous infusion
   - Lorazepam for Status –MS use from initial study to develop dosing for second efficacy trial
   - Meropenem – MS used to develop dosing strategy and PK design for sampling.
• Morphine in infants – MS to determine dosing (prior dose led to toxicity). Developmental model derived from prior models including incorporation of data/models from literature.
• Pleconaril – MS performed as the basis to develop PK aspects for pleconaril protocols in collaboration with CASG.

III. Proteomics Discovery
• Aminoglycoside toxicity
• APAP Toxicity
• Azithromycin
• Ibuprofen (Det)
• Remicaide

IV. Tissue based PK modeling
• Azithromycin (BPCA Proposal)
  – BAL concentrations
  – Intracellular concentrations
• Breast Milk ARV penetration (supplemental funds)
• Codeine Pain initiative – CSF penetration study
• Cisapride disposition – small intestinal translocation assay
• Meropenem (BPCA sub study)
• Small molecule Bcl2 inhibitor tissue distribution – Infant ALL disease model (translational studies – CTSA and leukemia society funds)

V. Clinical trials with PK/PG emphasis
• Absense Epilepsy
• Azithromycin PK
• Buspirone
• Lorazepam Sedation
• Midazolam
• Morphine Infant Pain
• Mycophenolic acid in renal transplant
• Pantoprazole

VI. Imaging research studies
• Autism
  – Early Pharmacotherapy Guided by Biomarkers in Autism
  – Utilizing PET Imaging
• Laser Doppler flowimetry to quantitate microvascular response to drugs
• Use of stable isotopes to quantitate gastric emptying (13C acetate) and DME activity (13C dextromethorphan)
Appendix D

Analytical Pharmacology Core
Library Assays
## Drug Assays Available at PPRU Sites

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Appendix E

PG Publications Emanating from the PPRU Network
PPRU Network Publications Involving Pharmacogenetics / Pharmacogenomics 1998 to 2008

Studies Exploring Developmental Pharmacogenomics (Ontogeny)


Pharmacogenetic/Pharmacogenomic Studies Supporting Clinical Trials


**Pharmacogenomics of Disease Expression**


**Studies Exploring Gene Frequency and/or Genotype / Phenotype Association**


**Discovery, Method Development/Validation, Method Application/Review Articles**


37. **Leeder JS, Kearns GL**. The challenges of delivering pharmacogenomics into clinical pediatrics. Pharmacogenomics J. 2002; 2: 141-143.


Appendix F

*PPRU Data Repository White Paper*
PPRU Clinical Data Repository (PeDaR)

SUMMARY

The development of a process and environment to capture, store and visualize PPRU-generated data is being pursued by a sub-team of the PPRU Network with the intention of developing a strategy and proposal for broader dissemination, feedback and eventual acceptance. In conjunction with the NIH Roadmap Initiative as well as NIH’s data sharing policy, this effort aims to provide a standardized, secure environment to house data generated within the PPRU. While the primary focus of the effort will be constructed around ongoing and future trials, there will be a strategy to accumulate historical data as well. The proposed PPRU Clinical Data Repository (PeDaR) will provide a single secure location for the storage of all investigator initiated study data to promote data sharing and meta data analysis. The foundation of the PeDaR is built upon existing and widely adopted standards such as CDISC and BRIDG models. In addition, the PPRU Repository PK module potential to provide additional analysis capabilities is also discussed along with the potential for linking to additional data stores (e.g., non-PPRU data). The purpose of this document is to garner feedback from the PPRU investigators so that a more definitive path forward can be defined and that an agreement with the various stakeholders can be pursued.

BACKGROUND

In 1994, NICHD formed the Pediatric Pharmacology Research Units (PPRU) Network to address the information gaps regarding the safety and efficacy of pediatric drugs and the Pediatric Plan published by FDA’s Center for Drug Evaluation and Research (CDER). The PPRU mission is to develop and disseminate new information that facilitates drug development and improves drug therapy for children. The Network has evolved over the 13 years since its inception and currently its focus reflects the increasing biological complexity in research.

Early drug oriented therapeutics focused on pharmacokinetic (PK) and labeling studies and understanding drug response and drug disposition. The focus evolved to exploring disease oriented therapeutics and increasingly is directed to understanding patient oriented therapeutics and the molecular determinants of drug responsiveness to explain pharmacokinetics, pharmacogenetics (PG), drug toxicity, genomics, proteomics, modeling, and lack of efficacy. To address these research areas, the PPRU performs PK studies (Phase I-II), PK/PD investigations and translation science integrating drug metabolism and PG and proteomics. Innovative approaches to trial design and execution enable the Network to explore the effects of childhood development on the pharmacokinetics of drugs, the influence of age-specific changes in drug disposition and pharmocodynamics, and the interplay between disease states and stage of development. The PPRU Network sites are conducting clinical studies in a wide array of therapeutic areas. Interventions for common disorders, such as allergies, asthma, and upper respiratory infections, as well as less common disorders, such as cystic fibrosis, severe infections, AIDS, sickle cell anemia, cancer, and childhood depression have been studied.
by the Network.

The PPRU has been extremely productive during its existence and its output can be measured in patient experience. From 1994 through June of 2007, 9292 children have been enrolled in 264 studies (161 designed/co-designed by industry sponsor and 103 designed by investigator). While much of these data have been used in various publications, submitted to NIH and/or FDA and presented in various scientific forums, the location of the actual source data may be unknown. While there have been efforts to pool data for various meta analyses, these have been typically pursued on a project by project basis without any attempt to do this for a network wide objective. Some data pooling projects have also occurred without an exhaustive effort to ensure that all data available was included in the meta analysis. More importantly, there is no insurance that the data are being maintained in a reasonable electronic format beyond the time they are reported. The data are a valuable resource. The utility of such data beyond their original intended purpose is being appreciated particularly in the design of subsequent, prospective studies in similar populations. In addition, much of the PPRU-generated data are embedded in product labels or drug monographs. Such data are often used to drive dosing guidance, warnings and/or contraindications. Likewise, a more comprehensive strategy to house, maintain and provide access to this data is warranted.

This white paper discusses the project scope and functional requirements for a PPRU Clinical Data Repository (PeDaR). The repository will consist of a data warehouse maintained by the Network Coordinating Center (CC) with a user interface for downloading into analytic platforms. One such platform, iClinical, is designed for member access to data once compliance/permissions are established. PeDaR will contain not only PK data but will also house data generated from Network-affiliated studies regardless of study design or objectives. Thus, the repository can be used to:

- house study-related data from PPRU-affiliated trials
- index and join PK, PD, PK/PD and relevant PG data for across agent, therapeutic class and patient population
- create a data mart of PK, PD, PK/PD and relevant PG data that can be accessed and queried by PPRU CDR members
- index and join demographic and physiologic parameters for patients participating in PPRU trials
- create a data mart of demographic and physiologic parameter data that can be accessed and queried by PPRU PeDaR members

Other uses will certainly be defined and should be prioritized as they will impact the final functional requirements that define the IT effort.

**PROJECT SCOPE**

The project scope will address the following:
• Define and adopt standard data dictionaries for the definition of clinical, PK, PK/PD data, protocol/study elements etc to be stored in the PPRU data repository

• Define the process for identifying data to be collected and stored by CC into the PeDaR.

• Define the process for assigning rules / permissions on data access, within and across studies in the PPRU repository.

• Define requirements for the analytical interface to allow investigators to view, select and abstract data from the repository.

FUNCTIONAL REQUIREMENTS

Assuming the PPRU investigators support and agree with the PeDaR, the development of formal project requirements will proceed. Requirements will focus on the development of procedures to ensure the seamless registration of studies to the PeDaR and the details of accessibility and governance.

Development of standard data dictionaries is underway as is the development of common data collection forms. These are essential first steps in the workflow to be formalized upon broader acceptance of this proposal.

ACCESS and GOVERNANCE

Given the previous concerns around privacy, intellectual property and industry consent, much of the initial effort for the PeDaR project will be focused on detailing proposals for access and governance. As the initial effort will be focused on current and future studies, it is proposed that the PPRU craft language around the requirements of PeDaR to fulfill its commitment to the NIH data sharing policy and communicate this prospectively when dealing with industrial sponsors. Likewise, initially PeDaR will reflect the current PPRU data stakeholders so language on the privileges, access and accountability extended to PPRU sites and investigators will be defined in an agreement to be signed by those participating in the PeDaR creation. It should be appreciated by all that this may be a requirement in future RFPs of the PPRU.

Once the protocol is approved, the Coordinating Center will define the study template for the data warehouse. After study completion, access rights to the data will be determined and assigned.

Based on each investigator’s profile and the definition of study stakeholder status and privileges, access to data will be provided. Likewise, access to completed and/or historical data can be petitioned to the PPRU CDR Committee (to be designated) so that meta-data can be assembled for further analysis. These details will be captured in the PeDaR agreement that all participants would ultimately agree to and sign.
APPENDIX A: Timeline

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<td>Demo of iClinical for Pharmacometrics</td>
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<td>Develop Governance and Data Sharing Policies</td>
<td>2/1/2008</td>
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<td>Core Forms &amp; Commons; Data Elements Finalized</td>
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Appendix G

List of Patient Oriented Publications
Patient-Oriented Therapeutics Publications


**Kennedy MJ**, Davis DA, Smith NB, Pierce WM, Pearce RE, **Gaedigk A**, **Kearns GL**. Growth Hormone Has No Effect on Activities of CYP1A2, N-acetyltransferase 2, Xanthine Oxidase or CYP2D6 in Children with Idiopathic Growth Hormone Deficiency. Submitted for publication

**Kennedy MJ**, Griffin AR, Su R, Merchant M., Klein JB. Urine collected from diapers can be used for proteomic profiling in infants and young children. Submitted for publication


Appendix H

List of Publications in Neonatology
PPRU Network Publications Involving Neonatology 1994 to 2008

**Neonatal Publications 1994-1998**


**Neonatal Publications 1999-2003**


De Wildt SN, **Kearns GL.** Hop WC, Murry DJ, Abdel-Rahman SM, **van den Anker JN.** Pharmacokinetics and metabolism of intravenous midazolam in preterm infants. Clin Pharmacol & Therapeutics 2001; 70(6):525-531.


**Neonatal Publications 2004-Present**


Kovacs A, Cowles MK, Britto P, **Capparelli E**, et al. Pharmacokinetics of didanosine and drug resistance mutations in infants exposed to ZDV during gestation or postnatally and treated with didanosine and zidovudine in the first three months of life. Ped Infect Dis J 2005; 24:503-509.

Lehr VT, Cepeda E, Frattarelli DA, Thomas R, LaMothe J, Aranda JV. Lidocaine 4% cream compared with lidocaine 2.5% and prilocaine 2.5% or dorsal penile block for circumcision. Am J Perinatol 2005; 22(5):231-237.


Lugo RA, Ballard J. Albuterol delivery from MDI and spacer is reduced following short duration manual ventilation in a neonatal ventilator-lung model. Respiratory Care 2004; 49(9):1029-1034.


Appendix I

Trainee Publications and Career Progression
Trainee Publications and Career Progression  
(all trainees are in bold)

1995


1996


1998


1999


2000


2001


2002


2003


2004


**2005**


Carlsson KC, Hoem NO, Glauser TA, Vinks AA. Development of a population


2006


Gaedigk A, Bradford LD, Alander SW, Leeder JS. CYP2D6*36 gene arrangements within the cyp2d6 locus: association of CYP2D6*36 with poor metabolizer status. Drug Metab Dispos. 2006; 34; 563-569.


Appendix I: Trainee Publications


2007


Glauser TA. Designing practical evidence-based treatment plans for children with prolonged seizures and status epilepticus. J Child Neurol. 2007 May; 22(5 Suppl):38S-46S.


Appendix I: Trainee Publications


Appendix I: Trainee Publications

2008


Menon D, Mondick JT, Jayaraman B, Thompson PA, Blaney SM, Adamson PC, Barrett JS. Population Pharmacokinetics of Imatinib Mesylate and its Metabolite in Children and Young Adults. (accepted, Cancer Chemother and Pharmacol)


Santos RP, Mayo TW, Siegel JD Active Surveillance Cultures and Contact Precautions for Control of Multidrug-Resistant Organisms: Ethical Considerations Clinical Infectious Diseases Accepted for publication (3-19-08)

Skolnik JM and Barrett JS. Refining the Phase 1 Pediatric Trial. (accepted, Pediatric Health)


Smith PB, Li JS, Murphy DM, Califf RM, and Benjamin DK Jr. Adverse Events in Placebo-controlled Pediatric Hypertension Hypertension (2008; 51 in press; [Epub ahead of print])


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<th>Description of Training</th>
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<td>Arkansas</td>
<td>Laura James, MD</td>
<td>1994-1996</td>
<td>Pediatric Clinical Pharmacology Fellow; Associate Clinical Pharmacologist</td>
<td>PI for the Arkansas PPRU</td>
<td>R03, R01, STTR grant recipient; Diplomat ABCP</td>
<td>Associate Editor, Clinical Pharmacology and Therapeutics</td>
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<td>Arkansas</td>
<td>Jim Marshall, MD</td>
<td>1994-1996</td>
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<td>Cook Children's Hosp, TX</td>
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<td>Arkansas</td>
<td>Cindy Stowe, PharmD</td>
<td>1996-1998</td>
<td>Associate Clinical Pharmacologist</td>
<td>Associate Dean, UAMS School of Pharmacy</td>
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<td>Arkansas</td>
<td>Holly Maples, PharmD</td>
<td>2001-2003</td>
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<td>UAMS School of Pharmacy; Arkansas Children's Hospital</td>
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<td>Arkansas</td>
<td>Brian Donahoo</td>
<td>2004-2007</td>
<td>Pharmacology graduate student</td>
<td>Research associate, UAMS Cancer Institute</td>
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<td>Arkansas</td>
<td>Catherine O'Brian, PharmD</td>
<td>2008-Current</td>
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<td>Baylor</td>
<td>Lisa Bongars, MD</td>
<td>1999-2000</td>
<td>PPRU Associate Clinical Pharmacologist</td>
<td>Associate PI for Baylor; PPRU Assistant Professor of Pediatrics</td>
<td>Diplomate, American Board of Clinical Pharmacology; Chair, ASCPT Education Committee</td>
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<td>Baylor</td>
<td>Kathleen Neville, MD</td>
<td>2001-2002</td>
<td>MISCIDA fellow</td>
<td>Mentoring Pediatric Pharmacology and Pharmacogenetics Fellow.</td>
<td>K23 grant recipient (NHLBI); Diplomat of ABCP</td>
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<td>Patrick Thompson, MD</td>
<td>2005-Current</td>
<td>MISCIDA fellow</td>
<td>Assistant Professor Pediatrics BCM</td>
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<td>Lindsay Kilburn, MD</td>
<td>2005-Current</td>
<td>T32 - BCM Training Research Program for Pediatrics: K12 Faculty Fellowship in Hematology-Oncology Clinical Pharmacology Research Track</td>
<td>Clinical Instructor Pediatrics BCM</td>
<td>Diplomate American Board of Clinical Pharmacology; Clinical Pharmacology Reviewer; US FDA</td>
<td>Clinical Pharmacology Reviewer; US FDA</td>
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<td>Emma Jones, M.D.</td>
<td>2007-Current</td>
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<td>Fellow Department of Pediatrics BCM</td>
<td>T32 Research Training Grant recipient</td>
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<td>Patricia Baxer, M.D.</td>
<td>2007-Current</td>
<td>Current Clinical Pharmacology Fellow; T32 - BCM Training Research Program for Pediatrics</td>
<td>Fellow Department of Pediatrics BCM</td>
<td>T32 Research Training Grant recipient</td>
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<td>Divya Menon, PhD</td>
<td>2006-2008</td>
<td>Pharmacometrics Fellow - GSK Postdoc</td>
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<td>Assistant Professor, Pediatrics, U. Penn School of Medicine</td>
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<td>Olivia Marzine, MD</td>
<td>2007-Current</td>
<td>Clinical Pharmacology Fellow</td>
<td>Fellow, Neurology</td>
<td>ACCP New member award (2006); ACCP Postdoc award (2007)</td>
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<td>2007-Current</td>
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<td>2005-2006</td>
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<td>Marish Gupta, PhD</td>
<td>2005-2007</td>
<td>Pharmacometrics Fellow - Pfizer Postdoc</td>
<td>CHOP Postdoc</td>
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<td>Principal Scientist, Modeling &amp; Simulation, Genentech Pharmaceuticals; Clinical Pharmacology Reviewer; US FDA</td>
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<td>Divya Menon, PhD</td>
<td>2006-2008</td>
<td>Pharmacometrics Fellow - GSK Postdoc</td>
<td>CHOP Postdoc</td>
<td>ACCP New member award (2006); ACCP Postdoc award (2007)</td>
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<td>Mark Solomon, MD</td>
<td>2000-2003</td>
<td>Clinical Pharmacology and Pediatric Clinical Trials; Supervised collaborative clinical trials initiated through the PPRU.</td>
<td>Private Practice, Pulmonary Medicine, Galveston, Texas</td>
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<td>Cincinnati</td>
<td>Tracy Glauser, MD</td>
<td>2000-2003</td>
<td>Clinical Pharmacology and Pharmacogenetics as part of K08 training.</td>
<td>Professor, Division of Neurology, Cincinnati Children's Hospital Medical Center</td>
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<td>Cincinnati</td>
<td>Diego Morla, MD</td>
<td>2002-present</td>
<td>Clinical Pharmacology and Pharmacogenetics and pharmacokinetic/pharmacodynamic modeling approaches to individualized therapy</td>
<td>Assistant Professor; Division of Neurology, Cincinnati Children's Hospital Medical Center</td>
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<td>Ivana Kadrova, MD</td>
<td>2003-2004</td>
<td>Pediatric Clinical Trials and Therapeutic Drug Management</td>
<td>Assistant Professor, Ostrava University, Czech Republic</td>
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<td>Red Clin Pharmacology Fellow</td>
<td>Assistant Professor, Division of Hematology/Oncology, Cincinnati Children's Hospital Medical Center</td>
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<td>2004-2005</td>
<td>Clinical Pharmacology and Peds Clinical Trials</td>
<td>Fellow, Clinical Pharmacology, University of Chicago</td>
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<td>Reuven Schore, MD</td>
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<td>Red Clin Pharmacology Fellow, MISCIDA candidate</td>
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<td>Population PK/PD modeling and simulation</td>
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<td>Stephanie Mehar, MD</td>
<td>2007-present</td>
<td>Phase II study design in neonates, Population PK/PD modeling and simulation</td>
<td>Fellow, Neonatology/PPRU</td>
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<tr>
<td>Cleveland</td>
<td>Janice Sullivan, MD</td>
<td>1994-1996</td>
<td>Peds Clin Pharmacology Fellow</td>
<td>Assoc Prof Nova SE Univ College of Pharmacy Fl Lauderdale FL</td>
<td></td>
<td></td>
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<tr>
<td>Cleveland</td>
<td>Mark Glover, PharmD</td>
<td>2000 - 2002</td>
<td>Red Clin Pharmacology Fellow</td>
<td>Assoc Prof Pharmacy Practice, Auburn Univ, Harrison School of Pharmacy, Mobile AL</td>
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</tr>
<tr>
<td>Cleveland</td>
<td>Todd Kociancic, PharmD</td>
<td>2001 - 2003</td>
<td>Red Clin Pharmacology Fellow</td>
<td>BCPS Clin Specials, Ctr Care Med, Rose Dominican Hospitals, Nevada</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cleveland</td>
<td>Michelle Bestic, PharmD</td>
<td>2004 - 2006</td>
<td>Red Clin Pharmacology Fellow</td>
<td>Instructor in Pediatrics, Case Western Res Univ, Cleveland OH; Staff, Rainbow Babies &amp; Children's Hospital, Cleveland OH</td>
<td></td>
<td></td>
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<tr>
<td>Cleveland</td>
<td>Martha Blackford, PharmD</td>
<td>2006-2007</td>
<td>Red Clin Pharmacology Fellow</td>
<td>UC Rainbow Babies and Children's Hospital on 06/30/07 to complete fellowship at Akron Children's Hospital</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CNMC</td>
<td>Julia Finkel, MD</td>
<td>2004-2006</td>
<td>PPRU Adjunct Clinical Pharmacologist</td>
<td>Assoc PI CNMC PPRU; Assoc Professor Peds and Anesth</td>
<td>Vice Chair of Anesthesia and Pain Medicine at CNMC</td>
<td></td>
</tr>
<tr>
<td>CNMC</td>
<td>Darbari, MD</td>
<td>2005-2007</td>
<td>Red Clin Pharmacology Fellow</td>
<td>Ass Prof Peds Georgia Washington Univ</td>
<td>WI start fellowship Pediatric Hematology/Oncology at Hopkins July 2008</td>
<td></td>
</tr>
<tr>
<td>CNMC</td>
<td>Rackmanina, MD</td>
<td>2008-now</td>
<td>PPRU Adjunct Clinical Pharmacologist</td>
<td>Ass Prof Peds Georgia Washington Univ</td>
<td>Program Director HIV/AIDS at CNMC and currently funded through K-12 award</td>
<td></td>
</tr>
<tr>
<td>CNMC</td>
<td>Best, MD</td>
<td>2005-2007</td>
<td>Red Clin Pharmacology Fellow</td>
<td>Ass Prof Peds Georgia Washington Univ</td>
<td>Has received several grants for her studies in passive smoking in African American children</td>
<td></td>
</tr>
<tr>
<td>CNMC</td>
<td>Rhotz, MD</td>
<td>2006-2008</td>
<td>PPRU Adjunct Clinical Pharmacologist</td>
<td>Ass Prof Peds Georgia Washington Univ</td>
<td>Member AMP Committee on Drugs</td>
<td></td>
</tr>
<tr>
<td>North Carolina</td>
<td>Brad Harris, MD</td>
<td>7/1/04 - 6/30/06</td>
<td>Clinical trial, PhD program Assistant Professor, UNC Department of Pediatrics</td>
<td>Assistant Professor of Pediatrics, University of North Carolina</td>
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<tr>
<td>North Carolina</td>
<td>Cassandra Moran, MD</td>
<td>7/1/04 - 6/30/06</td>
<td>Pharmacology position</td>
<td>Instructor, Duke University</td>
<td></td>
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<tr>
<td>North Carolina</td>
<td>Brian Smith MD</td>
<td>2006-2008</td>
<td>MPh Biostatistics with concentration in PK-PD</td>
<td>Assistant Professor Neonatology Duke University</td>
<td></td>
<td></td>
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<tr>
<td>North Carolina</td>
<td>Micky Cohen-Walkowitz, MD</td>
<td>2006-2009</td>
<td>PhD School of Pharmacy UNC</td>
<td>Fellow, Pediatric Infectious Disease Duke University</td>
<td></td>
<td></td>
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<tr>
<td>North Carolina</td>
<td>Suzzan Yaniri</td>
<td>2006-2010</td>
<td>PhD School of Pharmacy UNC</td>
<td>Doctoral Student University of North Carolina</td>
<td></td>
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</tr>
<tr>
<td>Kansas City</td>
<td>Jennifer A. Lowry, M.D.</td>
<td>1996-2002</td>
<td>MScCk fellow, joint fellowship in Pediatric Clinical Pharmacology and Medical Toxicology</td>
<td>Assistant Professor of Pediatrics and Director, Regional Poison Control Ctr., University of Kansas School of Medicine, Kansas City, KS</td>
<td>ASCPT President's Award; Midwest SSPR Young Investigator's Award</td>
<td></td>
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<tr>
<td>Kansas City</td>
<td>Mary Jayne Kennedy, Pharm.D</td>
<td>2000-2002</td>
<td>Pediatric Clinical Pharmacology Fellow</td>
<td>Assistant Professor of Pediatrics and Pharmacology, Associate Director, Kosair Charities Pediatric Clinical Research Unit, University of Louisville and Kosair Children's Hospital, Louisville, KY</td>
<td>Invited Member, NHLBI Early Pseudomonas Infection Control (EPIC) Trial DSMB, Editorial Board, Journal of Pediatric Pharmacology and Therapeutics</td>
<td></td>
</tr>
<tr>
<td>Kansas City</td>
<td>Martin O. Bahm, M.D.?</td>
<td>2001-2004</td>
<td>Pediatric Clinical Pharmacology Fellow</td>
<td>Medical Director, Drug Safety McNeil Consumer Products Division, Johnson &amp; Johnson Co., Inc.</td>
<td>ASCPT President’s Award</td>
<td></td>
</tr>
<tr>
<td>Kansas City</td>
<td>Kathy Williams, M.D.</td>
<td>2001-2003</td>
<td>Combined Infectious Disease and Clinical Pharmacology Fellowship</td>
<td>Private practice of Pediatrics, London, England</td>
<td>ASCPT President’s Award</td>
<td></td>
</tr>
<tr>
<td>Kansas City</td>
<td>Sarah W. Alander, M.D.</td>
<td>2001-2003</td>
<td>Pediatric Clinical Pharmacology Fellowship</td>
<td>Dept. of Emergency Medicine, St. John's Hospital, St. Louis, MO</td>
<td></td>
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<tr>
<td>Kansas City</td>
<td>Michael J. Blake, M.D., Ph.D.</td>
<td>2002-2004</td>
<td>Pediatric Clinical Pharmacology Fellow</td>
<td>Pediatric Practice, Ottawa, Iowa</td>
<td>ASCPT President’s Award</td>
<td></td>
</tr>
<tr>
<td>Kansas City</td>
<td>Lisa M. Castro, M.D.</td>
<td>2004 – 2005</td>
<td>Pediatric Clinical Pharmacology Fellowship</td>
<td>Assistant Professor of Pediatrics and member, Divisions of Neonatology and Pediatric Pharmacology &amp; Medical Toxicology, University of Missouri-Kansas City School of Medicine and Children's Mercy Hospitals and Clinics, Kansas City, MO</td>
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<tr>
<td>Site</td>
<td>Name</td>
<td>Dates of training</td>
<td>Description of Training</td>
<td>Titles or Position / Institution</td>
<td>Special honors/ recognition</td>
<td>Current Professional Leadership Roles in Clinical Pharmacology</td>
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<tr>
<td>Kansas City</td>
<td>Bridgette A. Jones, M.D.</td>
<td>August 2007 - present</td>
<td>Pediatric Clinical Pharmacology Fellowship</td>
<td>Assist. Clinical Professor in Pediatrics, Member, Division of Allergy/Asthma/Clinical Immunology, Children's Mercy Hospitals and Clinics and UMCK School of Medicine, Kansas City, MO</td>
<td>ASCPT President's Award</td>
<td></td>
</tr>
<tr>
<td>Louisville</td>
<td>Amanda Myers, MD, MSPH</td>
<td>2004 - 2006</td>
<td>PPRU Adjunct Clinical Pharmacologist</td>
<td>Assistant Professor of Pediatrics, Division of Emergency Medicine; Medical staff of the Kosair Charities Pediatric Clinical Research Unit and Louisville PPRU, Louisville, KY</td>
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<tr>
<td>Louisville</td>
<td>Carmen T. Condurache, M.D.</td>
<td>2007 -</td>
<td>PPRU Adjunct Clinical Pharmacologist</td>
<td>Instructor in Pediatrics, division of Hospitals and Kosair Charities Pediatric Clinical Research Unit and Louisville PPRU, Louisville, KY</td>
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<tr>
<td>Louisville</td>
<td>Katherine Potter, M.D.</td>
<td>2004 - 2007</td>
<td>Fellow</td>
<td>Assistant Professor, Division of Pediatric Critical Care, Department of Pediatrics, University of Louisville, Louisville, KY</td>
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<tr>
<td>LSU</td>
<td>Ken Adcock, MD</td>
<td>1998-2000</td>
<td>Fellow</td>
<td>Assistant Professor Pediatrics/University of Mississippi Medical Center</td>
<td></td>
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<tr>
<td>LSU</td>
<td>Roy Pantal, PharmD</td>
<td>1995-1996</td>
<td>Fellow</td>
<td>British Health Service</td>
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<tr>
<td>LSU</td>
<td>Margaret Ann Springst, MD</td>
<td>2001-2003</td>
<td>Faculty trainee</td>
<td>Assistant Professor Pediatrics/LSUHS-Shreveport</td>
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<tr>
<td>LSU</td>
<td>Neera Sirac, PhD</td>
<td>1996</td>
<td>Staff Trainee</td>
<td>Industry</td>
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<tr>
<td>LSU</td>
<td>James Hision, MD</td>
<td>1996</td>
<td>Graduate student</td>
<td>Industry</td>
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<tr>
<td>Tennessee</td>
<td>Shannan Eades, Pharm.D.</td>
<td>7/1/96 - 6/30/98</td>
<td>Pediatric Clinical Pharmacology</td>
<td>Director Clinical Pharmacy Services, National Children's Hospital, Washington, DC</td>
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<tr>
<td>Tennessee</td>
<td>Robin Mckeen, Pharm.D.</td>
<td>7/1/96-6/30/00</td>
<td>Pediatric Clinical Pharmacology</td>
<td>Pediatric Clinical Pharmacist, Denver Children's Hospital</td>
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<tr>
<td>Tennessee</td>
<td>Majed Al-Jeraisy, Pharm.D.</td>
<td>7/1/00-6/30/01</td>
<td>Pediatric Clinical Pharmacology</td>
<td>Director Pediatric Clinical Pharmacist Services, King Faisal Hospital, Riyadh, Saudi Arabia</td>
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<tr>
<td>Tennessee</td>
<td>John Whitworth, M.D.</td>
<td>7/1/06-6/30/03</td>
<td>Pediatric Clinical Trials</td>
<td>Fellow, Pediatric Otolaryngology, University of Colorado College of Medicine, Denver Children's Hospital</td>
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<tr>
<td>UCSD</td>
<td>Linda Wu, Pharm.D.</td>
<td>7/1994-6/1995</td>
<td>Fellowship</td>
<td>Clinical Faculty Appointment with University of Toledo School of Pharmacy</td>
<td></td>
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</tr>
<tr>
<td>UCSD</td>
<td>Mark M trochick, MD</td>
<td>9/1997-3/1998</td>
<td>Mini-sessional</td>
<td>Professor &amp; Chief Neonatology, Boston University Medical Center</td>
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<tr>
<td>UCSD</td>
<td>Brooke Bost, Pharm.D.</td>
<td>7/2000-6/2004</td>
<td>Fellowship / NRSA</td>
<td>UCSD PPRU-Associate Pharmacologist, Faculty UCSD School of Pharmacy and Pediatrics</td>
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<tr>
<td>UCSD</td>
<td>Suzette Blanchard, Ph.D.</td>
<td>5/2002-4/2006</td>
<td>mini-sessional</td>
<td>Faculty at City of Hope Hospital</td>
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<tr>
<td>UCSD</td>
<td>Adrina Herrera-Tremolet, M.D.</td>
<td>7/2006-6/2007</td>
<td>Fellowship</td>
<td>Faculty UCSD School of Medicine, PhD awardee</td>
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<tr>
<td>UCSD</td>
<td>Elizabeth Sarks, Pharm.D.</td>
<td>2006-2007</td>
<td>Pharmacy student</td>
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<tr>
<td>Utah</td>
<td>W. Etienne Lee, PharmD</td>
<td>7/1/2000-6/30/2002</td>
<td>Pediatric Clinical Pharmacology</td>
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<tr>
<td>Utah</td>
<td>Kristin Satterfield, PhD</td>
<td>7/1/2005-7/1/2007</td>
<td>Pediatric Clinical Pharmacology Fellowship</td>
<td>Medical Student University of Utah</td>
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<tr>
<td>Utah</td>
<td>Christopher Orton, PhD</td>
<td>8/1/2006-present</td>
<td>Postdoctoral fellowship in Pediatric Clinical Pharmacology studying pulmonary metabolism of steroids by CYPs 3A4,5,7</td>
<td>Fellow, University of Utah</td>
<td></td>
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<tr>
<td>UT SW</td>
<td>Roberto Santos, MD</td>
<td>2005-2008</td>
<td></td>
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<tr>
<td>Wayne</td>
<td>Randy Prescella, MD</td>
<td>1999-2001</td>
<td>Clinical Pharmacology Fellowship</td>
<td>Assistant Professor of Pediatrics, Children's Hospital, Harvard, Boston</td>
<td></td>
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<tr>
<td>Wayne</td>
<td>Hakan Engin, MD, PhD</td>
<td>2000-2002</td>
<td>NATO Scholar</td>
<td>Professor of Pharmacology, University of Ankara, Turkey</td>
<td></td>
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<tr>
<td>Wayne</td>
<td>Daniel Frattarelli, MD</td>
<td>2001-2003</td>
<td>Clinical Pharmacology Fellowship</td>
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<tr>
<td>Wayne</td>
<td>Indu Warriner, MD</td>
<td>(Completing 12/2006)</td>
<td>Pediatric Clinical Pharmacology Fellowship including 1 year of Allergy-Immunology-Pharmacology</td>
<td>Fellow, Wayne St</td>
<td></td>
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</tr>
<tr>
<td>Wayne</td>
<td>Melene Mathew, MD</td>
<td>2006-2008</td>
<td>Clinical and Molecular Pharmacology Fellowship</td>
<td>Fellow, Wayne St</td>
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</table>
Appendix J

List of Publications with Multi-Disciplinary Investigators
Examples of PPRU Multidisciplinary Studies
(2001-2004)


Jiang Z, Dragin N, Jorge-Nebert LF, Martin MV, Guengerich FP, Aklillu E, et al. Search for an association between the human CYP1A2 genotype and CYP1A2 metabolic phenotype. Pharmacogenet Genomics 2006; 16(5):359-67 (Multi disciplinary pharmacogenetics group spearheaded by Dan Nebert)

Weimert NA, DeRotte M, Alloway RR, Woodle ES and Vinks AA. Monitoring of Inosine Monophosphate Dehydrogenase Activity as a Biomarker for Mycophenolic Acid Effect: Potential Clinical Implications. Ther Drug Monit, 2007 29(2): 141-149 (Collaboration between kidney transplant programs at UC and CCHMC) This has now expanded to 3 other PPRU sites: Utah, Arkansas and Dallas
Examples of studies of the PPRU in collaboration with other networks (Past and Future)

**J. Steven Leeder**, PharmD, PhD; Bob Batterson, MD  ADR: Atypical Antipsychotic-Induced Weight Gain/Obesity. **Proposed study of PPRU and the NIGMS-supported Pharmacogenetics Research Network (PGRN).**

**Susan Rahman**  Disruptions in bilirubin translocation related to developmental, genetic and environmental factors that alter the expression and/or activity of OATP transporters. **Proposed collaboration with the PPRU and an OPRU center in Galveston, TX**

**Laura Greer** (Fellow in OB/GYN), **Jeanne Sheffield, Pablo Sanchez and George McCracken**  Clinical pharmacology of oseltamivir in pregnant and post-partum women. **Collaboration with PPRU and OPRU** (Protocol to be submitted to PPRU and OPRU soon)

**Sanchez, Pablo**  David Kimberlin and other centers in PPRU and CASG. Pharmacokinetics and safety of oseltamivir in infants and young children **Collaboration of PPRU centers and the Collaborative Antiviral Study Group [CASG]**, currently in progress

**Sanchez, P Ward, R** and investigators from Neonatal Research network. Study of inositol in newborn infants. **Collaboration of PPRU and Neonatal Research Network centers.** In progress

**Ardura, Monica** (Fellow), **Ramilo, O, Kaplan, S** and others. Clinical Benefit of Adding a Bactericidal Antibiotic and Application of Transcriptional Profiles in Pediatric Patients with *Staphylococcus aureus* Sepsis. **Proposed study of PPRU centers and the NIGMS-supported Pharmacogenetics Research Network (PGRN).**

Aman MG, **Vinks AA**, Remmerie, B, Mannaert E, Ramadan Y, Masty, J, Lindsay RL, Malone K,. Plasma pharmacokinetics of risperidone and their relationship to saliva concentrations in children with psychiatric or neurodevelopmental disorders. Clinical Therapeutics, 2007, 29 (7): 1476-1486 **Collaboration with the Research Units of Pediatric Psychopharmacology (RUPP) network**

**Benjamim, D** et al Fluconazole prophylaxis for prevention of neonatal candidiasis. **Collaboration between PPRO and Pediatrix centers,** one of several on-going studies


Mirochnick M, Thomas T, Capparelli E, Zeh C, Holland D, Masaba R, Odhiambo P, Fowler MG, Weidle PJ, Thigpen M. Plasma antiretroviral concentrations in breast-feeding infants whose mothers are receiving HAART. Presented at Conference for Retroviruses and Opportunistic Infections 2007 Study in a neonatal population in **collaboration with CDC support KISUMU** (PPRU approved support for assay development)