Linking Clinical Pharmacology to Basic Science Training

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Cincinnati Children’s Hospital Medical Center

- Ranked in Top 3 of pediatric programs in the U.S
- 628 beds; >15,000 employees; 822 faculty
- Operations of $2.1 Billion
- 7 Million square feet of facilities; 14 off-site facilities
- Over 1.4 Million sq.ft. of research space
- $173 Million Research Funding ($140 Million from the NIH)
Background Pediatric Training

- Pediatric clinical pharmacology is not a formally recognized subspecialty of adult clinical pharmacology
- Pediatric pharmacologists have adapted adult methodologies and tools to pediatrics
- During the past decade fewer than 30 individuals completed a fellowship in pediatric clinical pharmacology
- Lack of pediatric clinical pharmacology training in adult clinical pharmacology programs
- The **NICHD - NIGMS T32 Postdoctoral Program** supported by the BPCA is a vehicle for adding a pediatric clinical pharmacology training component

BPCA, Best Pharmaceuticals for Children Act
Clinical Pharmacology: A Bridge and Multidisciplinary Subspecialty

- Basic Sciences (System Biology)
- Regulatory Affairs
- Pediatrics
- Other Medical Subspecialties
- Pharmacology
- Informatics
- Internal Medicine
- Psychiatry
- Anesthesiology
Dr. George Giacoia: “Knock Down the Walls”

NIH/FDA

Pediatric Subspecialists
Pharma/Biotech

Adult Clinical Pharmacologists
Pediatric Clinical Pharmacologists

Pediatric-Adult Efficacy Extrapolation
History of Cincinnati Program

• Funding started in 2011
  – Funding through Best Pharmaceuticals Act for Children (BPCA)
  – 3 postdoctoral positions - Vinks, PI
• RFA-HD-16-015 posted April 20, 2015
  – Postdoctoral Research Training in Pediatric Clinical Pharmacology (T32)
• Renewal in 2016 pending
  – Vinks, PI
Program Themes

Pharmacokinetics
- Population modeling
- Allometric scaling
- Physiologically based PK modeling

Pharmacodynamics
- Effect Measures
- Biomarkers
- Adverse Drug Reactions

Metabolomics
- Drug and metabolites
- Other matrices
- Biomarkers

Modeling & Simulation
- Exposure-Response prediction
- Targeted therapy
- Disease progression

Study Design
- Pediatric Dosing
- Optimal Samples
- Study Assessments

Informatics
- Dosing Algorithms
- Model and Pediatric Data Libraries
- Bayesian Algorithms

2014-2015
NICHD Program Activities

• Principles of Pediatric Clinical Pharmacology Lecture Series
• Summer J. Yaffe Memorial Lecture Series
• Journal club
• Annual face to face meetings
• Fellow to fellow “Ambassador” program
• *PedPharmHub*
  • web site of the virtual network of pediatric clinical pharmacology training programs - Network wide
Program Highlights

- 7 trainees (5 MDs and 2 PhDs)
- 2 out of 7 (29%) URM
- 4 graduates:
  - two are in faculty positions
  - two at research-intensive institutions
- 14 peer reviewed publications
- 2 competitive research awards
Opportunities & Challenges

• How do we train *translational communication* and *behavior*?

• Qualifications entry level candidates
  – Pharmacometrics and systems pharmacology

• Attracting minority candidates

• Time commitment program faculty

• Infrastructure support
  – Program management, renewal application
  – Outcomes tracking
T32 Postdoctoral Training is a **Team Sport**

Clinical Pharmacology

Genetic Pharmacology Program

Heart Institute
Perinatal Institute
UC Transplantation

Biomedical Informatics

Anesthesiology

Nephrology

Human Genetics

Cincinnati Children’s
change the outcome®
Acknowledgements

Clinical Pharmacology
Chie Emoto, PhD
Tsuyoshi Fukuda, PhD
Min Dong, PhD
David Hahn, PhD
Tomoyuki Mizuno, PhD
Kana Toyama-Mizuno, PhD
Raja Venkatasubramanian, PhD
Tracy Glauser, MD
Senthil Sadhasivam, MD, MPH
Vidya Chidambaran, MD

Supported by:
NIH 5U10-HD037249, 1K24HD050387,
1T32HD069054, 1U01 FD004573,
HHSF223201310224C
UC Translational Research Initiative