ASCPT 2013 ANNUAL MEETING

March 5-9, 2013 • JW Marriott Hotel • Indianapolis, IN

PROGRAM

ASCPT

www.ascpt.org

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WELCOME LETTER

DEAR COLLEAGUES,

It gives me great pleasure to welcome you to the 114th Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (ASCPT), in Indianapolis. We have developed an excellent scientific program complete with new and exciting sessions, pre-conferences, a curriculum review course, cutting-edge symposia, and opportunities to network with your colleagues from around the world.

We extend a warm welcome to our colleagues who attended the pre-conference programs. We welcome our colleagues from the Food and Drug Administration who showcased their work in a pre-conference and will be speaking throughout the Annual Meeting.

The 2013 scientific program includes world-class State of the Art lectures by Trevor Mundel, MD, PhD, Bill and Melinda Gates Foundation; Andrew Dahlem, PhD, Lilly Research Laboratories; and Olufunmilayo Falusi Olopade, MD, FACP, University of Chicago. Our Featured Speakers spotlight two outstanding member scientists, Steven Shafer, MD, and Issam Zineh, PharmD, MPH.

We are pleased to honor a number of outstanding scientists for their work in advancing clinical pharmacology, improving patient care, and their contributions to ASCPT. This year's honorees are: William E. Evans, PharmD; William J. Jusko, PhD; Mary Relling, PharmD; Federico Innocenti, MD, PhD; Thaddeus Grasela, PharmD, PhD; Gregory L. Kearns, PharmD, PhD; and David Le Couteur, MD, PhD.

Join us at the Town Hall Session which features several ASCPT members leading roundtable discussions, or the International Forum with a discussion of Clinical Pharmacology in Asia. ASCPT is proud to offer new programming this year including the Science at Sunrise sessions, as well as the Clinical Pharmacology Quiz Bowl. You won't want to miss these fun events!

Make sure you visit the poster and exhibit hall showcasing more than 325 scientific posters, along with a wide range of exhibitors sharing their clinical pharmacology related products and services.

Last, but not least, I wish to thank many people for their tireless work this year in planning this meeting: First and most importantly, the Scientific Program Committee, and its Chair, Christine Haller, MD; second, the leadership of the Scientific Sections for their review and selection of speakers, workshop topics, abstracts and events; third, my fellow officers, Richard L. Lalonde, Russ B. Altman, and Gregory L. Kearns, who provided leadership, support and a strong commitment to outstanding science. Finally, this meeting would not take place without the enormous behind-the-scenes efforts of Sharon Swan and the excellent staff at ASCPT.

I encourage you to participate in the many learning and networking opportunities available and thank you for attending the ASCPT 2013 Annual Meeting!

Sincerely,

Kathleen M. Giacomini, PhD
President

WE ARE LISTENING

Your opinion is very important to ASCPT. Based on last year's evaluations we have made a number of changes to the Annual Meeting in order to serve you better.

CASH AND CARRY LUNCH IN THE EXHIBIT HALL

The evaluations stated that you wanted to be on your own for lunch so that you had the freedom to walk the exhibit hall floor, check out the posters, network with colleagues, or head back to your room to check email. This year we are featuring casual Cash and Carry Lunches which provide you the opportunity to buy healthy lunch options to meet your needs. Salads, sandwiches, fruit, waters, sodas and more will be available for purchase on the trade show floor.

RECEPTIONS

You also asked for less organized dinner options. This year the receptions have been designed to be just that, receptions that are more conducive to networking and interacting with your peers. The hours of the receptions allow for you to explore Indianapolis and enjoy dinners with your colleagues. The hotel concierge staff can assist you in finding the right dining options for you and your group. For dinner and nightlife recommendations, please visit the hotel concierge desk in the lobby, or dial "0" from your room and ask for a member of the concierge staff. Maps and listings of restaurants and nightlife will also be available in ASCPT Central.

EDUCATION

You asked for more options in how you receive your education and this year we have introduced Science at Sunrise. These sessions detail skills and knowledge which will be useful to the participant in the design or conduct of research in clinical pharmacology, and will feature didactic discussion group. All State of the Art Lectures have stand alone times so that you won't miss a moment of their talks. Of course, the ASCPT Annual Meeting still features the best scientific program which you have come to expect, with Featured Speakers, Symposia and Workshops, among many session types.

EVALUATIONS

Thank you for your feedback from last year! Please take a moment to complete the online Annual Meeting evaluation at www.ascpt.org so we can continue to improve the ASCPT Annual Meeting to meet your unique learning and networking needs.

SCHEDULE AT A GLANCE

TUESDAY, MARCH 5

12:00 pm – 5:00 pm	CPT Editorial Team Meeting *(By Invitation Only)*	Room 310
6:30 pm – 9:00 pm	ASCPT Board of Directors and CPT and CPT:PSP Editorial Teams Dinner *(By Invitation Only)*	

WEDNESDAY, MARCH 6

8:00 am – Noon	CPT:PSP Editorial Team Meeting *(By Invitation Only)*	Room 311
10:00 am – 5:00 pm	ASCPT Registration Open • ASCPT Central Open	JW Grand Ballroom Foyer
11:30 am – 12:30 pm	ASCPT Board of Directors and CPT and CPT:PSP Editorial Teams Lunch *(By Invitation Only)*	Room 312
12:30 pm – 2:00 pm	Contemporary Issues in Clinical Pharmacology – The FDA Office Of Clinical Pharmacology Experience	JW Grand 9/10
12:45 pm – 1:45 pm	New Member Welcome	Room 309/310
1:15 pm – 1:45 pm	Award Reception *(By Invitation Only)*	Room 313
2:15 pm – 3:00 pm	Opening Session	JW Grand 5
3:00 pm – 4:00 pm	STATE OF THE ART LECTURE I: Trevor Mundel, MD, PhD	JW Grand 5
4:30 pm – 5:00 pm	Showcase of Top Trainee Abstracts	Griffin Hall Foyer
5:00 pm – 6:30 pm	Opening Reception and Exhibit Hall Open	Griffin Hall
6:45 pm – 7:45 pm	Quiz Bowl	JW Grand 7
8:00 pm – 9:00 pm	Board Dessert Reception *(By Invitation Only)*	President's Suite

THURSDAY, MARCH 7

7:00 am – 5:00 pm	ASCPT Registration Open • ASCPT Central Open	JW Grand Ballroom Foyer
7:00 am – 8:15 am	CPT & CPT:PSP Editorial Boards Meeting *(By Invitation Only)*	JW Grand 1/2
7:00 am – 9:00 am	ABCP Board Meeting *(By Invitation Only)*	Room 301
7:30 am – 8:15 am	Scientific Section Leadership Orientation *(By Invitation Only)*	Room 309/310
8:00 am – 3:00 pm	Exhibits and Posters Open	Griffin Hall
8:00 am – 9:00 am	Continental Breakfast in Exhibit Hall	Griffin Hall
8:00 am – 9:30 am	POSTER SESSIONS	Griffin Hall/ JW Grand Ballroom Foyer
8:00 am – 9:30 am	Integration of Systems Modeling in Clinical Development: Successes, Challenges, and Future Outlook	JW Grand 7/8
8:00 am – 9:30 am	Submitting an Investigational New Drug (IND) Application to the FDA: The Keys to Success for Researchers!	JW Grand 9/10
8:15 am – 9:15 am	CCSS & Scientific Sections *(By Invitation Only)*	Room 309/310
8:30 am – 9:30 am	RAWLS-PALMER PROGRESS IN MEDICINE AWARD LECTURE: Mary Relling, PharmD	JW Grand 5
9:45 am – 11:45 am	Development of Biosimilar Biologic Products	JW Grand 3/4
9:45 am – 11:45 am	From Genetics to Therapy: Drugging The Cancer Genome	JW Grand 5
9:45 am – 11:45 am	Regulatory Science and The Brave New World of Health IT	JW Grand 7/8

SCHEDULE AT A GLANCE

9:45 am – 11:45 am	The Future of Drug Development in Diabetes and Obesity: Challenges and Quantitative Approaches in Combining New Chemical Agents	JW Grand 9/10
11:45 am – 12:30 pm	Cash and Carry Lunch in the Exhibit Hall	Griffin Hall
Noon – 1:15 pm	Trainee Luncheon *(Ticketed Event)*	JW Grand 1/2
12:45 pm – 1:45 pm	SHEINER-BEAL PHARMACOMETRICS AWARD LECTURE: William J. Jusko, PhD	JW Grand 5
12:45 pm – 1:45 pm	Oral Session OI: Drug Safety: From Genetics to Data Mining	JW Grand 7/8
2:00 pm – 3:00 pm	FEATURED SPEAKER I: Steven L. Shafer, MD	JW Grand 5
3:15 pm – 3:50 pm	Town Hall Session	JW Grand 1/2
3:15 pm – 3:50 pm	International Forum	JW Grand 7/8
4:00 pm – 5:00 pm	STATE OF THE ART LECTURE II: Andrew M. Dahlem, PhD	JW Grand 5
5:00 pm – 5:15 pm	Transition to the Future	JW Grand 5
5:15 pm – 6:45 pm	SECTION MEETING: Drug Development and Regulatory Sciences (DDR)	Room 307
5:15 pm – 6:45 pm	SECTION MEETING: Drug Safety (SAF)	Room 308
5:15 pm – 6:45 pm	SECTION MEETING: Infectious Diseases (INF)	Room 301
5:15 pm – 6:45 pm	SECTION MEETING: Oncology (ONC)	Room 309/310
5:15 pm – 6:45 pm	SECTION MEETING: Organ Specific Diseases (OSD)	Room 313
5:15 pm – 6:45 pm	SECTION MEETING: Special Populations (SPO)	Room 311
5:30 pm – 7:00 pm	President's Reception for UCSF Faculty, Alumni, and Friends *(By Invitation Only)*	Room 103/104
6:00 pm – 7:00 pm	Donor Reception *(By Invitation Only)*	JW Grand 4
6:30 pm – 8:00 pm	PhRMA Foundation Reception *(By Invitation Only)*	Room 312
8:00 pm – 9:00 pm	Gavel Club Dessert Reception *(By Invitation Only)*	President's Suite

FRIDAY, MARCH 8

7:00 am – 5:00 pm	ASCPT Registration Open • ASCPT Central Open	JW Grand Ballroom Foyer
7:00 am – 8:00 am	Finance Committee Meeting *(By Invitation Only)*	Room 300
7:00 am – 8:00 am	Clinical Pharmacology Program Directors Meeting *(By Invitation Only)*	Room 309/310
7:30 am – 8:30 am	Best Practices for Population Pharmacokinetic Reporting	JW Grand 3/4
7:30 am – 9:00 am	Recent Changes in Early Exploratory Clinical Studies in Japan	JW Grand 7/8
7:30 am – 9:00 am	The International Transporter Consortium: Transporter Polymorphisms in Drug Development	JW Grand 9/10
8:00 am – 3:00 pm	Exhibits and Posters Open	Griffin Hall
8:00 am – 9:00 am	Continental Breakfast in Exhibit Hall	Griffin Hall
8:00 am – 9:30 am	POSTER SESSIONS	Griffin Hall/ JW Grand Ballroom Foyer
8:15 am – 9:00 am	Education Committee Meeting *(By Invitation Only)*	Room 301
8:30 am – 9:15 am	Meet the Editor - CPT:PSP Piet van der Graaf, PhD, PharmD	JW Grand Ballroom Foyer
9:15 am – 10:15 am	STATE OF THE ART LECTURE III: Olufunmilayo (Funmi) Falusi Olopade, MD, FACP	JW Grand 5
10:30 am – 12:30 pm	Understanding Complex Drug Interactions – Impact on Drug Development	JW Grand 3/4

SCHEDULE AT A GLANCE

10:30 am – 12:30 pm	Pharmacometric and Portfolio Analysis to Support Asset Planning and Defining Probability of Technical Success	JW Grand 7/8
10:30 am – 12:30 pm	Recognizing Drug Induced Liver Injury – Current Challenges and Future Opportunities	JW Grand 9/10
10:30 am – 12:30 pm	Novel Translational Research Approaches to Drug-Drug Interactions in Diabetes	JW Grand 1/2
12:45 pm – 1:30 pm	Cash and Carry Lunch in the Exhibit Hall	Griffin Hall
1:00 pm – 1:45 pm	Meet the Editor - CPT Scott A. Waldman, MD, PhD	JW Grand Ballroom Foyer
1:45 pm – 2:45 pm	OSCAR B. HUNTER MEMORIAL AWARD IN THERAPEUTICS LECTURE: William E. Evans, PharmD	JW Grand 5
1:45 pm – 3:15 pm	An Integrated Perspective on Translation of Mouse Model Data to The Clinic – From Tumor Biology to Mathematical Modeling	JW Grand 3/4
1:45 pm – 3:15 pm	Clinical Pharmacology Strategies and Considerations for the Accelerated Approval of Biologics	JW Grand 7/8
1:45 pm – 3:15 pm	Bringing Pharmacogenetics to Underserved US Populations: Building Community–Based Research Capacity	JW Grand 9/10
2:45 pm – 3:45 pm	International Transporter Consortium (ITC) Special Interest Group Meeting *(By Invitation Only)*	Room 308
3:15 pm – 3:45 pm	Afternoon Break	JW Grand Ballroom Foyer
3:45 pm – 4:45 pm	FEATURED SPEAKER II: Issam Zineh, PharmD, MPH	JW Grand 5
3:45 pm – 4:45 pm	Oral Session OII-A: Special Populations	JW Grand 3/4
3:45 pm – 4:45 pm	Oral Session OII-B: Modeling Applications in Drug Development	JW Grand 7/8
5:00 pm – 6:30 pm	SECTION MEETING: Biomarkers and Imaging (BIO)	JW Grand 1/2
5:00 pm – 6:30 pm	SECTION MEETING: Molecular Pharmacology and Pharmacogenetics (MOL)	JW Grand 7/8
5:00 pm – 6:30 pm	SECTION MEETING: Pharmacometrics and Pharmacokinetics (PMK)	JW Grand 9/10
5:00 pm – 7:00 pm	Meeting of NIGMS and NICHD T32 Trainees in Pediatric Clinical Pharmacology	Room 309/310
5:30 pm – 6:30 pm	International Reception *(By Invitation Only)*	Room 314
7:00 pm – 8:30 pm	President's Reception	JW Grand 6

SATURDAY, MARCH 9

7:00 am – 8:30 am	ASCPT Board of Directors Meeting *(By Invitation Only)*	Room 301
7:00 am – 10:00 am	ASCPT Registration Open • ASCPT Central Open	JW Grand Ballroom Foyer
7:00 am – 8:00 am	POSTER SESSIONS	Griffin Hall
7:00 am – 11:00 am	Posters on Display	Griffin Hall
7:00 am – 3:00 pm	Clinical Pharmacology Curriculum Review Course	JW Grand 9/10
8:00 am – 9:00 am	LEON I. GOLDBERG YOUNG INVESTIGATOR AWARD LECTURE: Federico Innocenti, MD, PhD	JW Grand 7/8
8:00 am – 9:00 am	Oral Session OIII: Proof-of-Concept and Biomarkers	JW Grand 3/4
9:15 am – 11:15 am	Putting Pharmacogenetics into Practice	JW Grand 3/4
9:15 am – 11:15 am	Role of Pharmacometrics in The Development of Prophylactic and Therapeutic Antiviral Treatments	JW Grand 7/8

Invited Chairs and Speakers are subject to change. Please refer to the ASCPT website for up-to-date information.

SPECIAL EVENTS & HIGHLIGHTS

WEDNESDAY, MARCH 6

Contemporary Issues in Clinical Pharmacology – The FDA Office of Clinical Pharmacology Experience
12:30 pm – 2:00 pm, JW Grand 9/10

This highly relevant Pre-conference will examine current and emerging clinical pharmacology issues from an FDA perspective. Not to be confused with the full-day *FDA Pharmaceutical Science and Clinical Pharmacology Advisory Committee Meeting,* this Pre-conference will be a 90-minute presentation immediately prior to the Opening Session. Speakers will be senior staff from the Office of Clinical Pharmacology. This session is open to all ASCPT Pre-conference and ASCPT Annual Meeting attendees.

David Goldstein and Jason Morrow Trainee Awards
2:15 pm – 3:00 pm, JW Grand 5

The David Goldstein and Jason Morrow Trainee Awards recognize top scoring trainee abstracts. The awards are named in honor of David J. Goldstein, MD, PhD, and Jason D. Morrow, MD, long-time ASCPT members who were committed to trainees and the future of the discipline of clinical pharmacology.

The 2013 recipient of the David Goldstein Trainee Award is Sirarat Sarntivijai, PhD. The 2013 recipients of the Jason Morrow Trainee Award are Marloes ten Brink, PharmD, Salman Yakub, MBBS, and Arik Zur, PhD. All recipients will be recognized during the Opening Session.

Showcase of Top Trainee Abstracts
4:30 pm – 5:00 pm, Griffin Hall Foyer

View the top trainee abstracts submitted by the 2013 Presidential Trainee Award recipients, while supporting your peers and networking with colleagues. Posters will be displayed throughout the Annual Meeting.

Opening Reception and Exhibits
5:00 pm – 6:30 pm, Griffin Hall

ASCPT invites you to join your colleagues on Wednesday night for the first networking event of the meeting. Interact with fellow scientists from all over the globe and exhibitors representing a wide range of services and products.

Sponsored by Pfizer

STATE OF THE ART LECTURES

Don't miss out! Plan to attend the State of the Art Lectures from three top professionals in their fields:

Wednesday, March 6 • 3:00 pm – 4:00 pm, JW Grand 5
Gates Foundation's Investments in Global Health
Trevor Mundel, MD, PhD, Bill and Melinda Gates Foundation

Thursday, March 7 • 4:00 pm – 5:00 pm, JW Grand 5
Why Drugs Fail and What We Can Do About It
Andrew M. Dahlem, PhD, Lilly Research Laboratories

Friday, March 8 • 9:15 am – 10:15 am, JW Grand 5
Can Precision Medicine Close the Knowledge Disparities Gap?
Olufunmilayo (Funmi) Falusi Olopade, MD, FACP, University of Chicago Medical Center

FEATURED SPEAKERS

Join us for the two ASCPT 2013 Annual Meeting Featured Speaker sessions and hear presentations from your fellow ASCPT members:

Thursday, March 7 • 2:00 pm – 3:00 pm, JW Grand 5
The Role of Clinical Pharmacology in the Trial of Conrad Murray
Steven Shafer, MD, Stanford University

Friday, March 8 • 3:45 pm – 4:45 pm, JW Grand 5
Clinical Pharmacology and the Turning Tide of Drug Regulation
Issam Zineh, PharmD, MPH, US Food and Drug Administration

SCIENCE AT SUNRISE SESSIONS

New in 2013! In addition to symposia and workshop sessions, the ASCPT Scientific Program Committee has added "Science at Sunrise" sessions. Science at Sunrise sessions are designed to teach attendees a new skill or knowledge that can be applied to research in clinical pharmacology.

Thursday, March 7 • 8:00 am – 9:30 am
Integration of Systems Modeling in Clinical Development: Successes, Challenges, and Future Outlook

Submitting An Investigational New Drug (IND) Application To The FDA: The Keys To Success For Researchers!

Friday, March 8 • 7:30 am – 9:00 am
Recent Changes in Early Exploratory Clinical Studies in Japan

The International Transporter Consortium: Transporter Polymorphisms in Drug Development

Sponsored by

SPECIAL EVENTS & HIGHLIGHTS

THURSDAY, MARCH 7

International Forum
3:15 pm – 3:50 pm, JW Grand 7/8

A Global Clinical Pharmacology Focus on Asia featuring Members of the International Task Force.

Transition to the Future
5:00 pm – 5:15 pm, JW Grand 5

Please join us as Russ B. Altman, MD, PhD, receives the Presidential Gavel as the incoming President of ASCPT.

John A. Wagner, MD, PhD, will be introduced as the new President-Elect of ASCPT.

Witness these two outstanding scientists take their place as the new vanguard of leadership for ASCPT.

FRIDAY, MARCH 8

Meet the Editor
ASCPT Central – JW Grand Ballroom Foyer
8:30 am – 9:15 am: Piet van der Graaf, PhD, PharmD (CPT:PSP)
1:00 pm – 1:45 pm: Scott Waldman, MD, PhD, FCP (CPT)

Best Practices for Population Pharmacokinetic Reporting
7:30 am – 8:30 am, JW Grand 3/4
Special Session *(sponsored by the Model-based Drug Development Consortium, which includes ASCPT, AAPS, ACCP, and ISoP)*

ASCPT's President's Reception
7:00 pm – 8:30 pm, JW Grand 6

Join us to honor and recognize the contributions of Kathleen M. Giacomini, PhD, as President of ASCPT. We'll be entertained by the Joel Michael Trio, a tremendous jazz combo featuring jazz standards, as well as jazz impressions of popular songs. The food and beverages will be great, and the networking and conversations even better. Join us for an enjoyable evening!

Sponsored by CliniLabs

CLINiLABS
www.clinilabs.com

SATURDAY, MARCH 9

Clinical Pharmacology Curriculum Review Course
7:00 am – 3:00 pm, JW Grand 9/10
Separate registration required and admission is by ticket only.

Chaired by Darrell R. Abernethy, MD, PhD, and David A. Flockhart, MD, PhD, the Clinical Pharmacology Curriculum Review Course will provide attendees with key components of drug development and clinical pharmacology. The panel of speakers includes a broad array of scientific experts from industry, academia, government, and consulting. See pages 46 – 49 for the full agenda.

TRAINEE LUNCHEON

TRAINEE LUNCHEON

Thursday, March 7, Noon – 1:15 pm, JW Grand 1/2

This is a ticketed event; you must have registered and received a ticket with your registration materials to attend this luncheon.

In support of ASCPT's initiative to build capacity through the development, promotion, recognition, and support of career development programs for junior and mid-career investigators, ASCPT is pleased to offer the highly successful Trainee Luncheon. This luncheon – open only to trainees/students – is a roundtable discussion for participants to meet with established clinical pharmacologists to network and to discuss potential career paths.

Participants will rotate between tables to allow for multiple facilitator discussions. Discussions are designed to center around aspects of a career in clinical pharmacology, but are informal and largely driven by trainee/students' questions. Information about how to become involved within ASCPT will also be provided. Faculty listed will be seated at tables bearing their names and type of employment sector they represent. A short summary of each facilitator's background and current position will be distributed to all trainees/students who are signed up for the luncheon.

TRAINEE LUNCHEON FACILITATORS

Bridgette L. Jones, MD
Jun J. Yang, PhD

Academia

Jeffrey S. Barrett, PhD, FCP
Robert Bies, PharmD, PhD
Gregory L. Kearns, PharmD, PhD
Mary Jayne Kennedy, PharmD
Kathryn Momary, PharmD, BCPS
Kathleen A. Neville, MD, MS
Michelle A. Rudek, PharmD, PhD
Michael Spigarelli, MD, PhD
John Van Den Anker, MD, PhD

Consulting

Diane Mould, PhD

Government

Dionna Jeter Green, MD
Vijay A. Ramchandani, PhD
Anne Zajicek, MD, PharmD

Industry

Rebecca Blanchard, PhD
Maurice G. Emery, PharmD, PhD
Megan A. Gibbs, PhD
Amita S. Joshi, PhD
Bert L. Lum, PharmD
Virginia Schmith, PhD, FCP
Edwin Spaans, PharmD
John A. Wagner, MD, PhD

TOWN HALL MEETING • MARCH 7

JW Grand 1/2 • 3:15 pm – 3:50 pm

The ASCPT Town Hall session has been reformatted to encourage open discussion on topics important to all members of the Society. All members are invited to participate in round table discussions led by ASCPT volunteer leaders.

STAGE

BOARD OF DIRECTORS
Kathleen M. Giacomini, PhD
Dhanesh Gupta, MD

BOARD OF DIRECTORS
John A. Wagner, MD, PhD
Jim Keirns, PhD

TRAINEES & FELLOWS
Gregory L. Kearns, PharmD, PhD
Saskia de Wildt, MD, PhD

CPT & PSP EDITORS
Piet van der Graaf, PhD, PharmD
Kellie Reynolds, PharmD

CPT & PSP EDITORS
Scott Waldman, MD, PhD
Don Mager, PharmD, PhD

MENTORING
Kathleen Neville, MD, MS
Michelle Rudek, PharmD, PhD
Darrell R. Abernethy, MD, PhD

SCIENTIFIC SECTIONS
Shirley Tsunoda, PharmD
Scott Oglesby, PhD

SCIENTIFIC SECTIONS
Virginia Schmith, PhD, FCP
Bert L. Lum, PharmD

YOUR SOCIETY YOUR THOUGHTS
Russ B. Altman, MD, PhD
Karthik Venkatakrishnan, PhD

COMMITTEES & TASK FORCES
Jean Gray, MD, FRCPC
Julie Johnson, PharmD
Deanna Kroetz, PhD
Nancy Lass, MD

COLLABORATION AND SPECIAL INTEREST GROUPS
Kim Brouwer, PharmD, PhD
Lei Zhang, PhD

SOCIAL MEDIA
Kathryn Momary, PharmD, BCPS
Geert W. 't Jong, MD, PhD

ENTRANCE

QUIZ BOWL • WEDNESDAY, MARCH 6

JW Grand 7 • 6:45 pm – 7:45 pm

HOST

Gregory L. Kearns, PharmD, PhD

Quiz Bowl is a new session where four teams, each representing academia, consultants, industry, and government, will be quizzed in categories including clinical pharmacology and ASCPT history. Join host Gregory L. Kearns, PharmD, PhD, for this fun and interactive way to network and learn with your peers. This is sure to be one of many enjoyable and entertaining sessions at the Annual Meeting!

INDUSTRY TEAM

Maurice G. Emery, PharmD, PhD

Megan Gibbs, PhD

Mark Hovde, MBA

J.F. Marier, PhD, FCP

ACADEMIA TEAM

Saskia de Wildt, MD, PhD

Raymond J. Hohl, MD, PhD

Lawrence Lesko, PhD

Howard McLeod, PharmD

Mark Ratain, MD

CONSULTING TEAM

Kevin Dykstra, PhD

Nancy Lass, MD

Diane Mould, PhD

Gary Novack, PhD

GOVERNMENT TEAM

Darrell R. Abernethy, MD, PhD

Jerry Collins, PhD

Juan Lertora, MD, PhD

Kellie S. Reynolds, PharmD

AWARD RECIPIENTS

2013 GARY NEIL PRIZE FOR INNOVATION IN DRUG DEVELOPMENT

Thaddeus H. Grasela, PharmD, PhD
President & CEO
Cognigen Corporation

2013 HENRY W. ELLIOTT DISTINGUISHED SERVICE AWARD

Gregory L. Kearns, PharmD, PhD
Chief Scientific Officer and Chairman
Children's Mercy Hospital and Clinics
University of Missouri, Kansas City,
Professor of Pediatrics and Pharmacology

2013 LEON I. GOLDBERG YOUNG INVESTIGATOR AWARD

Federico Innocenti, MD, PhD
University of North Carolina Institute for
Pharmacogenomics and Individualized Therapy

2013 OSCAR B. HUNTER MEMORIAL AWARD IN THERAPEUTICS

William E. Evans, PharmD
Director and CEO
St. Jude Children's Research Hospital

2013 SHEINER-BEAL PHARMACOMETRICS AWARD

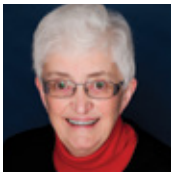
William J. Jusko, PhD
Professor and Chair
State University of New York at Buffalo
Department of Pharmaceuticals Sciences

2013 RAWLS-PALMER PROGRESS IN MEDICINE AWARD

Mary V. Relling, PharmD
Professor
St. Jude Children's Research Hospital
Pharmaceutical Department

2013 WILLIAM B. ABRAMS AWARD IN GERIATRIC CLINICAL PHARMACOLOGY

David Le Couteur, MD, PhD
University of Sydney
Centre for Education and Research
on Ageing, Concord Hospital



2013 ASCPT MENTOR AWARD

Jean D. Gray, MD, FRCPC

2012 TOP MEMBERSHIP RECRUITER

Jae-Yong Chung, MD, PhD
Seoul National University
Seoul, Republic of Korea

2012 MEMBERSHIP RECRUITER HONORABLE MENTION

Jin Yan Jin, PhD
Genentech
South San Francisco, CA

2012 MEMBERSHIP RECRUITER HONORABLE MENTION

Jason Karnes, PharmD, PhD
Vanderbilt University
Nashville, TN

2013 DAVID J. GOLDSTEIN TRAINEE AWARD

Sirarat Sarntivijai, PhD
US Food and Drug Administration

2013 JASON MORROW TRAINEE AWARD

Marloes H. ten Brink, PharmD
Leiden University Medical Center

2013 JASON MORROW TRAINEE AWARD

Salman Y. Yakub, MBBS
University of Utah

2013 JASON MORROW TRAINEE AWARD

Arik A. Zur, PhD
University of California, San Francisco

2012-2013 ASCPT YOUNG INVESTIGATOR AWARD

Jieru Egeria Lin, PhD
Thomas Jefferson University

AWARD RECIPIENTS

ASCPT PRESIDENTIAL TRAINEE AWARD RECIPIENTS

Sirarat Sarntivijai, PhD
US Food and Drug Administration

Marloes H. ten Brink, PharmD
Leiden University Medical Center

Salman Y. Yakub, MBBS
University of Utah

Arik A. Zur, PhD
University of California, San Francisco

Leon Darghosian, MD
Vanderbilt University School of Medicine

Sophie Stocker, PhD
University of California, San Francisco

Xiaoyu Yan, PhD
University at Buffalo – The State University of New York

Connie Remsberg, PharmD, PhD
University of California, San Francisco

Xi-Ling Jiang, PhD
University of Florida

Mohamed H. Shahin, BPharm
University of Florida

Nieves Velez de Mendizabal, PhD
Indiana University

Melanie Ren, BS
Genentech

Raja Venkatasubramanian, PhD
Cincinnati Children's Hospital Medical Center

Maryann Mazer-Amirshahi, PharmD, MD
Children's National Medical Center
George Washington University

Chun-yu Wei, PhD
Institution of Biomedical Sciences, Academia Sinica

Richa Dua, PharmD
University of North Carolina
Eshelman School of Pharmacy

Sony Tuteja, PharmD
University of Pennsylvania
School of Medicine

Janine Micheli, BS
University of California, San Francisco

Wenndy Hernandez, PhD
University of Chicago

Sumita Bhatta, MD
University of Chicago

Eugene Chen, BA
University of California, San Francisco

PhRMA FOUNDATION AWARDS

2013 AWARD IN EXCELLENCE IN CLINICAL PHARMACOLOGY

Juan J. L. Lertora, MD, PhD
Director, Clinical Pharmacology Program
NIH Clinical Center

2012 FACULTY DEVELOPMENT AWARD

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Assistant Professor
Department of Molecular Pharmacology and Experimental Therapeutics
Vanderbilt University

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JW Grand Ballroom Foyer

Wednesday, March 6, 10:00 am – 5:00 pm
Thursday, March 7, 7:00 am – 5:00 pm
Friday, March 8, 7:00 am – 5:00 pm
Saturday March 9, 7:00 am – 10:00 am

TARGET AUDIENCE

Clinical pharmacologists, including physicians, pharmacists, scientists, and others interested in learning about the most current advances in drug discovery, development, regulation and safe utilization of drugs in humans.

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For security reasons, all attendees MUST wear their badge at all time for admission to sessions, the poster and exhibit hall, and social events.

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JW Grand Ballroom Foyer

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Thursday, March 7, 8:00 am – 3:00 pm
Friday, March 8, 8:00 am – 3:00 pm
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GENERAL INFORMATION

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JW Grand Ballroom Foyer

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Room 306

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Sections are categorized into two main groups: Tools (or Methods) and Applications. As the primary forum for member exchange and networking, ASCPT's Scientific Sections and SIGs promote interaction among members who share a common field of interest. Each symposium, workshop, and science at sunrise session is sponsored by a section(s). See the Scientific Agenda for the sessions representing your field of interest.

Tools/Methods
BIO Biomarkers and Imaging
MOL Molecular Pharmacology and Pharmacogenetics
PMK Pharmacometrics and Pharmacokinetics

Applications
DDR Drug Development and Regulatory Sciences
INF Infectious Diseases
ONC Oncology
OSD Organ Specific Diseases
SAF Drug Safety
SPO Special Populations

Special Interest Groups
ITC Special Interest Group

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The ASCPT Annual Meeting is geared toward adult participation. For their safety, children under the age of 16 are not permitted in the session room for the duration of the conference. We appreciate your cooperation and understanding.

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Should you need childcare during the Pre-conference, the organization that is most frequently at the hotel is Sitters to the Rescue. Please contact Nancy Reiter at (317) 257-7999 for further information. ASCPT has not made any group arrangements or discounts and is not able to endorse the use of this firm; this is informational only.

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ASCPT Central | Main floor
Friday, March 8th
8:30am & 1:00pm

Clinical Pharmacology & Therapeutics

CPT: Pharmacometrics & Systems Pharmacology

meet THE EDITORS

Friday March 8th | ASCPT Central | Main Floor

TWO ENGAGING OPPORTUNITIES

8:30am – 9:15am

Piet H. van der Graaf, PharmD, PhD
Editor-in-Chief
CPT: Pharmacometrics & Systems Pharmacology

1:00pm – 1:45pm

Scott A. Waldman, MD, PhD
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Scientific Program Committee Chair

SCIENTIFIC AGENDA

SPEAKERS & SESSIONS

SCIENTIFIC AGENDA • MARCH 5

12:00 pm – 5:00 pm	CPT EDITORIAL TEAM MEETING *(By Invitation Only)*	Room 310
6:30 pm – 9:00 pm	ASCPT BOARD OF DIRECTORS AND CPT AND CPT:PSP EDITORIAL TEAMS DINNER *(By Invitation Only)*	

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SCIENTIFIC AGENDA • MARCH 6

8:00 am – Noon	CPT:PSP EDITORIAL TEAM MEETING *(By Invitation Only)*	Room 311
10:00 am – 5:00 pm	ASCPT REGISTRATION OPEN • ASCPT CENTRAL OPEN	JW Grand Ballroom Foyer
11:30 am – 12:30 pm	ASCPT BOARD OF DIRECTORS AND CPT AND CPT:PSP EDITORIAL TEAMS GRAB-AND-GO LUNCH *(By Invitation Only)*	Room 312
12:30 pm – 2:00 pm	CONTEMPORARY ISSUES IN CLINICAL PHARMACOLOGY – THE FDA OFFICE OF CLINICAL PHARMACOLOGY EXPERIENCE	JW Grand 9/10
12:45 pm – 1:45 pm	NEW MEMBER WELCOME	Room 309/310
1:15 pm – 1:45 pm	AWARD RECEPTION *(By Invitation Only)*	Room 313
2:15 pm – 3:00 pm	OPENING SESSION	JW Grand 5

Introduction
Shiew-Mei Huang, PhD, Deputy Office Director, Office of Clinical Pharmacology (OCP)

Model-Informed Drug Development and Regulatory Review
Speaker Vikram Sinha, PhD, Director, Division of Pharmacometrics, OCP
Panelists Vikram Sinha, PhD
Nitin Mehrotra, PhD, Acting Team Leader, Division of Pharmacometrics, OCP
Ping Zhao, PhD, Senior Staff Scientist, PBPK Program, OCP

Development and Regulatory Evaluation of Targeted Therapies
Speaker Michael Pacanowski, PharmD, MPH, Acting Associate Director, Genomics Group, OCP
Panelists Michael Pacanowski, PharmD, MPH
Issam Zineh, PharmD, MPH, Office Director, Office of Clinical Pharmacology (OCP)

Pediatric Drug Development
Speaker Dionna Green, MD, Staff Scientist, Pediatrics Program, OCP
Panelists Dionna Green, MD
Kevin Krudys, PhD, Interdisciplinary Review Lead, QT and Reviewer, Division of Pharmacometrics, OCP

Closing Remarks
Issam Zineh, PharmD, MPH

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State of the Society Address
Kathleen M. Giacomini, PhD, University of California, San Francisco
President

AWARD PRESENTATIONS

William B. Abrams Award in Geriatric Clinical Pharmacology
Presenter Darrell R. Abernethy, MD, PhD, US Food and Drug Administration
Recipient David Le Couteur, MD, PhD, University of Sydney

Henry W. Elliott Distinguished Service Award
Presenter Susan M. Abdel-Rahman, PharmD, Children's Mercy Hospitals and Clinics
Recipient Gregory L. Kearns, PharmD, PhD, Children's Mercy Hospitals and Clinics

SCIENTIFIC AGENDA • MARCH 6

2:15 pm – 3:00 pm

OPENING SESSION CONTINUED — JW Grand 5

Gary Neil Prize for Innovation in Drug Development
Presenter Jill B. Fiedler-Kelly, MS, Cognigen Corporation
Recipient Thaddeus H. Grasela, PharmD, PhD, Cognigen Corporation

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Recipient Jae-Yong Chung, MD, PhD, Seoul National University

2012-2013 Membership Recruiting Honorable Mentions
Recipient Jin Yan Jin, PhD, Genentech
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Presenter Kathleen M. Giacomini, PhD
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PhRMA Foundation Awards
Presenter Darrell R. Abernethy, MD, PhD, US Food and Drug Administration

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Juan J. L. Lertora, MD, PhD, NIH Clinical Center

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Cyndya Shibao, MD, Vanderbilt University

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Robert Freilich, Boston University School of Medicine
Jessica Wilson, MD, University of Illinois, Chicago
Yixi Zhang, Harvard Medical School

CEO Remarks
Sharon J. Swan, FASAE, CAE

3:00 pm – 4:00 pm

STATE OF THE ART LECTURE I — JW Grand 5

Trevor Mundel, MD, PhD, Bill and Melinda Gates Foundation
Gates Foundation's Investments in Global Health

Chair Russ B. Altman, MD, PhD, Stanford University

Trevor Mundel, MD, PhD

SCIENTIFIC AGENDA • MARCH 6

4:30 pm – 5:00 pm	SHOWCASE OF TOP TRAINEE ABSTRACTS (SEE PAGE 25 - 26) **ASCPT Presidential Trainee Award Recipients** **Presenter** Kathleen M. Giacomini, PhD Sirarat Sarntivijai, PhD, US Food and Drug Administration Marloes H. ten Brink, PharmD, Leiden University Medical Center Salman Y. Yakub, MBBS, University of Utah Arik A. Zur, PhD, University of California, San Francisco Leon Darghosian, MD, Vanderbilt University School of Medicine Sophie Stocker, PhD, University of California, San Francisco Xiaoyu Yan, PhD, University at Buffalo – The State University of New York Connie Remsberg, PharmD, PhD, University of California, San Francisco Xi-Ling Jiang, PhD, University of Florida Mohamed Shahin, BParm, University of Florida Nieves Velez de Mendizabal, PhD, Indiana University Melanie Ren, BS, Genentech Raja Venkatasubramanian, PhD, Cincinnati Childrens Hospital Medical Center Maryann Mazer-Amirshahi, PharmD, MD, Children's National Medical Center, George Washington University Chun-yu Wei, PhD, Institution of Biomedical Sciences, Academia Sinica Richa Dua, PharmD, University of North Carolina, Eshelman School of Pharmacy Sony Tuteja, PharmD, University of Pennsylvania School of Medicine Janine Micheli, BS, University of California, San Francisco Wenndy Hernandez, PhD, University of Chicago Sumita Bhatta, MD, University of Chicago Eugene Chen, BA, University of California, San Francisco	Griffin Hall Foyer
5:00 pm – 6:30 pm	OPENING RECEPTION AND EXHIBIT HALL OPEN *Sponsored by Pfizer*	Griffin Hall
6:45 pm – 7:45 pm	QUIZ BOWL **Host** Gregory L. Kearns, PharmD, PhD Teams representing Academia, Industry, Government, and Consulting (See page 10)  *Gregory L. Kearns, PharmD, PhD*	JW Grand 7
8:00 pm – 9:00 pm	BOARD DESSERT RECEPTION *(By Invitation Only)*	President's Suite

SHOWCASE OF TOP TRAINEE ABSTRACTS

PT-1
AN INTEGRATIVE TRANSLATIONAL BIOINFORMATICS APPROACH TO STUDY TYROSINE KINASE INHIBITOR INDUCED NON-QT CARDIOTOXICITY.
S. Sarntivijai,[1] S. Hwang,[1] J. Shon,[1] P. Zhichkin,[1] Y. He,[2] B. D. Athey,[2] D. R. Abernethy[1]; [1]Food and Drug Administration, Silver Spring, MD, [2]University of Michigan, Ann Arbor, MI.

PT-2
EXPLORATORY ANALYSIS OF 1,936 SNPS IN 225 ADME GENES FOR ASSOCIATION WITH BUSULFAN CLEARANCE IN ADULT HEMATOPOIETIC STEM CELL RECIPIENTS.
M. H. ten Brink, J. J. Swen, J. Zwaveling, T. van der Straaten, J. A. Wessels, H. J. Guchelaar; Leiden University Medical Center, Leiden, Netherlands.

PT-3
TRENDS OF USE OF VANCOMYCIN IN NEONATES.
S. Y. Yakub, S. Campbell, C. Sherwin, J. Constance, A. Balch, M. Spigarelli; University of Utah, Salt Lake City, UT.

PT-4
IDENTIFICATION OF SELECTIVE, POTENTIALLY CLINICALLY RELEVANT MATE1-INHIBITORS THROUGH PRESCRIPTION DRUG PROFILING AND COMPUTATIONAL MODELING.
A. A. Zur,[1] M. B. Wittwer,[1] N. Khuri,[1] Y. Kido,[2] A. Kosaka,[3] K. M. Morrissey,[1] X. Zhang,[3] A. Sali,[1] Y. Huang,[3] K. M. Giacomini[1]; [1]University of California, San Francisco, San Francisco, CA, [2]Shionogi & Co., Osaka, Japan, [3]Optivia Biotechnology Inc., Menlo Park, CA.

PT-5
INFLAMMATORY BIOMARKERS AND RISK OF VENTRICULAR ARRHYTHMIA AND SUDDEN CARDIAC DEATH.
L. Darghosian,[1] J. Li,[1] T. Gebretsadik,[1] J. F. Solus,[1] B. McBride,[1] M. B. Shoemaker,[2] A. Shintani,[1] J. Rottman,[2] D. Darbar,[1] C. Stein[1]; [1]Vanderbilt University School of Medicine, Nashville, TN, [2]Nashville Veterans Affairs Medical Center, Nashville, TN.

PT-6
METFORMIN DISPOSITION AND RESPONSE IN AFRICAN AMERICAN AND ASIAN AMERICAN POPULATIONS.
S. Stocker,[1] S. Yee,[1] K. Morrissey,[1] J. Mefford,[1] R. Castro,[1] F. Xu,[2] S. Goswami,[1] J. Witte,[1] C. Brett,[1] K. M. Giacomini,[1] M. Hedderson[2]; [1]University of California San Francisco, San Francisco, CA, [2]Kaiser Permanente Northern California, Oakland, CA.

PT-7
QUANTITATIVE ASSESSMENT OF MINIMAL EFFECTIVE CONCENTRATION OF ERYTHROPOIESIS-STIMULATING AGENTS.
X. Yan, W. Krzyzanski; Department of Pharmaceutical Sciences, University at Buffalo, Buffalo, NY.

PT-8
IDENTIFICATION OF A NEW DRUG-DRUG INTERACTION BETWEEN CLOPIDOGREL AND ROSUVASTATIN MEDIATED THROUGH OATP1B1.
C. M. Remsberg, L. A. Frassetto, H. Okochi, L. Z. Benet; University of California, San Francisco, San Francisco, CA.

PT-9
APPLICATION OF PHYSIOLOGICALLY-BASED PHARMACOKINETIC (PBPK) MODEL IN PREDICTING DRUG METABOLISM AND PHARMACOKINETICS IN PEDIATRIC POPULATIONS – A CASE STUDY OF ACETAMINOPHEN.
X. Jiang,[1] P. Zhao,[2] L. J. Lesko,[1] S. Schmidt[1]; [1]University of Florida, Orlando, FL, [2]US Food and Drug Administration, Silver Spring, MD.

PT-10
VKORC1 ASP36TYR GEOGRAPHIC DISTRIBUTION AND ITS IMPACT ON WARFARIN DOSE REQUIREMENTS IN EGYPTIANS.
M. H. Shahin,[1] S. I. Khalifa,[2] A. Dvorak,[3] T. Langaee,[1] S. Patel,[4] K. Perry,[4] M. Perera,[4] L. H. Cavallari,[4] H. L. McLeod,[3] J. A. Johnson[1]; [1]University of Florida, Gainesville, FL, [2]Qatar Univeristy, Doha, Qatar, [3]University of North Carolina, Chapel Hill, NC, [4]University of Illinois, Chicago, IL.

PT-11
DISCRETE DISTRIBUTION MODELS FOR RELAPSING-REMITTING DYNAMICS OBSERVED IN MULTIPLE SCLEROSIS.
N. Velez de Mendizabal,[1] I. F. Troconiz,[2] M. M. Hutmacher,[3] R. R. Bies[1]; [1]Indiana University, Indianapolis, IN, [2]University of Navarra, Pamplona, Spain, [3]Ann Arbor Pharmacometrics Group, Ann Arbor, MI.

PT-12
LITERATURE-BASED META-ANALYSIS TO EVALUATE THE SURROGACY OF PROGRESSION-FREE SURVIVAL IN GLIOBLASTOMA MULTIFORM.
M. M. Ren, K. Han, J. Li, Z. Su, A. Das, A. Joshi, J. Y. Jin; Genentech, South San Francisco, CA.

PT-13
PHARMACOKINETIC AND PHARMACODYNAMIC MODELING OF PROPOFOL DEPTH OF ANESTHESIA IN MORBIDLY OBESE CHILDREN.
V. Chidambaran,[1] R. Venkatasubramanian,[1] S. Sadhasivam,[1] H. R. Esslinger,[1] S. L. Cox,[1] J. Diepstraten,[2] T. Fukuda,[1] T. H. Inge,[1] C. A. Knibbe,[2] A. A. Vinks[1]; [1]Cincinnati Children's Hospital Medical Center, Cincinnati, OH, [2]St. Antonius Hospital, Nieuwegein, Netherlands.

SHOWCASE OF TOP TRAINEE ABSTRACTS

PT-14

EFFECT OF WITHDRAWAL OF OVER-THE-COUNTER COUGH AND COLD MEDICATIONS ON PEDIATRIC INGESTIONS REPORTED TO US POISON CENTERS.

M. E. Mazer-Amirshahi,[1] N. Reid,[2] J. van den Anker,[1] T. Litovitz[3]; [1]Children's National Medical Center, George Washington University, Washington, DC, [2]National Capital Poison Center, Washington, DC, [3]National Capital Poison Center, George Washington University, Georgetown University, Washington, DC.

PT-15

HLA MOLECULES FOR DRUG SCREEN IN PREDICTING SEVERE DRUG HYPERSENSITIVITY.

C. Wei, C. Lin, L. Lu, S. Lai, M. M. Lee, Y. Chen; Institution of Biomedical Sciences, Academia Sinica, Taipei, Taiwan.

PT-16

DIRECT *N*-GLUCURONIDATION OF THE CYP3A PROBE MIDAZOLAM: EFFECTS OF A CYP3A AND DUAL CYP3A/UGT1A4 INHIBITOR IN HEALTHY VOLUNTEERS.

R. Dua,[1] V. González-Pérez,[1] K. S. Frederick,[2] C. L. Denton,[3] Y. V. Scarlett,[4] M. B. Fisher,[5] M. F. Paine[1]; [1]Division of Pharmacotherapy and Experimental Therapeutics, UNC Eshelman School of Pharmacy, Chapel Hill, NC, [2]Boehringer-Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, [3]GlaxoSmithKline, Research Triangle Park, NC, [4]Division of Gastroenterology and Hepatology, UNC School of Medicine, Chapel Hill, NC, [5]ProPharma Services, LLC, Oxford, CT.

PT-17

PHARMACOGENOMICS OF THE FLUSHING RESPONSE TO ACUTE NIACIN ADMINISTRATION.

S. Tuteja, R. L. Dunbar, L. Qu, M. Li, M. Mucksavage, S. DerOhannessian, M. Reilly, D. J. Rader; University of Pennsylvania School of Medicine, Philadelphia, PA.

PT-18

GENETIC PREDICTORS OF NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITOR (NRTI) AND HIV INDUCED SENSORY PERIPHERAL NEUROPATHY.

J. E. Micheli,[1] L. W. Chinn,[1] J. Mefford,[1] T. Mushiroda,[2] M. Kubo,[2] J. N. Martin,[1] E. M. Jorgenson,[3] J. S. Witte,[1] D. W. Bangsberg,[4] Y. Nakamura,[5] D. L. Kroetz1; [1]University of California, San Francisco, San Francisco, CA, [2]RIKEN Center for Genomic Medicine, Yokohama, Japan, [3]Kaiser Permanente Research Division, Oakland, CA, [4]Harvard Medical School, Boston, MA, [5]University of Chicago, Chicago, IL.

PT-19

A NOVEL PHARMACOGENOMICS DOSING ALGORITHM FOR AFRICAN AMERICANS TAKING WARFARIN: ABLE TO PREDICT WHERE IWPC'S ALGORITHM CANNOT.

W. Hernandez,[1] M. A. Perera,[1] E. R. Gamazon,[1] K. Perry,[1] K. Aquino-Michaels,[1] S. Patel,[2] T. O'Brien,[3] A. Harralson,[3] D. Nicolae,[1] L. Cavallari[2]; [1]The University of Chicago, Department of Medicine, Section of Genetic Medicine, Chicago, IL, [2]University of Illinois, Chicago, Department of Pharmacy, Chicago, IL, [3]George Washington University, Washington, DC.

PT-20

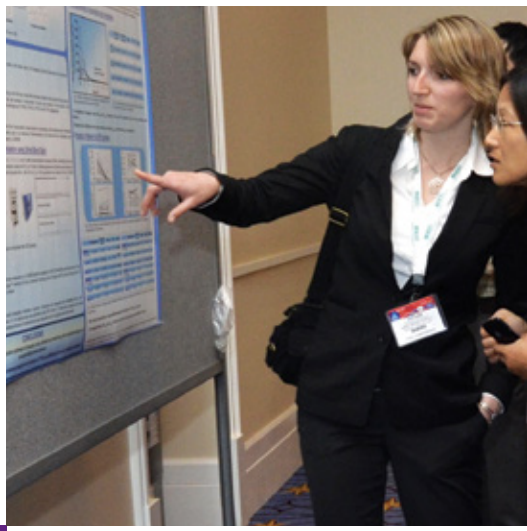
TRENDS IN SPENDING ON ORAL CHEMOTHERAPEUTIC AGENTS 2006-2012.

S. Bhatta, A. Fein, R. M. Conti; University of Chicago, Chicago, IL.

PT-21

HIGH-THROUGHPUT SCREENING OF A PRESCRIPTION LIBRARY FOR INHIBITIONS OF ORGANIC CATION TRANSPORTER 3.

E. C. Chen,[1] L. Xu,[2] K. M. Giacomini[1]; [1]University of California San Francisco, San Francisco, CA, [2]University of the Pacific, Stockton, CA.



SCIENTIFIC AGENDA • MARCH 7

7:00 am – 5:00 pm	ASCPT REGISTRATION OPEN • ASCPT CENTRAL OPEN	JW Grand Ballroom Foyer
7:00 am – 8:15 am	CPT & CPT:PSP EDITORIAL BOARDS MEETING *(By Invitation Only)*	JW Grand 1/2
7:00 am – 9:00 am	ABCP BOARD MEETING *(By Invitation Only)*	Room 301
7:30 am – 8:15 am	SCIENTIFIC SECTION LEADERSHIP ORIENTATION *(By Invitation Only)*	Room 309/310
8:00 am – 9:00 pm	CONTINENTAL BREAKFAST IN EXHIBIT HALL	Griffin Hall
8:00 am – 3:00 am	EXHIBITS AND POSTERS OPEN	Griffin Hall
8:00 am – 9:30 am	POSTER SESSION I ATTENDED	Griffin Hall
8:00 am – 9:30 am	LATE-BREAKING POSTER SESSION I ATTENDED	Griffin Hall
8:00 am – 3:00 pm	PRESIDENTIAL TRAINEE POSTERS	Griffin Hall Foyer
8:00 am – 3:00 pm	QUANTITATIVE SYSTEMS PHARMACOLOGY POSTERS	JW Grand Ballroom Foyer
8:00 am – 9:30 am *2 Concurrent Science at Sunrise Sessions*	INTEGRATION OF SYSTEMS MODELING IN CLINICAL DEVELOPMENT: SUCCESSES, CHALLENGES, AND FUTURE OUTLOOK *endorsed by DDR* **Chairs** Sreeneeranj Kasichayanula, PhD, Bristol-Myers Squibb Tarek Leil, PhD, Bristol-Myers Squibb **Speakers** Tarek Leil, PhD, Bristol-Myers Squibb *Current States, Challenges, and Future Trends of Systems Pharmacology in Drug Development* Matthew Riggs, PhD, Metrum Research Group *Multiscale Modeling: The Quantitative Integration of Systems Biology, Clinical Pharmacology and Translational Research* Oleg Demin, Sr., PhD, Institute for Systems Biology SPb *Systems Pharmacology Modeling in Research and Development* **Learning Objectives** 1. To highlight current status of systems pharmacology approaches that are increasingly being used for quantitative integration of clinical data and to facilitate the rational design of clinical trials. 2. To provide a "case-study" based analysis of successes and challenges involved in integration and application of systems-based modeling approaches in drug development, and demonstrate the applicability and impact of systems-based modeling approaches on clinical development.	JW Grand 7/8  *Sreeneeranj Kasichayanula, PhD*

SCIENTIFIC AGENDA • MARCH 7

8:00 am – 9:30 am
2 Concurrent Science at Sunrise Sessions

SUBMITTING AN INVESTIGATIONAL NEW DRUG (IND) APPLICATION TO THE FDA: THE KEYS TO SUCCESS FOR RESEARCHERS!

JW Grand 9/10

endorsed by DDR

Chairs
Bridgette Jones, MD, Children's Mercy Hospital
Lei Zhang, PhD, US Food and Drug Administration

Speakers
Kellie S. Reynolds, PharmD, US Food and Drug Administration
Overview of the IND Process: An FDA Perspective

Kathleen Neville, MD, MS, Children's Mercy Hospital and Clinics
Submitting an IND as Part of a Clinical Research Study: The Real World

Jelena P. Berglund, PhD, RAC, Duke Translational Medicine Institute
Submitting an IND: An Academic Perspective


Bridgette Jones, MD


Lei Zhang, PhD


Kellie S. Reynolds, PharmD


Kathleen Neville, MD, MS


Jelena P. Berglund, PhD

Learning Objectives

1. To learn the content of an IND and its review/approval process-FDA perspective.
2. To learn the process of IND application preparation/submission-academic perspective.

8:15 am – 9:15 am — CCSS & SCIENTIFIC SECTIONS *(By Invitation Only)* — Room 309/310

8:30 am – 9:30 am

RAWLS-PALMER PROGRESS IN MEDICINE AWARD LECTURE

JW Grand 5

Mary Relling, PharmD, St. Jude Children's Research Hospital
Clinical Implementation Of Pharmacogenomics

Presenter Kathleen M. Giacomini, PhD, University of California, San Francisco


Mary Relling, PharmD

SCIENTIFIC AGENDA • MARCH 7

9:45 am – 11:45 am
4 Concurrent Symposia

DEVELOPMENT OF BIOSIMILAR BIOLOGIC PRODUCTS

JW Grand 3/4

endorsed by DDR/PMK

Chairs
Darrell R. Abernethy, MD, PhD, US Food and Drug Administration
J. Frederick Pritchard, PhD, Celerion

Speakers
Gillian Woollett, MA, DPhil, Avalere Health
Global Development for Biosimilar Products: Challenges and Opportunities
Mark Rogge, PhD, Biogen Idec, Inc.
Clinical PK/PD Assessments are a Pivotal Element in the Risk-Based Approach to Establish Large Molecule Comparability
Darrell R. Abernethy, MD, PhD, US Food and Drug Administration
Evaluation of Biosimilar Products to Access Clinically Meaningful Differences
Stanley (SeungSuh) Hong, PhD, Celltrion, Inc.
Global Development of Monoclonal Antibody Biosimilars-Strategy and Case Study


Darrell R. Abernethy, MD, PhD


J. Frederick Pritchard, PhD


Gillian Woollett, MA, DPhil

Learning Objectives

1. To present an overview of the key challenges in both technical and clinical development of biosimilars.
2. To discuss pharmacokinetic and pharmacodynamic considerations in the clinical development of biosimilars.
3. To discuss FDA perspectives on the evaluation of biosimilar products to assess clinically meaningful differences.

9:45 am – 11:45 am
4 Concurrent Symposia

FROM GENETICS TO THERAPY: DRUGGING THE CANCER GENOME

JW Grand 5

endorsed by MOL/ONC

Chairs
Federico Innocenti, MD, PhD, University of North Carolina
Sharyn D. Baker, PharmD, PhD, St. Jude Children's Research Hospital

Speakers:
Federico Innocenti, MD, PhD, University of North Carolina
Cancer Genome: Current Status and Opportunities
William E. Evans, PharmD, St. Jude Children's Research Hospital
The Pediatric Cancer Genome Project
Juan Luengo, PhD, GlaxoSmithKline
Redesigning Drug Discovery on the Basis of Cancer Genome Screens
Lillian L. Siu, Princess Margaret Hospital
Real-Time Delivery of Therapies From Cancer Genome Sequences


Federico Innocenti, MD, PhD


Sharyn D. Baker, PharmD, PhD


William E. Evans, PharmD

Learning Objectives

1. To understand the current application of the results of the cancer genome to modern clinical care and drug development.
2. To learn about the prioritization process of druggable targets for intervention among the myriad of somatic alterations in the context of intratumor heterogeneity and genomic evolution.
3. To obtain a critical evaluation of the implications of the proposed "N=1" approaches for patient treatment.

SCIENTIFIC AGENDA • MARCH 7

9:45 am – 11:45 am
4 Concurrent Symposia

REGULATORY SCIENCE AND THE BRAVE NEW WORLD OF HEALTH IT

JW Grand 7/8

endorsed by DDR/SAF

Chairs
Tobias Gerhard, PhD, Rutgers University
Geert W. 't Jong, MD, PhD, Winnipeg Children's Hospital

Speakers
Miriam Sturkenboom, PharmD, PhD, Erasmus University Medical School
Electronic Medical Record Data for Research: Opportunities and Challenges

Sean Hennessy, PharmD, PhD, Perelman School of Medicine at the University of Pennsylvania
FDA's Mini-Sentinel Program-Progress and Direction

Judy A. Staffa, RPh, PhD, US Food and Drug Administration
Active Medical Product Surveillance, Pharmacoepidemiologic Research, and the Regulatory Science Paradigm

Tobias Gerhard, PhD, Rutgers University
Synthesis and Discussion


Tobias Gerhard, PhD


Geert W. 't Jong, MD, PhD


Sean Hennessy, PharmD, PhD

Learning Objectives

1. To appreciate the ongoing advances in health IT, medical informatics and analytic methods. To understand and discuss opportunities and challenges of using electronic medical record data for observational research on drug safety.
2. To understand and discuss the key features and roles of passive and active medical product safety surveillance systems and learn about the progress and direction of FDA's Mini-Sentinel Initiative.
3. To discuss the roles of active medical product safety surveillance and pharmacoepidemiologic studies in the regulatory science paradigm.

9:45 am – 11:45 am
4 Concurrent Symposia

THE FUTURE OF DRUG DEVELOPMENT IN DIABETES AND OBESITY: CHALLENGES AND QUANTITATIVE APPROACHES IN COMBINING NEW CHEMICAL AGENTS

JW Grand 9/10

endorsed by DDR/PMK/OSD

Chairs
Robin O'Connor-Semmes, PhD, GlaxoSmithKline
Jenny Y. Chien, PhD, Eli Lilly and Company

Speakers
Derek Nunez, MD, FRCP, GlaxoSmithKline
Challenges in Developing Combinations of New Chemical Agents for the Treatment of Type 2 Diabetes and Obesity

Donald E. Mager, PharmD, PhD, State University of New York at Buffalo
Theoretical, Translational and Technical Capabilities in Applying Quantitative Approaches to Combination Therapy

Brian Topp, PhD, Eli Lilly and Company
Systems and PK/PD Approaches to Optimizing Combination Therapy for Antidiabetics-Leveraging Knowledgebase and Literature Data for Clinical Application

Kevin Hall, PhD, National Institutes of Health, NIDDK
Physiological Model of Body Weight Regulation and Application for Development of Weight Loss Therapies


Donald E. Mager, PharmD, PhD


Brian Topp, PhD

Learning Objectives

1. To state the medical needs, challenges and issues in drug development and review the theoretical complexities involved when developing drug-drug combinations with very little to limited prior knowledge for at least one or both of the therapeutic agents in the combination.
2. To present applications, mathematical and biochemical assumptions of modeling approaches for combination therapy for treatment of type 2 diabetes.
3. To present a physiological model of human weight loss regulation with application to weight loss therapies.

SCIENTIFIC AGENDA • MARCH 7

11:45 am – 12:30 pm	CASH AND CARRY LUNCH IN THE EXHIBIT HALL	Griffin Hall
Noon – 1:15 pm	TRAINEE LUNCHEON *(Ticketed Event)*	JW Grand 1/2
12:45 pm – 1:45 pm *2 Concurrent Sessions*	SHEINER-BEAL PHARMACOMETRICS AWARD LECTURE William J. Jusko, PhD, State University of New York at Buffalo *Evolution of Mechanistic PK/PD Modeling – Our Future?* **Presenter** David Z. D'Argenio, PhD, University of Southern California	JW Grand 5  *William J. Jusko, PhD*
12:45 pm – 1:45 pm *2 Concurrent Sessions*	ORAL SESSION OI: DRUG SAFETY: FROM GENETICS TO DATA MINING **Chairs** Russ B. Altman, MD, PhD, Stanford University Louis R. Cantilena, Jr., MD, PhD, Uniformed Services University of the Health Sciences **OI-1 An Integrative Translational Bioinformatics Approach to Study Tyrosine Kinase Inhibitor Induced Non-QT Cardiotoxicity.** **Presenter** Sirarat Sarntivijai, PhD, US Food and Drug Administration **OI-2 Role Of Carnitine Palmitoyltransferase LI in Drug-Induced Rhabdomyolysis.** **Presenter** PeiFan J. Bai, PhD, US Food and Drug Administration **OI-3 HLA Molecules for Drug Screen in Predicting Severe Drug Hypersensitivity.** **Presenter** Chun-yu Wei, PhD, Institution of Biomedical Sciences, Academia Sinica **OI-4 Identification of Selective, Potentially Clinically Relevant MATE1-Inhibitors Through Prescription Drug Profiling and Computational Modeling.** **Presenter** Arik A. Zur, PhD, University of California	JW Grand 7/8  *Russ B. Altman, MD, PhD*
2:00 pm – 3:00 pm	FEATURED SPEAKER I Steven L. Shafer, MD, Stanford University *The Role of Clinical Pharmacology in the Trial of Conrad Murray* **Chair** Donald R. Stanski, MD, Novartis Pharma, AG	JW Grand 5  *Steven L. Shafer, MD*
3:15 pm – 3:50 pm *(Afternoon Break)*	TOWN HALL SESSION Meet the ASCPT Board of Directors, CPT and CPT:PSP Journal Editors, Scientific Section Leaders, Mentors and Committee and Task Force Leadership	JW Grand 1/2
3:15 pm – 3:50 pm *(Afternoon Break)*	INTERNATIONAL FORUM: GLOBAL CLINICAL PHARMACOLOGY FOCUS ON ASIA **Chairs** Lawrence J. Lesko, PhD, University of Florida at Lake Nona (Orlando) Donald R. Stanski, MD, Novartis Pharma, AG **Prospects and Barriers for Growing the Opportunities for Clinical Pharmacology in Asia** **Speakers** Kourosh Parivar, MPharm, Pfizer Min Soo Park, MD, PhD, Severance Hospital, Yonsei University College of Medicine Naoto Uemura, MD, PhD, Merck Research Laboratories This session will be followed by a question and answer session.	JW Grand 7/8  *Lawrence J. Lesko, PhD*  *Donald R. Stanski, MD*

SCIENTIFIC AGENDA • MARCH 7

4:00 pm – 5:00 pm	STATE OF THE ART LECTURE II Andrew M. Dahlem, PhD, Eli Lilly and Company *Why Drugs Fail and What We Can Do About It* **Chair** Christine A. Haller, MD, BioMarin Pharmaceutical, Inc.	JW Grand 5  *Andrew M. Dahlem, PhD*
5:00 pm – 5:15 pm	TRANSITION TO THE FUTURE	JW Grand 5
5:15 pm – 6:45 pm *6 Concurrent Section Meetings*	DRUG DEVELOPMENT AND REGULATORY SCIENCES (DDR) **Review of *In Vitro* Transporter Data in Recently Approved New Drug Applications** Lei Zhang, PhD, US Food and Drug Administration, Silver Spring, MD **The Effects of CYP3A Inhibitors on Sildenafil and Midazolam Pharmacokinetics are Highly Correlated** Xiang Gao, PhD, Pfizer, Groton, CT **Is There a Need for Pharmacokinetic Studies in Child-Pugh Class A Patients?** Islam R. Younis, PhD, US Food and Drug Administration, Silver Spring, MD **Development and Application of a Literature Model of Weight Loss in Diabetes and Obesity Drug Development** Karen B. Schneck, PharmD, Eli Lilly and Company, Wake Forest, NC	Room 307
5:15 pm – 6:45 pm *6 Concurrent Section Meetings*	DRUG SAFETY (SAF) **Use of Glucose Lowering Drugs and the Risk of Adenocarcinoma Among Patients with Type 2 Diabetes: A Case-Control Study in the Netherlands** Geert W. 't Jong, MD, PhD, Winnipeg Children's Hospital, Manitoba, Canada	Room 308
5:15 pm – 6:45 pm *6 Concurrent Section Meetings*	INFECTIOUS DISEASES (INF) **Population Pharmacokinetics of Meropenem in Obese and Non-Obese Hospitalized Patients** Christina Chung, PharmD, Purdue University, Indianapolis, IN **Population Pharmacokinetics of Azithromycin and Chloroquine in Healthy Adults and Pediatric Malaria Subjects Following Oral Administration of Azithromycin and Chloroquine Tablets** Qinying Zhao, PhD, Pfizer, Madison, CT **Alterations of Docetaxel Pharmacokinetics by Efavirenz and Ritonavir: Implications for Dosing** Cathy Chang, University of Maryland, Baltimore, MD **Pharmacokinetics and Drug Interaction Evaluations for the Novel Triazole Antifungal Agent Isavuconazole** Amit Desai, PhD and Takao Yamazaki, PhD Astellas Pharma Global Development, Inc., Deerfield, IL	Room 301
5:15 pm – 6:45 pm *6 Concurrent Section Meetings*	ONCOLOGY (ONC) **Effect of Ketoconazole on the Pharmacokinetics (PK) and Safety Profile of Linifanib (ABT-869) In Patients with Advanced Solid Tumors** Lionel D. Lewis, MD, Dartmouth University, Lebanon, NH **Development of the Braf Inhibitor Dabrafenib: PK, PD and Exposure-Response** Daniele Ouellet, PhD, GlaxoSmithKline, Research Triangle Park, NC **A Developing Drug Development: Meet the Expert** Jerry Collins, PhD, National Cancer Institute, Rockville, MD	Room 309/310

SCIENTIFIC AGENDA • MARCH 7

5:15 pm – 6:45 pm *6 Concurrent Section Meetings*	ORGAN SPECIFIC DISEASES (OSD) **Using On-Line User Groups to Conduct Clinical Research and Another Failure of a SNP to Predict Drug Response - Clinical Pharmacology Research in Drug Abusers and Addicts** John Mendelson, MD, California Pacific Medical Center Research, San Francisco, CA **P-glycoprotein Function in Peripheral Blood Mononuclear Cells in Renal Transplant Recipients: Sex and Race Influences** Kathleen Tornatore, PharmD, University at Buffalo, School of Pharmacy & Pharmaceutical Sciences, Buffalo, NY	Room 313
5:15 pm – 6:45 pm *6 Concurrent Section Meetings*	SPECIAL POPULATIONS (SPO) **Pharmacokinetics of Fentanyl in Morbidly Obese Adolescent Patients** Victoria Ziesenitz, University of Heidelberg, Heidelberg, Germany **The Role of Social Media in Recruiting for Clinical Trials in Pregnancy** Mahvash Shere, BSc, Hospital for Sick Children, Ontario, Canada	Room 311
5:30 pm – 7:00 pm	PRESIDENT'S RECEPTION FOR UNIVERSITY OF CALIFORNIA, SAN FRANCISCO (USCF) FACULTY, ALUMNI AND FRIENDS *(By Invitation Only)*	Room 103/104
6:00 pm – 7:00 pm	DONOR RECEPTION *(By Invitation Only)*	JW Grand 4
6:30 pm – 8:00 pm	PhRMA FOUNDATION RECEPTION *(By Invitation Only)*	Room 312
8:00 pm – 9:00 pm	GAVEL CLUB DESSERT RECEPTION *(By Invitation Only)*	President's Suite

SCIENTIFIC AGENDA • MARCH 8

7:00 am – 5:00 pm	ASCPT REGISTRATION OPEN • ASCPT CENTRAL OPEN	JW Grand Ballroom Foyer
7:00 am – 8:00 am	FINANCE COMMITTEE MEETING *(By Invitation Only)*	Room 300
7:00 am – 8:00 am	CLINICAL PHARMACOLOGY PROGRAM DIRECTORS MEETING *(By Invitation Only)*	Room 309/310

7:30 am – 8:30 am
Special Session

BEST PRACTICES FOR POPULATION PHARMACOKINETIC REPORTING
(sponsored by the Model-based Drug Development Consortium, which includes ASCPT, AAPS, ACCP, and ISoP)

Chairs Kevin Dykstra, PhD
Virginia D. Schmith, PhD

Learning Objectives

1. To summarize results of the survey on population PK reporting.
2. To present and begin discussion of best practice recommendations.

JW Grand 3/4

Kevin Dykstra, PhD

Virginia D. Schmith, PhD

7:30 am – 9:00 am
2 Concurrent Science at Sunrise Sessions

RECENT CHANGES IN EARLY EXPLORATORY CLINICAL STUDIES IN JAPAN
endorsed by BIO/DDR

Chairs Masako P. Nakano, MD, PhD, Eli Lilly Japan K.K.
Yuji Kumagai, MD, PhD, Kitasato University East Hospital

Speakers Toshio Miyata, MD, Ministry of Health, Labour and Welfare
Japanese Government's Recent Policies on Early Phase Clinical Trials in Japan
Kazuo Umemura, MD, PhD, Hamamatsu University School of Medicine
Early Phase Clinical Study Environment in Japan and the Trends of Phase 1 Studies Conducted in Japan
Masako P. Nakano, MD, PhD, Eli Lilly Japan K.K.
Opportunities in Japan for Phase 1 and PoC Studies-From the Industry Perspective

Learning Objectives

1. To convey to the audience the new governmental initiatives for early exploratory clinical studies at Japan.
2. To describe the recent changes in early exploratory clinical trial environment and the opportunities in Japan.
3. To explain the pros and cons of conducting early exploratory clinical studies in Japan.

JW Grand 7/8

Masako P. Nakano, MD, PhD

Yuji Kumagai, MD, PhD

SCIENTIFIC AGENDA • MARCH 8

7:30 am – 9:00 am
2 Concurrent Science at Sunrise Sessions

THE INTERNATIONAL TRANSPORTER CONSORTIUM: TRANSPORTER POLYMORPHISMS IN DRUG DEVELOPMENT

endorsed by DDR/MOL

JW Grand 9/10

Chairs Lei Zhang, PhD, US Food and Drug Administration
Sook Wah Yee, PhD, University of California San Francisco

Lei Zhang, PhD

Speakers Mikko Niemi, MD, PhD, University of Helsinki
Clinical Importance of Transporter Polymorphisms
Richard B. Kim, MD, University of Western Ontario
Methods to Study Transporter Polymorphisms
Kathleen M. Giacomini, PhD, University of California San Francisco, *Panelist*

Sook Wah Yee, PhD

Learning Objectives

1. To list the major polymorphisms in OATP1B1, OATP1B3, and BCRP and their allele frequencies in major ethnic and racial groups.
2. To briefly provide an overview of *in vitro* and *in vivo* methods for functional analysis of transporter polymorphisms and their association with variation in drug disposition, response, or toxicity.

8:00 am – 9:00 pm	CONTINENTAL BREAKFAST IN EXHIBIT HALL	Griffin Hall
8:00 am – 3:00 am	EXHIBITS AND POSTERS OPEN	Griffin Hall
8:00 am – 9:30 am	POSTER SESSION II ATTENDED	Griffin Hall
8:00 am – 9:30 am	LATE-BREAKING POSTER SESSION II ATTENDED	Griffin Hall
8:00 am – 3:00 pm	PRESIDENTIAL TRAINEE POSTERS	Griffin Hall Foyer
8:00 am – 3:00 pm	QUANTITATIVE SYSTEMS PHARMACOLOGY POSTERS	JW Grand Ballroom Foyer
8:15 am – 9:00 am	EDUCATION COMMITTEE MEETING *(By Invitation Only)*	Room 301
8:30 am – 9:15 am	MEET THE EDITOR – CPT:PSP Piet van der Graaf, PhD, PharmD	

9:15 am – 10:15 am

STATE OF THE ART LECTURE III

JW Grand 5

Olufunmilayo (Funmi) Falusi Olopade, MD, FACP, University of Chicago
Can Precision Medicine Close the Knowledge Disparities Gap?

Olufunmilayo (Funmi) Falusi Olopade, MD, FACP

Chair Kathleen M. Giacomini, PhD, University of California, San Francisco

SCIENTIFIC AGENDA • MARCH 8

10:30 am – 12:30 pm
4 Concurrent Symposia

UNDERSTANDING COMPLEX DRUG INTERACTIONS – IMPACT ON DRUG DEVELOPMENT

endorsed by DDR/PMK

JW Grand 3/4

Luna Musib, PhD

Chairs
Luna Musib, PhD, Genentech
Lei Zhang, PhD, US Food and Drug Administration

Speakers
Nina Isoherranen, PhD, University of Washington
Role of Metabolites in Drug Interactions
Stephen D. Hall, PhD, Eli Lilly and Company
Prediction of Complex Metabolism Based Interactions
Yuichi Sugiyama, PhD, Riken Innovation Center
Do PBPK Models Predict Complex DDIs Where the Alterations of Transport and Metabolism/Excretion Take Place Simultaneously?
Shiew-Mei Huang, PhD, US Food and Drug Administration
Regulatory Perspective on Assessing Complex DDIs

Learning Objectives

1. To understand the mechanisms of drug interactions from multiple substrates/metabolites and pathways and how to delineate mechanism of complex interactions.
2. To understand the time-and-concentration-dependent interplay between the potential induction and inhibition of the drug metabolizing enzymes and transporter by a drug and effects this interplay may have on the clearance of other drugs.
3. To learn how to use modeling and simulation to advance the understanding of complex DDI and to understand regulatory perspectives on evaluation of complex DDI.

10:30 am – 12:30 pm
4 Concurrent Symposia

PHARMACOMETRIC AND PORTFOLIO ANALYSIS TO SUPPORT ASSET PLANNING AND DEFINING PROBABILITY OF TECHNICAL SUCCESS

endorsed by DDR/MOL/PMK

JW Grand 7/8

Manish Gupta, PhD

Michael A. Tortorici, PharmD, PhD

Richard L. Lalonde, PharmD

Bill Poland, PhD

Chairs
Manish Gupta, PhD, FCP, Bristol-Myers Squibb
Michael A. Tortorici, PharmD, PhD, Pfizer

Speakers
Richard L. Lalonde, PharmD, Pfizer
The Use of the Probability of Technical and Regulatory Success in Portfolio and Decision Analysis
Russ Wada, PhD, Quantitative Solutions
Model Based Meta-Analysis to Support Portfolio Decisions in Cardio-Vascular Therapeutic Area
Bill Poland, PhD, Pharsight, A Certara™ Company
Disease Modeling to Support Portfolio Decisions in Virology
David Swank, MS, Bristol-Myers Squibb
Strategy, Policy, and Decision Analysis to Support Asset Planning

Learning Objectives

1. To present conceptual framework on the use of the probability of technical and regulatory success in portfolio and decision analysis.
2. To understand how portfolio and asset strategy can be used to rank and prioritize compounds within the portfolio and benchmark it against competitors.
3. To understand how viral dynamic modeling can be used to support optimal drug and/or combination therapy and influence portfolio decisions in virology therapeutic area.

SCIENTIFIC AGENDA • MARCH 8

10:30 am – 12:30 pm
4 Concurrent Symposia

RECOGNIZING DRUG INDUCED LIVER INJURY – CURRENT CHALLENGES AND FUTURE OPPORTUNITIES

endorsed by BIO/DDR/SAF

JW Grand 9/10

Chairs
Katarina Ilic, MD, PhD, MPH, University of Belgrade
Keith Burkhart, MD, FACMT, US Food and Drug Administration

Katarina Ilic, MD, PhD, MPH

Keith Burkhart, MD

Ann K. Daly, PhD

Speakers

Richard B. Kim, MD, University of Western Toronto
Genetic Variants in Hepatic Transporters and DILI

Ayako Suzuki, MD, PhD, MSc, University of Arkansas for Medical Science
Epigenetics of Drug-Induced Liver Injury

Paul Watkins, MD, The Hamner – University of North Carolina
In Silico Tools and In Vitro Assays for Early Pre-Clinical Safety Testing of DILI

Ann K. Daly, PhD, Newcastle University
HLA Genes as Risk Factors in Drug-Induced Liver Injury

Learning Objectives

1. To emphasize the importance of drug induced liver injury (DILI) for drug development and to consider genetics and epigenetics of DILI.
2. To summarize biomarkers qualified as valid by the FDA, key features for DILI biomarkers and give future perspectives.
3. To explore the current status of existing *in silico* models and *in vitro* assays predicting hepatoxicity.

THERE IS STILL TIME TO SIGN UP FOR THE CRC!

Clinical Pharmacology Curriculum Review Course
SATURDAY, MARCH 9 • 7:00 am – 3:00 pm
JW Grand 9/10

Chairs
Darrell R. Abernethy, MD, PhD
David A. Flockhart, MD, PhD

(More information on pages 46 – 49)

SCIENTIFIC AGENDA • MARCH 8

10:30 am – 12:30 pm
4 Concurrent Symposia

NOVEL TRANSLATIONAL RESEARCH APPROACHES TO DRUG-DRUG INTERACTIONS IN DIABETES

JW Grand 1/2

endorsed by SAF/MOL/PMK/DDR

Chairs Sean Hennessy, PharmD, PhD, Perelman School of Medicine at the University of Pennsylvania
David A. Flockhart, MD, PhD, Indiana University School of Medicine


Sean Hennessy, PharmD, PhD

Speakers: Darrell R. Abernethy, MD, PhD, US Food and Drug Administration
Mechanistic Understanding and Evaluation of Clinically Reported DDIs


David A. Flockhart, MD, PhD

Nicholas P. Tatonetti, PhD, Columbia University Medical Center
Detection and Validation of Latent DDI from Large Observational Clinical Data: Paroxetine with Pravastatin Leads to Worsened Glucose Control

Sean Hennessy, PharmD, PhD, Perelman School of Medicine at the University of Pennsylvania
Pharmacoepidemiologic Research on the Incidence and Clinical Importance of DDIs Involving Sulfonylureas and Lipid Lowering Drugs


Darrell R. Abernethy, MD, PhD

Lang Li, PhD, Indiana University School of Medicine
Identification and Characterization of Sulfonylurea and Statin Related DDIs Through Literature Mining Studies of In Vitro Metabolic Inhibition

Learning Objectives

1. To illustrate that different types of research across the translational spectrum (e.g., mining of published pharmacologic data; mining of adverse event reporting data; *in vitro* studies; *in vivo* studies; pharmacoepidemiologic studies) each provides different and complementary information about the existence, mechanisms, and clinical importance of drug-drug interactions.
2. To illustrate alternative approaches to data mining to identify potential drug-drug interactions.
3. To present novel empiric data on drug-drug interactions involving diabetes and anti-diabetic drugs.


Nicholas P. Tatonetti, PhD


Lang Li, PhD

12:45 pm – 1:30 pm — CASH AND CARRY LUNCH IN THE EXHIBIT HALL — Griffin Hall

1:00 pm – 1:45 pm — MEET THE EDITOR – CPT — JW Grand Ballroom Foyer

Scott A. Waldman, MD, PhD, FCP

1:45 pm – 2:45 pm — OSCAR B. HUNTER MEMORIAL AWARD IN THERAPEUTICS LECTURE — JW Grand 5

William E. Evans, PharmD, St. Jude Children's Research Hospital
Cancer Pharmacogenomics: Childhood Leukemia as a Model

Presenter Dan M. Roden, MD, Vanderbilt University School of Medicine


William E. Evans, PharmD

SCIENTIFIC AGENDA • MARCH 8

1:45 pm – 3:15 pm
3 Concurrent Workshops

AN INTEGRATED PERSPECTIVE ON TRANSLATION OF MOUSE MODEL DATA TO THE CLINIC – FROM TUMOR BIOLOGY TO MATHEMATICAL MODELING

endorsed by ONC/PMK

JW Grand 3/4

Chairs
Mark Stroh, PhD, Genentech
Paolo Vicini, PhD, Pfizer

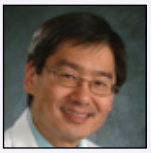

Mark Stroh, PhD

Speakers
Dan G. Duda, DMD, PhD, Massachusetts General Hospital
Clinical Translation of Mouse Model Data in Cancer

Chris H. Takimoto, MD, PhD, FACP, Janssen Research & Development
Translational Research Strategies in Oncology Early Drug Development

Shinji Yamazaki, PhD, Pfizer
Modeling and Simulation Approaches for Projecting Biologically Efficacious Concentrations in the Clinic Based Upon Mouse Data


Paolo Vicini, PhD


Chris H. Takimoto, MD, PhD


Shinji Yamazaki, PhD

Learning Objectives

1. To review historical challenges with the use of mouse models in cancer drug development.
2. To review the following considerations that impact our ability to translate preclinical findings to the clinic: a. Differences in tumor pathophysiology between the mouse model and the human condition; b. Selection of robust, translatable metrics regarding action of the drug in mouse models.
3. To encourage discussion regarding the use of mouse models in clinical development of anticancer drugs.

1:45 pm – 3:15 pm
3 Concurrent Workshops

CLINICAL PHARMACOLOGY STRATEGIES AND CONSIDERATIONS FOR THE ACCELERATED APPROVAL OF BIOLOGICS

endorsed by DDR/MOL/PMK

JW Grand 7/8

Chairs
Manish Gupta, PhD, FCP, Bristol-Myers Squibb
Shruti Agrawal, PhD, Bristol-Myers Squibb


Manish Gupta, PhD

Speakers
Bernd Meibohm, PhD, FCP, University of Tennessee Health Science Center
Translational Approaches to Facilitate Accelerated Development of Biologics

Eric Masson, PharmD, Bristol-Myers Squibb
Clinical Pharmacology Strategies and Considerations in Support of Accelerated Approval of Biologics

Hong Zhao, PhD, US Food and Drug Administration
Regulatory Perspectives on Clinical Pharmacology Requirements for Accelerated Approval of Biologics


Shruti Agrawal, PhD

Learning Objectives

1. To describe how translational and quantitative approaches can be used to facilitate accelerated approval of biologics.
2. To describe clinical pharmacology challenges and considerations for recent accelerated approval of biologics, which can later be converted to full approval pending additional efficacy data.
3. To discuss regulatory perspectives on clinical pharmacology requirements for recent accelerated approval of biologics, which can later be converted to full approval pending additional efficacy data.

SCIENTIFIC AGENDA • MARCH 8

1:45 pm – 3:15 pm
3 Concurrent Workshops

BRINGING PHARMACOGENETICS TO UNDERSERVED US POPULATIONS: BUILDING COMMUNITY–BASED RESEARCH CAPACITY

JW Grand 9/10

endorsed by MOL/SPO

Chairs Erica L. Woodahl, PhD, University of Montana
Lawrence J. Lesko, PhD, University of Florida at Lake Nona (Orlando)

Erica L. Woodahl, PhD

Speakers

Scarlett Hopkins, RN, MA, Center for Alaska Native Health Research
Sharing Genetic Research Results and Progress with Yup'ik Eskimos in Southwest Alaska

Kenneth E. Thummel, PhD, University of Washington
Engaging Indigenous (AI/AN) Populations in Pharmacogenetic Research: Investigator Perspectives and Research Finding

Lawrence J. Lesko, PhD, University of Florida at Lake Nona (Orlando)
Population Genomic Studies: Importance of Pharmacogenetics in Underserved Populations to Our Nation's Public Health

Lawrence J. Lesko, PhD

Learning Objectives

1. To discuss community-based participatory research (CBPR) in the context of translating pharmacogenetic research to improve therapeutics in underserved populations; lessons learned from research with American Indian and Alaska Native (AI/AN) populations with broad applications to other underserved populations in the US and North America.
2. To examine the novel variation among AI/AN people in genes that contribute to drug disposition and response as compared to other populations in order to adjust actionable options.
3. To discuss some of the common limitations in implementing pharmacogenetic testing in underserved populations and how these can be overcome to improve health disparities unique to those populations.

2:45 pm – 3:45 pm

INTERNATIONAL TRANSPORTER CONSORTIUM (ITC) – SPECIAL INTEREST GROUP MEETING *(By Invitation Only)*

Room 308

3:15 pm – 3:45 pm

AFTERNOON BREAK

JW Grand Ballroom Foyer

3:45 pm – 4:45 pm
3 Concurrent Sessions

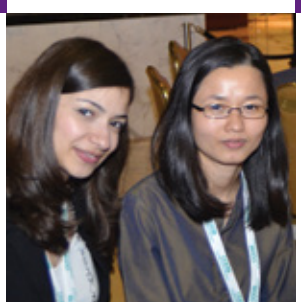
FEATURED SPEAKER II

JW Grand 5

Issam Zineh, PharmD, MPH, US Food and Drug Administration
Clinical Pharmacology and the Turning Tide of Drug Regulation

Issam Zineh, PharmD, MPH

Chair Karthik Venkatakrishnan, PhD, Millennium Pharmaceuticals, Inc.



SCIENTIFIC AGENDA • MARCH 8

3:45 pm – 4:45 pm
3 Concurrent Sessions

ORAL SESSION OII-A: SPECIAL POPULATIONS

JW Grand 3/4

Chairs Sarah A. Holstein, MD, PhD, University of Iowa
Rebecca Blanchard, PhD, Merck & Co Inc.

Sarah A. Holstein, MD, PhD

Rebecca Blanchard, PhD

OII-A-1 Trends of Use of Vancomycin in Neonates.
Presenter Salman Y. Yakub, MBBS, University of Utah

OII-A-2 Application Of Physiologically-Based Pharmacokinetic (PBPK) Model in Predicting Drug Metabolism and Pharmacokinetics in Pediatric Populations A Case Study of Acetaminophen.
Presenter Xi-Ling Jiang, PhD, University of Florida

OII-A-3 Metformin Disposition and Response in African American and Asian American Populations.
Presenter Sophie Stocker, PhD, University of California, San Francisco

OII-A-4 Association Between Frequency of Acute Cellular Rejection and Cytochrome P450 3A5 Genotype of the Graft Liver Rather than that of the Native Intestine in Living-Donor Liver Transplant Patients.
Presenter Satorhiro Masuda, PhD, Kyoto University Hospital

3:45 pm – 4:45 pm
3 Concurrent Sessions

ORAL SESSION OII-B: MODELING APPLICATIONS IN DRUG DEVELOPMENT

JW Grand 7/8

Chairs Michael J. Avram, PhD, Northwestern University Feinberg School of Medicine
Mark Dresser, PhD, Genentech

Michael J. Avram, PhD

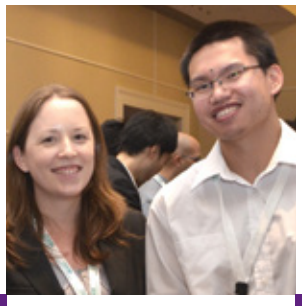
Mark Dresser, PhD

OII-B-1 Exposure-Response Analysis of the Effect Of Dabrafenib, a Braf Inhibitor, on Tumor Size in Patients with V600 Braf Mutation Positive Melanoma.
Presenter Noelia Nebot, PhD, GlaxoSmithKline

OII-B-2 A Mechanism-Based Pharmacokinetic-Pharmacodynamic Model for RN316 (Pf-04950615), a Humanized Mab Against Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9), and its Application in Early Clinical Development.
Presenter Chandrasekhar Udata, PhD, Pfizer

OII-B-3 Modeling the Dose-Response and the Probability of Clinical Efficacy in Presence of Varying Placebo Response.
Presenter Navin Goyal, GlaxoSmithKline

OII-B-4 Role of Concentration-Response Modeling with Phase I Data in Evaluating QT Interval Prolongation: Results With Ten Compounds.
Presenter Yeamin Huh, PhD, University of Michigan



SCIENTIFIC AGENDA • MARCH 8

5:00 pm – 6:30 pm *3 Concurrent Section Meetings*	BIOMARKERS AND IMAGING (BIO) **Hot Topics in Biomarkers & Imaging in DDRU** Dhanesh K. Gupta, MD, Northwestern University Feinberg School of Medicine, Chicago, IL Barry Mangum, PharmD, Duke University Medical Center, Durham, NC	JW Grand 1/2
5:00 pm – 6:30 pm *3 Concurrent Section Meetings*	MOLECULAR PHARMACOLOGY AND PHARMACOGENETICS (MOL) **Expression of Clinically Relevant Drug Transporter Proteins Along the Entire Human Intestine** Stefan Oswald, PhD, University of Greifswald, Greifswald, Germany **High-Throughput Screening of a Prescription Library for Inhibitions of Organic Cation Transporter 3** Eugene Chen, BA, University of California, San Francisco	JW Grand 7/8
5:00 pm – 6:30 pm *3 Concurrent Section Meetings*	PHARMACOMETRICS AND PHARMACOKINETICS (PMK) **Pharmacometrics of the Future: Non-traditional Uses** • Portfolio Management: David Swank, MS, Bristol-Myers Squibb, Princeton, NJ • Inlicensing: Paul N. Mudd, Jr., PharmD, MBA, GlaxoSmithKline, Research Triangle Park, NC • Health Information: Pravin Jadhav, PhD, FCP, Merck Research Laboratories, North Wales, PA	JW Grand 9/10
5:00 pm – 7:00 pm	MEETING OF NIGMS AND NICHD T32 TRAINEES IN PEDIATRIC CLINICAL PHARMACOLOGY, THEIR PROGRAM DIRECTORS, AND MENTORS	Room 309/310
5:30 pm – 6:30 pm	INTERNATIONAL RECEPTION *(By Invitation Only)*	Room 314
7:00 pm – 8:30 pm	PRESIDENT'S RECEPTION *Sponsored by CliniLabs* CLINILABS www.clinilabs.com	JW Grand 6

SCIENTIFIC AGENDA • MARCH 9

7:00 am – 8:30 am	ASCPT BOARD OF DIRECTORS MEETING *(By Invitation Only)*	Room 301
7:00 am – 10:00 am	ASCPT REGISTRATION OPEN • ASCPT CENTRAL OPEN	JW Grand Ballroom Foyer
7:00 am – 8:00 am	CONTINENTAL BREAKFAST	Griffin Hall
7:00 am – 8:00 am	POSTER SESSION III ATTENDED	Griffin Hall
7:00 am – 8:00 am	LATE-BREAKING POSTER SESSION III ATTENDED	Griffin Hall
7:00 am – 11:00 am	PRESIDENTIAL TRAINEE POSTERS	Griffin Hall Foyer
7:00 am – 11:00 am	POSTERS ON DISPLAY	Griffin Hall
7:00 am – 3:00 pm	CLINICAL PHARMACOLOGY CURRICULUM REVIEW COURSE (Advance Registration Required) See pages 46 – 49 for complete program.	JW Grand 9/10
8:00 am – 9:00 am *2 Concurrent Sessions*	LEON I. GOLDBERG YOUNG INVESTIGATOR AWARD LECTURE Federico Innocenti, MD, PhD, University of North Carolina *A Pharmacogenomics Imperative: "Get the Phenotype Right!"* **Presenter** Mark J. Ratain, MD, The University of Chicago Medical Center  *Federico Innocenti, MD, PhD*	JW Grand 7/8
8:00 am – 9:00 am *2 Concurrent Sessions*	ORAL SESSION OIII: PROOF-OF-CONCEPT AND BIOMARKERS **Chairs** Paul J. Deutsch, MD, PhD, Sanofi-Aventis John A. Wagner, MD, PhD, Merck & Co., Inc.  *Paul J. Deutsch, MD, PhD*  *John A. Wagner, MD, PhD* **OIII-1 Assessment of 4β-Hydroxycholesterol as a CYP3A Activity Marker in Humans After Ketoconazole, Rifampin and Placebo Treatment.** **Presenter** Sreeneeranj Kasichayanula, PhD, Bristol-Myers Squibb **OIII-2 Exploratory Analysis of 1,936 SNPS in 225 Adme Genes for Association with Busulfan Clearance in Adult Hematopoietic Stem Cell Recipients.** **Presenter** Marloes H. ten Brink, PharmD, Leiden University Medical Center **OIII-3 Uncontrolled Resistant Hypertension is Accompanied by Decreased Levels of Adiponectin Compared to Controlled Resistant Hypertension.** **Presenter** Vanessa Fontana, PhD, UNICAMP **OIII-4 Quantitative Decision Making in Proof of Concept Study in Acute Schizophrenia: An Application of Longitudinal Model-Based Meta-Analysis to Validate Results and Benchmark Clinical Candidate.** **Presenter** Vikas Kumar, PhD, Pfizer	JW Grand 3/4

SCIENTIFIC AGENDA • MARCH 9

9:15 am – 11:15 am
2 Concurrent Symposia

PUTTING PHARMACOGENETICS INTO PRACTICE

endorsed by MOL/ONC/PMK

JW Grand 3/4

Chairs
Jesse J. Swen, PharmD, Leiden University Medical Center
J. Kevin Hicks, PharmD, PhD, St. Jude Children's Research Hospital

Speakers
Michelle Carrillo, PhD, Stanford University
PharmGKB: From Pharmacogenomics Knowledge to Clinical Interpretation and Implementation

Henk-Jan Guchelaar, PharmD, PhD, Leiden University Medical Center
Development of Pharmacogenetic Guidelines by the Dutch Pharmacogenetics Working Group

Peter H. O'Donnell, MD, University of Chicago
The 1200 Patients Project

Mary Relling, PharmD, St. Jude Children's Research Hospital
Clinical Implementation of Pharmacogenetics


Jesse J. Swen, PharmD


J. Kevin Hicks, PharmD, PhD


Henk-Jan Guchelaar, PharmD, PhD


Mary Relling, PharmD

Learning Objectives

1. To discuss the efforts of the Pharmacogenomics Research Network, Clinical Pharmacogenetics Implementation Consortium, Dutch Pharmacogenetics Working Group, and PharmGKB to develop pharmacogenetic resources for clinicans including gene-based drug-dosing guidelines and online pharmacogenetics resources.
2. To describe and present preliminary results from current prospective pharmacogenetic trials including the University of Chicago 1200 Patients Project and St. Jude Children's Research Hospital PG4KDS project.
3. To discuss different strategies for implementing pharmacogenetics into clinical practice and identify key factors for success and pitfalls for each approach.

SCIENTIFIC AGENDA • MARCH 9

9:15 am – 11:15 am
2 Concurrent Symposia

ROLE OF PHARMACOMETRICS IN THE DEVELOPMENT OF PROPHYLACTIC AND THERAPEUTIC ANTIVIRAL TREATMENTS

JW Grand 7/8

endorsed by INF/PMK

Chairs

Steven M. Belknap, MD, Northwestern University Feinberg School of Medicine

Craig W. Hendrix, MD, Johns Hopkins University School of Medicine

Steven M. Belknap, MD

Speakers

Lynn McFadyen, PhD, Pfizer
Clinical Development of Maraviroc: Pharmacometrics for Efficient Development and Approval

Lynn McFadyen, PhD

Jeffry Florian, PhD, US Food and Drug Administration
Regulatory Approval of Boceprevir and Telapravir: Role of Pharmacometrics

Craig W. Hendrix, MD, Johns Hopkins University School of Medicine
Clinical Pharmacology of Tenofovir in Pre-Exposure Prophylaxis (PreP)

Craig W. Hendrix, MD

Terrence F. Blaschke, MD, Bill and Melinda Gates Foundation
Adherence Assessment and Impact on Antiviral Outcomes

Terrence F. Blaschke, MD

Learning Objectives

1. To outline effective application of model based drug development concepts for the development of antiviral medications.
2. To tell specific case studies utilizing pharmacostatistical models for describing dose response relationships, trial simulation strategies, regulatory perspectives and assessing the impact of non-adherence in the development of prophylactic and therapeutic antiviral treatments.
3. To explain the importance of adherence for the success of prophylactic therapies under development for prevention of HIV and modeling strategies for adherence.

Invited Chairs and Speakers are subject to change. Please refer to the ASCPT website for up-to-date information.

CLINICAL PHARMACOLOGY CURRICULUM REVIEW COURSE

CLINICAL PHARMACOLOGY CURRICULUM REVIEW COURSE CLINICAL TRACK

JW Grand 9

Chairs Darrell R. Abernethy, MD, PhD, US Food and Drug Administration
David A. Flockhart, MD, PhD, Indiana University School of Medicine

Darrell R. Abernethy, MD, PhD

David A. Flockhart, MD, PhD

Learning Objective

1. Identify core concepts in clinical pharmacology in the areas of pharmacokinetics, aging, pediatrics, drug safety and drug interactions as well as pharmacogenetics.

7:00 am – 7:25 am	CONTINENTAL BREAKFAST
7:30 am – 8:10 am	PROVING NO EFFECT – EQUIVALENCE TRIALS AND TQT STUDIES John C. Pezzullo, PhD, Georgetown University (Adjunct)
8:15 am – 8:55 am	PHARMACOKINETICS David J. Greenblatt, MD, Tufts University, School of Medicine
9:00 am – 9:40 am	CLINICAL PHARMACOGENOMICS David A. Flockhart, MD, PhD, Indiana University School of Medicine
9:40 am – 9:55 am	BREAK
10:00 am – 10:40 am	EFFECTS OF AGING PATHOPHYSIOLOGY ON DRUG DISPOSITION AND EFFECT Darrell R. Abernethy, MD, PhD, US Food and Drug Administration
10:45 am – 11:25 am	PEDIATRIC CLINICAL PHARMACOLOGY Kathleen Neville, MD, Children's Mercy Hospital

John C. Pezzullo, PhD

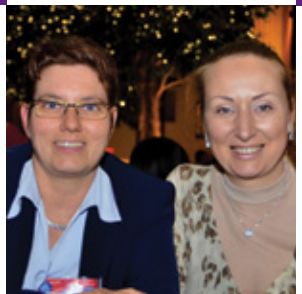
David J. Greenblatt, MD

Kathlee Neville, MD

CLINICAL PHARMACOLOGY CURRICULUM REVIEW COURSE

CLINICAL TRACK CONTINUED

11:30 am – 12:10 pm	DRUGS IN PREGNANCY – TREATING THE MOTHER, PROTECTING THE UNBORN Gideon Koren, MD, FRCPC, The Hospital for Sick Children	 *Gideon Koren, MD*
12:10 pm – 12:40 pm	LUNCH	
12:45 pm – 1:25 pm	PRINCIPLES OF ANTIRETROVIRAL THERAPY Craig W. Hendrix, MD, Johns Hopkins University School of Medicine	 *Craig W. Hendrix, MD*
1:30 pm – 2:10 pm	PHARMACOEPIDEMIOLOGY: THE STUDY OF DRUGS IN POPULATIONS Brian L. Strom, MD, MPH, University of Pennsylvania School of Medicine	 *Brian L. Strom, MD*
2:15 pm – 2:55 pm	PSYCHIATRY: CLINICAL PHARMACOLOGY OF ANTIPSYCHOTICS AND ANTIDEPRESSANTS Sheldon H. Preskorn, MD, University of Kansas Medical Center	 *Sheldon H. Preskorn, MD*



CLINICAL PHARMACOLOGY CURRICULUM REVIEW COURSE

CLINICAL PHARMACOLOGY CURRICULUM REVIEW COURSE DRUG DEVELOPMENT TRACK

JW Grand 10

Chairs Darrell R. Abernethy, MD, PhD, US Food and Drug Administration
David A. Flockhart, MD, PhD, Indiana University School of Medicine

Darrell R. Abernethy, MD, PhD

David A. Flockhart, MD, PhD

Learning Objective

1. Describe the key approaches to drug development in the areas of clinical trials, drug interactions, biologics, modeling, pediatrics and pharmacokinetics.

7:00 am – 7:25 am	CONTINENTAL BREAKFAST	
7:30 am – 8:10 am	CLINICAL PHARMACOLOGY IN DRUG DEVELOPMENT Carl C. Peck, MD, UCSF Center for Drug Development Science	 *Carl C. Peck, MD*
8:15 am – 8:55 am	CLINICAL TRIALS IN DRUG DEVELOPMENT: THINKING QUANTITATIVELY David W. Feigal, Jr., MD, MPH, NDA Partners LLC	
9:00 am – 9:40 am	PROTEIN THERAPEUTICS Mark Rogge, PhD, Biogen Idec, Inc.	
9:40 am – 9:55 am	BREAK	
10:00 am – 10:40 am	DRUG INTERACTIONS: AN EVOLUTION IN DRUG DEVELOPMENT Shiew-Mei Huang, PhD, US Food and Drug Administration	 *Shiew-Mei Huang, PhD*
10:45 am – 11:25 am	EARLY CLINICAL DEVELOPMENT STRATEGIES FOR MONOCLONAL, ANTIBODIES IN NON-ONCOLOGIC INDICATORS Mary Ann Mascelli, PhD, Centocor	 *Mary Ann Mascelli, PhD*
11:30 am – 12:10 pm	DRUGS USED FOR PHENOTYPING IN CLINICAL PHARMACOLOGY David Jones, PhD, Indiana University School of Medicine	 *David Jones, PhD*

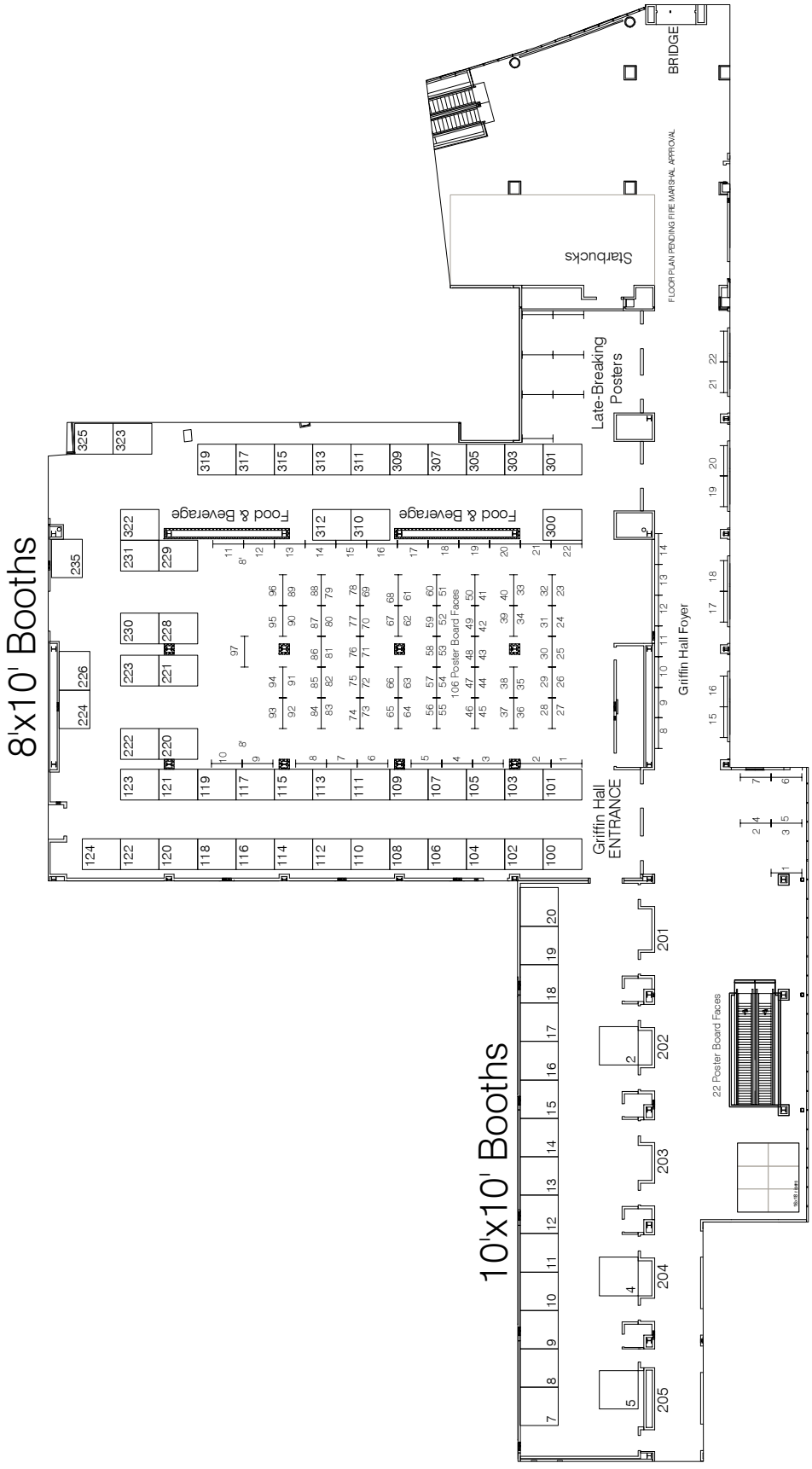
CLINICAL PHARMACOLOGY CURRICULUM REVIEW COURSE

DRUG DEVELOPMENT TRACK CONTINUED

12:10 pm – 12:40 pm	LUNCH	
12:45 pm – 1:25 pm	PHYSIOLOGICALLY BASED PHARMACOKINETIC MODELING (PBPK) Amin Rostami-Hodjegan, PharmD, PhD, University of Manchester	 *Amin Rostami-Hodjegan, PharmD, PhD*
1:30 pm – 2:10 pm	POPULATION PHARMACOKINETICS/PHARMACODYNAMICS: BAYESIAN APPROACHES TO PHARMACOLOGIC DATA ANALYSIS Robert Bies, PharmD, PhD, Indiana University	 *Robert Bies, PharmD*
2:15 pm – 2:55 pm	MECHANISTIC PHARMACOKINETIC/PHARMACODYNAMIC MODELS Donald E. Mager, PharmD, PhD, State University of New York at Buffalo	 *Donald E. Mager, PharmD, PhD*

HOTEL FLOOR PLAN

EXHIBITOR FLOOR PLAN



EXHIBITORS

CLINICAL TRIALS

OPEN ACCESS | RAPID REVIEW | FAST-TRACK PUBLICATION

Clinical Pharmacology & Therapeutics considers manuscripts developed from well-conducted, well-reported, and relevant clinical trials. If advanced for consideration, manuscripts can be selected for rapid review and potential fast-track publication. Submission requirements for clinical trials are provided in the Clinical Trials Guide to Authors available at **www.nature.com/cpt.**

Authors of clinical trials may opt for Open Access publication. Open access articles are deposited in PubMed Central at the time of publication and are freely available immediately to researchers worldwide. Marketing opportunities include press releases via the Nature News Service, target banner advertising across Nature Publishing Group's pharmacology titles and related disciplines, post publication opportunities, and podcasts.

QUESTIONS?

Contact the Clinical Trial Editors, **Peter K. Honig, MD, MPH,** and **Raymond J. Hohl, MD, PhD**, at cpt@ascpt.org or 703-836-6981. Submit online at http://mts-cpt.nature.com.

EXHIBITORS BY COMPANY NAME

Griffin Hall • Wednesday, March 6, 5:00 pm – 6:30 pm. Thursday, March 7, 8:00 am – 3:00 pm. Friday, March 8, 8:00 am – 3:00 pm

COMPANY	BOOTH
AIT Bioscience	114
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Advanced Pharma CR, LLC	12
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Bayer Technology Services GmbH	103
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ProMedica CRC	101
QPS, LLC	305
QuantIon Technologies	121
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SIMCYP Limited	2
Simulations Plus, Inc.	123
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Verified Clinical Trials	313
Vince and Associates Clinical Research	110
WCCT Global, LLC	300
Wake Research	16

Exhibitors as of 2/26/13

EXHIBITORS BY BOOTH NUMBER

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BOOTH	COMPANY
2	SIMCYP Limited
4	BASi
5	Aspire IRB
7	EUROFINS OPTIMED
8	Accel Research Sites
10	Medpace Clinical Pharmacology
11	Biomedical Systems
12	Advanced Pharma CR, LLC
13	OBS Medical Limited
14	Medimetrics Personalized Drug Delivery, Inc.
15	Entelos
16	Wake Research
17	BioPharma Services Inc.
18	ClinicalRSVP
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313	Verified Clinical Trials
315	Coram
317	Pediatric Pharmacokinetic Consortium
319	PRACS Institute
322	American College of Clinical Pharmacology
323	Ce3 Inc.
325	Spaulding Clinical Research, LLC

Exhibitors as of 2/26/13

EXHIBITS

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AIT Bioscience
Booth 114
7840 Innovation Blvd
Indianapolis, IN 46278
www.aitbioscience.com

AIT Bioscience is a bioanalytical contract research organization supporting pre-clinical and clinical drug development and was created by veteran industry experts. It is the first CRO to run regulated projects and studies through an electronic lab notebook, providing sponsors with faster, higher quality data.

Accel Research Sites
Booth 8
860 Peachwood Dr.
Deland, FL 32720
www.accelclinical.com

Accel Research Sites are industry-leading clinical research sites with the clinical expertise, therapeutic experience and capabilities to successfully fulfill clinical trials in a wide range of therapeutic indications. We pride ourselves on delivering high quality work to our customers, which include major Pharmaceutical, Biotechnology, and Clinical Research Organizations. We conduct Phase I, In-Hospital, Oncology, Vaccine and Outpatient Phase II-IV trials. Speed to delivery, a dedicated in-house patient recruitment team, disciplined process management and quality data collection ensure our sponsors receive the highest value for their clinical research investments.

Advanced Pharma CR, LLC
Booth 12
1951 NW 7th Avenue
Miami, FL 33136
www.advancedpharmacr.com

Advanced Pharma CR (APCR) is a dedicated Phase I-IV Clinical Research Facility, located within the City of Miami's Health District, the second largest in the nation. Our state-of-the-art clinical research facility houses 150 beds, including two Intensive Procedure Units (IPU).

Algorithme Pharma, Inc.
Booth 307
575 Armad-Frappier
Laval, QCH7V4B3
Canada
www.algopharm.com

Algorithme Pharma, a member of Altasciences, is an early stage clinical CRO with a full service offering, from study design to study conduct, PK analysis and bioanalysis. Working along with their sister company, Simbec Research in the UK, we have been servicing international pharmaceutical, biotechnology and generic drug companies for over 35 years. Algorithme Pharma's GLP-compliant bioanalytical facilities perform large and small molecule bioanalysis on samples from preclinical to Phase IV studies. The team, of almost 500 professionals from the medical and scientific fields, works together to conduct over 275 clinical trials annually in Phase I/IIa, Bioequivalence and 505(b)(2) studies, involving over 5,000 participants including patient populations.

American College of Clinical Pharmacology
Booth 322
PO Box 1637
Rockville, MD 20849
www.accp1.org

For 40+ years, American College of Clinical Pharmacology, a non-profit membership association, has provided interdisciplinary, credited Continuing Education programs, publications, networking & career-enhancing opportunities to a spectrum of healthcare professionals using clinical pharmacology in disciplines from research to patient care.

ARENSIA Exploratory Medicine
Booth 312
Moskauer Str. 25
Duesseldorf, 40227
Germany
www.arensia-em.com

ARENSIA EXPLORATORY MEDICINE is specialized to perform complex early patient studies in own modern Phase I units, located in large university clinics in Eastern Europe. ARENSIA has a proven track record for extraordinary fast recruitment and quality in numerous indications.

Aspire IRB
Booth 5
11491 Woodside Avenue
Santee, CA 92071
www.aspire-irb.com

Aspire Independent Review Board provides efficient, high quality and cost effective ethical review services to the research community with an emphasis on communication and flexibility. We oversee a variety of indications in all phases of research, specializing in Phase I clinical trials. Aspire IRB is a women and minority owned business which has recently been audited by the FDA as well as received AAHRPP re-accreditation for the next 5 years.

BASi
Booth 4
2701 Kent Ave
Lafayette, IN 47906
www.basinc.com

BASi develops innovative services and products that increase efficiency and reduce costs associated with taking new drugs to market: drug discovery services, small and large molecule bioanalysis, preclinical toxicology, pharmaceutical analysis, Culex automated *in vivo* sampling system.

Bayer Technology Services GmbH
Booth 103
Chempark Building K9
Leverkusen, 51368
Germany
www.bayertechnology.com

To support decision making in drug development, Bayer Technology Services provides software products for predictive simulation of drug behavior and modeling of cellular pathways as well as professional consulting services. Areas of special expertise are disease modeling and pediatric trial design.

Exhibitors as of 2/26/13

EXHIBITS

Griffin Hall • Wednesday, March 6, 5:00 pm – 6:30 pm. Thursday, March 7, 8:00 am – 3:00 pm. Friday, March 8, 8:00 am – 3:00 pm

Biomedical Systems

Booth 11
77 Progress Parkway
Hazelwood, MO 63043
www.biomedsys.com

Biomedical Systems is a global provider of centralized diagnostic services for clinical trials Phases I–IV as well as post-marketing safety studies. Our methods have improved data accuracy, shortened timeframes, and lowered costs for sponsors. Biomedical Systems offers unprecedented stability at all levels of our organization, from low turnover rates among our clinical project managers to the same name and ownership for over 35 years. Our reliability has led to over 80 active master service agreements and 220 active clients worldwide. Biomedical Systems partners with all top 10 pharmaceutical companies and has experience with various regulatory agencies.

BioPharma Services Inc.

Booth 17
4000 Weston Road
Toronto, ON M9L3A2
Canada
www.biopharmaservices.ca

BioPharma Services Inc. is a physician-owned, US FDA-inspected Phase I CRO, with a 174 bed clinical facility and onsite bioanalytical laboratory in Toronto, Canada, and access to >16,000 healthy volunteers, patients and special populations such as first generation Japanese volunteers.

Biotrial

Booth 221
7-9 Rue Jean-Louis Bertrand 35000
Rennes, EC4Y 0HP
France
www.biotrial.com

Founded in 1989, Biotrial is a leading CRO specialized in Early Development with a large range of services from Non-Clinical Pharmacology, Phase I studies, Phase II-IV Trial Management, Oncology, Data Management, Biostatistics, Core Lab (ECG, Imaging, cognitive assessments…), Regulatory Affairs to Medical Writing. Based in France, the UK, Belgium and USA, Biotrial performs hundreds of studies a year and offers tailor-made solutions to Pharma and Biotech companies.

Ce3 Inc.

Booth 323
246 Goose Lane
Suite 202
Guilford, CT 06437
www.ce3inc.com

Ce3 is a full service contract research organization focused on providing biotechnology companies with Phase I-III clinical trial execution and regulatory submission services. Our seasoned staff works across a broad range of therapeutic areas, with particular expertise in oncology and infectious disease indications. CE3 stands for Collaborative, Experience, Efficiency & Excellence which are qualities that represent our core values and serve as the foundation for all that we do. Clients benefit from our flexibility, process efficiency, value pricing, and our collaborative relationships with state-of-the-art niche providers; a competitive edge that amplifies value in this highly regulated environment.

Exhibitors as of 2/26/13

CNS Network, Inc.

Booth 19
12772 Valley View St3
Garden Grove, CA 92845
www.cnstrial.com

CNS Network, Inc. is a leading research institution specializing in disease specific early phase studies. Our 25,000 square foot facility is located in Long Beach, California with 45 beds on our Phase I/II unit and 20 in our licensed psychiatric facility. Our area of expertise is in recruiting challenging patient populations for complex research protocols including schizophrenia, Alzheimer's disease, Parkinson's disease, migraine and depression. Additionally, CNS Network has outpatient clinics for later phase research in Garden Grove, Long Beach, Torrance and Oakland, CA.

CRCHUM (Centre de recherche du Centre hospitalier de l'Université de Montréal)

Booth 115
3850, Saint-UrbainPavillon Jeanne-Mance, 7-322
Montreal, QCH2W 1T7
Canada
www.chumtl.qc.ca/crchum.fr.html

Leading hospital research centre in Canada. Quebec's largest university hospital. 6,500m2 clinical research facilities including Phase I-II unit (15 beds). Specialized expertise and immense pool of patients -Quebec's largest centre in: cancer treatment, neuroscience clinics, solid organ transplant-Expertise in diabetes and cv disorders.

CRI Lifetree

Booth 309
16000 Horizon Way
Suite 100
Masonville, NJ 08054
www.crilifetree.com

CRI Lifetree is a leader in clinical research with expertise in pain, abuse liability, psychiatry, neurology and diabetes. CRI Lifetree offers Phase I-IV services to meet the requirements of complex clinical trials in Philadelphia, New Jersey and Salt Lake City.

Celerion

Booth 229
621 Rose Street
Lincoln, NE 68502
www.celerion.com

Celerion is the leader in providing comprehensive clinical research, clinical pharmacology sciences, bioanalytical and drug development services. With six global locations and over 730 beds, our experience and expertise is applied to provide solutions to pharmaceutical, biotechnology and generic clients.

Griffin Hall • Wednesday, March 6, 5:00 pm – 6:30 pm. Thursday, March 7, 8:00 am – 3:00 pm. Friday, March 8, 8:00 am – 3:00 pm

Clinical Pharmacology of Miami, Inc.

Booth 106
550 W 84 St
Hialeah, FL 33014
www.clinpharmmiami.com

Clinical Pharmacology of Miami, Inc. (CPMI) is an independent clinical research organization dedicated to performing safe, precise and scientifically valid clinical research studies, applying our experience, eduction, skills and integrity. CPMI conducts clinical trials (Phase I-IV) in the South Florida, Miami area. Kenneth C. Lasseter, MD, Stacy C. Dilzer, RN, BSN and E. Cooper Shamblen are the principals and have 90+ years of clinical research experience. CPMI has a state of the art, custom designed, 120 bed, facility. Our database includes a large volunteer population, including healthy males and females, Hepatically Impaired, Renal insufficiency, Hypertensive, Geriatric, Diabetic and Obese volunteers.

ClinicalRSVP

Booth 18
401 E. Las Olas Blvd.130-395
Fort Lauderdale, FL 33301
www.clinicalrsvp.com

ClinicalRSVP is the leading subject clearinghouse within early drug development. This simple biometric tool allows sponsors and sites to ensure that study volunteers do not "dual enroll" in multiple clinical trials.

Clinilabs, Inc.

Booth 113
423 West 55th Street
4th Floor
New York, NY 10019
www.clinilabs.com

Clinilabs is a full-service contract research organization (CRO) that provides early-phase and specialty clinical drug development services. Clinilabs is recognized globally as a leading specialty CRO, and has made important contributions to twelve successful new drug applications.

Community Research

Booth 117
4460 Red Bank Expy.
Ste 200
Cincinnati, OH 45227
www.communityresearch.com

Community Research is a dedicated, multi-specialty, Phase I-IV clinical research site located in Cincinnati, OH. CR operates 3 outpatient facilities that conduct Phase II-IV trials in the following specialties (Internal Medicine, Cardiology, Dermatology, Ophthalmology, Psychiatry, and Sleep Medicine) as well as a 60 bed Phase I unit located on an active hospital campus. CR has experience with First-in-Human, SAD, MAD, Drug Interaction, PK/PD trials with added expertise in sleep disorders, human performance and neuropsychiatric research. With a database of 60,000 individuals CR has access to both normal healthy subjects as well as patient populations.

Compass Research, LLC

Booth 119
100 W. Gore St.
2nd floor
Orlando, FL 32806
www.compassresearch.com

Compass Research is a multi-specialty clinical research site in Orlando, Florida, offering Phase I-IV services. Our 34-bed Phase I unit is staffed by 4 full-time doctors and includes a 10-bed intensive treatment room. Staff has combined experience in 1,300 trials.

Comprehensive Clinical Development

Booth 311
3100 SW 145th Avenue
Suite 340
Miramar, FL 33027
www.comprehensivecd.com

A leading early phase clinical research company with the tools and infrastructure to take a drug from Phase 0 through proof of concept. Providing access to healthy and special populations, Comprehensive delivers a full range of clinical development services across an array of therapeutic areas, consistently delivering on time and within budget.

Coram

Booth 315
555 17th Street Suite 1500
Denver, CO 80202
www.coramclinicaltrials.com

CCT is a nationwide provider of nursing and pharmacy services that supports in-home clinical trials, which enhance subject recruitment and retention. Coram offers centralized medication distribution and a local network of over 70 branch pharmacies for delivery of IP, and features a staff of 650 experienced home care nurses.

Covance

Booth 228
210 Carnegie Center
Princeton, NJ 08540
www.covance.com

Covance is one of the world's largest and most comprehensive drug development services companies with more than 11,000 employees in 60 countries. Through its discovery, nonclinical, clinical and commercialization services, Covance has helped pharmaceutical and biotech companies develop one-third of all prescription medicines in the market today.

DaVita Clinical Research

Booth 107
825 South 8th Street
Suite 300
Minneapolis, MN 55404
www.davitaclinicalresearch.com

DCR is committed to advancing the knowledge and practice of kidney care. Through our experience and pursuit of innovation, we continue to lead the charge. Our extensive array of patients, data points, and clinics is unparalleled. We remain focused on our services and uphold our duty as premier specialists in the field.

Exhibitors as of 2/26/13

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Duke Clinical Research Institute

Booth 222
300 W. Morgan Street Suite 800
Durham, NC 27701
www.dcri.org

The Duke Clinical Research Institute's early phase unit offers the full-service operational capabilities of a contract research organization combined with clinical expertise, academic leadership, and business acumen to conduct science-driven proof-of-concept studies in adults and children. We provide rapid start-up, direct patient access, and first-rate facilities in a hospital-based unit.

ERT

Booth 235
1818 Market Street
Suite 1000
Philadelphia, PA 19103
www.ert.com

ERT is a global technology-driven provider of customizable medical devices and health outcomes research services. ERT harnesses internet and telecommunications technology to provide stakeholders with multiple modes of available technology for collecting health outcomes data, including Patient (PRO), Clinician (ClinRO) and Observer (ObsRO) reported outcomes.

Elsevier

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New York, NY 10010
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Explore Elsevier's high impact journals and learn the latest in research news from journals such as *Clinical and Experimental Pharmacology* and *Pharmacology and Therapeutics*. Our exciting books include Principles of Clinical Pharmacology and Clinical Pharmacology During Pregnancy. Discover our online research tools such as ScienceDirect, giving you the latest peer reviewed full text articles.

Entelos

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Two Waters Park Drive Suite 200
San Mateo, CA 94403
www.entelos.com

Entelos's sophisticated whole body biosimulations with virtual patients help our customers with target confirmation, biomarker identifications, translation, patient stratification and clinical trial design in type 2 diabetes, atherosclerosis, R/A and hypertension.

EUROFINS OPTIMED

Booth 7
1, rue des Essarts
Gieres, 38610
France
www.optimed.fr

French company founded in 1990 and certified ISO 9001:2008, EUROFINS OPTIMED provides tailor-made services for Full Clinical Trial Management, in Europe and emerging countries, for early development, thanks to its Clin Pharm Unit and extensive experience in various therapeutics areas.

ICON Development Solutions

Booth 220
7740 Milestone Parkway
Suite 150
Hanover, MD 21076
www.iconclinical.com

ICON Development Solutions specializes in the strategy and delivery of early-phase clinical development services to enable informed, timely decision making for our clients. We offer industry-leading capabilities in clinical pharmacology, bioanalytical/immunoassay, biomarkers, PK/PD modeling & simulation and the full range of support services.

INC Research

Booth 20
RiverviewThe Meadows Business Park
Surrey, Camberley G417 9AB
United Kingdom
www.incresearch.com

INC Research is a leading global clinical research organization providing the full range of Phase I to IV clinical development services across 6 continents.

Kinetigen, Inc.

Booth 124
2525 Meridian Pkwy
Suite 280
Durham, NC 27713
www.kinetigen.com

Kinetigen, Inc. wants to be your source for PK and clinical pharmacology needs. We are changing the paradigm in the pharmaceutical and biotech service industry by offering innovative methods for engaging our services and options to meet any budget and need.

Logos Technologies

Booth 224
91 Peterborough Rd.
London, SW6 3BU
United Kingdom
www.logostechnologies.com

AZPHADAS(R) is the market leading eSource pro-active EDC and site automation system for early phase clinical trials. It is a mobile, schedule driven event based system which provides real time EDC at the bedside station or remote location.

MASIMO

Booth 226
40 Parker
Irvine, CA 92618
www.masimo.com

A key medical technology innovator, Masimo is responsible for the invention of award-winning noninvasive technologies, medical devices, and a wide array of sensors that are revolutionizing patient monitoring in various care settings.

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Medimetrics Personalized Drug Delivery, Inc.
Booth 14
345 Scarborough Road
Briarcliff Manor, NY 10510
www.medimetrics.com

Medimetrics offers an electronic controlled capsule that can deliver a drug at a desired location in the GI tract and at a desired rate by remote control. Drug release is correlated with blood level to develop clear PK data.

Medpace Clinical Pharmacology
Booth 10
4620 Wesley Avenue
Cincinnati, OH 45209
www.medpace.com

Medpace Clinical Pharmacology Unit (CPU) is dedicated to conducting early-phase clinical pharmacology studies. The CPU, located centrally in Cincinnati, Ohio, conducts Phase I studies in healthy volunteers, as well as Phase Ib/IIa studies in patient populations that include diabetes, hypertension, obesity, healthy elderly, and various other cardiometabolic disorders. Medpace CPU is a fully owned subsidiary of Medpace, Inc. (Medpace).

Mortara Instrument
Booth 120
7865 N. 86th Street
Milwaukee, WI 53224
www.mortara.com

From ECG acquisition at the investigator site to FDA ECG Warehouse development, Mortara has developed a unique platform to help smoothly marshal a study from site to submission. Mortara understands that clinical trial requirements often cannot be satisfied with traditional healthcare products.

Nature Publishing Group
Booth 223
75 Varick Street
9th fl.
New York, NY 10013
www.nature.com

Nature Publishing Group brings you leading scientific and medical research. The NPG portfolio combines the continued excellence of Nature, its associated research and review journals, and 50 leading academic and society journals in the life, physical and clinical sciences. Visit Booth 223 for free sample copies.

New Orleans Center for Clinical Research/ Volunteer Research Group
Booth 105
1928 Alcoa Hwy
Ste G50
Knoxville, TN 37920
www.noccr.com

Hospital based, NOCCR is a privately owned multispecialty facility, providing expertise in all areas of Phase I-IV clinical research. Features included: 52 bed Phase I unit, level I trauma center location, access to specialty PI's in all therapeutic areas.

OBS Medical Limited
Booth 13
Brook House, 174 Brooke Drive
Milton Park Abingdon
Oxon, OX14 4SD
United Kingdom
www.obsmedical.com

BioQT, fully automated ECG waveform analysis tool for screening potential risk of adverse events in new drug developments from arrhythmia induced cardiac toxicity. BioQT provides benefits to Phase I Units, Core ECG Laboratories and Pharmaceutical Sponsors for cardiac safety solutions.

OmniComm Systems, Inc.
Booth 108
2101 West Commercial Blvd. Suite 3500
Fort Lauderdale, FL 33309
www.omnicomm.com

OmniComm provides web-based electronic data capture (EDC), and eClinical solutions to pharmaceutical, biotechnology, medical device, CRO, Sponsor, and medical research organizations conducting clinical trials around the world. Our EDC and eClinical technologies have been used in over 3,000 clinical trails.

Orlando Clinical Research Center
Booth 104
5055 S Orange Ave
Orlando, FL 32809
www.ocrc.net

Orlando Clinical Research Center is a cutting edge independent Phase I-IV custom-built 35,000 sq.ft. research site. Designed specifically for Phase I clinical trials, OCRC includes 100 in-house volunteer beds, dual lead digital telemetry, CCTV security system, and cardkey access.

PRA
Booth 116
4130 Parklake Avenue
Raleigh, NC 27612
www.prainternational.com

PRA's Early Development Service group conducts Phase I-IIa studies in our clinics in Europe and the U.S. with bioanalytical laboratories in close proximity to each, facilitating analysis of time-critical patient samples. Additionally, we operate our Unit on Demand model in Central and Eastern Europe for early phase patient studies. PRA operates two bioanalytical laboratories with a choice of GLP and GLP-like services, providing clients with the flexibility to customize analysis to meet regulatory requirements and timelines. The strategic locations of the laboratories close to our Phase I units facilitate an innovative working collaboration, enabling rapid turnaround of time-critical samples.

Exhibitors as of 2/26/13

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PRACS Institute
Booth 319
4801 Amber Valley Parkway
Fargo, ND 58104
www.pracs.com

A leading early-phase contract research organization, PRACS has conducted more than 20,000 clinical pharmacology studies- more than any other CRO. With facilities across North America, PRACS offers flexible, quality clinical development services in a range of therapeutic areas.

PAREXEL
Booth 301
195 West Street
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Exhibitors as of 2/26/13

Griffin Hall • Wednesday, March 6, 5:00 pm – 6:30 pm. Thursday, March 7, 8:00 am – 3:00 pm. Friday, March 8, 8:00 am – 3:00 pm

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Exhibitors as of 2/26/13

POSTER SESSION I • MARCH 7

Griffin Hall • 8:00 am – 3:00 pm • Attended Posters 8:00 am – 9:30 am

Biomarkers and Imaging (BIO)

PI-1

ANALYSIS OF THE STABILITY OF MIRNA IN WHOLE BLOOD.

E. A. Benson, T. C. Skaar; Indiana University School of Medicine, Indianapolis, IN.

PI-2

NORMATIVE PUPILLOMETRY IN PEDIATRICS.

J. Brown,[1] M. Connelly,[1] C. Nickols,[2] J. Weigel,[1] K. Neville[1]; [1]Children's Mercy Hospitals and Clinics, Kansas City, MO, [2]University of Missouri-Kansas City, Kansas City, MO.

PI-3

PHARMACOGENOMIC BIOMARKER DEVELOPMENT AND TRANSLATIONAL SIMULATIONS TO BRIDGE CLINICAL INDICATIONS FOR AN ANTI-INTERFERON ALPHA RECEPTOR ANTIBODY.

B. Wang,[1] B. W. Higgs,[2] L. Chang,[1] I. Vainshtein,[1] Z. Liu,[2] K. Steicher,[2] M. Liang,[1] W. I. White,[2] S. Yoo,[2] L. Richman,[2] B. Jallal,[2] L. Roskos,[1] Y. Yao[2]; [1]MedImmune LLC, Hayward, CA, [2]MedImmune LLC, Gaithersburg, MD.

PI-4

GLOBAL METABOLOMICS PROFILING OF HUMAN URINE REVEALS CHANGE IN ENDOGENOUS METABOLITES AFTER METFORMIN AND PIOGLITAZONE ADMINISTRATION.

K. Cho,[1] S. Cho,[2] J. Chung,[1] S. Yoon,[1] I. Jang,[1] J. Cho[1]; [1]Department of Clinical Pharmacology and Therapeutics, Seoul National University College of Medicine and Hospital, Seoul, Republic of Korea, [2]Department of Pharmacology, Yonsei University College of Medicine, Seoul, Republic of Korea.

PI-5

VALIDATION OF A SCINTIGRAPHIC TECHNIQUE FOR THE INVESTIGATION OF THE EFFECT OF GLP-1 ANALOGUES/AGONISTS ON GALLBLADDER MOTILITY IN HEALTHY SUBJECTS.

A. Connor,[1] J. Collier,[1] I. Nowotny,[2] J. Pinquier,[2] A. Perkins[3]; [1]Quotient Clinical, Nottingham, United Kingdom, [2]Sanofi-Aventis, Frankfurt, Germany, [3]University of Nottingham, Nottingham, United Kingdom.

PI-6

SCINTIGRAPHIC ASSESSMENT OF THE IMPACT OF PUR118 ON MUCOCILIARY CLEARANCE VELOCITY IN SUBJECTS WITH MILD COPD.

A. Connor,[1] J. Collier,[1] L. Patrick,[1] S. Mair,[1] M. Rosano,[2] J. Hanrahan[2]; [1]Quotient Clinical, Nottingham, United Kingdom, [2]Pulmatrix, Inc, Lexington, MA.

PI-7

POLYDRUG USE BY PREGNANT METHADONE USERS.

K. Delano, J. Gareri, G. Koren; Hospital for Sick Children, Toronto, ON, Canada.

Drug Development and Regulatory Sciences (DDR)

PI-8

EVALUATION OF CLINICAL DESIGN CONSTRUCTS FOR APREPITANT ADMINISTRATION TO TREAT HIV-ASSOCIATED NEUROCOGNITIVE DISORDERS (HAND).

J. S. Barrett,[1] D. Wu,[1] J. McGuire,[1] F. Tuluc,[1] S. Spitsin,[1] P. Tebas,[2] D. L. Evans,[2] S. D. Douglas[1]; [1]The Children's Hospital of Philadelphia, Philadelphia, PA, [2]Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA.

PI-9

PRECLINICAL ACTIVITY PREDICTS HIGHER DOSING REQUIREMENTS FOR THE NK-1R ANTAGONIST APREPITANT IN HIV-ASSOCIATED NEUROCOGNITIVE DISORDERS (HAND): DISPOSITIONAL AND PHARMACOLOGIC RATIONALE FOR MULTIMODAL THERAPEUTIC WINDOW.

J. S. Barrett,[1] D. Wu,[1] G. Moorthy,[1] P. Srivastata,[1] K. J. Barrett,[1] S. Spitsin,[1] F. Tuluc,[1] J. McGuire,[1] A. Mexas,[2] K. Lynch,[3] P. Tebas,[3] K. Baker,[4] A. Lackner,[4] D. L. Evans,[3] S. D. Douglas[1]; [1]The Children's Hospital of Philadelphia, Philadelphia, PA, [2]School of Veterinary Medicine, University of Pennsylvania, Philadelphia, PA, [3]Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, [4]Tulane National Primate Research Center, Tulane University, Covington, LA.

PI-10

EFFECT OF RENAL IMPAIRMENT ON THE PHARMACOKINETICS OF BRENTUXIMAB VEDOTIN, AN ANTIBODY-DRUG CONJUGATE, IN PATIENTS WITH CD30-POSITIVE HEMATOLOGIC MALIGNANCIES.

T. H. Han, L. E. Grove, C. M. Lynch; Seattle Genetics, Inc., Bothell, WA.

PI-11

THE EFFECTS OF CYP3A INHIBITORS ON SILDENAFIL AND MIDAZOLAM PHARMACOKINETICS ARE HIGHLY CORRELATED.

X. Gao, J. A. Cook; Pfizer, Groton, CT.

PI-12

LONGITUDINAL PK PD MODELING TO PROJECT THE EFFECT SIZES AND UNCERTAINTIES OF THE TOPICAL APPLICATION OF TOFACITINIB IN PSORIASIS PATIENTS.

X. Gao,[1] M. Hutmacher,[2] S. Khan,[3] S. Lan,[1] W. Ports[1]; [1]Pfizer, Inc, Groton, CT, [2]Ann Arbor Pharmacometrics Group (A2PG), Ann Arbor, MI, [3]PharmaNet/i3, Princeton, NJ.

PI-13

A SIMPLIFIED APPROACH TO A SILDENAFIL POPULATION PK SIMULATION: AN EXAMPLE IN BRIDGING WITH JAPANESE PEDIATRIC PAH PATIENTS.

X. Gao,[1] L. O. Harnisch[2]; [1]Pfizer, Groton, CT, [2]Pfizer, Sandwich, United Kingdom.

*Presenting author is in **bold**.*

Drug Safety (SAF)

PI-14
ASSESSING PRO-ARRHYTHMIC RISK DUE TO QTC PROLONGATION - EXPERIENCE WITH TARGETED THERAPIES IN ONCOLOGY.
N. Budha, S. Saif, M. Dresser, S. Sahasranaman; Genentech, South San Francisco, CA.

PI-15
QTC PROLONGATION ASSESSMENT USING CONCENTRATION-QT ANALYSIS FROM A PHASE I FIRST-IN-HUMAN STUDY OF AN AKT INHIBITOR, GDC-0068.
N. Budha,[1] M. Dresser,[1] P. Patel,[1] R. Funke,[1] M. Tatipalli,[1] J. Zhu,[1] J. Tabernero,[2] A. Cervantes,[3] L. Musib[1]; [1]Genentech, South San Francisco, CA, [2]Vall d'Hebron University Hospital, Barcelona, Spain, [3]University of Valencia, Valencia, Spain.

PI-16
EXAMINATION OF INTRAPARTUM USE OF MAGNESIUM SULFATE AND POTENTIAL DRUG-DRUG INTERACTIONS.
S. C. Campbell, C. M. Sherwin, A. H. Balch, E. A. Clark, M. G. Spigarelli; University of Utah, Salt Lake City, UT.

PI-17
WITHDRAWN

PI-18
PHASE I CLINICAL TRIAL FOR TOLERABILITY OF DAN QI TONG MAI TABLET.
P. Feng,[1] Z. Gou,[2] M. Li,[2] J. Mou,[2] Z. Luo,[2] L. Zheng,[2] Y. Wang,[2] Q. Shen,[2] N. Xu[2]; [1]Institute of Drug Clinical Trials, The First Affiliated Hospital of Chongqing Medical University, Chongqing, China, [2]Institute of Drug Clinical Trials, West China Hospital, Sichuan University, Chengdu, China.

PI-19
AN INTEGRATED FIRST-IN-HUMAN STUDY DESIGN INVOLVING SEQUENTIAL SINGLE AND MULTIPLE ASCENDING DOSE COHORTS: AN EMERGING TREND IN PHASE I CLINICAL TRIALS.
M. Francis, J. Basque, E. Legault, M. Rufiange, E. Sicard, M. Lefebvre; Algorithme Pharma, Laval, QC, Canada.

PI-20
INFLUENCE OF LOW DOSE OF DIFFERENT PROTON PUMP INHIBITORS ON THE ANTI-PLATELET FUNCTION OF CLOPIDOGREL.
T. Furuta, M. Sugimoto, M. Yamade, T. Uotani, S. Sahara, H. Ichikawa, H. Watanabe, K. Umemura; Hamamatsu University School of Medicine, Hamamatsu, Japan.

PI-21
CASE SERIES OF RHABDOMYOLYSIS ASSOCIATED WITH ROSUVASTATIN USE WITH TRANSPORTER GENOTYPING AND DRUG LEVEL ANALYSIS.
S. E. Gryn,[1] M. K. DeGorter,[2] N. Facca,[1] R. G. Tirona,[2] R. B. Kim[1]; [1]London Health Sciences Center, London, ON, Canada, [2]Western University, London, ON, Canada.

PI-22
VANCOMYCIN SERUM TROUGH CONCENTRATION AND RISK FACTORS FOR NEPHROTOXICITY IN PATIENTS WITH THERAPEUTIC DRUG MONITORING.
H. Han, H. An, K. Shin, I. Jang, K. Yu, S. Shin, K. S. Lim; Department of Clinical Pharmacology and Therapeutics, Seoul National University College of Medicine, Seoul, Republic of Korea.

Infectious Diseases (INF)

PI-23
POPULATION PHARMACOKINETICS OF MEROPENEM IN OBESE AND NON-OBESE HOSPITALIZED PATIENTS.
C. E. Chung,[1] S. C. Cheatham,[2] M. R. Fleming,[3] M. B. Kays[1]; [1]Purdue University College of Pharmacy, Indianapolis, IN, [2]St. Francis Hospital, Indianapolis, IN, [3]Methodist Dallas Medical Center, Dallas, TX.

PI-24
LACK OF DRUG-DRUG INTERACTION BETWEEN MERICITABINE AND RITONAVIR-BOOSTED DANOPREVIR.
S. Moreira,[1] P. Goelzer,[1] P. Weigl,[1] E. Badman,[1] A. Poirer,[2] B. J. Brennan,[1] Y. Chen[1]; [1]Roche, Nutley, NJ, [2]F. Hoffmann-La Roche Ltd., Basel, Switzerland.

*Presenting author is in **bold**.*

POSTER SESSION I • MARCH 7

Griffin Hall • 8:00 am – 3:00 pm • Attended Posters 8:00 am – 9:30 am

Molecular Pharmacology and Pharmacogenetics (MOL)

PI-25
ASSOCIATION OF THE CYP2B6*6 ALLELE WITH EFAVIRENZ-INDUCED QT INTERVAL CHANGES AT STEADY STATE IN HEALTHY SUBJECTS.
A. M. Abdelhady,[1] N. Thong,[2] Y. Kreutz,[2] J. E. Tisdale,[1] Z. Desta,[2] B. R. Overholser[1]; [1]Purdue University, West Lafayette, IN, [2]Indiana University School of Medicine, Indianapolis, IN.

PI-26
GENOME-WIDE DISCOVERY OF DRUG-DEPENDENT ENHANCERS.
R. P. Smith, K. M. Morrissey, T. J. Hoffman, D. L. Kroetz, K. M. Giacomini, N. Ahituv; University of California, San Francisco, San Francisco, CA.

PI-27
EVALUATION OF ENDOGENOUS METABOLITES AS MARKERS FOR CYP3A ACTIVITY IN HEALTHY SUBJECTS.
L. Ahn, K. H. Shin, K. S. Lim, K. S. Yu, I. J. Jang, J. Y. Cho; Department of Clinical Pharmacology and Therapeutics, Seoul National University College of Medicine and Hospital, Seoul, Republic of Korea.

PI-28
CYP2C19 GENOTYPE SIGNIFICANTLY AFFECTS THE PHARMACOKINETICS OF TOLPERISONE.
J. Byeon,[1] H. Lee,[1] C. Choi,[1] Y. Lee,[1] C. Jang,[1] J. Bae,[2] S. Lee[1]; [1]Laboratory of Pharmacology, School of Pharmacy, Sungkyunkwan University, Suwon, Republic of Korea, [2]College of Pharmacy, Keimyung University, Daegu, Republic of Korea.

PI-29
EFFECTS OF CYP2D6 GENETIC POLYMORPHISM ON THE PHARMACOKINETICS OF TOLPERISONE IN KOREANS.
J. Byeon,[1] H. Lee,[1] C. Choi,[1] C. Jang,[1] J. Bae,[2] S. Lee[1]; [1]Laboratory of Pharmacology, School of Pharmacy, Sungkyunkwan University, Suwon, Republic of Korea, [2]College of Pharmacy, Keimyung University, Daegu, Republic of Korea.

PI-30
THE INVOLVEMENT OF CYP3A IN THE CLEARANCE OF EVACETRAPIB AND THE EFFECT OF CO-ADMINISTRATION OF KETOCONAZOLE ON THE PHARMACOKINETICS OF EVACETRAPIB IN HEALTHY SUBJECTS.
E. A. Cannady, J. F. Rehmel, S. Friedrich, W. Zhang, K. A. Krueger, J. G. Suico; Eli Lilly and Company, Indianapolis, IN.

PI-31
CURCUMIN ATTENUATES TUMOR INITIATING STEM-LIKE PROPERTY OF HEAD AND NECK CANCER THROUGH MIR145/SOX9/ADAM17 AXIS.
Y. L. Chang,[1] Y. C. Chou,[1] S. H. Chiou[2]; [1]Department of Pharmacy, Taipei Veterans General Hospital, Taipei, Taiwan, [2]Department of Research and Education, Taipei Veterans General Hospital, Taipei, Taiwan.

PI-32
IMPACT OF UGT2B17 GENETIC POLYMORPHISMS ON THE DISPOSITION OF EXEMESTANE IN HEALTHY VOLUNTEERS.
S. M. Chen,[1] D. H. Atchley,[1] M. A. Murphy,[1] B. J. Gurley,[2] L. K. Kamdem[1]; [1]Harding University, Searcy, AR, [2]University of Arkansas Medical School, Little Rock, AR.

PI-33
PHARMACOKINETIC PROFILES OF IMMEDIATE-RELEASE OMEPRAZOLE WITH RESPECT TO CYP2C19 GENOTYPE.
D. Cho, B. Kim; Ajou University School of Medicine, Suwon, Republic of Korea.

PI-34
THE EFFECTS OF IL28B AND ITPA GENOTYPES ON ANTIVIRAL RESPONSE AND HEMOLYTIC ANEMIA IN HCV GENOTYPE 1 PATIENTS TREATED WITH PEGYLATED INTERFERON AND RIBAVIRIN COMBINATION THERAPY.
J. Choi,[1] H. Kim,[1] S. Park,[2] M. Oh,[1] E. Jung,[2] Y. Lee,[2] J. Shin[1]; [1]Department of Pharmacology and PharmacoGenomics Research Center, Inje University College of Medicine, Busan, Republic of Korea, [2]Department of Gastroenterology, Inje University Busan Paik Hospital, Busan, Republic of Korea.

PI-35
RELATIONSHIP BETWEEN 4β-HYDROXYCHOLESTEROL CONCENTRATION, CONCOMITANT MEDICATIONS, AND GENOTYPE IN A PATIENT POPULATION.
M. K. DeGorter, U. I. Schwarz, P. Z. Yin, Y. Choi, R. A. Hegele, R. G. Tirona, R. B. Kim; University of Western Ontario, London, ON, Canada.

PI-36
A PARADOXICAL DOSE-RESPONSE RELATIONSHIP FOR METHOTREXATE-MEDIATED ACCUMULATION OF AMINOIMIDAZOLECARBOXAMIDE RIBOTIDE *IN VITRO*.
R. S. Funk, L. van Haandel, M. L. Becker, J. S. Leeder; Children's Mercy Hospital, Kansas City, MO.

PI-37
CHARACTERIZATION OF THE CYP2D6 GENE LOCUS AND METABOLIC ACTIVITY IN INDO AND AFRO-TRINIDADIANS: DISCOVERY OF NOVEL ALLELIC VARIANTS.
K. Montane,[1] A. Lalla,[1] W. Steimer,[2] A. Gaedigk[3]; [1]The University of The West Indies, St. Augustine, Trinidad and Tobago, [2]Technische Universität München, Munich, Germany, [3]The Children's Mercy Hospital and Clinics, Kansas City, MO.

PI-38
EXPRESSION QUANTITATIVE TRAIT LOCI ANALYSIS OF STABLE WARFARIN DOSE IDENTIFIES NOVEL ASSOCIATIONS: FINDING SIGNAL WITHIN THE NOISE.
E. R. Gamazon,[1] R. Daneshjou,[2] L. H. Cavallari,[3] N. A. Limdi,[4] M. Wadelius,[5] J. A. Johnson,[6] T. E. Klein,[7] S. Scott,[8] T. Tsunoda,[9] P. Deloukas,[10] R. Altman,[2] N. Cox,[1] M. A. Perera[1]; [1]University of Chicago, Chicago, IL, [2]Stanford Univeristy, Stanford, CA, [3]University of Illinois, Chicago, IL, [4]University of Alabama, Birmingham, AL, [5]University Hospital, Uppsala, Sweden, [6]University of Florida, Gainesville, FL, [7]Stanford University, Stanford, CA, [8]Mount Sinai School of Medicine, New York, NY, [9]Center for Genomic Medicine, RIKEN, Yokohama, Japan, [10]Wellcome Trust Sanger Institute, Cambridge, United Kingdom.

*Presenting author is in **bold**.*

POSTER SESSION I • MARCH 7

Griffin Hall • 8:00 am – 3:00 pm • Attended Posters 8:00 am – 9:30 am

PI-39

SLCO1B1 521T>C GENOTYPE AFFECTS THE CYCLOSPORINE-PRAVASTATIN INTERACTION.

M. M. Giacomini, A. Coelho, S. L. Stocker, C. Brett, R. Castro, H. Horng, D. L. Kroetz; University of California, San Francisco, San Francisco, CA.

PI-40

CYP3A4*22 SINGLE NUCLEOTIDE POLYMORPHISM IS AN IMPORTANT DETERMINANT OF ENDOXIFEN PLASMA CONCENTRATION.

I. Y. Gong,[1] W. A. Teft,[1] B. Dingle,[2] K. Potvin,[2] J. Younus,[2] T. Vandenberg,[2] M. Brackstone,[2] F. Perera,[2] Y. Choi,[3] G. Zou,[3] R. Legan,[1] R. Tirona,[1] R. B. Kim[1]; [1]Division of Clinical Pharmacology, University of Western Ontario, London, ON, Canada, [2]Department of Oncology, University of Western Ontario, London, ON, Canada, [3]Department of Epidemiology and Biostatistics, University of Western Ontario, London, ON, Canada.

PI-41

FASTING GLUCOSE LOCI ASSOCIATED WITH GLUCOSE RESPONSE TO ANTIHYPERTENSIVES- RESULTS FROM THE PHARMACOGENOMIC EVALUATION OF ANTIHYPERTENSIVE RESPONSES (PEAR) STUDY.

Y. Gong,[1] M. J. Moore,[1] J. H. Karnes,[1] C. W. McDonough,[1] Z. Wang,[2] T. Y. Langaee,[1] A. L. Beitelshees,[3] S. T. Turner,[4] A. B. Chapman,[5] J. G. Gums,[1] K. R. Bailey,[4] E. Boerwinkle,[2] J. A. Johnson,[1] R. M. Cooper-DeHoff[1]; [1]University of Florida, Gainesville, FL, [2]University of Texas, Houston, TX, [3]University of Maryland, Baltimore, MD, [4]Mayo Clinic, Rochester, MN, [5]Emory University, Atlanta, GA.

PI-42

EXPRESSION OF DRUG TRANSPORT PROTEINS IN DIFFERENT TISSUES OF THE RESPIRATORY SYSTEM AND PERIPHERAL BLOOD MONOCYTES IN HEALTHY VOLUNTEERS.

M. Grube,[1] J. Penski,[2] C. Schäper,[3] S. Gläser,[3] C. Modess,[2] G. Wallner,[4] E. Steinmeier,[4] W. Hosemann,[4] R. Ewert,[3] W. Siegmund[2]; [1]University Medicine of Greifswald, Center of Drug Absorption and Transport, C_DAT, Department of General Pharmacology, Greifswald, Germany, [2]University Medicine of Greifswald, Center of Drug Absorption and Transport, C_DAT, Department of Clinical Pharmacology, Greifswald, Germany, [3]University Medicine of Greifswald, Department of Internal Medicine B - Pulmonary Medicine and Infectious Diseases, Greifswald, Germany, [4]University Medicine of Greifswald, Department of Otolaryngology, University Medicine Greifswald, Greifswald, Germany.

PI-43

COMPARISON OF EFFICACY AND SAFETY BETWEEN INTERMEDIATE AND EXTENSIVE/ULTRA-RAPID METABOLIZERS OF ATOMOXETINE IN ADULT PATIENTS WITH ATTENTION-DEFICIT HYPERACTIVITY DISORDER PARTICIPATING IN A LARGE PLACEBO-CONTROLLED MAINTENANCE OF RESPONSE CLINICAL TRIAL.

Y. Guo,[1] B. Fijal,[1] S. Marshall,[2] G. Li,[2] J. Ahl,[1] L. Nisenbaum,[1] T. Goto,[1] Y. Tanaka,[1] H. Upadhyaya[1]; [1]Eli Lilly and Company, Indianapolis, IN, [2]BioStatSolutions, Inc., Mt. Airy, MD.

PI-44

INTESTINAL DIAMINE OXIDASE: A POTENTIAL NEW TARGET FOR METFORMIN.

A. N. Gupta, S. Yee, M. Merski, M. J. Keiser, B. K. Shoichet, K. M. Giacomini; University of California, San Francisco, San Francisco, CA.

PI-45

IN VITRO GLUCURONIDATION OF APREPITANT: A POTENTIAL INHIBITOR OF INTESTINAL UGT2B7.

L. K. House, J. Ramirez, M. J. Ratain; University of Chicago, Chicago, IL.

PI-46

A PROBE DRUG COCKTAIL TO STUDY CYP2C8, 1A1 AND 2D6 IN THE HUMAN HEART.

J. Huguet,[1] F. Gaudette,[2] V. Michaud,[3] J. Turgeon[3]; [1]University of Montreal, Montreal, QC, Canada, [2]CRCHUM, Montreal, QC, Canada, [3]University of Montreal - CRCHUM, Montreal, QC, Canada.

PI-47

EFFECT OF UDP-GLUCURONOSYLTRANSFERASE 1A3, 1A9 AND 2B7 GENETIC POLYMORPHISMS ON 20-HETE GLUCURONIDATION IN HUMAN LIVER TISSUES.

Y. B. Jarrar,[1] K. S. Oh,[1] E. Y. Cha,[1] Y. R. Kim,[1] Y. W. Kim,[2] D. H. Kim,[1] S. J. Lee,[1] J. G. Shin[3]; [1]Department of Pharmacology and PharmacoGenomics Research Center, Inje University College of Medicine, Busan, Republic of Korea, Busan, Republic of Korea, [2]Department of Emergency Medicine, Inje University Busan Paik Hospital, Busan, Korea, Busan, Republic of Korea, [3]Department of Clinical Pharmacology, Inje University Busan Paik Hospital, Busan, Korea, Busan, Republic of Korea.

POSTER SESSIONS

*Presenting author is in **bold**.*

POSTER SESSION I • MARCH 7

Griffin Hall • 8:00 am – 3:00 pm • Attended Posters 8:00 am – 9:30 am

Oncology (ONC)

PI-48

IMPACT OF ENDOXIFEN DOSE ON ENDOXIFEN LEVELS IN BREAST CANCER PATIENTS: RESULTS FROM A PROSPECTIVE, OPEN-LABEL PHARMACOKINETICS AND SAFETY TRIAL.

A. Ahmad,[1] S. Sheikh,[1] R. Nagarkar,[2] J. K. Singh,[3] K. Srinivasan,[4] S. P. Shrivastav,[5] P. Shetty,[6] P. Kale,[6] R. C. Rane,[7] I. Ahmad[1]; [1]Jina Pharmaceuticals, Libertyville, IL, [2]Manavata Curie Cancer Center, Nasik, India, [3]Mahavir Cancer Sansthan, Patna, India, [4]Dr. Rai Memorial Medical Centre, Chennai, India, [5]New Civil Hospital, Surat, India, [6]Lambda Ther. Research Ltd, Ahmedabad, India, [7]Intas Pharmaceuticals, Ahmedabad, India.

PI-49

THE EFFECT OF FOOD ON THE SINGLE DOSE PHARMACOKINETICS OF A NOVEL MEK INHIBITOR, TRAMETINIB, IN SUBJECTS WITH SOLID TUMORS.

D. S. Cox,[1] L. Fang,[2] J. W. Bauman,[2] C. B. Pendry,[2] K. P. Papadopoulos,[3] P. M. LoRusso,[4] A. W. Tolcher,[3] A. Patnaik,[3] K. Orford,[5] D. Ouellet[2]; [1]GlaxoSmithKline, King of Prussia, PA, [2]GlaxoSmithKline, Research Triangle Park, NC, [3]South Texas Accelerated Research Therapeutics, San Antonio, TX, [4]Karmanos Cancer Institute/Wayne State University, Detroit, MI, [5]GlaxoSmithKline, Collegeville, PA.

PI-50

OATP1B1-MEDIATED HEPATIC UPTAKE OF SN-38, AN ACTIVE METABOLITE OF IRINOTECAN, AND ITS INHIBITION BY UREMIC TOXINS IN HUMANS.

K. Fujita,[1] T. Sugiura,[2] H. Okumura,[2] S. Umeda,[2] N. Nakamichi,[2] Y. Sasaki,[1] Y. Kato[2]; [1]Saitama Medical University, Hidaka, Japan, [2]Kanazawa University, Kanazawa, Japan.

PI-51

CLINICAL PHARMACOKINETICS (PK) OF INTRAVENOUS (IV) AND ORAL (PO) MLN9708, AN INVESTIGATIONAL PROTEASOME INHIBITOR: POOLED ANALYSIS FROM MONOTHERAPY AND COMBINATION STUDIES ACROSS VARIOUS INDICATIONS.

N. Gupta, D. Noe, G. Liu, D. Berg, T. Kalebic, Y. Shou, A. Hui, K. Venkatakrishnan; Millennium Pharmaceuticals, Inc., Cambridge, MA.

Organ Specific Diseases (OSD)

PI-52

ASCENDING SINGLE-DOSE STUDY WITH ACT-280778, A NON-DIHYDROPYRIDINE, DUAL L/T-TYPE CALCIUM CHANNEL BLOCKER: SAFETY, TOLERABILITY, PHARMACOKINETICS, AND EFFECT OF FOOD IN HEALTHY MALE SUBJECTS.

M. Mueller,[1] K. Shakeri-Nejad K,[1] M. Gutierrez,[1] J. Taubel,[2] J. Dingemanse[1]; [1]Actelion Pharmaceuticals Ltd, Department of Clinical Pharmacology, Allschwil, Switzerland, [2]Richmond Pharmacology Ltd, St George's University of London, London, United Kingdom.

PI-53

EFFICACY AND SAFETY OF ACT-280778, A DUAL L- AND T-TYPE CALCIUM CHANNEL BLOCKER, IN PATIENTS WITH MILD-TO-MODERATE ESSENTIAL HYPERTENSION: RESULTS FROM A PHASE 2A, RANDOMIZED, DOUBLE-BLIND, PLACEBO- AND ACTIVE-CONTROLLED TRIAL (REDUCE-1).

J. Dingemanse,[1] P. Otasevic,[2] K. Shakeri-Nejad,[1] E. Klainman,[3] B. Putnikovic,[4] H. Kracker,[5] M. Mueller,[1] R. Zimlichman[6]; [1]Actelion Pharmaceuticals Ltd, Department of Clinical Pharmacology, Allschwil, Switzerland, [2]Dedinije Cardiovascular Institute, University of Belgrade, Belgrade, Serbia, [3]Gefen Cardiac Health Centre, Givatayim and Israeli Academic College, Givatayim, Israel, [4]Clinical Hospital Center Zemun, University of Belgrade, Belgrade, Serbia, [5]Actelion Pharmaceuticals Ltd, Department of Biostatistics, Allschwil, Switzerland, [6]Wolfson Medical Center and Sackler School of Medicine, Tel Aviv University, Tel Aviv, Israel.

PI-54

ASCENDING MULTIPLE-DOSE STUDY WITH ACT-280778, A NON-DIHYDROPYRIDINE, DUAL L/T-TYPE CALCIUM CHANNEL BLOCKER: SAFETY, TOLERABILITY, AND PHARMACOKINETICS IN HEALTHY MALE SUBJECTS.

M. Mueller,[1] K. Shakeri-Nejad,[1] M. Gutierrez,[1] B. Sanderson,[2] J. Dingemanse[1]; [1]Actelion Pharmaceuticals Ltd, Department of Clinical Pharmacology, Allschwil, Switzerland, [2]Chiltern (Early Phase) Ltd, Dundee, United Kingdom.

PI-55

COLISTIN NEPHROTOXICITY: A MURINE MODEL REVEALING AN ALTERED GENE SIGNATURE DAYS PRIOR TO KIDNEY INJURY.

M. T. Eadon, B. K. Hack, C. Xu, M. E. Dolan, P. N. Cunningham; University of Chicago, Chicago, IL.

*Presenting author is in **bold**.*

Pharmacometrics and Pharmacokinetics (PMK)

PI-56
PROBING PACLITAXEL-INDUCED TUMOR PRIMING OF NANOPARTICULATE DOXORUBICIN WITH PHARMACOKINETIC/PHARMACODYNAMIC SYSTEMS ANALYSIS.
S. Ait-Oudhia, R. M. Straubinger, D. E. Mager; SUNY at Buffalo, Buffalo, NY.

PI-57
INHIBITORY EFFECT OF SIX COMMONLY USED HERBAL EXTRACTS ON CYP2C8 ENZYME ACTIVITY.
A. A. Albassam, R. F. Frye; University of Florida, Gainesville, FL.

PI-58
THE DEVELOPMENT AND APPLICATION OF A PHYSIOLOGICALLY-BASED PHARMACOKINETIC MODEL TO PREDICT MIDAZOLAM PK IN HEALTHY VOLUNTEERS AND CANCER PATIENTS.
R. Bell, D. Coutant, S. Hall, J. Chien; Eli Lilly and Company, Indianapolis, IN.

PI-59
EFFECT OF THE OATP INHIBITOR CYCLOSPORINE ON THE ORAL PHARMACOKINETICS OF PF-04991532, AN OATP MEDIATED LIVER TARGETED SUBSTRATE.
A. Bergman,[1] J. Pfefferkorn,[2] C. Wang,[1] M. Varma,[1] J. Litchfield,[1] D. J. Kazierad[2]; [1]Pfizer, Groton, CT, [2]Pfizer, Cambridge, MA.

PI-60
EFFECT OF RENAL IMPAIRMENT ON THE PHARMACOKINETICS OF PF-04991532, A LIVER-TARGETED GLUCOKINASE ACTIVATOR AND OATP SUBSTRATE.
A. Bergman,[1] J. Pfefferkorn,[2] J. Litchfield,[1] X. Wang,[1] D. J. Kazierad[2]; [1]Pfizer, Groton, CT, [2]Pfizer, Cambridge, MA.

PI-61
TOLERABILITY AND PHARMACOKINETICS OF KM-023, A NOVEL NNRT INHIBITOR AFTER ORAL ADMINISTRATION IN HEALTHY VOLUNTEERS.
Y. Cha,[1] M. Park,[1] B. L. Bray,[2] S. E. Schneider,[2] S. Cho,[1] K. Lim,[1] J. Cho,[1] S. Yoon,[1] K. Yu[1]; [1]Seoul National University College of Medicine and Hospital, Seoul, Republic of Korea, [2]Kainos Medicine, Morrisville, NC.

PI-62
THE IMPORTANCE OF VILLOUS PHYSIOLOGY AND MORPHOLOGY IN MECHANISTIC PHYSIOLOGICALLY-BASED PHARMACOKINETIC MODELS: APPLICATION TO INTESTINAL CYP3A METABOLISM USING MIDAZOLAM AS TOOL COMPOUND.
E. P. Chen, G. Tai, H. Ellens; GlaxoSmithKline, King of Prussia, PA.

PI-63
PHARMACOKINETICS AND RELATIVE BIOAVAILABILITY OF FIXED-DOSE COMBINATION OF CLOPIDOGREL AND ASPIRIN VERSUS CO-ADMINISTRATION OF INDIVIDUAL FORMULATIONS IN HEALTHY SUBJECTS.
H. Choi,[1] J. Ghim,[2] M. Oh,[2] J. Shon,[2] S. Park,[2] J. Seo,[2] J. Shin[2]; [1]Department of Pharmacology and PharmacoGenomics Research Center, Inje University College of Medicine, Busan, Republic of Korea, [2]Department of Clinical Pharmacology, Inje University Busan Paik Hospital, Busan, Republic of Korea.

PI-64
COMPARISON OF PHARMACOKINETICS OF ITOPRIDE ER AND ITOPRIDE IR AFTER MULTIPLE ADMINISTRATIONS IN HEALTHY VOLUNTEERS.
Y. Choi,[1] S. Yoon,[1] Y. Cha,[1] T. Kim,[1] S. Lee,[1] D. Chee,[2] K. Yu,[1] I. Jang,[1] S. Shin[1]; [1]Department of Clinical Pharmacology and Therapeutics, Seoul National University Hospital, Seoul, Republic of Korea, [2]Department of Clinical Pharmacology and Therapeutics, Seoul National University Hospital, Seoul, Republic of Korea.

PI-65
AN EXPOSURE-RESPONSE MODEL CHARACTERIZING THE TIME-COURSE OF ACR20, ACR50, AND ACR70 IN RHEUMATOID ARTHRITIS (RA) PATIENTS ON BARICITINIB.
S. Choi, W. L. Macias, L. Tham; Eli Lilly and Company, Indianapolis, IN.

PI-66
AN EXPOSURE-RESPONSE MODEL CHARACTERIZING THE TIME-COURSE OF DAS28-HSCRP IN RHEUMATOID ARTHRITIS (RA) PATIENTS ON BARICITINIB.
L. Chua, W. L. Macias, L. Tham; Eli Lilly and Company, Indianapolis, IN.

PI-67
PHARMACOKINETICS AND BIODISTRIBUTION OF IDURSULFASE IN CYNOMOLGUS MONKEYS AFTER INTRATHECAL-LUMBAR ADMINISTRATION.
J. Chung, H. Xie, M. Mascelli, T. McCauley; Shire HGT, Lexington, MA.

PI-68
RIFAMPICIN MODIFIES THE HEPATIC CONCENTRATIONS OF THE HEPATOBILIARY DRUG GD-BOPTA BY ACTING ON BOTH SINUSOIDAL AND CANALICULAR TRANSPORTERS.
Y. Daali, P. Millet, P. Dayer, C. Pastor; Geneva University Hospitals, Geneva, Switzerland.
Presenter: J. Desmeules, Geneva University Hospitals, Geneva, Switzerland

PI-69
WITHDRAWN

PI-70
ISAVUCONAZOLE DOES NOT AFFECT PREDNISOLONE PHARMACOKINETICS IN HEALTHY SUBJECTS FOLLOWING COADMINISTRATION OF MULTIPLE DOSE ISAVUCONAZOLE.
A. Desai, N. Zadeikis, C. Howieson, T. Yamazaki, D. Kowalski, R. Townsend; Astellas Pharma Global Development, Inc., Northbrook, IL.

PI-71
EFFECT OF MULTIPLE DOSES OF ISAVUCONAZOLE ON THE PHARMACOKINETICS OF CYP3A4 SUBSTRATE TACROLIMUS IN HEALTHY SUBJECTS.
A. Desai, N. Zadeikis, H. Pearlman, T. Yamazaki, D. Kowalski, R. Townsend; Astellas Pharma Global Development, Inc., Northbrook, IL.

*Presenting author is in **bold**.*

POSTER SESSION I • MARCH 7

Griffin Hall • 8:00 am – 3:00 pm • Attended Posters 8:00 am – 9:30 am

PI-72
ISAVUCONAZOLE DOES NOT SIGNIFICANTLY AFFECT THE PHARMACOKINETICS OF P-GLYCOPROTEIN SUBSTRATE DIGOXIN IN HEALTHY SUBJECTS.
A. Desai, N. Zadeikis, N. Breese, T. Yamazaki, D. Kowalski, R. Townsend; Astellas Pharma Global Development, Inc., Northbrook, IL.

PI-73
POPULATION PHARMACOKINETIC-PHARMACODYNAMIC ANALYSIS OF DONEPEZIL DOSE-RESPONSE IN A SCOPOLAMINE CHALLENGE STUDY IN HEALTHY VOLUNTEERS.
S. Duvvuri,[1] D. Raunig,[2] C. Leurent,[1] T. Nicholas,[3] T. Rapp[1]; [1]Pfizer, Cambridge, MA, [2]ICON, North Wales, PA, [3]Pfizer, Groton, CT.

PI-74
DEVELOPMENT OF A PHYSIOLOGICALLY-BASED PHARMACOKINETICS (PBPK) MODEL FOR SIROLIMUS TO EXPLAIN INTER-PATIENT VARIABILITY.
C. Emoto,[1] T. Fukuda,[1] S. Cox,[1] B. Schniedewind,[2] U. Christians,[2] A. A. Vinks[1]; [1]Division of Clinical Pharmacology, Cincinnati Children's Hospital Medical Center, Cincinnati, OH, [2]iC42 Integrated Solutions in Clinical Research and Development, University of Colorado, Aurora, CO.

PI-75
A SEMI-MECHANISTIC MODEL CHARACTERIZING THE TIME-COURSE OF NEUTROPHIL COUNTS IN RHEUMATOID ARTHRITIS (RA) PATIENTS ON BARICITINIB.
C. S. Ernest II, J. Satterwhite, W. L. Macias, D. L. Hyslop, L. Tham; Eli Lilly and Company, Indianapolis, IN.

PI-76
A SEMI-MECHANISTIC MODEL CHARACTERIZING THE TIME-COURSE OF RETICULOCYTES (RET), RED BLOOD CELLS (RBC), AND HEMOGLOBIN (HB) IN RHEUMATOID ARTHRITIS (RA) PATIENTS ON BARICITINIB.
C. S. Ernest II, J. Satterwhite, W. L. Macias, D. L. Hyslop, L. Tham; Eli Lilly and Company, Indianapolis, IN.

PI-77
EFFECT OF MULTIPLE-DOSE SETIPIPRANT, A SELECTIVE ORAL CRTH2 ANTAGONIST, ON THE PHARMACOKINETICS OF SINGLE-DOSE SIMVASTATIN IN HEALTHY MALE SUBJECTS.
M. Géhin,[1] A. Mackie,[1] P. N. Sidharta,[1] P. Kadlecovà,[2] M. Petersen-Sylla,[3] A. Halabi,[3] J. Dingemanse[1]; [1]Actelion Pharmaceuticals Ltd, Allschwil, Switzerland, [2]ADDS s.r.o., Brno, Czech Republic, [3]CRS, Kiel, Germany.

PI-78
EXPOSURE-RESPONSE (E-R) ANALYSIS OF PERTUZUMAB (PTZ) IN PATIENTS WITH HER2-POSITIVE (HER2+) METASTATIC BREAST CANCER (MBC): EFFECT ON QTC PROLONGATION AND OTHER ECG PARAMETERS.
A. Garg,[1] J. Li,[1] E. Clark,[2] A. Knott,[2] T. J. Carrothers,[3] D. Aeschliman,[3] J. Marier,[3] J. Cortés,[4] J. Visich,[1] B. Lum[1]; [1]Genentech, South San Francisco, CA, [2]Roche, Welwyn, United Kingdom, [3]Pharsight, Inc., Sunnyvale, CA, [4]Vall d'Hebron University Hospital, Vall d'Hebron Institute of Oncology, Barcelona, Spain.

PI-79
A MODEL-BASED APPROACH TO CHARACTERIZE THE LONG-LASTING PHARMACOKINETIC (PK) TIME-COURSE OF RBP-7000, A NEW SUSTAINED RELEASED FORMULATION OF RISPERIDONE.
R. Gomeni,[1] C. Heidbreder,[2] P. J. Fudala,[2] A. Nasser[2]; [1]Alleantis, Research Triangle Park, NC, [2]Reckitt Benckiser Pharmaceuticals, Richmond, VA.

PI-80
A MODEL-BASED APPROACH TO CHARACTERIZE THE RELATIONSHIP BETWEEN THE LONG-LASTING PHARMACOKINETIC (PK) TIME-COURSE AND THE SAFETY PROFILE OF RBP-7000, A NEW SUSTAINED RELEASED FORMULATION OF RISPERIDONE.
R. Gomeni,[1] C. Heidbreder,[2] P. J. Fudala,[2] A. Nasser[2]; [1]Alleantis, Research Triangle Park, NC, [2]Reckitt Benckiser Pharmaceuticals, Richmond, VA.

PI-81
POPULATION PHARMACOKINETIC MODELING OF MOTESANIB AND ITS METABOLITE, M4, IN CANCER PATIENTS.
N. H. Gosselin,[1] C. P. Hsu,[2] M. S. Mouksassi,[1] J. Lu[2]; [1]Pharsight – A Certara™ Company, Montreal, QC, Canada, [2]Amgen Inc., Thousand Oaks, CA.

PI-82
QUANTITATIVE STRUCTURE PHARMACOKINETIC (PK) PROPERTY RELATIONSHIP(S) (QSPKR) FOR BENZODIAZEPINES (BZD) IN HUMANS.
G. Gottipati, J. Venitz; Virginia Commonwealth University, Richmond, VA.

PI-83
INTERSPECIES PHARMACOKINETIC (PK) - ALLOMETRIC SCALING FOR BENZODIAZEPINES (BZD).
G. Gottipati, J. Venitz; Virginia Commonwealth University, Richmond, VA.

PI-84
NEW MYOTOXIC DRUG INTERACTIONS BETWEEN STATINS AND RIFAMPICIN.
X. Han,[1] S. Quinney,[2] T. Skaar,[1] J. Elmendord,[3] D. Flockhart,[1] L. Li[4]; [1]Division of Clinical Pharmacology, Indiana University School of Medicine, Indianapolis, IN, [2]Department of Obstetrics and Gynecology, Indiana University School of Medicine, Indianapolis, IN, [3]Department of Cellular & Integrative Physiology, Indiana University School of Medicine, Indianapolis, IN, [4]Department of Medical and Molecular Genetics, Indiana University School of Medicine, Indianapolis, IN.

*Presenting author is in **bold**.*

PI-85

PREDICTION OF CYP3A MEDIATED DRUG-DRUG INTERACTIONS: ESTIMATION OF GUT WALL AND HEPATIC CONTRIBUTIONS.

B. Han, G. L. Dickinson, P. K. Turner, S. D. Hall; Eli Lilly and Company, Indianapolis, IN.

PI-86

CHARACTERIZATION OF ABATACEPT PHARMACOKINETICS AND EXPOSURE-RESPONSE RELATIONSHIP IN SUPPORT OF SUBCUTANEOUS DOSE FOR JAPANESE RHEUMATOID ARTHRITIS.

M. Hasegawa,[1] A. Roy,[2] Y. Imai,[1] M. Hiraoka[1]; [1]Bristol-Myers Squibb, Tokyo, Japan, [2]Bristol-Myers Squibb, Princeton, NJ.

PI-87

THE APPLICATION OF DRUG-DISEASE AND CLINICAL UTILITY MODELS IN THE DESIGN OF AN ADAPTIVE SEAMLESS PHASE 2/3 STUDY.

M. A. Heathman, Z. Skrivanek, B. L. Gaydos, M. Geiger, J. Y. Chien; Eli Lilly and Company, Indianapolis, IN.

PI-88

A MODEL-BASED APPROACH FOR PHENOTYPE-DEPENDENT DOSING SUPPORTS SIMULTANEOUS ADMINISTRATION OF TAMOXIFEN AND ENDOXIFEN IN BREAST CANCER PATIENTS WITH IMPAIRED CYP2D6 ENZYME ACTIVITY.

K. Dickschen,[1] M. Hobe,[2] L. Kuepfer,[2] K. Thelen,[2] T. Eissing,[2] S. Willmann,[2] G. Hempel[1]; [1]Institut für Pharmazeutische und Medizinische Chemie, Klinische Pharmazie, Westfälische Wilhelms-Universität Münster, Münster, Germany, [2]Bayer Technology Services GmbH, Leverkusen, Germany.

PI-89

EFFECTS OF CYTOCHROME P450 3A MODULATORS KETOCONAZOLE, ERYTHROMYCIN AND CARBAMAZEPINE ON BITOPERTIN PHARMACOKINETICS.

C. Hofmann,[1] F. Pizzagalli,[1] C. Boetsch,[1] N. Parrott,[1] D. Hainzl,[1] C. Denot,[2] B. Astruc,[2] M. Martin-Facklam[1]; [1]F. Hoffmann-La Roche Ltd., Basel, Switzerland, [2]Biotrial, Rennes, France.

PI-90

POPULATION PHARMACOKINETIC/PHARMACODYNAMIC ASSESSMENT OF PHARMACOLOGICAL EFFECT OF A SELECTIVE ESTROGEN RECEPTOR β AGONIST ON TOTAL TESTOSTERONE IN HEALTHY MEN.

L. Hu, Y. G. Li, Y. Jin; Eli Lilly and Company, Indianapolis, IN.

PI-91

APPLICATION OF PHYSIOLOGICALLY BASED PHARMACOKINETIC (PBPK) MODELING FOR PREDICTION OF COMPLEX DRUG-DRUG INTERACTIONS (DDIS) INVOLVING INHIBITION OF OATP1B1-MEDIATED UPTAKE AND CYP2C8 METABOLISM BY GEMFIBROZIL AND ITS MAJOR METABOLITE GEMFIBROZIL 1-*O*-β GLUCURONIDE.

H. E. Humphries,[1] Z. E. Barter,[1] A. Rostami-Hodjegan,[2] K. Rowland Yeo[1]; [1]Simcyp Ltd, Sheffield, United Kingdom, [2]Simcyp Ltd and University of Manchester, Sheffield, United Kingdom.

PI-92

METHADONE MAINTENANCE THERAPY IN MALAYSIA: INADEQUACY OF DAILY 40 MG METHADONE DOSE AND ITS IMPLICATIONS.

R. Ismail,[1] N. Mohamad,[1] M. Nurfadhlina,[1] M. Nor Ilyani,[2] S. Hann Liang,[3] M. Mohd Khafidz,[4] T. Soo Choon,[3] L. Bertilsson,[5] G. Basyirah[1]; [1]Universiti Sains Malaysia, Kubang Kerian, Kelantan, Malaysia, [2]International Islamic University of Malaysia, Kuantan, Pahang, Malaysia, [3]Universiti Sains Malaysia, Pulau Pinang, Malaysia, [4]Klinik Dr Khafidz, Kajang, Selangor, Malaysia, [5]Division of Clinical Pharmacology, Karolinska Institutet, Karolinska University Hospital, Stockholm, Sweden.

PI-93

EFFECT OF AGING ON APPARENT CLEARANCE OF TOTAL AND FREE PHENYTOIN.

K. Jang, D. Shin, K. Lim, S. Shin, I. Jang, K. Yu; Department of Clinical Pharmacology and Therapeutics, Seoul, Republic of Korea.

Special Populations (SPO)

PI-94

INTRATHECAL MORPHINE VERSUS EPIDURAL EXTENDED-RELEASE MORPHINE FOR POSTOPERATIVE PAIN CONTROL IN PEDIATRIC SPINAL FUSION PATIENTS.

M. Cohen,[1] C. Aquilante,[2] J. Zuk,[1] J. Galinkin[1]; [1]Children's Hospital Colorado, University of Colorado School of Medicine, Aurora, CO, [2]University of Colorado School of Pharmacy, Aurora, CO.

PI-95

INTRAPARTUM USE OF MAGNESIUM SULFATE AND THE RELATIONSHIP BETWEEN MATERNAL AND NEONATAL MAGNESIUM BLOOD LEVELS.

J. Fredrickson, A. Balch, S. C. Campbell, C. M. Sherwin, E. A. Clark, M. G. Spigarelli; University of Utah, Salt Lake City, UT.

PI-96

ORGANIC CATION TRANSPORTER 1 GENETIC VARIANTS CONTRIBUTE TO DECREASED MORPHINE CLEARANCE IN CHILDREN.

T. Fukuda, V. Chidambaran, T. Mizuno, R. Venkatasubramanian, P. Ngamprasertwong, H. R. Esslinger, A. A. Vinks, S. Sadhasivam; Cincinnati Children's Hospital Medical Center, Cincinnati, OH.

PI-97

STEROID PATHWAY GENES AND NEONATAL RESPIRATORY DISTRESS AFTER BETAMETHASONE USE IN ANTICIPATED PRETERM BIRTH.

D. M. Haas,[1] D. Lai,[1] S. Sharma,[2] J. Glassburn,[1] K. Tantisira,[2] T. Foroud[1]; [1]Indiana University School of Medicine, Indianapolis, IN, [2]Harvard University, Channing Laboratory, Boston, MA.

*Presenting author is in **bold**.*

POSTER SESSION II • MARCH 8

Griffin Hall • 8:00 am – 3:00 pm • Attended Posters 8:00 am – 9:30 am

Drug Development and Regulatory Sciences (DDR)

PII-1

MULTIPLE DOSES OF EPA/DHA DO NOT ALTER THE PHARMACOKINETICS OF SIMVASTATIN OR THE ANTIPLATELET EFFECT OF ASA.

S. Kebir,[1] M. Davidson,[2] T. Marenco,[1] E. Offman,[1] J. Johnson,[2] D. Kling[2]; [1]Celerion, Montreal, QC, Canada, [2]Omthera Pharmaceuticals, Inc., Princeton, NJ.

PII-2

PHARMACOKINETIC DRUG INTERACTION STUDY OF A NOVEL NMDA-RECEPTOR ANTAGONIST ASP0777 AND DONEPEZIL IN HEALTHY VOLUNTEERS.

K. Erdman, C. Howieson, U. Tollemar, Y. Cao, A. Degroot, A. Abeyratne, S. Sutherland, T. Sawamoto, J. Keirns, J. Paul; Astellas Pharma Global Development, Northbrook, IL.

PII-3

EFFECTS OF INSULIN SECRETOGOGUE AND MILD HYPOGLYCEMIA ON QTC.

R. P. Kelly,[1] K. P. Yeo,[1] E. J. Pratt,[1] J. W. Miller[2]; [1]Lilly-NUS Centre for Clinical Pharmacology, Singapore, Singapore, [2]Eli Lilly and Company, Indianapolis, IN.

PII-4

SHORT-TERM DOSING OF THE GLUCOKINASE ACTIVATOR LY2608204 REDUCES BLOOD GLUCOSE IN PATIENTS WITH TYPE 2 DIABETES MELLITUS (T2DM).

R. P. Kelly,[1] X. Zhang,[2] M. Gutierrez,[3] S. T. Lim,[1] K. P. Yeo,[1] J. M. Bue-Valleskey[2]; [1]Lilly-NUS Centre for Clinical Pharmacology, Singapore, Singapore, [2]Eli Lilly and Company, Indianapolis, IN, [3]Comprehensive Phase One, Miramar, FL.

PII-5

SINGLE DOSES OF THE GLUCOKINASE ACTIVATOR LY2608204 REDUCE BLOOD GLUCOSE IN HEALTHY SUBJECTS AND PATIENTS WITH TYPE 2 DIABETES MELLITUS (T2DM).

R. P. Kelly,[1] X. Zhang,[2] S. T. Lim,[1] K. Yeo,[1] J. M. Bue-Valleskey[2]; [1]Lilly-NUS Centre for Clinical Pharmacology, Singapore, Singapore, [2]Eli Lilly and Company, Indianapolis, IN.

PII-6

RIVAROXABAN OR CONVENTIONAL THROMBOPROPHYLAXIS IN ROUTINE CLINICAL PRACTICE IN OVER 17,000 PATIENTS UNDERGOING MAJOR ORTHOPEDIC SURGERY: IMPACT OF CO-MEDICATIONS ON ADVERSE EVENTS.

R. Kreutz,[1] A. Schmidt,[2] A. G. Turpie,[3] M. R. Lassen,[4] L. G. Mantovani,[5] G. Holberg,[2] S. Haas[6]; [1]Institut für Klinische Pharmakologie und Toxikologie, Berlin, Germany, [2]Bayer HealthCare AG, Berlin, Germany, [3]Department of Medicine, Hamilton Health Services, Hamilton, ON, Canada, [4]Glostrup Hospital, University of Copenhagen, Glostrup, Copenhagen, Denmark, [5]CIRFF, Center of Pharmacoeconomics, Federico II University of Naples, Naples, Italy, [6]Institute for Experimental Oncology and Therapy Research, Technical University of Munich, Munich, Germany.

PII-7

HOW A STUDY DESIGN COULD IMPACT RECRUITMENT AND ENROLLMENT SUCCESS: A CASE STUDY.

E. Legault, R. Essalihi, M. Lahjou, N. Paquette, H. Paraskevopoulos, M. Lefebvre; Algorithme Pharma, Laval, QC, Canada.

PII-8

EVALUATION OF SINGLE DOSE SAFETY, PHARMACOKINETICS (PK), AND PHARMACODYNAMICS (PD) OF A NOVEL HUMAN ANTI-IL6 MONOCLONAL ANTIBODY PF-04236921 IN PHASE I HEALTHY VOLUNTEERS.

C. Li,[1] S. Sridharan,[2] R. Fogel,[2] J. Bradley,[3] R. Riese,[3] R. Labadie,[3] S. Menon,[3] P. Gupta,[3] S. Krishnaswami,[3] J. Beebe[1]; [1]Pfizer, Cambridge, MA, [2]Pfizer, Collegeville, PA, [3]Pfizer, Groton, CT.

PII-9

SAFETY AND PHARMACOKINETICS OF ESCALATING SINGLE DOSES OF INJECTABLE CEFETAMET SODIUM IN HEALTHY VOLUNTEERS.

J. Miao, J. Sun, Y. Qin, Y. Wang, M. Liang; Division of Clinical Pharmacology, Chengdu, China.

PII-10

COMPARISON OF SAFETY AND PHARMACOKINETICS AMONG EAST ASIAN POPULATIONS.

M. Oishi, S. Hiro, N. Matsuoka, S. Hotta, R. Ono, Y. Mori, N. Takenaka, T. Ishibashi, A. Arakawa, Y. Hirotoshi, S. Miyoshi, K. Hirai, N. Kawai; Pfizer Japan Inc., Tokyo, Japan.

PII-11

A PROOF-OF-CONCEPT (POC) STUDY INCLUDING EXPERIMENTAL PAIN MODELS (EPMS) TO ASSESS THE EFFECTS OF A CB_2 AGONIST (LY2828360) IN THE TREATMENT OF PATIENTS WITH OSTEOARTHRITIC (OA) KNEE PAIN.

A. Pereira,[1] A. Chappell,[2] J. Dethy,[1] H. Hoeck,[3] L. Arendt-Nielsen,[4] S. Verfaille,[5] B. Boulanger,[6] A. Jullion,[6] M. Johnson,[2] T. McNearney[2]; [1]Aepodia, Louvain La Neuve, Belgium, [2]Eli Lilly, Indianapolis, IN, [3]C4Pain, Aalborg, Denmark, [4]Aalborg University, Aalborg, Denmark, [5]Chorus - Eli Lilly, Indianapolis, IN, [6]Arlenda, Liege, Belgium.

PII-12

INHIBITION OF AROMATASE, CYP3A4 AND CYP3A5 BY E-, Z- FORMS OF NORENDOXIFEN.

J. Liu,[1] P. J. Flockhart,[2] D. Lu,[2] W. Lv,[3] M. Cushman,[3] D. A. Flockhart[2]; [1]Division of Clinical Pharmacology, Department of Biochemistry and Molecular Biology, Indiana University School of Medicine, Indianapolis, IN, [2]Division of Clinical Pharmacology, Department of Medicine, Indiana University School of Medicine, Indianapolis, IN, [3]Department of Medicinal Chemistry and Molecular Pharmacology, College of Pharmacy, and The Purdue Center for Cancer Research, Purdue University, West Lafayette, IN.

*Presenting author is in **bold**.*

PII-13

INHIBITION OF CYTOCHROME P450 BY NORENDOXIFEN.

J. Liu,[1] W. Lu,[2] P. J. Flockhart,[2] D. Lu,[2] X. Han,[3] M. Cushman,[4] D. A. Flockhart[2]; [1]Division of Clinical Pharmacology, Department of Biochemistry and Molecular Biology, Indiana University School of Medicine, Indianapolis, IN, [2]Division of Clinical Pharmacology, Department of Medicine, Indiana University School of Medicine, Indianapolis, IN, [3]Division of Clinical Pharmacology, Department of Pharmacology and Toxicology, Indiana University School of Medicine, Indianapolis, IN, [4]Department of Medicinal Chemistry and Molecular Pharmacology, College of Pharmacy, and The Purdue Center for Cancer Research, Purdue University, West Lafayette, IN.

PII-14

ANALOGS OF NORENDOXIFEN SERVE AS AROMATASE INHIBITORS AND SELECTIVE ESTROGEN RECEPTOR MODULATORS.

J. Liu,[1] W. Lv,[2] D. Lu,[3] M. Cushman,[2] D. A. Flockhart[3]; [1]Division of Clinical Pharmacology, Department of Biochemistry and Molecular Biology, Indiana University School of Medicine, Indianapolis, IN, [2]Department of Medicinal Chemistry and Molecular Pharmacology, College of Pharmacy, and The Purdue Center for Cancer Research, Purdue University, West Lafayette, IN, [3]Division of Clinical Pharmacology, Department of Medicine, Indiana University School of Medicine, Indianapolis, IN.

Drug Safety (SAF)

PII-15

DABIGATRAN PERSISTENCE IN THE COMMUNITY SETTING IN CANADA.

M. Levine,[1] S. Prajapati[2]; [1]McMaster University, Hamilton, ON, Canada, [2]Rx Canada, Mississauga, ON, Canada.

PII-16

ADVERSE DRUG REACTION SURVEILLANCE IN A PEDIATRIC HOSPITAL.

J. A. Lowry, A. K. Sullin, T. L. Sandritter, J. S. Leeder; Children's Mercy Hospital, Kansas City, MO.

Molecular Pharmacology and Pharmacogenetics (MOL)

PII-17

HUMAN LIVER METHYLATION CYCLE: MAT1A AND GNMT GENE RESEQUENCING, FUNCTIONAL GENOMICS AND HEPATIC GENOTYPE-PHENOTYPE CORRELATION.

Y. Ji,[1] K. K. Nordgren,[1] Y. Chai,[1] S. J. Hebbring,[1] G. D. Jenkins,[1] A. P. Ryan,[1] Y. Peng,[2] L. L. Pelleymounter,[1] I. Moon,[1] B. W. Eckloff,[1] X. Chai,[3] J. Zhang,1 B. L. Fridley,[1] V. C. Yee,[2] E. D. Wieben,[1] R. M. Weinshilboum[1]; [1]Mayo Clinic, Rochester, MN, [2]Case Western Reserve University, Cleveland, OH, [3]Century High School, Rochester, MN.

PII-18

EFFECTS OF PROTOTYPICAL NUCLEAR RECEPTOR LIGANDS ON THE EXPRESSSION OF ENZYMES AND TRANSPORTERS IN HUMAN PRIMARY HEPATOCYTES.

M. Keiser,[1] A. Sauer,[1] A. Ullrich,[2] D. Runge,[2] W. Siegmund,[1] S. Oswald[1]; [1]University Medicine of Greifswald, Greifswald, Germany, [2]Primacyt GmbH, Schwerin, Germany.

PII-19

CYP2D6 GENOTYPE-DEPENDENT INTERACTION OF PAROXETINE AND CLARITHROMYCIN WITH THE INFERTILITY DRUG CLOMIPHENE.

R. Kerb,[1] B. Ganchev,[1] G. M. Böhmer,[2] S. Igel,[1] M. Sonnenberg,[1] E. Schaeffeler,[1] W. Schroth,[1] U. Zanger,[1] H. Brauch,[1] M. Schwab,[1] T. E. Mürdter[1]; [1]IKP-Stuttgart, Stuttgart, Germany, [2]Klinische Pharmakologie, Universität Tübingen, Germany.

PII-20

PHARMACOKINETICS AND PHARMACODYNAMICS OF CLOPIDOGREL, CILOSTAZOL, AND THEIR METABOLITES IN RELATION TO CYP2C19 GENOTYPES.

H. Kim,[1] Y. Lim,[1] G. Kim,[1] J. Ghim,[2] E. Kim,[2] D. Kim,[1] J. Shin[1]; [1]Department of Pharmacology and PharmacoGenomics Research Center, Inje University College of Medicine, Busan, Republic of Korea, [2]Department of Clinical Pharmacology, Inje University Busan Paik Hospital, Busan, Republic of Korea.

PII-21

EFFECT OF GENETIC POLYMORPHISM OF ALCOHOL DEHYDROGENASE AND ALDEHYDE DEHYDROGENASE ON THE PHARMACOKINETICS OF ALCOHOL IN HEALTHY SUBJECTS.

A. Kim,[1] H. Han,[1] K. Shin,[1] H. An,[1] K. Lim,[1] S. Yoo,[2] K. Yu,[1] J. Chung[1]; [1]Department of Clinical Pharmacology and Therapeutics, Seoul National University College of Medicine and Hospital, Seoul, Republic of Korea, [2]Department of Forensic Medicine, Seoul National University College of Medicine, Seoul, Republic of Korea.

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PII-22

A COMBINED ANALYSIS OF GENETIC POLYMORPHISMS AND HAPLOTYPE STRUCTURES OF SULT1A1 AND SULT1A2 IN A KOREAN POPULATION.

S. J. Lee,[1] E. Y. Kim,[1] W. Y. Kim,[1] Y. B. Jarrar,[1] S. A. Cho,[1] Y. W. Kim,[2] S. S. Lee,[1] J. G. Shin[3]; [1]Pharmacogenomics Research Center, Inje University, Busan, Republic of Korea, [2]Department of Emergency Medicine, Inje University Busan Paik Hospital, Busan, Republic of Korea, [3]Department of Clinical Pharmacology; Inje University Busan Paik Hospital, Busan, Republic of Korea.

PII-23

DRUG-TRANSPORTER INTERACTIONS: INHIBITION OF MCT1 AND MCT4 BY STATINS AND OTHER ACIDIC DRUGS.

Y. Leung,[1] J. Lu,[1] F. Bélanger,[2] M. Papillon,[1] J. Turgeon,[2] V. Michaud[2]; [1]Université de Montréal, Montreal, QC, Canada, [2]CRCHUM, Montreal, QC, Canada.

PII-24

GENETIC POLYMORPHISMS OF CYTOCHROME P450 (CYP) 2C9, CYP2C19, CYP2D6, CYP3A4, AND CYP3A5 IN A KORSIAN POPULATION.

Y. Lim,[1] E. Kim,[2] Y. Lee,[1] E. Cha,[1] H. Jung,[1] J. Kim,[1] S. Lee,[1] J. Shin[1]; [1]Department of Pharmacology and PharmacoGenomics Research Center, Inje University College of Medicine, Busan, Republic of Korea, [2]Department of Clinical Pharmacology, Inje University Busan Paik Hospital, Busan, Republic of Korea.

PII-25

SIMULTANEOUS EVALUATION OF CYP2D6, CYP2C9, CYP2C19, CYP3A4, CYP1A2 HYDROXYLATION CAPACITY IN HUMANS.

F. De Andrés,[1] M. Paulmichl,[2] A. Llerena[1]; [1]Clinical Research Centre, Extremadura University Hospital and Medical School, Badajoz, Spain, [2]Institute of Pharmacology and Toxicology Paracelsus Medical University, Salzburg, Austria.

PII-26

TRICYCLIC DRUGS INHIBIT THE UPTAKE OF ROSUVASTATIN THROUGH THE OATP1A2 TRANSPORTER.

J. Lu,[1] L. Guilarte Moya,[1] Y. Leung,[1] F. Gaudette,[2] J. Turgeon[2]; [1]Montreal University, Montreal, QC, Canada, [2]CRCHUM, Centre de Recherche du Centre Hospitalier de l'Université de Montréal, Montreal, QC, Canada.

PII-27

INTEGRATING PHARMACOGENOMICS AND PROTEOMICS TO IDENTIFY GENETIC VARIANTS AFFECTING SUSCEPTIBILITY TO CHEMOTHERAPY.

A. G. Madian,[1] A. Gill,[2] A. L. Stark,[3] R. J. Hause Jr,[4] M. F. Ciaccio,[5] L. Gorsic,[3] G. Yu,[6] K. P. White,[7] R. B. Jones,[8] M. E. Dolan[9]; [1]Committee on Clinical Pharmacology and Pharmacogenomics, The University of Chicago, Chicago, IL, [2]Committee on Cancer Biology, The University of Chicago, Chicago, IL, [3]Department of Medicine, The University of Chicago, Chicago, IL, [4]Committee on Genetics, Genomics and Systems Biology, Ben May Department for Cancer Research and The Institute for Genomics and Systems Biology, The University of Chicago, Chicago, IL, [5]Ben May Department for Cancer Research and The Institute for Genomics and Systems Biology,The University of Chicago, Chicago, IL, [6]The Institute for Genomics and Systems Biology, The University of Chicago, Chicago, IL, [7]Department of Human Genetics, Committee on Genetics, Genomics and Systems Biology and The Institute for Genomics and Systems Biology, The University of Chicago, Chicago, IL, [8]Committee on Clinical Pharmacology and Pharmacogenomics, Ben May Department for Cancer Research and The Institute for Genomics and Systems Biology, The University of Chicago, Chicago, IL, [9]Committee on Clinical Pharmacology and Pharmacogenomics, Committee on Cancer Biology, Committee on Genetics, Genomics and Systems Biology,Ben May Department for Cancer Research and Department of Medicine, The University of Chicago, Chicago, IL.

PII-28

GENETIC DETERMINANTS AND GENE EXPRESSION SIGNATURES OF GLUCOCORTICOID INSENSITIVITY.

J. C. Maranville,[1] S. S. Baxter,[2] D. B. Witonsky,[2] M. Chase,[2] A. Di Rienzo[1]; [1]Committee on Clinical Pharmacology and Pharmacogenomics and Department of Human Genetics, University of Chicago, Chicago, IL, [2]Department of Human Genetics, University of Chicago, Chicago, IL.

PII-29

SNPS IN RIBONUCLEOTIDE REDUCTASE GENES RRM1 AND RRM2 ARE ASSOCIATED WITH MRNA EXPRESSION AND RESPONSE TO NUCLEOSIDE ANALOGS-BASED CHEMOTHERAPY.

A. K. Mitra,[1] T. Mitra Ghosh,[1] T. J. Feldberg,[1] S. Pounds,[2] X. Cao,[2] J. K. Lamba[1]; 1University of Minnesota, Minneapolis, MN, [2]St. Jude Children's Research Hospital, Memphis, TN.

PII-30

GENOTYPE OF *ABCC3* -211C>T INFLUENCES THE PHARMACOKINETICS OF MORPHINE GLUCURONIDE IN CHILDREN.

T. Mizuno, T. Fukuda, V. Chidambaran, R. Venkatasubramanian, J. Niu, P. Ngamprasertwong, H. R. Esslinger, A. A. Vinks, S. Sadhasivam; Cincinnati Children's Hospital Medical Center, Cincinnati, OH.

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PII-31

LOWER MDR1 MRNA EXPRESSION IN HEPATIC FETAL AND PEDIATRIC TISSUE COMPARED TO ADULTS.

M. G. Mooij,[1] S. N. De Wildt,[1] B. A. De Koning,[1] U. I. Schwarz,[2] D. Tibboel,[1] R. B. Kim[3]; [1]Erasmus MC - Sophia Children's Hospital, Rotterdam, Netherlands, [2]University of Western Ontario, London, ON, Canada, [3]The University of Western Ontario, London, ON, Canada.

PII-32

INVESTIGATION OF THE CLINICAL IMPACT OF NIZATIDINE, A SPECIFIC AND POTENT MATE2K INHIBITOR, ON THE PHARMACOKINETICS OF METFORMIN IN HEALTHY VOLUNTEERS.

K. M. Morrissey, S. L. Stocker, R. A. Castro, C. M. Brett, K. M. Giacomini; University of California San Francisco, San Francisco, CA

PII-33

IMPACT OF CYTOCHROME P450 3A5 GENOTYPE ON TACROLIMUS THERAPY IN PATIENTS WITH REFRACTORY ULCERATIVE COLITIS.

Y. Nishioka,[1] H. Nakase,[2] S. Maruyama,[1] I. Yano,[1] M. Matsuura,[2] T. Chiba,[2] K. Matsubara,[1] S. Masuda[1]; [1]Department of Pharmacy, Kyoto University Hospital, Kyoto, Japan, [2]Department of Gastroenterology, Kyoto University Hospital, Kyoto, Japan.

PII-34

INFLUENCE OF THE GENOTYPES OF CYP2C19 AND PARAOXONASE-1 ON THE PHARMACOKINETICS AND PHARMACODYNAMICS OF CLOPIDOGREL WHEN CO-ADMINISTERED WITH ASPIRIN.

J. Oh, D. Shin, K. Shin, K. Lim, J. Cho, K. Yu, H. Lee, I. Jang; Department of Clinical Pharmacology and Therapeutics, Seoul National University College of Medicine and Hospital, Seoul, Republic of Korea.

PII-35

EXPRESSION OF CLINICALLY RELEVANT DRUG TRANSPORTER PROTEINS ALONG THE ENTIRE HUMAN INTESTINE.

M. Drozdzik,[1] J. Penski,[2] J. Lapczuk,[1] M. Ostrowski,[3] L. M. Balogh,[4] Y. Lai,[4] B. Prasad,[5] J. D. Unadkat,[5] W. Siegmund,[2] S. Oswald[2]; [1]Pomeranian Medical University, Department of Experimental and Clinical Pharmacology, Szczecin, Poland, [2]University Medicine of Greifswald, Center of Drug Absorption and Transport (C_DAT), Department of Clinical Pharmacology, Greifswald, Germany, [3]Pomeranian Medical University, Department of General and Transplantation Surgery, Szczecin, Poland, [4]Pfizer Global Research and Development, Department of Pharmacokinetics, Dynamics and Metabolism, Groton, CT, [5]University of Washington, Department of Pharmaceutics, Seattle, WA.

PII-36

A GENOME WIDE APPROACH FOR DISCOVERING THE GENETIC DETERMINANTS OF VARIABILITY OF RESPONSE TO HYDROXYUREA IN SICKLE CELL DISEASE.

A. R. Panigrahi, E. R. Gamazon, J. M. Cunningham, M. E. Dolan; University of Chicago, Chicago, IL.

Oncology (ONC)

PII-37

EXPOSURE-RESPONSE MODELING OF THE EFFECT OF DABRAFENIB, A BRAF INHIBITOR, ON OBJECTIVE RESPONSE RATE (ORR) IN PATIENTS WITH BRAF V600 MUTATION POSITIVE MELANOMA.

N. Nebot,[1] B. Ma,[1] P. Haney,[2] A. O'Hagan,[3] R. S. Swann,[3] V. L. Goodman,[3] D. Ouellet[1]; [1]GlaxoSmithKline, Research Triangle Park, NC, [2]GlaxoSmithKline, Collegeville, NC, [3]GlaxoSmithKline, Collegeville, PA.

PII-38

CHARACTERIZATION OF THE ABSORPTION, DISTRIBUTION, METABOLISM AND ELIMINATION OF A SINGLE ORAL ^{14}C LABELED DOSE OF DABRAFENIB IN SUBJECTS WITH BRAF V600-MUTATION POSITIVE SOLID TUMORS.

N. Nebot,[1] L. E. Richards-Peterson,[2] D. A. Bershas,[2] D. B. Mamaril-Fishman,[2] P. D. Gorycki,[2] S. C. Blackman,[3] R. A. Morrison,[4] S. W. Carson,[1] D. Ouellet[1]; [1]GlaxoSmithKline, Research Triangle Park, NC, [2]GlaxoSmithKline, King of Prussia, PA, [3]GlaxoSmithKline, Collegeville, PA, [4]Comprehensive Clinical Development NW, Tacoma, WA.

PII-39

LENALIDOMIDE PHARMACOKINETICS IN COMBINATION WITH IDARUBICIN AND CYTARABINE IN PATIENTS WITH ACUTE MYELOID LEUKEMIA.

Y. Jiang,[1] J. Wang,[2] A. Walker,[3] X. Li,[4] A. Drake,[2] L. Schaaf,[2] J. Byrd,[3] G. Marcucci,[3] M. Grever,[5] W. Blum,[5] M. Phelps[1]; [1]College of Pharmacy, The Ohio State University, Columbus, OH, [2]The Comprehensive Cancer Center, The Ohio State University, Columbus, OH, [3]Division of Hematology, Department of Medicine, The Ohio State University, Columbus, OH, [4]Center for Biostatistics, The Ohio State University, Columbus, OH, [5]Division of Hematology, Department of Medicine. The Ohio State University, Columbus, OH.

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Organ Specific Diseases (OSD)

PII-40

ASSESSMENT OF THE PHARMACOGENOMIC EVIDENCE OF CARDIOVASCULAR DRUGS FOR CLINICAL IMPLEMENTATION.

A. L. Kaufman,[1] J. Spitz,[2] S. Yuen,[2] K. Danahey,[3] D. Saner,[3] M. J. Ratain,[4] P. H. O'Donnell[4]; [1]University of Chicago, Pritzker School of Medicine, Chicago, IL, [2]Center for Personalized Therapeutics, The University of Chicago, Chicago, IL, [3]Information Services, Biological Sciences Division, The University of Chicago, Chicago, IL, [4]Center for Personalized Therapeutics, Section of Hematology-Oncology, and Committee on Clinical Pharmacology and Pharmacogenomics, The University of Chicago, Chicago, IL.

PII-41

DEVELOPMENT AND TESTING OF A WEB-ENABLED COGNITIVE/NEUROPSYCHOLOGICAL EVALUATION SYSTEM FOR SUBSTANCE ABUSERS.

J. Mendelson,[1] O. Clavier,[2] R. Pal,[1] B. Kline-Shoder,[2] M. Baggott,[3] J. Coyle,[1] G. P. Galloway[1]; [1]CPMCRI, San Francisco, CA, [2]Creare, Hanover, NH, [3]University of Chicago, Chicago, IL.

PII-42

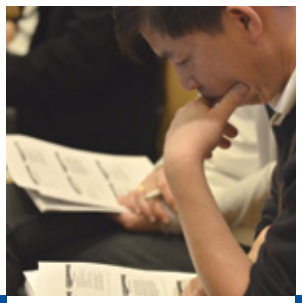
NON-MEDICAL KETAMINE USE IS ASSOCIATED WITH LOWER URINARY TRACT SIGNS AND SYMPTOMS.

R. Pal,[1] G. P. Galloway,[1] S. Balt,[1] E. Erowid,[2] F. Erowid,[2] M. J. Baggott,[3] J. Mendelson[1]; [1]CPMCRI, San Francisco, CA, [2]Erowid Center, Grass Valley, CA, [3]University of Chicago, Chicago, IL.

PII-43

A PHARMACOGENETIC TRIAL OF NALTREXONE FOR METHAMPHETAMINE DEPENDENCE.

J. Mendelson, K. Flower, J. Coyle, K. Garrison, G. P. Galloway; CPMCRI, San Francisco, CA.



Pharmacometrics and Pharmacokinetics (PMK)

PII-44

A CYP2C19 GENOTYPE-DIRECTED POPULATION PHARMACOKINETIC AND PHARMACODYNAMIC ANALYSIS OF CLOPIDOGREL IN HEALTHY ADULTS.

X. Jiang,[1] R. B. Horenstein,[2] A. R. Shuldiner,[2] L. M. Yerges-Armstrong,[2] L. J. Lesko,[1] S. Schmidt[1]; [1]University of Florida, Orlando, FL, [2]University of Maryland, Baltimore, MD.

PII-45

PHARMACOKINETICS OF A FIXED-DOSE COMBINATION OF ASPIRIN AND CLOPIDOGREL IN HEALTHY MALE SUBJECTS.

J. Jung,[1] J. Kim,[1] T. Kim,[1] S. Lee,[1] W. Huh,[1] K. Park,[2] J. Ko[1]; [1]Department of Clinical Pharmacology and Therapeutics, Samsung Medical Center, Seoul, Republic of Korea, [2]Clinical Research, Hanmi Pharmaceutical, Seoul, Republic of Korea.

PII-46

WITHDRAWN

PII-47

MODEL-BASED CHARACTERIZATION OF RENAL GLUCOSE REABSORPTION DYNAMICS IN RESPONSE TO DAPAGLIFLOZIN IN HEALTHY AND TYPE 2 DIABETES MELLITUS SUBJECTS.

S. Kasichayanula, Y. Hong, A. Roy, S. C. Griffen, F. P. LaCreta, D. W. Boulton; Bristol-Myers Squibb, Princeton, NJ.

PII-48

POPULATION PHARMACOKINETICS (PK) OF TRAMETINIB (GSK1120212), A MEK INHIBITOR, IN SUBJECTS WITH CANCER.

N. Kassir,[1] M. Mouksassi,[1] D. S. Cox,[2] D. J. DeMarini,[3] O. S. Gardner,[4] L. Sherman,[3] W. A. Crist,[3] D. Ouellet[4]; [1]Pharsight, Montreal, QC, Canada, [2]GlaxoSmithKline, King of Prussia, PA, [3]GlaxoSmithKline, Collegeville, PA, [4]GlaxoSmithKline, Research Triangle Park, NC.

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SIMPLIFIED PHARMACODYNAMIC (PD) MODELS FOR WARFARIN.

S. Kim,[1] A. E. Gaweda,[1] D. Wu,[1] L. Li,[2] M. Brier[3]; [1]University of Louisville, Louisville, KY, [2]Indiana University School of Medicine, Indianapolis, IN, [3]Robley Rex Veterans Medical Center, Louisville, KY.

PII-50

PHARMACOKINETICS OF NEWLY DEVELOPED 200-MG IMATINIB TABLET COMPARED WITH 2X100-MG MATINIB COMMERCIAL TABLET IN HEALTHY ADULT VOLUNTEERS.

N. Kim,[1] J. Jung,[2] T. Kim,[2] J. Kim,[2] S. Lee,[2] J. Ko,[2] W. Huh[2]; [1]Samsung Advanced Institute for Health Sciences & Technology, Sungkyunkwan University, Seoul, Republic of Korea, [2]Department of Clinical Pharmacology and Therapeutics, Samsung Medical Center, Seoul, Republic of Korea.

PII-51

GENETIC POLYMORPHISMS OF OCT2 AND MATE1 HAVE NO INFLUENCE ON PHARMACOKINETICS OF METFORMIN IN HEALTHY SUBJECTS.

Y. Kim,[1] S. Cho,[1] J. Chung,[2] K. Park[1]; [1]Yonsei University, Seoul, Republic of Korea, [2]Seoul National University Bundang Hospital, Seoungnam, Republic of Korea.

PII-52

THE SAFETY, TOLERABILITY, AND SERUM IBANDRONATE PHARMACOKINETIC PROFILE OF DP-R206, FIXED-DOSE IBANDRONATE AND CHOLECALCIFEROL COMBINATION COMPARED WITH IBANDRONATE 150 MG TABLET.

M. Kim,[1] K. Bae,[2] Y. Noh,[1] Y. Kim,[1] H. Choi[1]; [1]ASAN Medical Center, Seoul, Republic of Korea, [2]ASAN Medical Center, Ulsan University School of Medicine, Seoul, Republic of Korea.

PII-53

INSULIN PHARMACOKINETICS (PK) AND PHARMACODYNAMICS (PD) IN GESTATIONAL DIABETES (GD) COMPARED TO THOSE OF HEALTHY SUBJECTS (HS).

H. Kim,[1] Y. Moon,[1] R. Jain,[2] M. Khurana,[2] J. Lee,[2] J. Vaidyanathan,[2] C. Sahajwalla,[2] S. Chung[2]; [1]ORISE, Silver Spring, MD, [2]US Food and Drug Administration/CDER/OTS/OCP, Silver Spring, MD.

PII-54

COMPARATIVE PHARMACOKINETIC STUDIES OF CILOSTAZOL CONTROLLED-RELEASE FORMULATION COMPARED TO IMMEDIATE-RELEASE FORMULATION IN HEALTHY VOLUNTEERS.

J. W. Kim,[1] H. J. Lee,[2] S. Kim,[2] G. Song,[2] S. Jin,[2] W. Jung,[3] K. Nam,[3] Y. Choi,[3] S. Cho,[3] J. H. Hong[1]; [1]Chungnam National University Hospital, Daejeon, Republic of Korea, [2]Hopkins Bio Research Center, Inc., Seoul, Republic of Korea, [3]Korea United Pharm. Inc., Seoul, Republic of Korea.

PII-55

PHARMACOKINETICS OF SARPOGRELATE HYDROCHLORIDE CONTROLLED-RELEASE FORMULATION IN COMPARISON TO IMMEDIATE-RELEASE FORMULATION, AND INFLUENCE OF FOOD ON THE PHARMACOKINETICS OF SARPOGRELATE HYDROCHLORIDE CONTROLLED-RELEASE FORMULATION.

T. Kim, J. Kim, J. Jung, S. Lee, J. Ko, W. Huh; Samsung Medical Center, Seoul, Republic of Korea.

PII-56

EFFECT OF FIMASARTAN ON PHARMACOKINETICS IN PATIENTS WITH RENAL IMPAIRMENT.

S. Kim,[1] D. Shin,[1] Y. S. Kim,[2] S. H. Cho,[1] I. J. Jang,[1] H. Lee,[1] K. S. Yu[1]; [1]Department of Clinical Pharmacology and Therapeutics, Seoul National University College of Medicine and Hospital, Seoul, Republic of Korea, [2]Department of Internal Medicine, Seoul National University College of Medicine and Hospital, Seoul, Republic of Korea, Republic of Korea.

PII-57

A SEMI-MECHANISTIC PKPD MODEL DESCRIBING VISUAL ACUITY AS A FUNCTION OF THE AFFINITY AND INTRAVITREAL HALF-LIFE OF INTRAOCULAR ANTI-VEGF AGENTS IN AGE-RELATED MACULAR DEGENERATION.

K. N. Le, T. Lu, J. Visich; Genentech, South San Francisco, CA.

PII-58

DEVELOPMENT OF A POPULATION MODEL TO DESCRIBE DIURNAL AND SEASONAL VARIATION IN CILOSTAZOLPHARMACOKINETICS.

D. Lee, L. A. Lim, H. Son, K. Park; Yonsei University College of Medicine, Seoul, Republic of Korea.

PII-59

OPTIMIZATION OF BLOOD SAMPLING FOR BELATACEPT IN KIDNEY TRANSPLANT RECIPIENTS USING CLINICAL TRIAL SIMULATION.

S. Lee, R. Shi, Z. Zhou, A. Roy, C. Jones-Burton, L. Pupim, N. Bhakta, E. Masson, J. Shen; Bristol-Myers Squibb, Princeton, NJ.

PII-60

PHARMACOKINETIC AND PHARMACODYNAMIC COMPARISON OF CONTROLLED-RELEASE AND IMMEDIATE-RELEASE FORMULATIONS OF SARPOGRELATE IN HEALTHY MALE VOLUNTEERS.

S. Lee,[1] J. Jung,[2] T. Kim,[2] J. Kim,[2] S. Lee,[2] W. Huh,[2] J. Lee,[3] H. Jun,[3] J. Ko[2]; [1]Samsung Advanced Institute for Health Sciences & Technology, Sungkyunkwan University, Seoul, Republic of Korea, [2]Department of Clinical Pharmacology and Therapeutics, Samsung Medical Center, Seoul, Republic of Korea, [3]R&D Center, DreamPharma, Seoul, Republic of Korea.

PII-61

DETERMINATION OF AN INITIAL DOSE OF GENTAMICIN: EVALUATION OF 5 NOMOGRAMS IN A KOREAN POPULATION.

J. Lee, S. Yoon, D. Shin, K. Lim, I. Jang, H. Lee, S. Shin, K. Yu; Department of Clinical Pharmacology and Therapeutics, Seoul National University Hospital, Seoul, Republic of Korea.

*Presenting author is in **bold**.*

POSTER SESSION II • MARCH 8

Griffin Hall • 8:00 am – 3:00 pm • Attended Posters 8:00 am – 9:30 am

PII-62
POPULATION PHARMACOKINETIC MODELING OF CHLOROQUINE AND DESETHYLCHLOROQUINE AFTER A WEEKLY DOSE FOR 12 WEEKS.
K. Seng, L. Fan, H. Lee, **L. S. Lee;** National University of Singapore, Singapore, Singapore.

PII-63
PHARMACOKINETIC EVALUATION OF DA-8031, A NEW TREATMENT FOR PREMATURE EJACULATION, AND ITS METABOLITES IN HEALTHY MALE VOLUNTEERS.
S. Lee, S. Yi, S. Yoon, J. Cho, K. Lim, S. Shin, I. Jang, K. Yu; Department of Clinical Pharmacology and Therapeutics, Seoul National University College of Medicine and Hospital, Seoul, Republic of Korea.

PII-64
DEVELOPMENT AND VALIDATION OF A SEMI-PHYSIOLOGICAL MODEL OF AMYLOID-β BIOSYNTHESIS AND DEGRADATION IN HUMAN CEREBROSPINAL FLUID INCLUDING THE IMPACT OF THE βγ-SECRETASE INHIBITOR SEMAGACESTAT.
K. G. Haug,[1] A. Staab,[2] T. Lehr[3]; [1]University of Florida, Gainesville, FL, [2]Boehringer Ingelheim Pharma GmbH & Co KG, Biberach/Riss, Germany, [3]Saarland University, Saarbrücken, Germany.

PII-65
EFFECT OF KETOCONAZOLE ON THE PHARMACOKINETICS (PK) AND SAFETY PROFILE OF LINIFANIB (ABT-869) IN PATIENTS WITH ADVANCED SOLID TUMORS.
L. D. Lewis,[1] X. Li,[2] R. Pradhan,[2] M. McKee,[2] P. LoRusso[3]; [1]Dartmouth University, Lebanon, NH, [2]Abbott, Abbott Park, IL, [3]Karmanos Cancer Institute, Detroit, MI.

PII-66
NO EFFECT OF THERAPEUTIC AND SUPRATHERAPEUTIC DOSES OF IVACAFTOR ON QTC INTERVAL IN HEALTHY SUBJECTS.
C. Li, T. Song, C. Ordonez, J. Jiang, M. Rosario, K. Kumor, J. Zha; Vertex Pharmaceuticals Inc., Cambridge, MA.

PII-67
PHARMACOKINETICS AND TOLERABILITY OF PEG-INF-SA IN HEALTHY VOLUNTEERS.
Z. Li,[1] G. Z. Ping,[1] W. Ying,[1] C. Y. Ming,[2] L. Hua[3]; [1]Institute of Clinical Pharmacology ,West China Hospital of ShiChuan University, Chengdu, China, [2]Tianjin Institute of Pharmaceutical Research, Tianjin, China, [3]Chongqing Biomedical Co., Ltd, Chongqing, China.

PII-68
EXPOSURE-RESPONSE ANALYSIS OF RONTALIZUMAB IN PATIENTS WITH MODERATELY TO SEVERELY ACTIVE SYSTEMIC LUPUS ERYTHEMATOSUS (SLE): RESULTS FROM ROSE.
J. Li, **X. Wei,** R. Maciuca, Y. Wang, R. Mangat, W. Kennedy, J. McBride, M. Tang; Genentech, South San Francisco, CA.

PII-69
IN VITRO INHIBITION OF HUMAN RECOMBINANT CYP2C19 BY 6-GINGEROL.
Y. Lim; Department of Pharmacology, Chonnam National University Medical School, Gwangju, Republic of Korea.

PII-70
CHANGES OF CLEARANCE IN OBESE SUBJECTS: IS BODY SIZE THE ONLY REASON?
D. Liu, R. Jain, S. M. Chung, M. Khurana, J. Vaidyanathan, I. Zadezensky, C. G. Sahajwalla; Office of Clinical Pharmacology, Center for Drug Evaluation and Research, US Food and Drug Administration, Silver Spring, MD.

PII-71
PHARMACOKINETIC ANALYSIS OF TAMOXIFEN AND ITS METABOLITES IN RABBITS.
D. Lu, M. Swan, D. Hickman, Z. Desta, D. Flockhart; Indiana University, Indianapolis, IN.

PII-72
PHARMACOKINETICS (PK) OF ANTI-CD22 AND ANTI-CD79B ANTIBODY DRUG CONJUGATES (ADCS) IN RELAPSED OR REFRACTORY B-CELL NON-HODGKIN'S LYMPHOMA (NHL) PATIENTS: RESULTS FROM PHASE I DOSE-ESCALATION STUDIES.
D. Lu, P. Agarwal, S. Prabhu, D. Nazzal, R. Dere, O. Saad, Y. Chu, D. Li, S. Girish; Genentech, South San Francisco, CA.

PII-73
CHARACTERIZATION OF BEVACIZUMAB PHARMACOKINETICS IN PEDIATRIC PATIENTS WITH LOCALIZED RESECTABLE, UNRESECTABLE, OR METASTATIC OSTEOSARCOMA, AND A COMPARISON TO EXPOSURE IN ADULTS.
R. S. Mangat, Y. Zhang, J. Li, J. Jin, D. Allison; Genentech, South San Francisco, CA.

PII-74
MODELING AND SIMULATIONS TO DETERMINE THE EFFECT OF A FIXED-DOSE COMBINATION PRODUCT OF IMMEDIATE-RELEASE PHENTERMINE AND MODIFIED-RELEASE TOPIRAMATE (VI-0521) ON HEART RATE IN OBESE PATIENTS.
T. Peyret,[1] N. H. Gosselin,[1] M. S. Mouksassi,[1] **J. F. Marier,**[1] S. Yee,[2] W. W. Day[3]; [1]Pharsight, Montreal, QC, Canada, [2]Independent Consultant, Mountain View, CA, [3]Vivus, Mountain View, CA.

PII-75
MODELING AND SIMULATIONS TO SUPPORT DOSING REGIMEN OF A FIXED-DOSE COMBINATION PRODUCT OF IMMEDIATE-RELEASE PHENTERMINE AND MODIFIED-RELEASE TOPIRAMATE (VI-0521) IN PATIENTS WITH HEPATIC IMPAIRMENT.
M. S. Mouksassi,[1] M. M. Trinh,[1] C. Chang,[1] **J. F. Marier,**[1] C. Peterson,[2] S. Yee[3]; [1]Pharsight, Montreal, QC, Canada, [2]Vivus, Mountain View, CA, [3]Independent Consultant, Mountain View, CA.

*Presenting author is in **bold**.*

POSTER SESSION II • MARCH 8

Griffin Hall • 8:00 am – 3:00 pm • Attended Posters 8:00 am – 9:30 am

PII-76

MODELING AND SIMULATIONS TO SUPPORT DOSING REGIMEN OF A FIXED-DOSE COMBINATION PRODUCT OF IMMEDIATE-RELEASE PHENTERMINE AND MODIFIED-RELEASE TOPIRAMATE (VI-0521) IN PATIENTS WITH RENAL IMPAIRMENT.

M. M. Trinh,[1] M. S. Mouksassi,[1] C. Chang,[1] **J. F. Marier,[1]** C. Peterson,[2] S. Yee[3]; [1]Pharsight, Montreal, QC, Canada, [2]Vivus, Mountain View, CA, [3]Independent Consultant, Mountain View, CA.

PII-77

EFAVIRENZ INDUCES CYP3A ACTIVITY IN HEALTHY VOLUNTEERS IN CYP3A5 GENOTYPE-DEPENDENT MANNER.

I. F. Metzger, J. B. Lu, N. Thong, D. A. Flockhart, T. C. Skaar, S. Philips, Z. Desta; Division of Clinical Pharmacology, Department of Medicine, School of Medicine, Indiana University, Indianapolis, IN.

PII-78

EFFECT OF CYP2C9 GENOTYPE AND EFAVIREZ ON CYP2C9 ACTIVITY IN HEALTHY VOLUNTEERS.

I. F. Metzger, J. B. Lu, N. Thong, T. C. Skaar, S. Philips, D. A. Flockhart, Z. Desta; Division of Clinical Pharmacology, Department of Medicine, School of Medicine, Indiana University, Indianapolis, IN.

PII-79

CYP2B6 GENETIC VARIATION AND EFAVIRENZ AUTOINDUCTION INFLUENCES CYP2B6 A ACTIVITY AND EFAVIRENZ EXPOSURE IN HEALTHY VOLUNTEERS.

I. F. Metzger, J. B. Lu, Y. Kreutz, N. Thong, D. A. Flockhart, Z. Desta; Division of Clinical Pharmacology, Department of Medicine, School of Medicine, Indiana University, Indianapolis, IN.

PII-80

THE ANTIRETROVIRAL DRUG EFAVIRENZ INHIBITS CYP1A2 ACTIVITY IN HEALTHY VOLUNTEERS.

I. F. Metzger, J. B. Lu, N. Thong, Z. Desta; Division of Clinical Pharmacology, Department of Medicine, School of Medicine, Indiana University, Indianapolis, IN.

PII-81

PK/PD MODEL-BASED DRUG DEVELOPMENT OF MD 525797 (DI17E6), A NOVEL ANTI-αγ INTEGRIN MONOCLONAL ANTIBODY.

B. Meibohm,[1] B. Brockhaus,[2] M. Zuehlsdorf,[2] A. Kovar[2]; [1]University of Tennessee Health Science Center, Memphis, TN, [2]Merck Serono, Darmstadt, Germany.

PII-82

PHARMACODYNAMICS OF IPX066, AN EXTENDED-RELEASE CAPSULE FORMULATION OF CARBIDOPA-LEVODOPA (CD-LD), IN PATIENTS WITH EARLY PARKINSON'S DISEASE: A DISEASE PROGRESSION MODEL.

Z. Mao, A. Hsu, S. Gupta, **N. B. Modi;** Impax Pharmaceuticals, Hayward, CA.

PII-83

IMPACT OF MEAL TYPE, MEAL TIMING, AND A GLUCOSE DRINK ON THE PHARMACOKINETICS OF MIGALASTAT HCL.

P. N. Mudd Jr,[1] F. K. Johnson,[2] S. Janmohamed[3]; [1]GlaxoSmithKline, Research Triangle Park, NC, [2]Amicus Therapeutics, Cranberry, NJ, [3]GlaxoSmithKline, Middlesex, United Kingdom.

PII-84

VATALANIB POPULATION PHARMACOKINETICS IN PATIENTS WITH MYELODYSPLASTIC SYNDROME: CALGB 10105 (ALLIANCE).

X. Wang,[1] K. Owzar,2 P. Gupta,[3] R. A. Larson,[4] F. Mulkey,[2] A. A. Miller,[5] L. D. Lewis,[6] D. Hurd,[5] R. Vij,[7] M. J. Ratain,[4] D. Murry[1]; [1]University of Iowa, Iowa City, IA, [2]Alliance Statistics and Data Center, Duke University, Durham, NC, [3]Minneapolis Veterans Administration Medical Center, Minneapolis, MN, [4]University of Chicago, Chicago, IL, [5]Wake Forest University School of Medicine, Winston Salem, NC, [6]Dartmouth College, Dartmouth Medical School, Lebanon, NH, [7]Washington University School of Medicine, St Louis, MO.

PII-85

MULTIDRUG RESISTANCE-ASSOCIATED PROTEIN 2 (MRP2) AFFECTS TACROLIMUS DISPOSITION IN A HAPLOTYPE-SPECIFIC MANNER.

K. Ogasawara,[1] S. D. Chitnis,[1] R. Y. Gohh,[2] U. Christians,[3] F. Akhlaghi[1]; [1]University of Rhode Island, Kingston, RI, [2]Warren Alpert Medical School of Brown University, Rhode Island Hospital, Providence, RI, [3]University of Colorado Denver, Aurora, CO.

PII-86

SAMPLE SIZE REDUCTION BASED ON GENOTYPE OF ENRICHMENT DESIGN FOR BIOEQUIVALENCE STUDY.

M. Oh, H. Kim, J. Shon, J. Kim, J. Shin; Inje University College of Medicine, Busan, Republic of Korea.

PII-87

MINI-DOSE COCKTAIL OF FIVE CYP PROBE DRUGS AS A TOOL FOR THE PHENOTYPING OF CYP 1A2, 2C9, 2C19, 2D6 AND 3A IN HUMAN.

K. Oh,[1] S. Park,[1] M. Park,[2] E. Lee,[2] E. Jeong,[1] D. Kim,[1] J. Shin[1]; [1]Department of Pharmacology and Clinical Pharmacology, PharmacoGenomics Research Center, Inje University College of Medicine, Busan, Republic of Korea, [2]Formulation Innovation Unit, Yuhan Research Institute, Gyeonggi-do, Republic of Korea.

PII-88

POPULATION PHARMACOKINETICS OF DABRAFENIB (GSK2118436), A BRAF INHIBITOR IN DEVELOPMENT FOR THE TREATMENT OF BRAF V600 MUTATION POSITIVE MELANOMA.

E. Gibiansky,[1] A. O'Hagan,[2] P. Haney,[2] J. C. Switzky,[2] V. L. Goodman,[2] **D. Ouellet[3];** [1]QuantPharma LLC, North Potomac, MD, [2]GlaxoSmithKline, Collegeville, PA, [3]GlaxoSmithKline, Research Triangle Park, NC.

*Presenting author is in **bold**.*

POSTER SESSION II • MARCH 8

Griffin Hall • 8:00 am – 3:00 pm • Attended Posters 8:00 am – 9:30 am

PII-89

A NOVEL APPROACH OF RISK ASSESSMENT FOR EXCRETION OF DRUG AND AN ACTIVE METABOLITE INTO HUMAN MILK: POPULATION PK MODELING AND SIMULATION USING ONLY MILK COMPARTMENT DATA WITHOUT PLASMA LEVELS.

R. Tanoshima,[1] F. Garcia-Bournissen,[2] Y. Tanigawara,[3] J. H. Kristensen,[4] A. Taddio,[1] K. F. Ilett,[5] E. J. Begg,[6] I. Wallach,[7] S. Ito[1]; [1]Division of Clinical Pharmacology and Toxicology, The Hospital for Sick Children, University of Toronto, Toronto, ON, Canada, [2]National Research Council (CONICET), Buenos Aires, Argentina, [3]Department of Clinical Pharmacokinetics and Pharmacodynamics, School of Medicine, Keio University, Tokyo, Japan, [4]Department of Pharmacy, King Edward Memorial Hospital, Subiaco, Australia, [5]Pharmacology and Anaesthesiology Unit, School of Medicine and Pharmacology, University of Western Australia, Crawley, Australia, [6]Department of Medicine, University of Otago, Christchurch, New Zealand, [7]Department of Computer Science, University of Toronto, Toronto, ON, Canada.

PII-90

DISCRETE DISTRIBUTION MODELS FOR RELAPSING-REMITTING DYNAMICS OBSERVED IN MULTIPLE SCLEROSIS.

N. Velez de Mendizabal,[1] I. F. Troconiz,[2] M. M. Hutmacher,[3] R. R. Bies[1]; [1]Indiana University, Indianapolis, IN, [2]University of Navarra, Pamplona, Spain, [3]Ann Arbor Pharmacometrics Group, Ann Arbor, MI.

PII-91

PRECLINICAL TO CLINICAL TRANSLATION OF PHARMACOKINETICS AND PHARMACODYNAMICS FOR AN ORAL NOTCH INHIBITOR, LY900009.

E. Yuen,[1] B. Patel,[2] J. Graff,[2] J. D. Kursar,[2] M. Zamek-Gliszczynski,[2] E. Jones,[1] E. Chan[2]; [1]Eli Lilly and Company, Windlesham Surrey, United Kingdom, [2]Eli Lilly and Company, Indianapolis, IN.

Special Populations (SPO)

PII-92

AN OPEN-LABEL STUDY TO DETERMINE THE SAFETY AND PHARMACOKINETICS OF AT1001 IN SUBJECTS WITH IMPAIRED RENAL FUNCTION AND HEALTHY SUBJECTS WITH NORMAL RENAL FUNCTION.

F. K. Johnson,[1] P. N. Mudd, Jr.,[2] S. Sitaraman,[1] P. Boudes[1]; [1]Amicus Therapeutics, Cranbury, NJ, [2]GlaxoSmithKline, Research Triangle Park, NC.

PII-93

PREDICTING NONLINEAR PHARMACOKINETICS OF OMEPRAZOLE ENANTIOMERS AND RACEMIC DRUG USING PHYSIOLOGICALLY BASED PHARMACOKINETIC MODELING AND SIMULATION.

F. Wu, P. Zhao, S. H. Lee; US Food and Drug Administration, Silver Spring, MD.

PII-94

POTENTIAL IMPACT OF RENAL OR HEPATIC IMPAIRMENT ON DRUG TRANSPORTERS.

S. Lee, S. Chung, D. A. Volpe, D. Jappar, Y. Fan, L. Zhang; US Food and Drug Administration, Silver Spring, MD.

PII-95

PHARMACOKINETICS OF R- AND S-PANTOPRAZOLE IN PREGNANT WOMEN.

A. N. Mohamed,[1] J. Glassburn,[2] M. F. Hebert,[3] G. V. Hankins,[4] S. N. Caritis,[5] J. L. Renbarger,[2] S. K. Quinney,[2] for the Obstetric-Fetal Pharmacology Research UnitNetwork; [1]Purdue University College of Pharmacy, Indianapolis, IN, [2]Indiana University School of Medicine, Indianapolis, IN, [3]University of Washington, Seattle, WA, [4]University of Texas Medical Branch at Galveston, Galveston, TX, [5]University of Pittsburgh Medical Center, Pittsburgh, PA.

PII-96

PHARMACOKINETIC (PK) EVALUATION OF A POTENTIAL TRANSPORTER-MEDIATED INTERACTION BETWEEN GREEN TEA (GT) AND DIGOXIN (DIG).

A. Mohamed,[1] S. Liangpunsakul,[2] D. Foster[1]; [1]Purdue University, Indianapolis, IN, [2]Indiana University School of Medicine, Indianapolis, IN.

PII-97

DIFFERENTIAL EFFECTS OF MARASMUS AND KWASHIORKOR ON ^{13}C-CAFFEINE METABOLISM.

K. A. Oshikoya,[1] K. Smith[2]; [1]Academic Division of Child Health, University of Nottingham in Derby, Derby, United Kingdom, [2]Clinical Physiology Department, Medical School in Derby, Univesrity of Nottingham, Derby, United Kingdom.

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POSTER SESSION III • MARCH 9

Griffin Hall • 7:00 am – 11:00 am • Attended Posters 7:00 am – 8:00 am

Biomarkers and Imaging (BIO)

PIII-1

SAFETY, PHARMACOKINETICS AND PHARMACODYNAMICS (BONE TURNOVER) OF ODANACATIB: TWO DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED PHASE I STUDIES IN JAPANESE MEN AND POSTMENOPAUSAL WOMEN.

N. Uemura,[1] J. P. Willmer,[2] N. Nakamichi,[3] G. Mistry,[1] M. Miki,[4] Q. Liu,[1] J. Stone,[1] B. Jin,1 R. Witter,[1] C. Fukuda,[4] S. Yama,[4] C. Liu,[1] S. Zajic,[1] D. Panebianco,[1] G. Fujimoto,[4] K. Gottesdiener,[1] J. Wagner,[1] S. Stoch[1]; [1]Merck Research Laboratories, Rahway, NJ, [2](formerly) Prime Trials, Vancouver, BC, Canada, [3]Yokohama Minoru Clinic, Yokohama, Japan, [4]MSD KK, Tokyo, Japan.

PIII-2

PHARMACOKINETICS (PK) AND PHARMACODYNAMICS (PD) OF TOCILIZUMAB (TCZ) IN POLYARTICULAR-COURSE JUVENILE IDIOPATHIC ARTHRITIS (PCJIA).

X. Zhang,[1] J. Hsu,[1] H. Brunner,[2] F. De Benedetti,[3] C. Le Gallo,[1] Z. Zuber,[3] R. Cuttica,[3] V. Keltsev,[3] R. Xavier,[3] I. Calvo Penedes,[3] N. Rubio-Perez,[3] V. Chasnyk,[3] G. Horneff,[3] V. Opoka-Winiarska,[3] P. Quartier,[4] C. Silva,[3] A. Spindler,[3] E. Baildam,[3] M. L. Gamir,[5] A. Martin,[6] D. A. Siri,[7] E. Smolewska,[8] D. Lovell,[2] N. Ruperto,[3] A. Martini[3]; [1]Hoffmann-La Roche Inc., Nutley, NJ, [2]Pediatric Rheumatology Collaborative Study Group, Cincinnati, OH, [3]Paediatric Rheumatology International Trials Organisation, Genoa, Italy, [4]Necker-Enfants Malades Hospital, Paris, France, [5]Hospital Ramon y Cajal, Madrid, Spain, [6]Healthcare Research Consultants, Tulsa, OK, [7]CAICI Institute, Rosario, Argentina, [8]Medical University of Lodz, Lodz, Poland.

Drug Development and Regulatory Sciences (DDR)

PIII-3

VALIDATION OF THE PAPERSPRAY/MASS SPECTROMETRY METHOD TO TRADITIONAL LC/MS ASSAY METHOD FOR THERAPEUTIC MONITORING: A FOCUS PAZOPANIB IN THE PRE-CLINICAL SETTING.

J. A. Smith,[1] A. J. Tindall,[1] M. Jaffari,[1] L. W. Coffer,[1] N. E. Manke[2]; [1]UT MD Anderson Cancer Center, Houston, TX, [2]Purdue University, West Lafayette, IN.

PIII-4

PHARMACOKINETIC EVALUATION OF THE CO-ADMINISTRATION OF RIFAMPIN AND ODANACATIB IN HEALTHY SUBJECTS.

S. Stoch,[1] R. Witter,[1] C. Liu,[1] S. Zajic,[1] A. Mehta,[1] C. Brandquist,[2] B. DeGroot,[2] D. Stypinski,[2] M. Reitman[3]; [1]Merck Sharp & Dohme, Whitehouse Station, NJ, [2]Celerion, Lincoln, NE, [3]National Institutes of Health, Bethesda, MD

Presenter: N. Uemura, Merck Research Laboratories, Rahway, NJ.

PIII-5

PREDNISONE HAS NO EFFECT ON ODANACATIB PHARMACOKINETICS IN HEALTHY SUBJECTS.

G. Marcantonio,[1] C. Liu,[1] S. Zajic,[1] C. Mahon,[1] D. Hreniuk,[1] A. Mehta,[1] K. Mostoller,[1] D. Morris,[2] H. Xue,[2] S. Stoch[1]; [1]Merck Sharp & Dohme, Whitehouse Station, NJ, [2]Covance, Madison, WI.

Presenter: N. Uemura, Merck Research Laboratories, Rahway, NJ.

PIII-6

MULTIPLE DOSES OF ODANACATIB, A NOVEL CATHEPSIN-K INHIBITOR, HAVE NO INFLUENCE ON THE SINGLE-DOSE PHARMACOKINETICS OF DIGOXIN WITH CONCOMITANT ADMINISTRATION.

S. Stoch,[1] R. Witter,[1] C. Liu,[1] S. Zajic,[1] A. Mehta,[1] C. Brandquist,[2] C. Dempsey,[2] B. Degroot,[2] D. Stypinski[2]; [1]Merck Sharp & Dohme, Whitehouse Station, NJ, [2]Celerion, Lincoln, NE.

Presenter: N. Uemura, Merck Research Laboratories, Rahway, NJ.

PIII-7

CO-ADMINISTRATION OF ODANACATIB, A CATHEPSIN K INHIBITOR, DOES NOT AFFECT THE SINGLE DOSE PHARMACOKINETICS AND PHARMACODYNAMICS OF WARFARIN AFTER ADMINISTRATION IN HEALTHY POSTMENOPAUSAL FEMALE SUBJECTS.

S. Stoch,[1] R. Witter,[1] C. Liu,[1] S. Zajic,[1] A. Mehta,[1] P. Chandler,[2] D. Morris,[2] H. Xue[2]; [1]Merck Sharp & Dohme, Whitehouse Station, NJ, [2]Covance, Madison, WI.

Presenter: N. Uemura, Merck Research Laboratories, Rahway, NJ.

PIII-8

IS THERE A NEED FOR PHARMACOKINETIC STUDIES IN CHILD-PUGH CLASS A PATIENTS?

I. R. Younis, R. S. Uppoor, M. U. Mehta; US Food and Drug Administration, Silver Spring, MD.

PIII-9

UNINTENDED INTERPERSONAL TRANSFERABILITY OF TOPICAL ESTRADIOL AND TESTOSTERONE PRODUCTS: A SAFETY CONCERN FOR CHILDREN.

C. Yu,[1] S. Kim,[2] M. Kim[1]; [1]US Food and Drug Administration, Silver Spring, MD, [2]Bernard J Dunn School of Pharmacy, Shenandoah University, Winchester, VA.

PIII-10

REVIEW OF *IN VITRO* TRANSPORTER DATA IN RECENTLY APPROVED NEW DRUG APPLICATIONS.

H. K. Anathula,[1] S. Agarwal,[2] L. Zhang[2]; [1]The James L. Winkle College of Pharmacy, University of Cincinnati, Cincinnati, OH, [2]Office of Clinical Pharmacology, Office of Translational Sciences, CDER, US Food and Drug Administration, Silver Spring, MD.

*Presenting author is in **bold**.*

POSTER SESSION III • MARCH 9

Griffin Hall • 7:00 am – 11:00 am • Attended Posters 7:00 am – 8:00 am

Drug Safety (SAF)

PIII-11
KNOWLEDGE TRANSLATION (KT) NEEDS ASSESSMENT FOR APPLICATION OF AN AMIODARONE CARE PATHWAY FOR COMMUNITY CARE PHYSICIANS.
P. T. Pollak,[1] J. M. Holroyd-Leduc,[1] H. T. Stelfox,[1] D. R. Brocks[2]; [1]University of Calgary, Calgary, AB, Canada, [2]University of Alberta, Edmonton, AB, Canada.

PIII-12
EFFECTS OF MIRODENAFIL ON THE HEMODYNAMICS OF STABLE HYPERTENSIVE PATIENTS TAKING AMLODIPINE.
E. Shim,[1] J. Shon,[1] M. Oh,[1] S. Park,[1] J. Ryu,[2] D. Cho,[1] J. Ghim,[1] K. Bae,[3] J. Shin1; [1]Department of Clinical Pharmacology, Inje University Busan Paik Hospital, Busan, Republic of Korea, [2]Life Science Biz., SK Chemicals Co. Ltd., Seoul, Republic of Korea, [3]Department of Clinical Pharmacology and Therapeutics, ASAN Medical Center, University of Ulsan, Seoul, Republic of Korea.

PIII-13
WITHDRAWN

PIII-14
USE OF GLUCOSE LOWERING DRUGS AND THE RISK OF ADENOCARCINOMA AMONG PATIENTS WITH TYPE 2 DIABETES: A CASE-CONTROL STUDY IN THE NETHERLANDS.
G. W. 't Jong,[1] A. Simon,[1] V. Valkhoff,[1] M. Sturkenboom,[1] J. Hoekstra,[2] F. Holleman[3]; [1]Erasmus University Rotterdam, Rotterdam, Netherlands, [2]Academic Medical Centre, Amsterdam, Netherlands, [3]Academic Medical Centre, Rotterdam, Netherlands.

PIII-15
WITHDRAWN

Molecular Pharmacology and Pharmacogenetics (MOL)

PIII-16
EFFECT OF CHORIOAMNIONITIS ON THE EXPRESSION OF ABCG2, ABCB1 AND SLCO2B1 TRANSPORTERS IN HUMAN PLACENTA.
V. Petrovic, D. Kojovic, A. Cressman, M. Piquette-Miller; University of Toronto, Toronto, ON, Canada.

PIII-17
A PROSPECTIVE EVALUATION OF CYP2D6 ENZYME ACTIVITY USING A DEXTROMETHORPHAN BREATH TEST (DM-BT) IN WOMEN RECEIVING ADJUVANT TAMOXIFEN (TAM).
J. M. Reid,[1] V. J. Suman,[1] D. W. Northfelt,[2] D. I. Rosen,[3] S. L. Safgren,[1] J. A. Gilbert,[1] M. L. Kosel,[1] A. S. Modak,[4] M. M. Ames,[1] M. P. Goetz1; [1]Mayo Clinic, Rochester, MN, [2]Mayo Clinic, Scottsdale, AZ, [3]Physical Sciences Inc., Andover, MA, [4]Cambridge Isotope Laboratories Inc., Andover, MA.

PIII-18
PHARMACOKINETICS, SAFETY, AND TOLERABILITY OF PONESIMOD IN JAPANESE AND CAUCASIAN HEALTHY SUBJECTS.
M. Reyes, P. Brossard, J. Dingemanse; Actelion Pharmaceuticals Ltd, Allschwil, Switzerland.

PIII-19
EFFECTS OF MULTIPLE-DOSE PONESIMOD ON THE PHARMACOKINETICS OF A SINGLE DOSE OF ORTHO-NOVUM®1/35 IN HEALTHY FEMALE SUBJECTS.
M. Reyes, P. Brossard, J. Dingemanse; Actelion Pharmaceuticals Ltd, Allschwil, Switzerland.

PIII-20
BIOEQUIVALENCE, SAFETY, AND TOLERABILITY OF PONESIMOD CAPSULES VS. TABLETS IN HEALTHY SUBJECTS.
M. Reyes, P. Brossard, D. D'Ambrosio, J. Dingemanse; Actelion Pharmaceuticals Ltd, Allschwil, Switzerland.

PIII-21
P-GYLCOPROTEIN: A CLUE TO VITAMIN K ANTAGONIST STABILIZATION.
V. Rollason, L. Gschwind, Y. Daali, F. Boehlen, M. Rebsamen, C. Combescure, P. Bonnabry, P. Dayer, J. A. Desmeules; Geneva University Hospitals, Geneva 14, Switzerland.

PIII-22
RELEVANCE OF GENOTYPE AND PHENOTYPE DETERMINATION IN A CLINICAL SETTING.
V. Rollason, K. Ing Lorenzini, C. Samer, Y. Daali, M. Besson, V. Piguet, M. Escher, P. Dayer, J. A. Desmeules; Geneva University Hospitals, Geneva 14, Switzerland.

PIII-23
DEVELOPMENTAL CHANGES IN HEPATIC MICRORNA EXPRESSION.
T. C. Skaar, Y. Liu, L. Li, C. Goswami, Z. Desta, S. Philips, R. Gaedigk, A. Gaedigk; Indiana University, Indianapolis, IN.

PIII-24
INFLUENCE OF *CYP2C8*2* ON THE PHARMACOKINETICS OF PIOGLITAZONE IN HEALTHY AFRICAN AMERICAN VOLUNTEERS.
S. H. Spencer, M. F. Wempe, M. S. Sidhom, L. A. Kosmiski, J. A. Predhomme, C. L. Aquilante; University of Colorado, Aurora, CO.

PIII-25
P-GLYCOPROTEIN FUNCTION IN PERIPHERAL BLOOD MONONUCLEAR CELLS IN RENAL TRANSPLANT RECIPIENTS: SEX AND RACE INFLUENCES.
K. M. Tornatore,[1] H. Minderman,[2] S. Chiang,[3] K. O'Louglin,[2] K. Attwood,[4] R. C. Venuto[5]; [1]School of Pharmacy & Pharmaceutical Sciences, Buffalo, NY, [2]Flow & Image Cytometry Laboratories; Roswell Park Cancer Institute, Buffalo, NY, [3]Medicine Department; School of Medicine, Buffalo, NY, [4]Biostatistics; School of Public Health, Buffalo, NY, [5]Department of Medicine; School of Medicine; University at Buffalo, Buffalo, NY.

*Presenting author is in **bold**.*

POSTER SESSION III • MARCH 9

Griffin Hall • 7:00 am – 11:00 am • Attended Posters 7:00 am – 8:00 am

PIII-26
CELLULAR FOLATE POLYGLUTAMATE DISTRIBUTION IS ALTERED IN RESPONSE TO METHOTREXATE.
L. van Haandel, R. S. Funk, J. S. Leeder, M. L. Becker; Children's Mercy Hospitals and Clinics, Kansas City, MO.

PIII-27
INHIBITION EFFECT OF KETOCONAZOLE (KTZ) ON THE PHARMACOKINETICS OF A DUAL PI3K/MTOR INHIBITOR GDC-0980 IN HEALTHY VOLUNTEERS: ESTIMATION OF THE CYP3A METABOLIC CONTRIBUTION (FM_{CYP3A}) USING PHYSIOLOGICALLY- BASED PHARMACOKINETIC (PBPK) MODELING.
J. Mao, G. S. Smelick, L. Salphati, Y. Chen, J. Kenny, X. Ding, J. Y. Jin, E. L. Reyner, K. E. Bass, M. J. Dresser, D. Apt, S. N. Holden, J. A. Ware; Genentech, South San Francisco, CA.

PIII-28
PHARMACOGENETIC ANALYSIS OF CYP2D6, CYP3A4, CYP3A5, AND CYP2C9 AMONG THE CONFEDERATED SALISH AND KOOTENAI TRIBES IN MONTANA.
E. L. Woodahl,[1] A. Fohner,[2] L. L. Muzquiz,[3] M. Austin,[2] A. Gaedigk,[4] A. Gordon,[2] M. J. Rieder,[2] M. A. Pershouse,[1] E. A. Putnam,[1] K. Howlett,[3] P. Beatty,[5] K. E. Thummel[2]; [1]University of Montana, Missoula, MT, [2]University of Washington, Seattle, WA, [3]Confederated Salish and Kootenai Tribes, St. Ignatuis, MT, [4]Children's Mercy Hospital and Clinics, Kansas City, MO, [5]Montana Cancer Institute Foundation, Missoula, MT.

PIII-29
INDUCTION OF MRP3 (ABCC3) BY OMEPRAZOLE AND ITS UNDERLYING MECHANISMS.
Y. Q. Pan, Q. Y. Mi, B. S. He, S. L. Zhao, H. G. Xie; Nanjing Medical University Nanjing Hospital, Nanjing, China.

PIII-30
MRNA LEVELS OF CYTOCHROME P450S IN ENDOMETRIAL CANCER CELLS.
X. Yang,[1] F. Gaudette,[1] L. G. Guilarte,[2] C. Armstrong,[1] J. Turgeon[1]; [1]Centre Hospitalier de L'Universite de Montreal, Montreal, QC, Canada, [2]L'Universite de Montreal, Montreal, QC, Canada.

Oncology (ONC)

PIII-31
ALTERATION OF DOCETAXEL PHARMACOKINETICS BY EFAVIRENZ AND RITONAVIR: IMPLICATIONS FOR DOSING.
C. Y. Chang,[1] K. Steadman,[2] M. Zhao,[1] J. F. Deeken,[2] M. A. Rudek[1]; [1]Johns Hopkins University, Baltimore, MD, [2]Georgetown University Medical Center, Washington, DC.

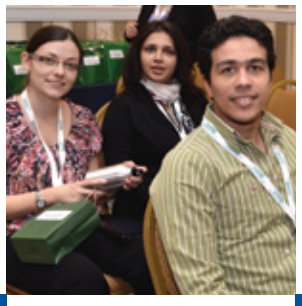
PIII-32
AN EVIDENCE-BASED APPROACH TO HEALTH-CARE REIMBURSEMENT FOR HIGH COST DRUGS FOR LIFE-THREATENING, RARE AND ORPHAN DISEASES.
G. H. Sokol,[1] L. Loftus,[2] L. R. Cantilena[1]; [1]Uniformed Services University, Bethesda, MD, [2]H Lee Moffitt Cancer Center, Tampa, FL.

PIII-33
AMELIORATION OF OXALIPLATIN NEUROTOXICITY BY DASATINIB.
J. A. Sprowl, R. A. Ness, G. Du, S. D. Baker, A. Sparreboom; St Jude Children's Research Hospital, Memphis, TN.

PIII-34
CONJUNCTIVE THERAPY OF CISPLATIN WITH OCT2 INHIBITORS: INFLUENCE ON ANTITUMOR EFFICACY AND SYSTEMIC CLEARANCE.
J. A. Sprowl,[1] L. van Doorn,[2] S. Hu,[1] L. van Gerven,[2] P. de Bruijn,[2] R. Mathijssen[2]; [1]St Jude Children's Research Hospital, Memphis, TN, [2]Department of Medical Oncology, Erasmus MC, Rotterdam, Netherlands.

PIII-35
IMPACT OF MICRORNAS/MRNAS ON CELLULAR RESPONSE TO THE CHEMOTHERAPEUTIC AGENT PEMETREXED.
Y. Wen, E. R. Gamazon, C. Wing, N. J. Cox, M. E. Dolan; University of Chicago, Chicago, IL.

PIII-36
BORTEZOMIB AND VESICULAR STOMATITIS VIRUS ARE ANTAGONISTIC IN MYELOMA.
D. N. Yarde, S. J. Russell; Mayo Clinic, Rochester, MN.



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POSTER SESSION III • MARCH 9

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Organ Specific Diseases (OSD)

PIII-37

A COMPARISON OF FREE VS TOTAL CIRCULATING 25-OH VITAMIN D LEVELS.

J. B. Schwartz,[1] L. Kane,[1] D. Bikle[2]; [1]Jewish Home/University of California, San Francisco, CA, [2]University of California, San Francisco, CA.

PIII-38

EFFECTS OF RENAL IMPAIRMENT ON LY2140023 AND LY404039 PHARMACOKINETICS.

J. Witcher,[1] A. J. Long,[1] M. E. Seger,[1] A. M. Wessels,[1] W. F. Annes,[1] M. Knadler,[1] T. C. Marbury,[2] M. Ayan-Oshodi[1]; [1]Eli Lilly and Company, Indianapolis, IN, [2]Orlando Clinical Research Center, Orlando, FL.

PIII-39

MODEL-BASED META-ANALYSIS IN RHEUMATOID ARTHRITIS: CORRELATIONS BETWEEN SHORT-TERM AND LONG-TERM TREATMENT EFFECTS.

Y. Wang,[1] R. Zhu,[1] J. Sun,[1] Z. Su,[1] J. C. Davis,[1] J. W. Mandema,[2] M. Tang,[1] J. D. Davis,[1] J. Jin,[1] J. Xiao[1]; [1]Genentech, South San Francisco, CA, [2]Quantitative Solutions, Menlo Park, CA.

PIII-40

MODEL-BASED META-ANALYSIS IN RHEUMATOID ARTHRITIS: CORRELATION OF DAS28 AND ACR50 TREATMENT EFFECTS.

R. Zhu,[1] Y. Wang,[1] J. Sun,[1] Z. Su,[1] J. C. Davis,[1] J. W. Mandema,[2] M. Tang,[1] J. D. Davis,[1] J. Jin,[1] J. Xiao[1]; [1]Genentech, South San Francisco, CA, [2]Quantitative Solutions, Menlo Park, CA.

Pharmacometrics and Pharmacokinetics (PMK)

PIII-41

POPULATION PK MODELING AND SIMULATIONS OF ALGALSIDASE ALFA TO SUPPORT DOSING RATIONALE IN CHILDREN AND ADULT PATIENTS WITH FABRY DISEASE.

L. H. Pheng,[1] N. H. Gosselin,[1] J. F. Marier,[1] T. G. McCauley,[2] M. A. Mascelli[2]; [1]Pharsight, Montreal, QC, Canada, [2]Shire Human Genetic Therapies, Lexington, MA.

PIII-42

SEMI-MECHANISTIC MODELING OF ALGALSIDASE ALFA AND GLOBOTRIAOSYLCERAMIDE IN PLASMA, A BIOMARKER OF EFFICACY IN CHILDREN AND ADULTS WITH FABRY DISEASE.

L. H. Pheng,[1] N. H. Gosselin,[1] J. F. Marier,[1] T. G. McCauley,[2] M. A. Mascelli[2]; [1]Pharsight, Montreal, QC, Canada, [2]Shire Human Genetic Therapies, Lexington, MA.

PIII-43

DEVELOPMENT OF SPARSE SAMPLING STRATEGIES DURING FIRST-IN-HUMAN ONCOLOGY STUDIES: A POTENTIAL APPROACH TO MINIMIZE CONFINEMENT AND FACILITATE ENROLLMENT OF CANCER PATIENTS.

N. H. Gosselin,[1] M. S. Mouksassi,[1] R. Bruno,[2] J. F. Marier[1]; [1]Pharsight, Montreal, QC, Canada, [2]Pharsight, Marseille, France.

PIII-44

MODULATION OF HEPATIC CYP2C AND CYP2E ACTIVITIES IN GUINEA PIG MODELS OF DIET-INDUCED METABOLIC SYNDROME.

S. Pilote, P. Mercier, D. Patoine, B. Drolet, C. Simard; Institut Universitaire de Cardiologie et de Pneumologie de Quebec, Quebec, QC, Canada.

PIII-45

EFFECT OF HEPATIC IMPAIRMENT ON BITOPERTIN PHARMACOKINETICS.

F. Pizzagalli,[1] C. Denot,[2] M. Homery,[2] Z. Kobalava,[3] M. Martin-Facklam[1]; [1]Hoffmann-La Roche Ltd., Basel, Switzerland, [2]Biotrial, Rennes, France, [3]Russian People's Friendship University, Moscow, Russian Federation.

PIII-46

FIXED DOSING VERSUS WEIGHT BASED DOSING FOR RN316 (PF-04950615) - A SIMULATION BASED EVALUATION.

V. S. Purohit, K. Sweeney, X. Gao; Pfizer, Groton, CT.

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PIII-47
ESTIMATION OF THE EFFECT OF FILIBUVIR (PF-00868554) ON S- AND R-METHADONE IN SUBJECTS RECEIVING CHRONIC METHADONE TREATMENT.
V. S. Purohit,[1] S. Srinivasan,[1] K. Matschke,[2] J. Hammond[2]; [1]Pfizer, Groton, CT, [2]Pfizer, Collegeville, PA.

PIII-48
PHARMACOKINETICS AND TOLERABILITY OF SINGLE AND MULTIPLE DOSES OF DESVENLAFAXINE IN HEALTHY KOREAN SUBJECTS.
R. Qiu,[1] Y. Liang,[1] S. Kim,[2] I. Jang,[2] W. Lee,[3] A. Plotka,[4] A. Nichols[4]; [1]Pfizer, Groton, CT, [2]Seoul National University College of Medicine and Hospital, Seoul, Korea, Democratic People's Republic of, [3]Pfizer, Seoul, Korea, Democratic People's Republic of, [4]Pfizer, Collegeville, PA.

PIII-49
PHARMACOKINETIC COMPARISON OF AN ORALLY SOLUBLE FILM FORMULATION WITH A FILM COATED TABLET FORMULATION OF SILDENAFIL IN HEALTHY KOREAN SUBJECTS: A RANDOMIZED, OPEN-LABEL, SINGLE DOSE, CROSS-OVER, 2 PART CLINICAL TRIAL.
H. Roh, H. Son, D. Lee, K. Park; Brain Korea 21 Project for Medical Science, Yonsei University, College of Medicine, Department of Pharmacology, Seoul, Republic of Korea.

PIII-50
POPULATION PHARMACOKINETICS OF LEVOFLOXACIN IN KOREAN PATIENTS WITH COMMUNITY ACQUIRED INFECTION.
S. Ryu,[1] Y. Lee,[2] Y. Kim,[3] H. Kim,[3] H. Jang,[3] Y. Joo,[3] K. Jin,[3] J. Shin,[1] S. Kim,[3] J. Ghim[2]; [1]Department of Pharmacology and PharmacoGenomics Research Center, Inje University College of Medicine, Busan, Republic of Korea, [2]Department of Clinical Pharmacology, Inje University Busan Paik Hospital, Busan, Republic of Korea, [3]Department of Internal Medicine, Inje University Haeundae Paik Hospital, Busan, Republic of Korea.

PIII-51
A PHARMACOKINETIC INTERACTION STUDY BETWEEN HSR-803 100 MG TABLETS AND RANITIDINE HYDROCHLORIDE 300 MG TABLETS IN HEALTHY MALE AND FEMALE VOLUNTEERS.
M. Rufiange, J. Massicotte, J. Morin, E. Sicard, M. Lefebvre; Algorithme Pharma Inc., Laval, QC, Canada.

PIII-52
PHARMACOKINETIC AND PHARMACODYNAMIC INTERACTIONS BETWEEN HSR-803 AND WARFARIN IN HEALTHY SUBJECTS.
M. Rufiange, J. Massicotte, E. Sicard, M. Lefebvre; Algorithme Pharma Inc., Laval, QC, Canada.

PIII-53
PHARMACOKINETICS OF LY2409021, A GLUCAGON RECEPTOR ANTAGONIST: METABOLISM, DISPOSITION AND EFFECT OF FOOD.
D. K. Satonin,[1] J. C. Chappell,[1] C. Lam,[2] C. N. Lim,[2] J. L. Ott,[1] J. Fayer Rehmel,[1] C. Kazda,[3] P. Garhyan[1]; [1]Eli Lilly and Company, Indianapolis, IN, [2]Eli Lilly and Company, Singapore, Singapore, [3]Eli Lilly and Company, Suresnes, France.

PIII-54
DEVELOPMENT AND APPLICATION OF A LITERATURE MODEL OF WEIGHT LOSS IN DIABETES AND OBESITY DRUG DEVELOPMENT.
K. B. Schneck, J. S. Geiser, H. Fu, D. H. Manner, B. A. Sheets, J. Y. Chien; Eli Lilly and Company, Indianapolis, IN.

PIII-55
NOVEL LC-MS/MS METHOD FOR SIMULTANEOUS ASSAY OF 20 ANTI-TUBERCULOSIS DRUGS IN HUMAN PLASMA AS A TOOL OF THERAPEUTIC DRUG MONITORING.
K. Seo, H. Kim, N. Abdalla, D. Kim, J. Shin; Department of Pharmacology and PharmacoGenomics Research Center, Inje University College of Medicine, Busan, Republic of Korea.

PIII-56
STEADY-STATE PHARMACOKINETIC PROPERTIES OF TAMSULOSIN IN HEALTHY MALE VOLUNTEERS.
S. Seong, J. Lee, M. Lim, S. Park, J. Park, J. Seo, H. Lee, Y. Yoon; Kyungpook National University Hospital Clinical Trial Center, Daegu, Republic of Korea.

PIII-57
POPULATION PHARMACOKINETICS OF ORAL SUMATRIPTAN IN HEALTHY KOREAN ADULTS.
S. Seong,[1] J. Lee,[1] S. Han,[2] S. Park,[1] J. Park,[1] J. Seo,[1] H. Lee,[1] M. Lim,[1] Y. Yoon[1]; [1]Kyungpook National University Hospital Clinical Trial Center, Daegu, Republic of Korea, [2]Department of Pharmacology, College of Medicine, the Catholic University, Seoul, Republic of Korea.

PIII-58
WITHDRAWN

PIII-59
VANCOMYCIN PHARMACOKINETICS IN PATIENTS WITH CONGESTIVE HEART FAILURE: LVEF AS COVARIATE FOR VANCOMYCIN CLEARANCE.
Y. Shimamoto,[1] T. Fukuda,[2] M. Dong,[2] K. Komori,[3] T. Kuwahara[1]; [1]National Cerebral and Cardiovascular Center, Osaka, Japan, [2]Cincinnati Children's Hospital Medical Center, Cincinnati, OH, [3]National Hospital Organization Osaka National Hospital, Osaka, Japan.

PIII-60
ADDITIVE PHARMACODYNAMIC EFFECT WITHOUT PHARMACOKINETIC INTERACTION BETWEEN GEMIGLIPTIN, A NOVEL DPP-IV INHIBITOR AND METFORMIN IN HEALTHY VOLUNTEERS.
D. Shin,[1] S. Lee,[1] K. Lim,[1] I. Jang,[1] S. Shin,[1] J. Ahn,[2] J. Kim,[2] K. Yu[1]; [1]Department of Clinical Pharmacology and Therapeutics, Seoul National University College of Medicine and Hospital, Seoul, Republic of Korea, [2]LG Life Sciences, Seoul, Republic of Korea.

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PIII-61

MACITENTAN, A NOVEL DUAL ENDOTHELIN RECEPTOR ANTAGONIST, DOES NOT PROLONG THE QT/QTC INTERVAL IN A THOROUGH QTC STUDY IN HEALTHY SUBJECTS.

P. N. Sidharta,[1] N. Lindegger,[1] K. Reseski,[2] J. Dingemanse[1]; [1]Actelion Pharmaceuticals Ltd, Allschwil, Switzerland, [2]PAREXEL International GmbH, Berlin, Germany.

PIII-62

VALIDATION OF LIMITED SAMPLING STRATEGIES FOR ESTIMATION OF TACROLIMUS AUC IN PEDIATRIC HEART TRANSPLANT RECIPIENTS.

L. Sid-Otmane,[1] C. Antczak,[2] N. Kassir,[3] M. Raboisson,[2] A. Lapeyraque,[4] Y. Théorêt,[5] C. Litalien[6]; [1]Research Center, Centre Hospitalier Universitaire Sainte-Justine, Montreal, QC, Canada, [2]Division of Cardiology, Department of Paediatrics, Centre Hospitalier Universitaire Sainte-Justine, Montreal, QC, Canada, [3]Pharsight, Clinical Pharmacology Unit, Centre Hospitalier Universitaire Sainte-Justine, Montreal, QC, Canada, [4]Division of Nephrology, Department of Paediatrics, Clinical Pharmacology Unit, Centre Hospitalier Universitaire Sainte-Justine, Montreal, QC, Canada, [5]Clinical Pharmacology Unit, Centre Hospitalier Universitaire Sainte-Justine, Montreal, QC, Canada, [6]Division of Paediatric Critical Care, Department of Paediatrics, Clinical Pharmacology Unit, Centre Hospitalier Universitaire Sainte-Justine, Montreal, QC, Canada.

PIII-63

QUANTITATIVE PREDICTION OF HUMAN PHARMACOKINETICS FOR MABS EXHIBITING TARGET-MEDIATED DISPOSITION: A 7 MABS META-ANALYSIS.

A. Singh,[1] W. Krzyzanski,[1] A. Zutshi,[2] P. Singh[2]; [1]School of Pharmacy and Pharmaceutical Sciences, Buffalo, NY, [2]Pfizer, Department of Pharmacokinetics, Pharmacodynamics and Metabolism, Cambridge, MA.

PIII-64

DEVELOPMENT OF AN INTERACTION MODEL FOR CO-ADMINISTRATION OF ROSUVASTATIN AND METFORMIN IN HEALTHY MALE KOREANS.

H. Son, D. Lee, K. Park; College of Medicine, Yonsei University, Seoul, Republic of Korea.

PIII-65

INFLUENCE OF ROSUVASTATIN ON THE BLOOD PRESSURE LOWERING EFFECT OF OLMESARTAN IN HEALTHY MALE KOREANS.

M. Son, H. Roh, H. Son, D. Lee, S. Cho, K. Park; Yonsei University, College of Medicine, Seoul, Republic of Korea.

PIII-66

PRELIMINARY DEVELOPMENT OF DISEASE PROGRESSION MODEL FOR HUNTINGTON'S DISEASE.

W. Sun,[1] G. Hochhaus,[1] Y. Wang[2]; [1]Department of Pharmaceutics, University of Florida, Gainesville, FL, [2]Office of Clinical Pharmacology, US Food and Drug Administration, Silver Spring, MD.

PIII-67

MILK THISTLE HERB-DRUG INTERACTION STUDY: NO EFFECT ON CYP3A, CYP2C9, AND CYP2D6 ACTIVITIES IN HEALTHY PARTICIPANTS.

M. Suzuki-Kawaguchi, R. F. Frye, J. S. Markowitz; University of Florida, Gainesville, FL.

*Presenting author is in **bold**.*

PIII-68

A SINGLE DOSE BIOCOMPARISON STUDY TO ASSESS TWO PEDIATRIC FORMULATIONS OF RIDAFOROLIMUS (RIDA) TO THE PROVISIONAL MARKET FORMULATION IN HEALTHY SUBJECTS.

J. E. Talaty,[1] N. Cardillo Marricco,[2] C. Brandquist,[3] A. Zandvliet,[4] B. DeGroot,[3] D. Panebianco,[5] S. P. Youngberg,[3] R. Iannone[5]; [1]Merck & Co., Inc., West Point, PA, [2]Celerion, Montreal, QC, Canada, [3]Celerion, Lincoln, NE, [4]Merck & Co., Inc., Oss, Netherlands, [5]Merck & Co., Inc., Upper Gwynedd, PA.

PIII-69

LACK OF PHARMACOKINETIC (PK) EFFECT OF PRELADENANT AS A PERPETRATOR OF PROBE DRUG-DRUG INTERACTIONS.

J. Udo de Haes, P. A. Kothare, F. Xuan, B. Kumar, I. Triantafyllou, Z. Wang, D. Rindgen, A. Ghosal, A. Moton, J. Seraj, M. Troyer; Merck, Whitehouse Station, NJ.

PIII-70

EFFECTS OF CYP3A4 PERPETRATORS ON THE PHARMACOKINETICS (PK) OF PRELADENANT, AN INVESTIGATIONAL ADENOSINE$_{2A}$ RECEPTOR ANTAGONIST FOR THE TREATMENT OF PARKINSON'S DISEASE.

J. Udo de Haes, P. A. Kothare, F. Xuan, B. Kumar, I. Triantafyllou, Z. Wang, D. Rindgen, A. Ghosal, G. Sedek, A. Moton, J. Seraj, M. Troyer; Merck, Whitehouse Station, NJ.

PIII-71

THE DRUG-DRUG INTERACTION MODEL-BASED PREDICTION ERROR RATES ON CUTOFF CRITERIA TO CONDUCT A CLINICAL STUDY.

T. H. Waterhouse, R. E. Higgs, S. D. Hall, J. Y. Chien, Food and Drug Administration/IQ DDI Working Group; Eli Lilly and Company, Indianapolis, IN.

PIII-72

TERIFLUNOMIDE: POTENTIAL FOR TRANSPORTER MEDIATED DRUG-DRUG INTERACTIONS.

D. Weitz,[1] W. Schmider,[1] F. Menguy-Vacheron,[2] P. Clot,[2] S. Hermabessiere,[3] J. Jiang,[4] Y. Su,[4] V. Thuillier,[2] S. Turpault[4]; [1]Sanofi, Frankfurt am Main, Germany, [2]Sanofi, Chilly-Mazarin, France, [3]Sanofi, Montpellier, France, [4]Sanofi, Bridgewater, NJ.

PIII-73

DRUG-DRUG INTERACTION ASSESSMENT OF TREBANANIB (AMG 386).

B. Wu, R. Melara, T. Wong, C. Kitahara, Y. Sun; Amgen Inc., Thousand Oaks, CA.

PIII-74

ENHANCED DASATINIB ABSORPTION IN HEALTHY VOLUNTEERS WITH PHARMACOLOGICALLY-INDUCED HYPOCHLORHYDRIA USING BETAINE HCL.

M. R. Yago,[1] A. Frymoyer,[2] L. Z. Benet,[1] G. S. Smelick,[3] L. Frassetto,[1] X. Ding,[3] B. Dean,[3] L. Salphati,[3] N. Budha,[3] J. Y. Jin,[3] M. J. Dresser,[3] J. A. Ware[3]; [1]University of California, San Francisco, San Francisco, CA, [2]Stanford University, Stanford, CA, [3]Genentech, South San Francisco, CA.

POSTER SESSION III • MARCH 9

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PIII-75
EFFECT OF MULTIPLE DOSES OF ISAVUCONAZOLE ON THE PHARMACOKINETICS OF SIROLIMUS IN HEALTHY SUBJECTS.
T. Yamazaki, N. Zadeikis, H. Pearlman, A. Desai, D. Kowalski, R. Townsend; Astellas Pharma Global Development, Inc., Northbrook, IL.

PIII-76
EFFECT OF MULTIPLE DOSES OF ISAVUCONAZOLE ON THE PHARMACOKINETICS OF CYP3A4 SUBSTRATE CYCLOSPORINE IN HEALTHY SUBJECTS.
T. Yamazaki, N. Zadeikis, H. Pearlman, A. Desai, D. Kowalski, R. Townsend; Astellas Pharma Global Development, Inc., Northbrook, IL.

PIII-77
BLOOD CONCENTRATION MONITORING OF EVEROLIMUS IN JAPANESE PATIENTS WITH RENAL CELL CARCINOMA.
I. Yano,[1] A. Tanaka,[1] K. Shinsako,[2] E. Sato,[2] M. Fukudo,[2] S. Masuda,[2] K. Matsubara,[2] T. Kamba,[3] T. Yamasaki,[3] O. Ogawa[3]; [1]Kyoto University Graduate School of Pharmaceutical Sciences, Kyoto, Japan, [2]Department of Pharmacy, Kyoto University Hospital, Kyoto, Japan, [3]Kyoto University Graduate School of Medicine, Kyoto, Japan.

PIII-78
PHARMACOKINETIC AND SAFETY EVALUATION OF TWO DIFFERENT FORMULATIONS OF MEGESTROL ACETATE IN HEALTHY VOLUNTEERS UNDER FASTING AND FED CONDITIONS.
S. Yoon,[1] D. Shin,[1] S. Kim,[1] J. Cho,[1] S. Yoon,[1] K. Yu,[1] J. Chung[2]; [1]Seoul National University College of Medicine and Hospital, Seoul, Republic of Korea, [2]Seoul National University Bundang Hospital, Seongnam, Republic of Korea.

PIII-79
PARAMETER OPTIMIZATION IN PHYSIOLOGICALLY-BASED PHARMACOKINETIC (PBPK) MODEL FOR THE PREDICTION OF TRANSPORTER-MEDIATED DRUG-DRUG INTERACTIONS WITH A NEW GLOBAL PARAMETER OPTIMIZATION METHOD.
K. Yoshida,[1] K. Maeda,[1] H. Kusuhara,[1] A. Konagaya,[2] Y. Sugiyama[3]; [1]The University of Tokyo, Tokyo, Japan, [2]Tokyo Institute of Technology, Yokohama, Japan, [3]RIKEN Research Cluster for Innovation, Yokohama, Japan.

PIII-80
WITHDRAWN

PIII-81
STOCHASTIC PREDICTION OF DESIPRAMINE DISPOSITION IN RESPONSE TO CYP2D6 MODULATION BY DRUG INTERACTIONS AND GENETIC VARIATION.
X. Zhang, Y. Guo-Avrutin, J. Baker, B. Ring, S. Hall; Eli Lilly and Company, Indianapolis, IN.

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STOCHASTIC PREDICTION AND EARLY CLINICAL ASSESSMENT OF CYP3A-MEDIATED DRUG-DRUG INTERACTIONS FOR A NOVEL AGLUCOKINASE ACTIVATOR LY2608204.
X. Zhang, J. Chien, C. Tang, N. Yumibe, J. Bue-Valleskey, K. Yeo, S. Lim, R. Kelly; Eli Lilly and Company, Indianapolis, IN.

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APPLYING THE LEARN-APPLY-CONFIRM PARADIGM TO CLINICAL DEVELOPMENT OF A NOVEL ORAL GLUCOKINASE ACTIVATOR WITH A SEMI-MECHANISTIC GLUCOSE-INSULIN-GLUCAGON MODEL.
X. Zhang, K. Schneck, C. Tang, R. Kelly, J. Bue-Valleskey, K. Yeo, D. Barrett, V. Sinha; Eli Lilly and Company, Indianapolis, IN.

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PREDICTION OF *IN VIVO* HEMODIALYSIS CLEARANCE OF EDOXABAN FROM *IN VITRO* DIALYSIS DATA.
Y. Yoshigae, N. Nakai, N. Murayama, T. Izumi; Drug metabolism and Pharmacokinetics Research Labs., Daiichi-Sankyo Co Ltd., Tokyo, Japan.

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IN VITRO INHIBITION OF PHENYLEPHRINE (PE) SULFATION BY PHENOLIC DIETARY COMPOUNDS.
Z. Zhang, P. M. Gerk; Virginia Commonwealth University, Richmond, VA.

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POPULATION PHARMACOKINETIC MODELING AND SIMULATION OF TG02 CITRATE FROM PHASE I CLINICAL TRIAL ON ACUTE MYELOID LEUKEMIA AND MULTIPLE MYELOMA PATIENTS.
Y. Zhao,[1] T. Parrott,[2] M. Syto,[2] F. J. Burrows,[2] R. Mansfield,[2] M. A. Phelps[1]; [1]Ohio State University, Columbus, OH, [2]Tragara Pharmaceuticals, San Diego, CA.

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POPULATION PHARMACOKINETICS OF AZITHROMYCIN AND CHLOROQUINE IN HEALTHY ADULTS AND PEDIATRIC MALARIA SUBJECTS FOLLOWING ORAL ADMINISTRATION OF AZITHROMYCIN AND CHLOROQUINE TABLETS.
Q. Zhao,[1] T. G. Tensfeldt,[1] R. Chandra,[1] D. Mould[2]; [1]Pfizer, Groton, CT, [2]Projections Research Inc., Phoenixville, PA.

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MECHANISTIC ASSESSMENT OF ANTI-DIABETIC DRUG EFFECTS FROM ORAL GLUCOSE TOLERANCE TEST USING INTEGRATED GLUCOSE-INSULIN MODELING: A SIMULATION-ESTIMATION APPROACH.
X. Zhao,[1] W. Gao,[2] J. Q. Dong,[2] G. Nucci[3]; [1]University at Buffalo, SUNY, Buffalo, NY, [2]WRD, Pfizer, Groton, CT, [3]WRD, Pfizer, Cambridge, MA.

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POPULATION PHARMACOKINETIC AND PHARMACODYNAMIC MODELING OF QUILIZUMAB, AN ANTI-M1 PRIME MONOCLONAL ANTIBODY, AND ITS EFFECT ON IGE REDUCTION IN TWO PHASE I STUDIES.
Y. Zheng, H. Scheerens, R. Zhu, Y. Wang, J. Harris, W. Putnam; Genentech, South San Francisco, CA.

Presenting author is in ***bold.***

POSTER SESSION III • MARCH 9

Griffin Hall • 7:00 am – 11:00 am • Attended Posters 7:00 am – 8:00 am

Special Populations (SPO)

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COMPARISON OF POPULATION PHARMACOKINETIC AND PHYSIOLOGIC BASED PHARMACOKINETIC MODELS FOR VINCRISTINE IN PEDIATRIC ACUTE LYMPHOBLASTIC LEUKEMIA.

S. K. Quinney,[1] C. Chiang,[1] C. H. Li,[1] L. Li,[1] R. R. Bies,[1] A. Egbelakin,[1] R. Ho,[2] R. Hutchinson,[3] E. L. Smith,[3] E. Wells,[4] J. L. Renbarger[1]; [1]Indiana University School of Medicine, Indianapolis, IN, [2]Vanderbilt University, Nashville, TN, [3]University of Michigan, Ann Arbor, MI, [4]Children's National Medical Center, Washington, DC.

PIII-91

APPLICATION OF PHYSIOLOGICALLY BASED PHARMACOKINETIC (PBPK) MODELING FOR PREDICTION OF THE DRUG-DRUG INTERACTION (DDI) BETWEEN PAROXETINE AND TERBINAFINE IN A JAPANESE POPULATION.

K. Rowland Yeo,[1] Z. Barter,[1] L. Almond,[1] A. Rostami-Hodjegan[2]; [1]Simcyp Ltd, Sheffield, United Kingdom, [2]Centre for Applied Pharmacokinetic Research, The School of Pharmacy and Pharmaceutical Sciences, The University of Manchester, Manchester, United Kingdom.

PIII-92

THE ROLE OF SOCIAL MEDIA IN RECRUITING FOR CLINICAL TRIALS IN PREGNANCY.

M. Shere, G. Koren; Hospital for Sick Children, Toronto, ON, Canada.

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DEVELOPMENT OF APIXABAN ORAL SOLUTION FORMULATION: EXCIPIENTS AND PALATABILITY.

Y. Song,[1] J. H. Worthington,[2] X. Wang,[1] D. Quamina-Edghill,[1] A. Elsrougy,[1] S. I. Badawy,[3] C. Frost[1]; [1]Bristol-Myers Squibb, Princeton, NJ, [2]Senopsys LLC, Woburn, MA, [3]Bristol-Myers Squibb, New Brunswick, NJ.

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BIOAVAILABILITY OF APIXABAN SOLUTION FORMULATION AND CRUSHED TABLET VIA NASOGASTRIC TUBE.

Y. Song,[1] X. Wang,[1] I. Perlstein,[1] J. Wang,[1] S. I. Badawy,[2] J. Pursley,[1] C. Frost[1]; [1]Bristol-Myers Squibb, Princeton, NJ, [2]Bristol-Myers Squibb, New Brunswick, NJ.

PIII-95

ADVERSE DRUG REACTIONS OF HALOPERIDOL USED IN CRITICALLY ILL CHILDREN FOR THE TREATMENT OF DELIRIUM.

E. Spaans,[1] V. Slooff,[1] E. van Puijenbroek,[2] N. Jessurun,[1] M. de Hoog,[1] D. Tibboel,[1] S. de Wildt[1]; [1]ErasmusMC Sophia Children's Hospital, Rotterdam, Netherlands, [2]Dutch Pharmacovigilance, Den Bosch, Netherlands.

PIII-96

THE STRUGGLE FOR OPTIMAL SEDATION IN PEDIATRIC INTENSIVE CARE PATIENTS: A SYSTEMATIC REVIEW.

N. J. Vet, E. Ista, S. N. de Wildt, M. van Dijk, D. Tibboel, M. de Hoog; Erasmus MC - Sophia Children's Hospital, Rotterdam, Netherlands.

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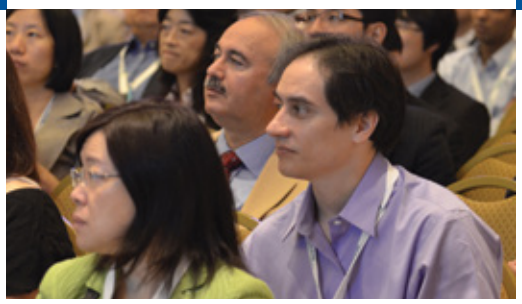
PHARMACOKINETICS OF FENTANYL IN MORBIDLY OBESE ADOLESCENT PATIENTS.

V. C. Ziesenitz,[1] J. D. Vaughns,[2] E. F. Williams,[3] A. Mushtaq,[3] R. Jantos,[4] G. Skopp,[4] G. Mikus,[5] J. N. van den Anker[3]; [1]Center for Translational Science, Children's National Medical Center, Washington, DC, United States and Department of Clinical Pharmacology and Pharmacoepidemiology, University of Heidelberg, Heidelberg, Germany, [2]Department of Anesthesia and Pain Medicine, Children's National Medical Center, Washington, DC, [3]Center for Translational Science, Children's National Medical Center, Washington, DC, [4]Institute of Legal and Traffic Medicine, University of Heidelberg, Heidelberg, Germany, [5]Department of Clinical Pharmacology and Pharmacoepidemiology, University of Heidelberg, Heidelberg, Germany.



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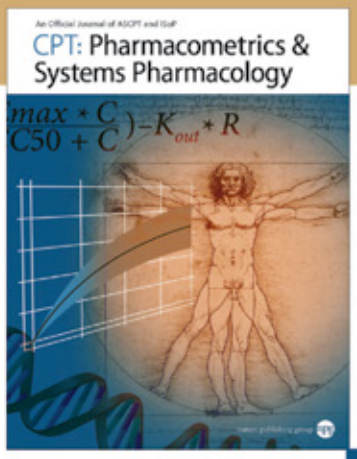

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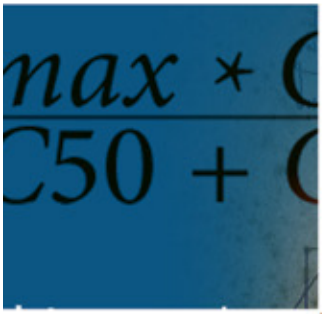

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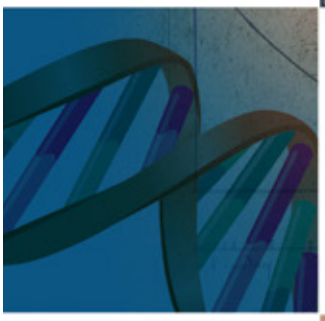

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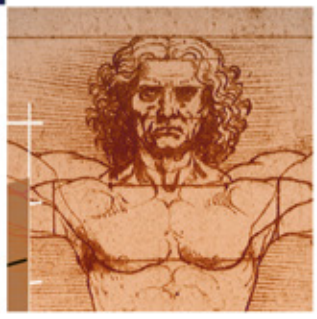

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LATE BREAKING POSTER SESSION I • MARCH 7

Griffin Hall • 8:00 am – 3:00 pm • Attended Posters 8:00 am – 9:30 am

LBI-1

NEONATAL POPULATION PHARMACOKINETICS AND PHARMACODYNAMICS MODELING OF VANCOMYCIN TO SIMULATE TARGET EXPOSURE ATTAINMENT.

J. Bhongsatiern, C. Stockmann, T. Yu, M. G. Spigarelli, C. M. Sherwin; University of Utah, Salt Lake City, UT.

BACKGROUND

Vancomycin is bactericidal against gram-positive organisms, including coagulase (+) and coagulase (-) Staphylococci. Several professional societies have recommended a ratio of area under the curve to minimum inhibitory concentration (AUC:MIC) >400, which has been associated with optimal adult outcomes. The objectives of this neonatal study were: 1) to construct a population PK/PD model for vancomycin serum concentrations and 2) to simulate the proportion who achieved an AUC:MIC >400.

METHODS

Population PK/PD modeling using NONMEM was conducted. Neonatal data (1 vancomycin serum concentration(s) from 2006-2011 were obtained from electronic medical records. These data were not complete before October 1, 2012.

RESULTS

A one compartment, first order elimination model evaluated 1081 vancomycin concentrations from 222 neonates. Estimated CL was 0.107 L/hr/kg and Vd was 1.10 L/kg. Coagulase (+) Staphylococci MIC values ranged from 0.5-2 mg/L and coagulase (-) Staphylococci MIC values ranged from 0.5-4 mg/L. Doses of 40 and 60 mg/kg/day infrequently achieved the AUC:MIC target of >400.

CONCLUSION

Conventional neonatal vancomycin dosing regimens infrequently achieve an adult PK/PD target associated with optimal bactericidal activity. Further research is needed to evaluate the clinical efficacy of this target in neonates.

Organism	Predicted % of Neonates with an AUC:MIC >400	
	40 mg/kg/day	60 mg/kg/day
Coagulase (+) Staphylococci	23.4%	36.2%
Coagulase (-) Staphylococci	2.2%	26.4%

LBI-2

MOLECULAR TARGET ANALYSIS OF DRUGS ASSOCIATED WITH STEVENS JOHNSON SYNDROME.

K. Burkhart,[1] D. Abernethy,[1] D. B. Jackson[2]; [1]US Food and Drug Administration, Silver Spring, MD, [2]Molecular Health GmbH, Heidelberg, Germany.

BACKGROUND

Stevens Johnson Syndrome (SJS) is a life threatening adverse event (AE) that is rarely seen in clinical trials, but is a common safety issue analyzed in the post-approval setting. This research analyzed biologic plausibility for the evaluation of SJS cases.

METHODS

MASE (Molecular Analysis of Side Effects) integrates the publicly available FAERS data with associated molecular information in a drug-centric manner. Proportional Reporting Ratios (PRR; PMID: 11998548) are calculated to determine the protein targets most highly associated with the drugs reported in SJS FAERS cases. The biological plausibility of an SJS association should be increased if a drug shares protein targets with other drugs known to cause SJS. The interaction with protein targets may serve as a surrogate for similarities in structure activity relationships common to the pathophysiology of SJS. MASE is used under a Research Collaboration Agreement. The analysis is ongoing and was last updated on November 2, 2102.

RESULTS

6473 SJS AE reports were analyzed. The top 5 drugs (PRR, N) were valdecoxib (39.2, 1553), zonisamide (11.1, 80), lamotrigine (10.0, 784), metamizole (8.7, 62), and phenytoin (8.1, 305). The most common targets by (frequency, PRR) were COX1 (3211, 2.0), COX2 (2644, 2.4), and carbonic anhydrase 2 (2016, 4.9), which are known to modulate the immune response. The most commonly associated metabolizing enzymes were CYP 3A4 (4709, 1.34) and CYP 2C9 (4371, 1.66) and the clearance related enzyme UGT1A1 (2370, 6.2). Drug transporters with high frequency/PRR scores were MRP1 (3638, 1.13), OAT1 (1467, 1.35) and PEPT2 (716, 2.11). Drug transporters determine intracellular concentrations and facilitate physiologic processes.

CONCLUSION

Data mining FAERS assists biological plausibility analyses related to a drug's association with an AE such as SJS. Hypotheses addressing the pathophysiologic mechanisms are developed for further study.

*Presenting author is in **bold**.*

LATE BREAKING POSTER SESSION I • MARCH 7

Griffin Hall • 8:00 am – 3:00 pm • Attended Posters 8:00 am – 9:30 am

LBI-3

HAIR CORTISOL IN PATIENTS WITH SYSTOLIC CONGESTIVE HEART FAILURE.

D. Pereg,[1] **J. Chan,[2]** E. Russell,[2] T. Berlin,[1] M. Mosseri,[1] J. Seabrook,[2] S. Van Uum,[2] G. Koren[3]; [1]Mier Medical Center, Tel-Aviv University, Tel-Aviv, Israel, [2]Western University, London, ON, Canada, [3]Hospital for Sick Children, Toronto, ON, Canada.

BACKGROUND

Activation of the hypothalamic-pituitary-adrenal axis and subsequent secretion of glucocorticoids including cortisol from the adrenal cortex is associated with the progression of chronic congestive heart failure (CHF). A previous study demonstrated that higher serum cortisol levels were independent predictors of increased mortality. However, serum cortisol reflects acute cortisol secretion and does not provide historical information. Since CHF is a chronic condition, the measurement of cortisol in scalp hair is a superior matrix for assessment and risk stratification of CHF patients. The aim was to evaluate whether hair cortisol levels correlate with heart failure severity and prognosis in ambulatory patients with stable chronic systolic heart failure. The primary endpoints included the correlation of hair cortisol levels with the New York Heart Association (NYHA) class, left ventricular ejection fraction LVEF, exercise capacity as measured by a treadmill exercise test and serum levels of NT-proBNP. Secondary endpoints included all-cause mortality and CHF-related hospitalizations at 1 year.

METHODS

This prospective observational study included 44 male patients above the age of 18 years with at least moderately reduced left ventricular systolic function defined as left ventricular ejection fraction (LVEF) ≤ 40%. Hair samples of at least 2 cm in length were taken from the posterior vertex as close to the scalp as possible. Hair cortisol concentrations were analyzed by enzyme-linked immunoassay (Alpco Diagnostics, USA) on October 2 and 4, 2012.

RESULTS

There was a positive correlation between hair cortisol concentrations and the NYHA functional classification ($r = 0.482$, $p < 0.01$). Median hair cortisol concentrations in NYHA class 1, 2, and 3 heart failure patients were 183.61 (137.51 - 1277.39 ng/g) and 278.60 (117.28 - 1224.49 ng/g), respectively. A negative correlation between hair cortisol concentrations and treadmill stress test results was also observed ($r = -0.365$, $p < 0.05$). CHF-related hospitalizations at 1 year trended toward higher hair cortisol levels ($p = 0.078$).

CONCLUSION

Our results suggest that higher hair cortisol levels correlate with the clinical severity of CHF as assessed by the NYHA score and treadmill exercise capacity. Therefore, measurement of hair cortisol may be useful as a quantitative mode for clinical follow-up of CHF patients. It is possible that CHF patients with high hair cortisol levels may benefit from a more intensive assessment and treatment of the existing conventional cardiovascular risk factors, since cortisol is known to adversely affect risk factors including hypertension and insulin resistance. Hair cortisol concentrations may be used as a biological marker to identify high risk patients and serve as an impetus for more aggressive treatment of other modifiable risk factors.

LBI-4

A PHASE I DOSE ESCALATION AND MOLECULAR PHARMACODYNAMIC STUDY OF CONJUGATED LINOLEIC ACID (CLA; CLARINOL®) IN PATIENTS WITH ADVANCED SOLID TUMORS.

S. A. Coker,[1] L. D. Lewis,[2] W. B. Kinlaw III,[3] R. P. Perez[4]; [1]Section of Clinical Pharmacology, Department of Medicine, The Geisel School of Medicine at Dartmouth and the Dartmouth-Hitchcock Medical Center, Lebanon, NH, [2]Sections of Clinical Pharmacology and Hematology/Oncology, Department of Medicine, The Geisel School of Medicine at Dartmouth, The Norris Cotton Cancer Center and the Dartmouth-Hitchcock Medical Center, Lebanon, NH, [3]Section of Endocrinology, Department of Medicine, The Geisel School of Medicine at Dartmouth and the Dartmouth-Hitchcock Medical Center, Lebanon, NH, [4]Section of Hematology/Oncology, Department of Medicine, The Geisel School of Medicine at Dartmouth and The Norris Cotton Cancer Center, Lebanon, NH.

BACKGROUND

Conjugated linoleic acid (CLA), a fatty acid present in foods derived from ruminant animals, has anti-proliferative activity against breast and liposarcoma cell lines *in vitro* with concomitant suppression of S14 protein. S14 is critical for the induction of key enzymes involved in the switching of cellular metabolism from the fasted to the fed state. The primary objective of this study was to define a tolerable daily, oral dose of CLA that maximally inhibited S14 expression in adipocytes of patients with advanced solid tumors.

METHODS

This was an open-label accelerated dose-escalation study of CLA in patients with advanced, refractory malignancies. Once daily, oral CLA was administered, with tumor biopsies pretreatment on D1 & D15. PK samples for CLA were obtained on days 1, 8 and 15. Toxicities were graded using the NCI CTCAE (v3.0). Cohort expansion to a 3+3 design was intended when either S14 mRNA reduction plateaued or any Grade II toxicity was observed. The effects of CLA on adipose tissue mRNA for lipogenic S14 transcripts was quantified using RT-PCR. Data were fully analyzed on or after December 4, 2012.

RESULTS

Four Caucasian patients (3M, 1F) median age 69 (range 68-71) years were enrolled; 2 had colorectal cancer, 1 melanoma and 1 breast cancer. CLA capsules contained a combined total of 750 mg of the 9t-11c and 10c-12t CLA isomers. We dose escalated CLA from 7.5g /day to 15.75 g/day without observing any toxicities ≥ grade 2. On Day 1 the median CLA T_{max} was 6 h (range 4-10), median C_{max} was 3.2mg/L (range 2.5-4.9) for the 10c-12t isomer and median T_{max} was 6 h (range 4-6) and median C_{max} was 4.1mg/L (range 3.7-5.9) for the 9t-12c isomer. CLA isomer concentrations, 2h post ingestion on days 8 and 15 were consistent with those on day 1. RT-PCR of S14 in adipose tissue in 3 of the 4 patients did not reveal consistent changes on D15 compared to pretreatment baseline. All patients completed 2 months of CLA treatment, but all had progressive disease.

CONCLUSION

In this study the MTD for CLA was 21 capsules (15.75 g/day) because patients complained that ingesting this many capsules was onerous, so further dose escalation could not be pursued. Alternative CLA formulations are necessary to continue this line of study. (Support: NIH- R21CA131820).

*Presenting author is in **bold**.*

LATE BREAKING POSTER SESSION I • MARCH 7

Griffin Hall • 8:00 am – 3:00 pm • Attended Posters 8:00 am – 9:30 am

LBI-5

DOSING OF VANCOMYCIN IN NEONATES: ON TARGET FOR THE THERAPEUTIC RANGE?

J. E. Constance, S. C. Campbell, M. W. Linakis, C. M. Sherwin, M. G. Spigarelli; University of Utah, Salt Lake City, UT.

BACKGROUND

Achieving therapeutic vancomycin concentrations in neonates is an ongoing challenge. Initial dosage is primarily based on weight but can also include consideration of gestational age. Therapeutic drug monitoring limits the potential for toxicity, treatment failure, and the development of bacterial resistance. This study examined the frequency of achieving an appropriate therapeutic trough concentration based upon the initial dosage.

METHODS

A multicenter retrospective study of 626 neonates, birth weight >1500g (0-27 days) who received vancomycin between 01/2006 and 09/2011 was performed using a large electronic health database. For each patient, the first vancomycin trough level was used to determine whether vancomycin blood concentrations fell into the therapeutic range (defined as 10-20 µg/mL). Neonates without evaluable vancomycin trough levels, or renal impairment were excluded from analysis. Weights were converted to z-scores using Epi Info 7, which was limited to infants with a birth weight >1500 g, and statistical analysis was performed in Prism 6 (Graphpad). These data were not complete before December 5, 2012.

RESULTS

Evaluable trough and creatinine levels were available for 402 patients (64% male). 185 patients (46%) had a trough concentration outside therapeutic range, 32% (n=127) below 10 µg/mL, and 14% (n=58) above 20 µg/mL. There was no statistical difference between males and females by age, number of vancomycin doses given, weight, or trough levels. However, the dose of vancomycin administered was higher for males with a median of 47.0 mg/dose (95% confidence interval (CI), 38.0-60.0) than females with 45.0 mg/dose (95% CI,35.0-53.0); p <0.02.

CONCLUSION

This study demonstrates that the standard dosing regimens for vancomycin in neonates results in trough levels outside of therapeutic range nearly half of the time. These results highlight the need for more effective strategies in vancomycin dosing in neonates.

LBI-6

ADOLESCENTS AT RISK: IDENTIFYING BIOMARKERS OF METABOLIC DYSFUNCTION IN OBESITY.

J. E. Constance, J. Skidmore, C. Tak, M. Spigarelli, M. N. Nanjee, N. Mihalopoulos; University of Utah, Salt Lake City, UT.

BACKGROUND

Identifying adolescents with obesity that are the most likely to develop diabetes and cardiovascular disease (CVD) is an urgent, unmet need. Off-label use of pharmaceutical agents, in addition to lifestyle modification are often used with metabolic dysfunction. This study was designed to identify biomarkers in adolescents with obesity associated with a 'high risk' (HR) waist circumference to height ratio (WHtR; HR>0.54) and increased risk for developing diabetes and CVD.

METHODS

Obese (BMI>95th percentile) adolescents (n=122) with a sexual maturity rating (SMR) between 1-4 (n=98, 45% male) were enrolled from 7/2010 - 9/2012. Height, weight, waist, blood pressure (BP), SMR and fasting venous blood samples were collected. Plasma was assayed for lipids (total and HDL cholesterol, triglycerides), adipokines (adiponectin, leptin), and insulin. BMI and BP were converted to Z-scores. Metabolic dysfunction criteria were estimated according to Cook *et al.* Multivariate logistic regression and OR analysis were performed in R.

RESULTS

Median: age 12.8 yrs, BMI 28.0 kg/m2; 29 were SMR 1 (median age 11.45), 24 were classified as HR. Among those with SMR 2-4 (median age 14.0), 62 were classified as HR. The only sex specific difference between SMR1 & SMR2-4 was weight. HR Pre-pubescent subjects, compared to their MH counterparts, had significantly ↑ BMI, trigs, leptin, L/A ratio and insulin, & ↓HDL and adiponectin. The HR pubescent group differed from MH for trigs & HDL. WHtR >0.54, controlled for age, was independently associated with ↑ L/A ratio (OR, 2.11; confidence interval (CI), 1.18-4.41), triglycerides (OR, 1.05; 1.02-1.09) & ↓adiponectin (OR, 1.88; 1.09-3.78). HR groups were more likely to have multiple metabolic dysfunctions (OR, 2.95; 1.25-8.61).

CONCLUSION

Heterogeneity in obesity leads to a divergence between the metabolically healthy and the diseased. WHtR combined with blood biomarkers may be of benefit in identifying younger adolescents at higher risk of progressing to diabetes or CVD who may benefit from early treatment with medication.

*Presenting author is in **bold**.*

LBI-7

PHARMACODYNAMIC MODELING OF CELL CYCLE EFFECTS OF CYTARABINE AND FLT3 INHIBITORS ON ACUTE MYELOID LEUKEMIA CELLS.

M. A. Elmeliegy,[1] J. Den Haese,[2] C. Talati,[3] W. J. Jusko,[1] M. Wetzler[3]; [1]Department of Pharmaceutical Sciences, School of Pharmacy and Pharmaceutical Sciences, State University of New York at Buffalo, Buffalo, NY, [2]Department of Medicine, Roswell Park Cancer Institute, Leukemia Section, D'Youville College, Department of Math and Natural Sciences, Buffalo, New York, USA, Buffalo, NY, [3]Department of Medicine, Roswell Park Cancer Institute, Leukemia Section, Buffalo, NY.

BACKGROUND

Acute myeloid leukemia (AML) patients with FLT3 mutations have poor response to cytarabine. Combining cytarabine with FLT3 inhibitors may improve outcome. Administration sequence of cytarabine and FLT3 inhibitors is thought to be important for synergism. Our goal was to provide a quantitative framework to characterize effects of cytarabine and FLT3 inhibitors on cell proliferation and cell cycle distribution.

METHODS

AML cell lines were exposed to varying concentrations of cytarabine and FLT3 inhibitors (AC220, PKC-412, and sorafenib) over 96 hours. Cell lines used are: 1. HEL (FLT3 depends on its ligand for activation), 2. EOL1 (constitutively expressing FLT3 without aberration), 3. MV4-11 (FLT3 with internal tandem duplication resulting in constitutively active kinase). Proliferation kinetics and cell cycle analysis were assessed using trypan blue and propidium iodide staining. A compartmental cell cycle model assuming first-order rate transition among consecutive phases (k1, k2, and k3) was developed. Cells in S phase may enter apoptosis at a first-order rate constant, kd (Figure 1). Estimated cell cycle and drug sensitivity parameters were used to simulate different combination regimens to predict synergism.

RESULTS

Experimental data and model selection criteria showed that cytarabine induced apoptosis in S-phase while FLT3 inhibitors caused cell cycle arrest at G1 phase. Cytarabine induced cell death in all cell lines with MV4-11 being most resistant. MV4-11 was most sensitive to specific FLT3 inhibitors, while HEL cells were resistant. Preliminary simulations predict better cell kill upon adding FLT3 inhibitors following cytarabine exposure. Combination experiments are ongoing. Cell cycle data for EOL1 and MV411 cell lines were generated and modeled after September 19, 2012. Thus, a global comparison between cell lines of different FLT3 profiles was not possible before that date. Date of analysis: November 2012.

CONCLUSION

Our model presents a mechanistic interpretation for the effects of cytarabine and FLT3 inhibitors in AML cell lines and provides a useful tool to optimize combination regimens.

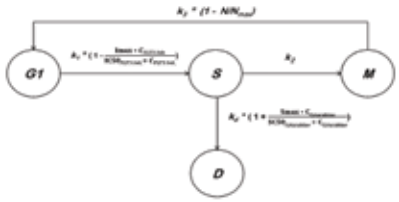


Figure 1. Compartmental model of cytarabine and FLT3 inhibitors effects on cell cycle.

LBI-8

SEX AND HAPLOTYPE ASSOCIATIONS WITH ADVERSE EFFECTS OF CALCINEURIN INHIBITORS POST-RENAL TRANSPLANT.

C. J. Meaney,[1] D. Brazeau,[2] R. C. Venuto,[3] S. Chang,[3] A. Gundroo,[3] N. Leca,[3] S. E. Morse,[1] J. Consiglio,[4] L. M. Cooper,[1] K. M. Tornatore[1]; [1]School of Pharmacy & Pharmaceutical Sciences, University at Buffalo, Buffalo, NY, [2]University of New England, Portland, ME, [3]School of Medicine & Biomedical Sciences, Buffalo, NY, [4]School of Public Health; University at Buffalo, Buffalo, NY.

BACKGROUND

P-glycoprotein (P-gp), an ABC transport protein contributes to the interpatient pharmacokinetic and pharmacodynamic variability of calcineurin inhibitors (CNI), tacrolimus (TAC) and cyclosporine (CYA). ABCB1 encodes P-gp and the single nucleotide polymorphisms (SNP) 1236C>T, 2677G>T/A, 3435C>T may alter protein expression or function. Our objective was to examine the association of ABCB1 haplotypes, sex and race with chronic CNI adverse effects (AE) in renal transplant recipients (RTR).

METHODS

A meta-analysis of 3 prospective observational studies was completed in 143 stable RTR [GFR= 51 ±17 ml/min/1.73m2] using identical inclusion and exclusion criteria in 62 African Americans (AA) and 81 Caucasians (C) treated with CYA (troughs: 50-150 ng/ml) and mycophenolate mofetil or TAC (troughs: 5-10 ng/ml) and mycophenolate sodium. Each RTR had AE assessed using standardized objective scales by study physicians. A Cumulative AE ratio was determined using 14 AE. Separate gastrointestinal (GI), central nervous system (CNS), and aesthetic AE ratios were also assessed. DNA from peripheral blood mononuclear cells was collected to characterize ABCB1 SNPs completed on 11/15/12. Haplotype computation and association with AE was completed by Thesias program on 12/3/12.

RESULTS

All genotypes were in Hardy-Weinberg equilibria. AA had a greater frequency of the T-T-T haplotype (SNPs: 1236-2677-3435) compared to C (71.6% vs. 44.2%; $p<0.001$). A gender difference was noted for Cumulative ($p<0.001$); GI ($p=0.046$); aesthetic ($p=0.0002$) and CNS ($p=0.051$) AE ratios with greater AE ratios in females. The Aesthetic AE ratio was associated with haplotype C-G-T ($p=0.008$). Haplotype T-G-C was associated with increased GI AE ratio ($p=0.02$) though the effect was not significant when sex was included as a covariate ($p=0.13$). Race had no associations with AE.

CONCLUSION

RTR receiving CNI based immunosuppression within the therapeutic range exhibited interpatient variability in AE with associations to sex and ABCB1 haplotypes.

*Presenting author is in **bold**.*

LATE BREAKING POSTER SESSION II • MARCH 8

Griffin Hall • 8:00 am – 3:00 pm • Attended Posters 8:00 am – 9:30 am

LBII-1

EPIGENETIC REGULATION OF ABCC2: MIRNA-379 DIFFERENTIALLY DOWN-REGULATES THE HUMAN DRUG TRANSPORTER ABCC2 DEPENDENT ON THE GENOTYPE.

A. N. Werk, H. Bruckmüller, S. Haenisch, **I. Cascorbi**; University of Kiel, Kiel, Germany.

BACKGROUND

There is increasing evidence that different ABCC2 haplotypes contribute to clinically relevant changes of drug bioavailability, although data is partly inconsistent recently. miR-379 was identified to down-regulate ABCC2 expression in HepG2 cells. The aim of our study was to elucidate whether various ABCC2 haplotypes underlie differential epigenetic regulation by miR-379 in human peripheral blood mononuclear cells (PBMCs).

METHODS

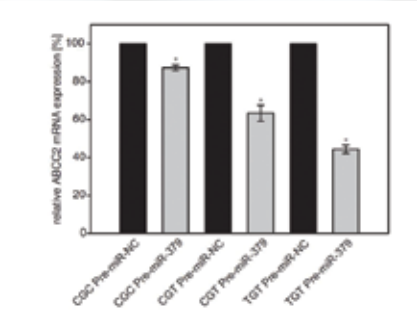
Genomic DNA (gDNA) of 15 healthy Caucasian volunteers was genotyped by pyrosequencing for the three ABCC2 SNPs -24C>T, 1249G>A and 3972C>T. PBMCs from three subjects homozygous for CGC, CGT or TGT were isolated from whole blood via ficoll gradient centrifugation and transfected with pre-miR-379 or Pre-miR negative control (pre-miR-NC). After 24 hours of incubation, Western Blot analysis and quantitative real-time PCR were performed. To characterize the functional impact of miR-379 on ABCC2 haplotype transport, glutathione-methylfluoresceine efflux assays were conducted. This very recent data could not be analyzed before September 19, 2012.

RESULTS

We could demonstrate a significant but differential ABCC2 down-regulation after pre-miR-379 transfection on mRNA and protein level in all diplotypes: CGC/CGC (mRNA: -12.7±4.2 %, p=0.04; protein: -9.9±0.1 %, p=0.04), CGT/CGT (mRNA: -36.7±2.4 %, p=0.04; protein: -21.6±0.4 %, p=0.04) and TGT/TGT (mRNA: -55.7±1.2 %, p=0.04; protein: -46.3±4.0 %, p=0.04). In addition, we observed a significant reduction of methylfluoresceine efflux in pre-miR-379 transfected PBMCs corresponding to the haplotype-dependent down-regulation of ABCC2 protein expression.

CONCLUSION

We showed for the first time a differential interaction of a microRNA with different haplotypes of ABCC2. This observation may contribute to the explanation that the impact of ABCC2 genetic variants differs in various tissues and that the outcome of clinical studies is not always consistent. The differential interaction of miR-379 with ABCC2 haplotypes may be caused by changes of the secondary structure of the 3'-region of ABCC2 mRNA or result of differential stabilities of mRNA may influence the mRNA/miRNA interplay.



*Presenting author is in **bold**.*

LBII-2

EFFECT OF AZD1152 ON BUBR1 HYPOMORPHISM.

E. L. Hurley, S. Yamada, A. Terzic, J. van Deursen; Mayo Clinic, Rochester, MN.

BACKGROUND

Germline mutations that decrease BubR1 protein levels cause mosaic variegated aneuploidy (MVA) syndrome, a recessive pediatric disorder without cure or treatment, characterized by short lifespan, premature aging and cancer in both humans and mice. In cultured cells, BubR1 insufficiency has been associated with hyperactivity of Aurora B. To explore the extent to which MVA syndrome traits underlie Aurora B hyperactivity, we tested the efficacy of an Aurora B inhibitor, AZD1152 (AZD), in a preclinical model (BubR1 hypomorphic mice; $BubR1^{H/H}$).

METHODS

Six ug/g AZD was injected IP twice weekly into 70 $BubR1^{H/H}$ mice starting at 5-7 days of age. Seventy control mice were injected with vehicle (0.3M Tris). Growth, incidence and timing to cataracts or sarcopenia, and survival were monitored. Death of $BubR1^{H/H}$ mice is typically cardiac-related therefore animals were assessed for cardiac parameters by echocardiograph (Vehicle n=10, AZD n=11; analyzed 7/18/12, 9/20/12, 11/27/12).

RESULTS

A significant increase (15%; p=0.04) in median lifespan was seen with AZD treatment (median survival 136 days vs. 118 days). No other age-related phenotypes improved with treatment. We also assessed cardiac function via echocardiograph. Preliminary data identified a new cardiac phenotype in $BubR1^{H/H}$ mice, persistent patent ductus arteriosus, and indicates that AZD treatment results in improved cardiac parameters.

CONCLUSION

Treatment with AZD increases lifespan in $BubR1^{H/H}$ mice without overt improvement in quality of life. Thus, Aurora B inhibition does not reverse any of the age-related phenotypes seen in $BubR1^{H/H}$ mice, but does improve a phenotype that is critical for survival. As the primary cause of death in $BubR1^{H/H}$ mice is due to cardiac dysfunction, and cardiac parameters were improved with AZD treatment, Aurora B hyperactivity is implicated in cardiac defects associated with BubR1 insufficiency. Ongoing experiments aim to determine mechanistically how Aurora B hyperactivity affects cardiac function in MVA syndrome.

LATE BREAKING POSTER SESSION II • MARCH 8

Griffin Hall • 8:00 am – 3:00 pm • Attended Posters 8:00 am – 9:30 am

LBII-3

INVOLVEMENT OF GQ-COUPLED RECEPTOR-DEPENDENT SIGNALING PATHWAY ON THE DNA SYNTHESIS OF HUMAN-INDUCED PLURIPOTENT STEM CELLS.

T. Ishizuka, H. Goshima, A. Ozawa, Y. Watanabe;
National Defense Medical College, Tokorozawa, Japan.

BACKGROUND

We previously demonstrated that stimulation with either α_1-adrenoceptor or angiotensin type 1 receptor (AT_1R) induces proliferation of mouse induced pluripotent stem (iPS) cells. Both α_1-adrenoceptor and AT_1R are guanine nucleotide binding protein q polypeptide (Gq)-coupled receptors. Therefore, in the present study, we determined the involvement of the two receptors in the DNA synthesis of human iPS cells.

METHODS

After the iPS cells were cultured without feeder cells on matrigel-coated plates, the cells were treated with or without l-phenylephrine (a selective α_1-adrenoceptor agonist) or angiotensin II (Ang II). After the 24 h treatment, the DNA synthesis of the cells was detected using a BrdU incorporation assay. The phosphorylation of Akt or p44/42 mitogen-activated protein kinase (MAPK) was analyzed by a western blot analysis.

RESULTS

Treatment with either l-phenylephrine or Ang II significantly increased the DNA synthesis of human iPS cells. The enhanced DNA synthesis was significantly inhibited by pretreatment with protein kinase C (PKC) inhibitors, a MAPK kinase (MEK) inhibitor, or a phosphatidylinositol-3 phosphate kinase (PI3K) inhibitor. Treatment with either l-phenylephrine or Ang II significantly increased Akt or p44/42 MAPK phosphorylation. siRNA directed against Gq significantly inhibited the DNA synthesis or the phosphorylation of Akt or p44/42 MAPK enhanced by l-phenylephrine or Ang II.

CONCLUSION

These results suggest that stimulation with α1-adrenoceptor or AT_1R may enhance DNA synthesis of human iPS cells via Gq-coupled receptor-dependent signaling pathways.

LBII-4

EXOME SCANNING REVEALS RYR1 AS A DETERMINANT FOR STATIN MYOPATHY RISK.

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BACKGROUND

Myopathy occurs in 1 of every 1000 patients exposed to statins. We tested the hypothesis that rare variants contribute to the risk of developing statin-induced myopathy in two independent clinical practice-based cohorts.

METHODS

Cases were identified using electronic medical records (EMRs), and validated manually. Inclusion was based on a plasma creatine kinase (CK) level exceeding 10 times the upper limit of normal (10xULN) during statin exposure. Subjects were excluded if their record contained evidence of trauma or acute coronary syndrome at the time of CK elevation. Fourteen validated cases of statin-induced myopathy were identified from an EMR-linked biobank at a large academic medical center (set #1), and sixteen cases were identified from the EMR of a large multispecialty group practice (set #2). Whole exomes were captured using Agilent technology, and sequenced on an Illumina platform. Two case-control analyses were then conducted in parallel: cases from set #1 were sequenced at Vanderbilt University and compared to exomes from the 1000 Genomes project (1KG); cases from set #2 were sequenced at University of Washington and compared to exomes from the Exome Sequencing Project (ESP). All rare variants were collapsed using genes as the functional unit, and the combined datasets were merged in November 2012.

RESULTS

A series of pharmacodynamic genes (known to influence excitation-contraction coupling and calcium homeostasis), and a series of pharmacokinetic genes (influencing absorption, distribution, metabolism and elimination of statins) were surveyed for their total burden of rare variants unique to myopathy cases. The only candidate gene containing rare variants predicted to be damaging in both case sets was the ryanodine receptor 1 (RYR1) gene. The RYR1 variant in set #1 was E3238A. The RYR1 variants in set#2 were R3366H and Y3933C.

CONCLUSION

Rare damaging variants near the calmodulin binding site (amino acids 3611-3642) in RYR1 may increase patient risk for statin-induced myopathy.

*Presenting author is in **bold**.*

LATE BREAKING POSTER SESSION II • MARCH 8

Griffin Hall • 8:00 am – 3:00 pm • Attended Posters 8:00 am – 9:30 am

LBII-5

CATALYTICALLY DEFICIENT METHADONE N-DEMETHYLATION BY THE COMMON CYP2B6 ALLELIC VARIANT CYP2B6.6 PREDICTS PHARMACOGENETICS VARIABILITY IN METHADONE DISPOSITION.

S. Gadel, A. Crafford, K. Regina, **E. Kharasch**; Washington University, St Louis, MO.

BACKGROUND

The long-acting opioid methadone displays considerable unexplained interindividual pharmacokinetic variability. Methadone metabolism clinically occurs primarily by N-demethylation to 2-ethyl-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP), catalyzed predominantly by cytochrome P450 2B6 (CYP2B6). Retrospective studies suggest an influence of the common allele variant CYP2B6*6 on methadone plasma concentrations. The catalytic activity of CYP2B6.6, encoded by CYP2B6*6, is highly substrate-dependent. This investigation evaluated methadone N-demethylation by CYP2B6.6, and in comparison to that by wild-type CYP2B6.1.

METHODS

Methadone enantiomer and racemate N-demethylation by recombinant expressed CYP2B6.6 and CYP2B6.1 was determined. Results were analyzed December 2012.

RESULTS

At substrate concentrations (0.25-2 μM) approximating plasma concentrations occurring clinically, rates of methadone enantiomer N-demethylation by CYP2B6.6, incubated individually or as the racemate, were one-third to one-fourth those by CYP2B6.1. For methadone individual enantiomers metabolism by CYP2B6.6 compared with CYP2B6.1, Vmax was diminished, Ks was greater, the *in vitro* intrinsic clearance was diminished 5- to 6-fold. The intrinsic clearance for R- and S-EDDP formation from racemic methadone was diminished approximately 6-fold and 3-fold for R- and S-methadone. Both CYP2B6.6 and CYP2B6.1 showed similar stereoselectivity ((S>R-methadone). Human liver microsomes with diminished CYP2B6 content due to a CYP2B6*6 allele had lower rates of methadone N-demethylation.

CONCLUSION

Results show that methadone N-demethylation catalyzed by CYP2B6.6, the CYP2B6 variant encoded by the CYP2B6*6 polymorphism, is catalytically deficient compared with wild-type CYP2B6.1. Diminished methadone N-demethylation by CYP2B6.6 may provide a mechanistic explanation for clinical observations of altered methadone disposition in individuals carrying the CYP2B6*6 polymorphism.

LBII-6

TICLOPIDINE INHIBITION OF METHADONE METABOLISM AND CLEARANCE DEMONSTRATES A PREDOMINANT ROLE FOR CYTOCHROME P4502B6 IN METHADONE DISPOSITION.

E. Kharasch; Washington University, St Louis, MO.

BACKGROUND

Methadone N-demethylation *in vitro* is catalyzed by hepatic cytochrome P4502B6 (CYP2B6) and CYP3A4, but clinical disposition is often attributed to CYP3A4. This investigation tested the hypothesis that CYP2B6 is a prominent CYP isoform responsible for clinical methadone N-demethylation and clearance, using the *in vivo* mechanism-based CYP2B6 inhibitor ticlopidine, given orally for 4 days. A preliminary clinical investigation evaluated the influence of ticlopidine in CYP3A activity.

METHODS

For the preliminary study, subjects received the CYP3A4/5 substrate probe oral alfentanil, before and after ticlopidine given orally for 4 days. For the primary investigation, subjects received intravenous plus oral (deuterium-labeled) racemic methadone before and after ticlopidine, given orally for 4 days. Results were analyzed October 2012.

RESULTS

Ticlopidine did not diminish alfentanil AUC or clearance. Ticlopidine significantly and stereoselectively (S>R) inhibited methadone N-demethylation, decreasing plasma metabolite/methadone area under the curve ratios and metabolite formation clearances. Ticlopidine also significantly increased the dose-adjusted plasma area under the curve for R- and S-methadone by 20% and 60%, respectively, after both intravenous and oral dosing.

CONCLUSION

Ticlopidine did not inhibit intestinal or hepatic CYP3A4/5, thus having selectivity for CYP2B6. Results demonstrate that CYP2B6 inhibition reduces methadone N-demethylation and clearance, and alters methadone concentrations, suggesting that CYP2B6 plays a predominant role in clinical methadone disposition.

*Presenting author is in **bold**.*

LATE BREAKING POSTER SESSION II • MARCH 8

Griffin Hall • 8:00 am – 3:00 pm • Attended Posters 8:00 am – 9:30 am

LBII-7

AN INVESTIGATION OF MORPHINE-TO-CODEINE METABOLIC RATIOS IN POSTMORTEM BLOOD, DRUG INTERACTIONS, AND CYTOCHROME P450 2D6 (CYP2D6) GENOTYPE.

J. Lam,[1] K. Woodall,[2] P. Solbeck,[2] C. J. Ross,[3] B. C. Carleton,[4] M. R. Hayden,[3] G. Koren,[1] P. Madadi[1]; [1]Hospital for Sick Children, Toronto, ON, Canada, [2]Center for Forensic Sciences, Toronto, ON, Canada, [3]Center for Molecular Medicine and Therapeutics, Vancouver, BC, Canada, [4]Children's and Women's Health Centre of British Columbia, Vancouver, BC, Canada.

BACKGROUND

Codeine depends on the activity of CYP2D6 to convert it into the active metabolite, morphine, to elicit its analgesic effects. The objective of this study was to investigate the correlation between CYP2D6 genotype, drug interactions, and morphine-to-codeine metabolic ratio (MR) in codeine-related deaths.

METHODS

The records of the Office of the Chief Coroner of Ontario were examined to identify all codeine-related deaths from 2006-2008. Deaths in which codeine and its metabolite, morphine, were quantified on the toxicological screen were included. From these, cases in which the manner of death was undetermined, heroin use was suspected, and/or morphine use was suspected were excluded. A total of 59 codeine-related deaths were included. Postmortem blood samples were analyzed for 17 polymorphisms in CYP2D6 as well as gene duplication. Genotype results were not received until November 2012, therefore data analysis could not be completed until that time.

RESULTS

The frequencies of CYP2D6 ultrarapid, extensive, intermediate, and poor metabolizer (PM) was not different in codeine-related deaths and a previously published healthy cohort taking opioids. Alcohol use prior to death was significantly associated with codeine-related deaths that were deemed to be accidental by the coroner (p=0.05). The presence of a selective-serotonin reuptake inhibitor was significantly associated with suicides (p=0.014). PM was associated with low MR.

CONCLUSION

These findings suggest that CYP2D6 genotype and drug-drug interactions should considered as part of the postmortem toxicological interpretation for codeine-related deaths, especially in cases with low or high MR.

LBII-8

NEW RISK FACTORS FOR OPIOID-RELATED DEATHS IN ONTARIO, CANADA.

P. Madadi,[1] D. Hildebrandt,[2] A. E. Lauwers,[2] G. Koren[1]; [1]Hospital for Sick Children, Toronto, ON, Canada, [2]Office of the Chief Coroner of Ontario, Toronto, ON, Canada.

BACKGROUND

The impact of the prescription opioid public health crisis has been illustrated by the dramatic increase in opioid-related deaths in North America. We aimed to characterize risk factors amongst a recent cohort of Ontarians whose cause of death was related to opioids.

METHODS

This was a population-based study of Ontarians between the years 2006 and 2008. All drug-related deaths during this time frame were reviewed at the Office of the Chief Coroner of Ontario, and opioid-related deaths were identified. Medical, toxicology, pathology, and police reports were analyzed and compiled in early October 2012 (i.e. this analysis was not available for the regular ASCPT abstract submission deadline of September 19, 2012).

RESULTS

Out of 2330 drug-related deaths in Ontario, 58% were attributed either in whole or in part, to opioids (n=1359). Oxycodone was involved in approximately one-third of all opioid related deaths, and methadone was associated with the highest proportion of accidental deaths. Codeine was disproportionately utilized in suicides. At least 8% of the entire cohort used opioids that were prescribed for friends and/or family, 19% inappropriately self-administered opioids (injection, inhalation, chewed oral patch), 3% were recently released from jail, and 5% had been switched from one opioid to another near the time of death. Accidental deaths were significantly associated with higher opioid risk scores, enrollment in a methadone maintenance program, cirrhosis, hepatitis, and cocaine use. Suicides were significantly associated with mental illness, previous suicide attempts, chronic pain, and a history of cancer.

CONCLUSION

We have identified novel risk factors associated with opioid-related deaths in Ontarians. These findings point to the need for multifaceted prevention strategies based on subpopulations of opioid users.

*Presenting author is in **bold**.*

LATE BREAKING POSTER SESSION II • MARCH 8

Griffin Hall • 8:00 am – 3:00 pm • Attended Posters 8:00 am – 9:30 am

LBII-9

PHARMACOMETABOLOMIC PATTERNS IN PATIENTS RECEIVING (R,S)-KETAMINE IN THE TREATMENT OF BIPOLAR DEPRESSION: A COMPARISON OF RESPONDERS AND NON-RESPONDERS.

A. Villaseñor,[1] **A. Ramamoorthy,**[2] G. Laje,[3] M. Silva,[4] C. A. Barbas,[4] C. ZarateJr,[3] I. W. Wainer[2]; [1]Universidad CEU San Pablo, Campus Montepríncipe, Madrid, Spain, [2]NIA/NIH, Baltimore, MD, [3]NIMH/NIH, Bethesda, MD, [4]Universidad CEU San Pablo, Campus Montepríncipe, Madrid, Spain.

BACKGROUND

Sub-anesthetic doses of ketamine (KET) produce rapid antidepressant effects in bipolar disorder (BD) patients. In this study, pharmacometabolomics was used to identify biomarkers for BD progression and therapeutic response.

METHODS

The study was approved by NIH's Combined Neuroscience IRB. 22 BD patients were enrolled in a double-blind, randomized, crossover, placebo-controlled study (completed in 2011). Symptoms and samples were collected after a single iv infusion of 0.5 mg/kg KET. Patients were also given lithium (Li) or valproate (VPA). Responders (R) and non-responders (NR) were identified at 230 min post-infusion.

Liquid chromatography-quadrupole time-of-flight mass spectrometry (LC-QTOF-MS) and capillary electrophoresis-laser induced fluorescence (CE-LIF) were used to study the metabolic patterns (bioanalysis-September 2012; data analysis-November 2012). Data analysis was performed using principal component analysis, partial least square discriminant analysis and loading column plot from orthogonal partial least square discriminant analysis. Databases were employed to putatively identify the metabolites. A genome-wide association study was performed.

RESULTS

The metabolite patterns of patients taking Li or VPA was significantly different; only 2/323 metabolites were in common. Within Li group, R and NR exhibited metabolic variability with significantly different metabolites. Of the 18 statistically significant compounds, phenyllactic acid and monoglyceride levels were increased; trimethyl-L-lysine, lysophosphatidyl-ethanolamine and -choline levels were decreased in NRs. In addition, D-serine was significantly higher in NRs.

CONCLUSION

Response to KET in BD patients appears to be based upon a variety of endogenous factors including maintenance of proper membrane structure and function, fatty acid metabolism, mitochondrial function and neurotransmission, as well as KET-induced decrease in serine racemase activity. The compounds identified in the study are under investigation as biomarkers of progression and response to treatment in BD.

*Presenting author is in **bold**.*

LATE BREAKING POSTER SESSION III • MARCH 9

Griffin Hall • 7:00 am – 11:00 am • Attended Posters 7:00 am – 8:00 am

LBIII-1

DEVELOPMENTAL CHANGES IN HUMAN INTESTINAL AND HEPATIC DRUG TRANSPORTER EXPRESSION.

M. G. Mooij,[1] S. N. De Wildt,[1] B. A. De Koning,[1] U. I. Schwarz,[2] J. N. Samsom,[3] E. Spaans,[1] D. Tibboel,[1] R. B. Kim[2]; [1]Erasmus MC - Sophia Children's Hospital, Rotterdam, Netherlands, [2]University of Western Ontario, London, ON, Canada, [3]Erasmus MC, Rotterdam, Netherlands.

BACKGROUND

Drug transporters are membrane-bound proteins involved in the absorption, disposition and clearance of many drugs. Little is known relating to developmental changes of transporter expression in human fetuses and children. The aim of this study was to assess whether transporter expression in the intestine and liver is age-related.

METHODS

Expressed levels were determined using post mortem liver (fetuses n=9, neonates n=21, infants n=8, children n=3, and adults n=11), surgical small bowel (neonates n=21, infants n=7, and children n=1) and small bowel biopsy samples (adults n=11). Target gene expression was determined using real time RT-PCR, relative to housekeeping gene (18S for liver and villin for intestine) and compared to adult mRNA expression, using the delta-delta CT method. Data was not analyzed before September 2012.

RESULTS

Hepatic mRNA expression of MRP2, OATP1B1 and OATP1B3 in fetuses and children was lower compared to adults (Table 1). Intestinal mRNA expression of MDR1 and MRP2 from fetuses and children was comparable with adult expression. However, intestinal OATP2B1 mRNA expression was significantly higher in neonates and infants compared to adults.

CONCLUSION

Expression of hepatic and intestinal drug transporters shows organ- and transporter-specific maturation patterns. This may have important implications for dosing of substrate drugs in children of different ages. Additional studies focused on transporter protein expression and *in vivo* activity are needed to more fully predict the clinical relevance of our observation.

Table 1: Relative mRNA expression. Data shown as median and IQR. *p<0.05**p<0.001#n=1

	Relative mRNA expression in liver			Relative mRNA expression in intestine		
	MRP 2/18S	OATP 1B1/18S	OATP 1B3/18S	MDR1/ Villin	MRP2/ Villin	OATP2B1/ Villin
Median-fold change in gene expression compared to adult expression; adult = 1.0 (IQR)						
Fetuses	0.006 (0.002-0.04)*	0.004 (0.001-0.06)*	0.01 (0.002-0.05)*	-	-	-
Neonates (birth-1 month)	0.004 (0.001-0.007)**	0.002 (0.001-0.007)**	0.002 (0.001-0.005)**	1.1 (0.7-3.5)	1.1 (0.6-1.9)	3.1 (2.2-13)**
Infants (1 month-12 months)	0.005 (0.003-0.05)*	0.007 (0.002-0.04)*	0.007 (0.002-0.02)*	2.0 (0.7-3.2)	0.07 (0.02-2.2)	2.2 (2.0-3.3)*
Children (12 months -7 years)	0.002 (0.001-0.004)*	0.005 (0.002-0.005)*	0.006 (0.003-0.008)*	1.6#	0.8#	0.8#

LBIII-2

MOVED TO LBII-9

LBIII-3

INFLUENCE OF STEADY-STATE AND BIPHASIC EXPOSURE PROFILES ON THE PHARMACODYNAMICS OF ACUTE INTRAVENOUS (IV) ALCOHOL IN YOUNG ADULTS.

V. Vatsalya, V. Y. Schmidt, **V. A. Ramchandani**; National Institute on Alcohol Abuse and Alcoholism, Bethesda, MD.

BACKGROUND

Previous studies have demonstrated acute tolerance to alcohol (ATA) effects; however, the effect of rate of change of breath alcohol concentration (BrAC) on development of ATA has not been well studied. We have developed steady-state and biphasic (ascending-descending) BrAC exposure profiles following IV alcohol based on a physiologically-based pharmacokinetic (PBPK) model (Ramchandani *et al.*, 2009), and we aimed to examine the effect of rate and direction of change of BrAC on subjective and motor responses to acute IV alcohol in young adults.

METHODS

19 male and female, 21-30 year-old, healthy social drinkers underwent this 2-session, randomized crossover study. Subjects underwent 2 infusion paradigms on separate days: steady-state exposure (target BrAC=0.06%), and biphasic exposure that mimicked the BrAC-time profile following a standard oral alcohol dose. Serial BrACs were obtained and subjective measures (Biphasic Alcohol Effects Scale (BAES)) and motor performance (completion time for grooved pegboard task (CT-GPB)) were assessed at baseline (B1), and at 20 min (B2) and 110 min (B3) during the infusion, at equivalent BrACs, during both sessions. Pharmacodynamic data were processed and analyzed in November 2012.

RESULTS

Both paradigms resulted in average BrACs of 0.060±0.005% at B2 and B3. BrACs during B2 and B3 were comparable between paradigms. BAES-Stimulation scale showed significant increase from B1 to B2 and return to baseline at B3, indicating ATA. BAES-Sedation scale showed significant increase from B1 to B2 and a further increase to B3. CT-GPB for non-dominant hand showed significant increase from B1 to B2, and sustained increase at B3. There were no differences in acute response or ATA between the steady-state and biphasic exposure profiles for any of the measures.

CONCLUSION

Acute IV alcohol resulted in increased stimulation, sedation and motor impairment. There was acute tolerance to alcohol for stimulation but not for sedation or motor impairment. The rate and direction of change of BrAC exposure did not have an effect on alcohol pharmacodynamics.

*Presenting author is in **bold**.*

LATE BREAKING POSTER SESSION III • MARCH 9

Griffin Hall • 7:00 am – 11:00 am • Attended Posters 7:00 am – 8:00 am

LBIII-4

A DRIED BLOOD SPOT METHOD FOR THERAPEUTIC DRUG MONITORING OF ETHAMBUTOL, PYRAZINAMIDE, AND MOXIFLOXACIN TO OPTIMIZE TUBERCULOSIS TREATMENT IN CHILDREN USING LC-MS/MS.

W. R. Martin,[1] M. Kim,[1] Y. Liu,[1] A. Mayer,[1] S. Abdel-Rahman,[2] **G. Ray**[1]; [1]KCAS, LLC, Shawnee, KS, [2]Children's Mercy Hospital, Kansas City, MO.

BACKGROUND

Conducting comprehensive pharmacokinetic (PK) studies relying on traditional venipuncture is not feasible in remote, resource-constrained settings. The study was designed to develop and validate a rapid and reproducible quantitation method for clinically relevant concentrations of Ethambutol (ETH), Pyrazinamide (PZA), and Moxifloxacin (MOX) from dried blood spots (DBS).

METHODS

ETH, MOX, and PZA were validated in DBS with K_2EDTA whole blood. ETH and MOX over a concentration range of 0.10 to 10 µg/mL and PZA over a concentration range of 1.00 to 100 µg/mL. Blood containing ETH, PZA, and MOX was spotted onto untreated DBS paper (PE 226) and 7 mm punches made. Each punch was extracted and analyzed on a Luna Phenyl-Hexyl (100 x 2.0 mm, 5µ) analytical column with gradient elution. Analytes were detected using an API 3000 LC-MS/MS system under positive MRM mode. Long term stability data of 57 days at room temperature, 30°C, and 65% relative humidity was ongoing on 9/19/2012 and analyzed on 11/9/2012.

RESULTS

ETH response was linear over the range of 0.10 -10.0 mcg/mL. Inter-assay precision and accuracy (P&A) was evaluated with a % bias and CV of ≤ 9.3% and 10.3%, respectively. Intra-assay P&A had a % bias and CV of ≤ 9.6% and 5.0%, respectively. PZA response was linear over the range of 1.00 -100 mcg/mL. Inter-assay P&A was evaluated with a % bias and CV of ≤ 18.8% and 20.0% at the LLOQ and ≤ 14.0% and 13.1% at all other levels, respectively. Intra-assay P&A had a % bias and CV of ≤ 10.3% and 14.6% at the LLOQ and ≤ 10.3% and 3.3% at all other levels, respectively. MOX response was linear over the range of 0.10 -10.0 mcg/mL. Inter-assay P&A was evaluated with a % bias and CV of ≤ 11.3 % and 8.5%, respectively. Intra-assay P&A had a % bias and CV ≤ 8.3% and 7.3%, respectively.

CONCLUSION

A reliable LC/MS/MS method has been developed for clinically relevant concentrations of ETH, PZA, and MOX in children supporting sample collection and transport for pediatric PK studies conducted in settings where venipucture is not practical without concern for sample integrity.

LBIII-5

B CELL ACTIVATING FACTOR BELONGING TO THE TUMOR NECROSIS FAMILY WERE RELATED TO EFFICACY OF GLUCOCORTICOID THERAPY IN MYASTHENIA GRAVIS PATIENTS.

S. Tanaka,[1] M. Masuda,[2] M. Yamamoto,[1] A. Maeno,[1] M. Takagi,[1] S. Ito,[2] H. Utsumi,[2] T. Hirano[1]; [1]TUPLS, Hachioji, Tokyo, Japan, [2]Tokyo Medical University, Tokyo, Japan.

BACKGROUND

Myasthenia gravis (MG) is an autoimmune disorder generally mediated by antibodies against the acetylcholine receptors (AChR) of the skeletal muscles. B-cell-activating factor (BAFF) induces immature B cell survival or growth of mature B cells through the receptors (BAFF-R). We investigated the relationship between BAFF or the receptor and clinical efficacy in 81 MG patients.

METHODS

We measured the BAFF levels in plasma by ELISA and the expression of BAFF-R on $CD19^+$ B cells by flow cytometry. We also evaluated clinical efficacy by using anti AChR antibody titer in plasma and QMG score over the course of the therapy for 12 months.

RESULTS

Compared to the healthy subjects, the concentration of BAFF in plasma in MG patients who were treated with prednisolone (PSL) and the percentage of $BAFF\text{-}R^+$ cells in $CD19^+$ Cells in the MG patients who were treated with calcineurin inhibitor in addition to glucocorticoid were lower($p<0.0001$, respectively). We also showed that both anti ACh-R antibody titer in plasma and QMG score were correlated with the percentage of $BAFF\text{-}R^+$ cells in $CD19^+$ Cells.

CONCLUSION

In our study, we concluded that BAFF-R expression on B cells might be a biomarker of therapeutic efficacy of PSL in MG patients.

*Presenting author is in **bold**.*

LBIII-6

LACK OF EFFECT OF GENETIC VARIANTS ON THE AGE-ASSOCIATED PROTEIN EXPRESSION OF OATP1B1 AND OATP1B3 IN HUMAN PEDIATRIC LIVER.

M. Thomson,[1] S. Krauel,[1] R. N. Hines,[2] E. G. Schuetz,[3] B. Meibohm[1]; [1]University of Tennessee, College of Pharmacy, Memphis, TN, [2]Medical College of Wisconsin, Translational and Biomedical Research Center, Milwaukee, WI, [3]St. Jude Children's Research Hospital, Department of Pharmaceutical Sciences, Memphis, TN.

BACKGROUND

The ontogeny of molecular mechanisms involved in the disposition of xenobiotics is currently evolving, especially for transport proteins. We recently reported on the age-associated expression patterns of the Organic Anion Transporting Polypeptide (OATP) 1B1 and 1B3 in pediatric liver (AAPS J 2012, 14, S2). Here, we report on the potential effect of commonly observed, functionally relevant single nucleotide polymorphisms on the age-associated protein expression of these transporters.

METHODS

Samples: 32 living-donor and 46 post-mortem non-pathologic liver specimens (subject age 0.04-12 yr) were acquired from tissue banks.

Data Collection: Protein expression of OATP 1B1 and 1B3 was quantified by immunoblotting with GAPDH as reference protein. Single nucleotide polymorphisms for OATP1B1 A388G, T521C, and OATP1B3 G334T and A699G were determined by Taqmanallelic discrimination assay. Samples were stratified by age into 4 groups: <0.7, 0.7<3, 3<6, 6-12 years. Statistical significance was determined by one- or two-way ANOVA and chi square test where appropriate.

RESULTS

OATP1B1 expression was lower in group B (18% of group D) than D (p=0.034). Glycosylated OATP1B3 expression was higher in group A (72% of D) compared to B (16% of D) (p=0.0077), and B was lower than D (p=0.0052). All determined alleles were in Hardy-Weinberg equilibrium (p>0.05). OATP 1B3 G334T and T521C were in complete linkage disequilibrium (p<0.001). None of the investigated genotypes correlated with the age-associated expression of the transporters or expression within each age group (p>0.05).

CONCLUSION

This study indicates no appreciable effect of genotype in modulating the ontogeny OATP1B1 and OATP1B3 expression in pediatric liver, suggesting that signals in pediatric development may mask the effect of functionally relevantgenetic variants in early childhood.

LBIII-7

ANALYSIS OF CICLETANINE PHARMACOKINETIC EXPOSURE AND THE EFFECT ON TROUGH CONCENTRATIONS OF BACKGROUND PAH DRUGS IN A PHASE 2, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, DOSE-RANGING CLINICAL TRIAL IN SUBJECTS WITH PULMONARY ARTERIAL HYPERTENSION (PAH).

S. Upadhyay, C. Blair, G. Walker, H. Gillies; Gilead Sciences, Foster City, CA.

BACKGROUND

Cicletanine Hydrochloride (CIC) is marketed for the treatment of systemic hypertension and evaluated for the treatment of pulmonary arterial hypertension (PAH). A Phase II dose ranging safety and efficacy study in PAH subjects, receiving stable background PAH therapy, was conducted and CIC PK following BID dosing in PAH subjects were determined from this study for the first time.

METHODS

A final analysis of pharmacokinetic data from this Phase II study was only available on October 3, 2012. Subjects, on stable background PAH therapy, were randomized to placebo or one of 3 CIC treatment regimens initiated at a dose of 75 mg QD, 75 mg BID or 150 mg QD for 2 weeks then increased (doubled) to a maintenance dose of 150 mg QD, 150 mg BID or 300 mg QD, respectively. Steady-state CIC PK parameters were calculated from plasma concentration-time profiles collected from 20 subjects during the initiation and maintenance dose periods. For background PAH drugs and their metabolites, ratios of trough concentrations at randomization to those at week 2 and week 4 (contrast ratios), were calculated using pooled data from all subjects in each CIC dose group.

RESULTS

Results: Steady-state CIC PK in Subjects with PAH

CIC PK Parameter	QD			BID	
	75 mg qd (N=6)	150 mg qd (N=9)	300 mg qd (N=3)	75 mg bid (N=10)	150 mg bid (N=7)
C_{max} (ng/mL) Mean (SD)	2108 (1055)	3389 (1788)	5477 (752)	3273 (1733)	6920 (3869)
AUC_{tau} (ngh/mL) Mean (SD)	14523 (2509)	21627 (3990)	39559 (2717)	19248 (7254)	41267 (18040)

Contrast ratios (week 2, week 4) were as follows: ambrisentan (0.88, 0.93); bosentan (0.82, 0.75); tadalafil (1.15, 1.16); sildenafil (1.14, 1.74); and N-desmethyl sildenafil (1.10, 1.37).

CONCLUSION

CIC plasma concentrations in PAH subjects were lower compared to healthy volunteers, as seen previously in elderly hypertensive subjects. CIC PK exhibited a dose-related increase in exposure. Cicletanine did not appear to markedly affect trough concentrations of the concurrently administered PAH drugs.

*Presenting author is in **bold**.*

LATE BREAKING POSTER SESSION III • MARCH 9

Griffin Hall • 7:00 am – 11:00 am • Attended Posters 7:00 am – 8:00 am

LBIII-8

IDENTIFICATION OF NOVEL OATP-INHIBITORS BY COMBINED *IN SILICO*- AND *IN VITRO*-APPROACHES.

M. B. Wittwer, N. Khuri, A. Sali, K. M. Giacomini;
University of California San Francisco, San Francisco, CA.

BACKGROUND

The Organic Anion Transporting Polypeptides (OATP) 1B1, 1B3, and 2B1 play important roles in drug uptake into the liver and consequently in the metabolism and excretion of drugs. Drug-drug interactions (DDIs) mediated by these transporters can lead to adverse drug reactions with severe clinical consequences.

METHODS

Six machine learning algorithms trained on 224 known inhibitors and non-inhibitors of the three OATP transporters were evaluated for virtual screening. The Random forest (RF) algorithm performed best. The model was successfully tested on an independent external validation data set of 27 OATP1B1 inhibitors. The applicability domain for the RF models was determined by principal component analysis, and the models were then used to screen the DrugBank *in silico*-library containing 5,192 compounds (completed on November 29th). Experimental determinations of IC_{50} values of selected hits were performed using ^{3}H-labeled estradiol-17β-glucuronide and estrone sulfate.

RESULTS

The performance of the RF models on external test sets was assessed by the area under the receiver operating curve (AUC) statistic (0.86 for OATP1B1 and 2B1; 0.92 for OATP1B3) and it had a prediction accuracy of approximately 70% on an independent external validation data set of 27 OATP1B1 inhibitors. Using the models, various selective *in silico*-hits of OATP1B1 (e.g., sulindac), 1B3 (e.g., arbekacin), and 2B1 (e.g., bicalutamide) have been identified. Follow-up experimental determination of the IC50-values of selected hits revealed several previously unknown OATP-inhibitors, e.g., the novel orally available direct thrombin inhibitor dabigatran inhibits OATP1B1 and 1B3 in the low micromolar range.

CONCLUSION

The current study, which combined *in silico*-methods with experimental follow-up validation to identify OATP-inhibitors, yielded several interesting novel OATP-inhibitors. Clinical studies are needed to determine the relevance of the inhibitors to transporter-mediated DDIs in the liver.

LATE-BREAKING ABSTRACTS

*Presenting author is in **bold**.*

QUANTITATIVE SYSTEMS PHARMACOLOGY:
AN INTEGRATING FRAMEWORK FOR TRANSLATIONAL MEDICINE POSTERS

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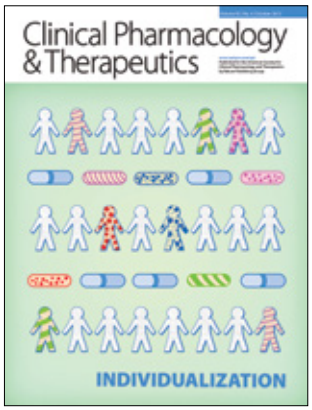

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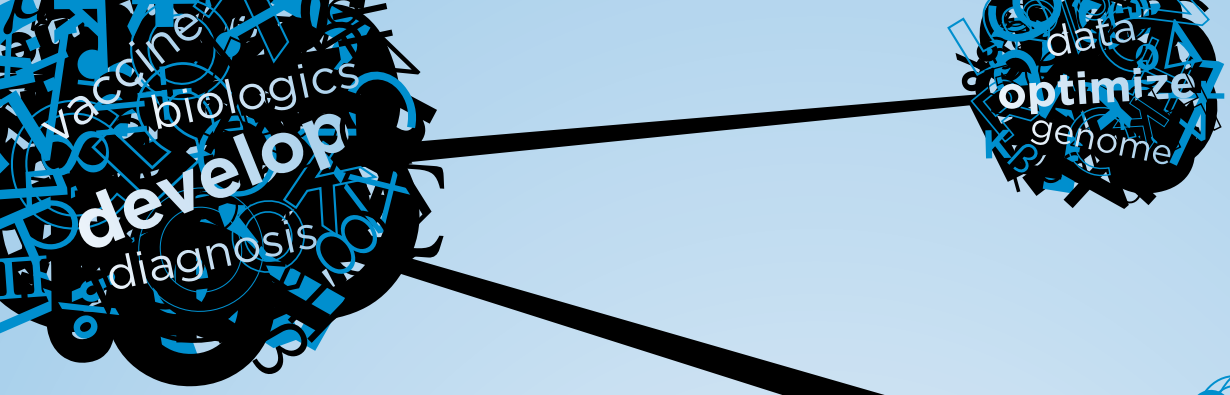

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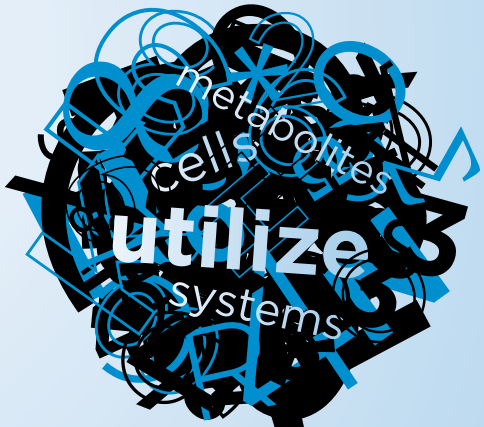

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