ASCPT 2012 ANNUAL MEETING
PROGRAM

AMERICAN SOCIETY FOR CLINICAL PHARMACOLOGY AND THERAPEUTICS

113TH ANNUAL MEETING ★ MARCH 14-17

GAYLORD NATIONAL HOTEL AND CONVENTION CENTER
NATIONAL HARBOR, MARYLAND
# ASCPT 2012 Annual Meeting

**March 14-17 ★ National Harbor, Maryland**

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Dear Colleague:

Welcome to Maryland and to the 2012 Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (ASCPT). As the premier organization in the field of clinical pharmacology, ASCPT is proud to offer you an outstanding scientific program, a robust roster of internationally renowned speakers, and abundant networking opportunities.

Consistent with the Society’s strategic plan, ASCPT seeks to increase our joint programming and coordinated scientific efforts with colleague organizations. We extend a warm welcome to our colleagues who attended the two preconference programs jointly sponsored by ASCPT. The second workshop of the International Transporter Consortium (ITC), and the American Society of Pharmacometrics (ASoP) Decision Making workshop. In addition, we also welcome our colleagues from the Food and Drug Administration who hosted their Clinical Pharmacology and Pharmaceutical Sciences Advisory Committee Meeting at the ASCPT meeting.

The 2012 scientific program includes three outstanding State of the Art lectures by Stephen Spielberg, MD, PhD, Deputy Commissioner, US Food and Drug Administration, discussing an interactive model for the future of therapeutics; Harvey Fineberg, MD, PhD, President of the Institute of Medicine, discussing the impact of the Institute of Medicine health policy; and Francis Collins, MD, PhD, Director, National Institutes of Health, discussing new partnerships to accelerate translation. This year’s featured speakers include Mary Jeanne Kreek, MD, Rockefeller University and Alex Sparreboom, PhD, St. Jude Children’s Research Hospital.

We are pleased to bring you new programming this year, including the Ask the Editors session on Thursday, March 15 from 2:45 pm - 3:45 pm. This is your opportunity to meet our new editor-in-chief of CPT: Pharmacometrics & Systems Pharmacology as well as Scott Waldman, MD, PhD, Editor-in-Chief of Clinical Pharmacology & Therapeutics. This highly interactive session will provide new information on both journals and answer any questions you may have on either journal. Also new this year is the Career Bootcamp, a half-day program providing career consultation and mentoring opportunities for trainees and junior faculty. You won’t want to miss this outstanding program.

ASCPT will honor a number of outstanding individuals for their work in advancing clinical pharmacology, improving patient care, and their contributions to ASCPT. The 2012 honorees are D. Craig Brater, MD; Malcolm Rowland, DSc, PhD; Scott Waldman, MD, PhD; Peter Honig, MD, MPH; Carl Peck, MD; Michael Maitland, MD, PhD; and Janice Schwartz, MD.

Join us at the Town Hall Session which will feature a host of ASCPT members leading roundtable discussions. As a member of ASCPT, this is your opportunity to meet the leadership of ASCPT and discuss issues of interest. This year table facilitators will include members of the ASCPT Board of Directors, CPT Editorial Team, and Scientific Section and Committee Chairs. We hope you will take the opportunity to participate in this session.

Visit the poster and exhibit hall where more than 300 scientific posters will be presented and will be available for viewing, Thursday, March 15 through Saturday, March 17. In addition, a wide range of exhibitors will be in attendance, eager to share their clinical pharmacology related products and services with attendees.

This year, ASCPT is proud and pleased to have the largest number of attendees from outside of North America. We wish to offer a very warm welcome to all of our international attendees.

Let me take this opportunity to thank the chairperson of this year’s Scientific Program Committee, John Wagner, MD, PhD, as well as the entire Committee for putting together an outstanding scientific program.

Finally, I encourage everyone to make the most of your time here and thank you for attending the 2012 ASCPT Annual Meeting!

Sincerely,

Richard L. Lalonde, PharmD
President
**TUESDAY • MARCH 13**

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<td>ASCPT Board of Directors and CPT Editorial Team Lunch (by invitation only)</td>
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<td>New Member Welcome</td>
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<td></td>
<td>Opening Session</td>
<td>Maryland B/4-6, pg. 20</td>
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<td>Maryland B/4-6, pg. 22</td>
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<td>Showcase of Top Trainee Abstracts</td>
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**Schedule at a Glance Key**

- ▪ ASCPT Central & Registration
- ▪ Award Lecture
- ▪ Committee Meeting
- ▪ Exhibits/Posters/Late-Breaking Posters
- ▪ Meal/Break
- ▪ Oral/Late-Breaking Session
- ▪ Reception
- ▪ Scientific Section
- ▪ Special Event
- ▪ State of the Art / Featured Speaker / Special Session
- ▪ Symposium
- ▪ Trainee & Student Event
- ▪ Workshop
### THURSDAY • MARCH 15 AM

<table>
<thead>
<tr>
<th>Time</th>
<th>Event Description</th>
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<tbody>
<tr>
<td>6:30</td>
<td>Scientific Section Leadership Orientation  (by invitation only)  Chesapeake G/H</td>
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<td>7:00</td>
<td>ASCPT Annual Meeting Registration &amp; ASCPT Central Open Maryland Foyer</td>
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<tr>
<td>7:30</td>
<td>ABCP Board Meeting  (by invitation only)  Chesapeake 1</td>
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<tr>
<td>8:00</td>
<td>Finance Committee Meeting  (by invitation only)  Chesapeake 11</td>
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<tr>
<td>8:30</td>
<td>Exhibits &amp; Posters Open Prince George's Hall C</td>
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<tr>
<td>9:00</td>
<td>CPT Editorial Board Meeting  (by invitation only)  Maryland I &amp; 2</td>
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<tr>
<td>9:30</td>
<td>Poster Session I  Prince George's Hall C</td>
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<tr>
<td>10:00</td>
<td>Late-Breaking Poster Session I  Prince George's Hall C</td>
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<tr>
<td>10:30</td>
<td>Continental Breakfast  Prince George's Hall C</td>
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<tr>
<td>11:00</td>
<td>CCSS &amp; Scientific Sections  (by invitation only)  Chesapeake G/H</td>
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<tr>
<td>11:30</td>
<td>ASCPT Town Hall  Maryland A  pg. 11</td>
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<tr>
<td>12:00</td>
<td>Trainee Luncheon  Chesapeake D  pg. 10</td>
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<tr>
<td>12:30</td>
<td>Box Lunch  Prince George's Hall C</td>
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<tr>
<td>1:00</td>
<td>Sheiner-Beal Pharmometrics Award Lecture  Maryland B/4-6  pg. 25</td>
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<tr>
<td>1:30</td>
<td>Featured Speaker  Maryland C  pg. 25</td>
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<tr>
<td>2:00</td>
<td>Oral Session OI-A  Maryland D  pg. 25</td>
</tr>
<tr>
<td>2:30</td>
<td>Ask the Editors  Maryland B/4-6  pg. 26</td>
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<tr>
<td>3:00</td>
<td>State of the Art Lecture  Maryland B/4-6  pg. 26</td>
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<tr>
<td>3:30</td>
<td>Section Meeting BIO  Maryland A  pg. 26</td>
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<tr>
<td>4:00</td>
<td>Section Meeting MOL  Maryland D  pg. 27</td>
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<tr>
<td>4:30</td>
<td>Section Meeting PMK  Maryland C  pg. 27</td>
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<tr>
<td>5:00</td>
<td>UCSF Reception  (by invitation only)  Maryland 2</td>
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<tr>
<td>5:30</td>
<td>Social for Students and Trainees  Students and Trainees Only  Chesapeake D</td>
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<tr>
<td>6:00</td>
<td>Donor Reception  (by invitation only)  Pose – Lower Level</td>
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<tr>
<td>6:30</td>
<td>International Reception  (by invitation only)  Maryland 1</td>
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<td>7:00</td>
<td>PhRMA Foundation Reception  (by invitation only)  Maryland 3</td>
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<tr>
<td>7:30</td>
<td>Gavel Club Dessert Reception  (by invitation only)  President’s Suite</td>
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### THURSDAY • MARCH 15 PM

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<th>Time</th>
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<tr>
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<td>Exhibits &amp; Posters Open Prince George's Hall C</td>
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<td>ASCPT Annual Meeting Registration &amp; ASCPT Central Open Maryland Foyer</td>
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<td>ASCPT Town Hall  Maryland A  pg. 11</td>
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<td>2:00</td>
<td>Trainee Luncheon  Chesapeake D  pg. 10</td>
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<td>Box Lunch  Prince George's Hall C</td>
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<td>3:00</td>
<td>Sheiner-Beal Pharmometrics Award Lecture  Maryland B/4-6  pg. 25</td>
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<td>3:30</td>
<td>Featured Speaker  Maryland C  pg. 25</td>
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<tr>
<td>4:00</td>
<td>Oral Session OI-A  Maryland D  pg. 25</td>
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<tr>
<td>4:30</td>
<td>Ask the Editors  Maryland B/4-6  pg. 26</td>
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<td>5:00</td>
<td>State of the Art Lecture  Maryland B/4-6  pg. 26</td>
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<td>5:30</td>
<td>Transition to the Future  Maryland B/4-6</td>
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<tr>
<td>6:00</td>
<td>Section Meeting BIO  Maryland A  pg. 26</td>
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<td>Section Meeting MOL  Maryland D  pg. 27</td>
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<td>7:00</td>
<td>Section Meeting PMK  Maryland C  pg. 27</td>
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<tr>
<td>7:30</td>
<td>UCSF Reception  (by invitation only)  Maryland 2</td>
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<td>8:00</td>
<td>Social for Students and Trainees  Students and Trainees Only  Chesapeake D</td>
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<td>Donor Reception  (by invitation only)  Pose – Lower Level</td>
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<td>International Reception  (by invitation only)  Maryland 1</td>
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<td>PhRMA Foundation Reception  (by invitation only)  Maryland 3</td>
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<td>10:00</td>
<td>Gavel Club Dessert Reception  (by invitation only)  President’s Suite</td>
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### Schedule at a Glance

#### FRIDAY • MARCH 16 AM

<table>
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<tr>
<th>Time</th>
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<tr>
<td>6:30</td>
<td>ASCPT Annual Meeting Registration &amp; ASCPT Central Open Maryland Foyer</td>
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<td>7:00</td>
<td>Exhibits &amp; Posters Open Prince George's Hall C</td>
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<td>7:30</td>
<td>Education Committee Meeting (by invitation only) Chesapeake D</td>
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<td>8:00</td>
<td>Section Meeting DDR Maryland A</td>
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<td>Section Meeting ONC Maryland D</td>
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<td>Section Meeting SPO Chesapeake 12</td>
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<tr>
<td>9:30</td>
<td>Clinical Pharmacology Program Directors Meeting (by invitation only) Maryland 1</td>
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<td>Poster Session II Prince George’s Hall C</td>
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<td>Late-Breaking Poster Session II Prince George’s Hall C</td>
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<tr>
<td>10:00</td>
<td>State of the Art Lecture Maryland B/4-6</td>
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<td>China Clinical Pharmacology Trials Maryland B/4-6 Page 28</td>
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<td>Gained in Translation Maryland C Page 29</td>
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<td></td>
<td>Optimizing Pediatric Therapeutics Maryland A Page 30</td>
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<td>Pharmacogenetics in Drug Development Maryland D Page 30</td>
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#### FRIDAY • MARCH 16 PM

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<td>Box Lunch All Attendees Prince George’s Hall C</td>
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<td>2:00</td>
<td>Rawls Palmer Progress in Medicine Award Lecture Maryland B/4-6 Page 32</td>
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<td>2:30</td>
<td>Oral Session OII-B Maryland A Page 31</td>
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<td>3:00</td>
<td>Oral Session OII-C Maryland C Page 32</td>
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<td>3:30</td>
<td>Oscar B. Hunter Memorial Award in Therapeutics Lecture Maryland B/4-6 Page 30</td>
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<td>4:00</td>
<td>Featured Speaker Maryland A Page 32</td>
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<td>4:30</td>
<td>New Perspectives in Drug-Induced Renal Injury Maryland B/4-6 Page 33</td>
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<tr>
<td>5:00</td>
<td>Novel Modeling and Simulation Approaches Maryland A Page 32</td>
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<tr>
<td>5:30</td>
<td>Codevelopment of Investigational Drugs Maryland C Page 34</td>
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<tr>
<td>6:00</td>
<td>Scientific Sections Meet and Greet Maryland 2/3</td>
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<tr>
<td>6:30</td>
<td>Leadership and Mentor Reception (by invitation only) Maryland 1</td>
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<tr>
<td>7:00</td>
<td>President's Reception Cherry Blossom Ballroom/Foyer</td>
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## SATURDAY • MARCH 17

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</table>
| 6:30  | ASCPT Board of Directors Meeting  
(by invitation only)  
Chesapeake D |
| 7am   | Poster Session III  
Prince George's  
Hall C |
| 7:30  | Late-Breaking  
Poster Session III  
Prince George's  
Hall C |
| 8am   | ASCPT Annual Meeting Registration & ASCPT Central Open  
Maryland Foyer |
| 8:30  | Career Bootcamp Half-Day Program  
(For Trainees And Students Only)  
Chesapeake H/I  
p. 40 |
| 9am   | Crossing Over: Innovation  
and Alternative Trial  
Design in Drug  
Development, Utilization,  
and Regulation  
Maryland A  
p. 35 |
| 9:30  | Leon I. Goldberg Young  
Investigator Award Lecture  
Maryland A  
p. 36 |
| 10am  | Oral Session  
OIII-A  
Maryland D  
p. 37 |
| 10:30 | Oral Session  
OIII-B  
Maryland C  
p. 37 |
| 11am  | Late-Breaking  
Oral Session  
Maryland A  
p. 36 |
| 11:30 | Evaluation of  
Concentration-QT  
Relationship in Early  
Clinical Development  
Maryland A  
p. 38 |
| 12n   | Imaging Studies of Drug  
Transport and Response  
Maryland C  
p. 39 |
| 12:30 | Novel Protein  
Therapeutics  
Maryland D  
p. 39 |
| 1pm   | Should We Tolerate the  
Maximally Tolerated  
Dose for Targeted  
Anti-Cancer Agents?  
Maryland C  
p. 36 |
| 1:30  | Oral Session  
OIII-A  
Maryland D  
p. 37 |
| 2pm   | Oral Session  
OIII-B  
Maryland C  
p. 37 |

### SAVE THE DATE: ASCPT 2013

**INDIANAPOLIS MARCH 6-9**

**ASCPT 114TH ANNUAL MEETING / JW MARRIOTT / INDIANAPOLIS, INDIANA**

Check for updates and more information at [www.ascpt.org](http://www.ascpt.org)
EVENTS & HIGHLIGHTS

@ASCPT_ClinPharm While at the meeting, stay up-to-date with session updates and schedule changes by following ASCPT on Twitter.

WEDNESDAY • MARCH 14

NEW MEMBER WELCOME
1:30 pm - 2:30 pm • Chesapeake D/E

This is a great opportunity to meet other new members and learn how to get involved in the Society. Find out more about your member benefits and how to get the most out of the ASCPT Annual Meeting.

DAVID GOLDSTEIN AND JASON MORROW TRAINEE AWARDS
3:00 pm • Maryland B/4-6

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, longtime ASCPT members who were committed to trainees and the future of the discipline of clinical pharmacology.

The 2012 recipients of the David Goldstein Trainee Award are Jason Sprowl, PhD, Cynthia S. Lancaster, PhD, and Xu Han. The 2012 recipient of the Jason Morrow Trainee Award is Qiping Feng, PhD. All recipients will be recognized during the Opening Session.

STATE OF THE ART LECTURE
4:00 pm - 5:00 pm • Chesapeake D/E

Join us as Stephen P. Spielberg, MD, PhD, ASCPT Past President and newly named Deputy Commissioner for Medical Products and Tobacco of the US Food and Drug Administration, will be delivering the lead-off State of the Art Lecture at the opening of the 2012 Annual Meeting. Dr. Spielberg’s presentation is entitled “Basic, Applied, Translational, and Regulatory Science: An Interactive Model for the Future of Therapeutics.”

SHOWCASE OF TOP TRAINEE ABSTRACTS
5:30 pm - 6:00 pm • Prince George’s Exhibit Hall C Foyer

View the top trainee abstracts submitted by the 2012 Presidential Trainee Award recipients while supporting your peers and networking with colleagues.

OPENING RECEPTION AND EXHIBITS
6:00 pm - 8:00 pm • Prince George’s Exhibit Hall C

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
THURSDAY • MARCH 15

ASCPT Town Hall
Noon - 1:15 pm • Maryland A
The 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 the ASCPT Board of Directors, CPT Editors, and Section and Committee Chairs. See page 11 for full details.

Trainee Luncheon: Careers in Clinical Pharmacology
Noon - 1:15 pm • Chesapeake D
Back by popular demand, the Trainee Luncheon allows trainees and students to connect with established clinical pharmacologists, colleagues, and peers in roundtable discussions. Trainees and students will have the opportunity to converse about their potential career paths and seek advice from leaders and experts in the academia, consulting, industry, and government sectors of clinical pharmacology. See page 10 for full details. Advance registration required.

SPECIAL SESSION
Ask the Editors
2:45 pm - 3:45 pm • Maryland B/4-6
All attendees are invited to participate in this special session where the latest information about Clinical Pharmacology & Therapeutics will be presented and ASCPT’s new journal, CPT: Pharmacometrics & Systems Pharmacology, will be discussed. The Ask the Editors session will provide a forum for member interaction with the editorial leadership of ASCPT’s journals to discuss the future of these two publications, and plans to showcase even more cutting-edge research.

Transition to the Future
5:00 pm - 5:15 pm • Maryland B/4-6
Please join us as Kathleen M. Giacomini, PhD, receives the Presidential Gavel as the incoming President of ASCPT. Russ B. Altman, 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 16

Scientific Sections Meet and Greet
6:00 pm - 7:00 pm • Maryland 2/3
In a social setting, this is an ideal opportunity to network with the members of your Scientific Section. Sections will discuss goals for the coming year including reviewers for the 2013 Annual Meeting as well as ideas for symposia, workshops and abstract submissions. Scientific Sections are the primary forum for member exchange and communication. They facilitate growth within the field of interest by promoting interaction among members.

President’s Reception
7:00 pm - 9:00 pm • Cherry Blossom Ballroom/Foyer
Join your colleagues and friends for an enjoyable evening of networking over food and beverages on the last night of the 2012 Annual Meeting. You won’t want to miss this event as ASCPT expresses its appreciation of Richard L. Lalonde, PharmD, for his service as President of ASCPT. Sponsored by CLiNiLABS www.clinilabs.com

SATURDAY • MARCH 17

Trainees & Students: Career Bootcamp Half-Day Program
7:30 am - 2:00 pm • Chesapeake H/I
Get your early career in shape! ASCPT has developed a half-day session to provide take-home points and prompt questions that stimulate discussion and mentoring opportunities exclusively for trainees and junior faculty. Some of the session content will include how to find a mentor, a five-year plan to jump-start your career, negotiating a starting package, grants 101, and meet the NIH. See page 40 for full program details. Advance registration required.
TRAINEE LUNCHEON
Thursday, March 15 | Noon-1:15pm | Chesapeake D

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, again. This luncheon – open only to trainees – is a roundtable discussion for students and fellows to meet with established clinical pharmacologists to network and to discuss potential career paths. This Luncheon is a perfect complement to the ASCPT Career Bootcamp being offered on Saturday March 17, 2012.

Trainee 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 trainees’ questions. 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’ signed up for the luncheon.

Trainee Luncheon Facilitators
Bridgette L. Jones, MD
and Kathleen A. Neville, MD, MS

Industry
Rebecca Blanchard, PhD • Merck & Co.
Ying-Jun Cao, MD, PhD • Astellas Pharmaceutical
Stephen D. Hall, PhD • Eli Lilly and Co.
Joan Korth-Bradley, PharmD • Pfizer
Masako Nakano, MD, PhD • Eli Lilly and Co.
Donald Stanski, MD • Novartis Pharma, AG
Aubrey Stoch, MD • Merck & Co.

Consulting
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Gary Novack, PhD

Government
Gilbert Burckart, PharmD
US Food and Drug Administration
Shiew-Mei Huang, PhD
US Food and Drug Administration
Kellie Reynolds, PhD
US Food and Drug Administration
Issam Zineh, PharmD, MPH
US Food and Drug Administration

Academia
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Indiana University School of Medicine
Jean D. Gray, MD, FRCPC
Dalhousie University
Patricia Slattum, PharmD, PhD, CGP
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Michael Spigarelli, MD, PhD
University of Utah
Janice Sullivan, MD
Kosair Children’s Hospital-University of Louisville
John van den Anker, MD, PhD
Children’s National Medical Center
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. The room will be set up with at least two volunteer leaders representing the following at each table:
# AWARD RECIPIENTS

## 2012 Henry W. Elliott
- Distinguished Service Award
- Peter K. Honig, MD, MPH
  - Head of Global Regulatory Affairs
  - AstaZeneca
  - Wilmington, DE

## 2012 Gary Neil Prize for Innovation in Drug Development
- Carl C. Peck, MD
  - Adjunct Professor
  - Center for Drug Development Science
  - University of California, San Francisco
  - San Francisco, CA

## 2012 Leon I. Goldberg Young Investigator Award
- Michael L. Maitland, MD, PhD
  - Assistant Professor
  - Department of Medicine
  - University of Chicago Medical Center
  - Chicago, IL

## 2012 William B. Abrams Award for Geriatric Clinical Pharmacology
- Janice B. Schwartz, MD
  - University of California, San Francisco
  - San Francisco, CA

## 2012 Rawls-Palmer Progress in Medicine Award
- Scott A. Waldman, MD, PhD
  - Samuel M.V. Hamilton Professor and Chair
  - Departments of Pharmacology and Experimental Therapeutics
  - Thomas Jefferson University
  - Philadelphia, PA

## 2012 Sheiner-Beal Pharmacometrics Award
- Malcolm Rowland, DSc, PhD
  - University of Manchester
  - Manchester, United Kingdom

## 2012 Oscar B. Hunter Memorial Award in Therapeutics
- D. Craig Brater, MD
  - Dean and Walter J. Daly Professor
  - Indiana University School of Medicine
  - Indianapolis, IN

## 2012 ASCPT Mentor Award
- Arthur J. Atkinson, Jr., MD
  - Northwestern University
  - Evanston, IL

## 2011 ASCPT Young Investigator Award Top Junior Faculty
- Landry Kamdem Kamdem, PharmD, PhD
  - Assistant Professor
  - Department of Pharmaceutical Sciences
  - Harding University College of Pharmacy
  - Searcy, AR

## 2011 ASCPT Young Investigator Award Top Fellow
- Laura J. Wozniak, MD
  - Pediatric Gastroenterology Fellow
  - Department of Pediatrics
  - University of California, Los Angeles
  - Los Angeles, CA

## 2011 Top Membership Recruiter Honorable Mention
- Jason Karnes, PharmD
  - University of Florida
  - Gainesville, FL

## 2012 David J. Goldstein Trainee Award Recipient
- Jason Sprowl, PhD
  - Postdoctoral Fellow
  - St. Jude Children's Research Hospital
  - Memphis, TN

## 2012 David J. Goldstein Trainee Award Recipient
- Cynthia S. Lancaster, PhD
  - Trainee Award Recipient
  - St. Jude Children's Research Hospital
  - Memphis, TN

## 2012 David J. Goldstein Trainee Award Recipient
- Xu Han
  - Department of Pharmacology and Toxicology
  - Indiana University School of Medicine
  - Indianapolis, IN

## 2012 Jason Morrow Trainee Award Recipient
- Qiping Feng, PhD
  - Trainee Award Recipient
  - Vanderbilt University
  - Nashville, TN

## PHRMA FOUNDATION AWARDS

### 2012 Awards in Clinical Pharmacology
- **2012 Award in Excellence in Clinical Pharmacology**
  - **ASCPT PRESIDENTIAL TRAINEE AWARD RECIPIENTS**
    - Jason Sprowl, PhD
      - St. Jude Children's Research Hospital
    - Cynthia S. Lancaster, PhD
      - St. Jude Children's Research Hospital
    - Xu Han
      - Indiana University School of Medicine
    - Qiping Feng, PhD
      - Vanderbilt University
    - Daniela Conrado, MS
      - University of Florida
    - Manuela Vieira, PhD
      - University of North Carolina
    - Geert W. ’t Jong, MD, PhD
      - Hospital for Sick Children
    - Virginie Ancrenaz, PhD Student
      - Geneva University Hospitals
    - Teodora Pene Dumitrescu, PhD
      - University of North Carolina

### 2012 Membership Recruiter Honorable Mention
- Scott A. Waldman, MD, PhD
  - Membership Recruiter Honorable Mention
  - University of Florida
  - Gainesville, FL

### 2012 David J. Goldstein Trainee Award Recipient
- Malcolm Rowland, DSc, PhD
  - St. Jude Children's Research Hospital
  - Memphis, TN

### 2012 David J. Goldstein Trainee Award Recipient
- Xu Han
  - St. Jude Children's Research Hospital
  - Memphis, TN

### 2012 David J. Goldstein Trainee Award Recipient
- Arthur J. Atkinson, Jr., MD
  - Mayo Clinic
  - Rochester, MN

### 2012 Paul Calabresi Medical Student Fellowship
- **2012 Faculty Development Award**
  - Timothy J. Nelson, MD, PhD
    - Mayo Clinic
    - Rochester, MN
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Patricia W. Slattum, PharmD, PhD, CGP
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GARY NEIL PRIZE FOR INNOVATION IN DRUG DEVELOPMENT
Terrence F. Blaschke, MD
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HENRY W. ELLIOTT DISTINGUISHED SERVICE AWARD
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Sue-Chih H. Lee, PhD

SHEINER-BEAL AWARD
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& Herman Cantrell

MATCHING GIFTS
Pfizer Foundation Matching Gifts Program
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ACKNOWLEDGEMENTS

Thank you to the ASCPT Board of Directors for their leadership and dedication in guiding the Society.

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ASCPT wishes to acknowledge the outstanding efforts of the Scientific Program Committee (SPC) in developing an exceptional educational offering.

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ASCPT would like to give special thanks to the leadership of the Coordinating Committee on Scientific Sections (CCSS) and recognize the Scientific Section Chairs for their dedicated leadership in support of section symposia, workshops, and other scientific endeavors.

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ACKNOWLEDGEMENTS

ASCPT would like to recognize the Scientific Awards Nominations Task Force for securing nominations for the 2012 Scientific Awards.

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ASCPT wishes to thank the abstract reviewers for their contributions to the 2012 ASCPT Annual Meeting.

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Mara L. Becker, MD, MSCE
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ASCPT would like to acknowledge the Scientific Awards Selection Task Force for selecting the 2012 Scientific Award recipients from a robust and highly competitive roster of exceptional nominees.

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ASCPT would like to recognize its members who have achieved ten year incremental membership anniversaries and thank them for their continued efforts on behalf of the Society and their contributions to the field of clinical pharmacology. These individuals exemplify ASCPT as an organization that provides valuable benefits throughout the careers of its members.
GENERAL INFORMATION

ASCPT Annual Meeting Sponsor
American Society for Clinical Pharmacology and Therapeutics
528 North Washington Street
Alexandria, VA 22314
Phone 703.836.6981 • Fax 703.836.5223
Web www.ascpt.org

Registration Hours
Maryland Lobby
Tuesday, March 13  Noon – 5:00 pm
Wednesday, March 14  7:00 am – 8:00 pm
Thursday, March 15  7:00 am – 5:00 pm
Friday, March 16  7:00 am – 5:00 pm
Saturday, March 17  7:00 am – Noon

Badges
For security reasons, all Annual Meeting attendees MUST wear their badges at all times for admission to sessions, the poster and exhibit hall, and social events.

Ribbons
Ribbons are available at the Registration kiosk located in the Maryland Lobby. Please pick up the appropriate ribbons at the registration area.

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.

ADA Compliance
ASCPT makes every effort to comply with the Americans with Disabilities Act.

ASCPT Ethics Statement
All scientific presentations at ASCPT-sponsored events must adhere to the highest standards of scientific ethics, including acknowledgements or references to sources (both scientific and financial), and the absence of promotional content or endorsement of commercial products. Any conflict of interest must be disclosed prior to the meeting.

ASCPT Disclaimer Statement
Authors and speakers are responsible for the content and ideas stated in their oral and written presentations. ASCPT is not responsible for, nor do we endorse any oral statements or written information given by presenters at this meeting.

Gather Digital Mobile Application
We’re excited to announce that this year ASCPT has collaborated with Gather Digital to provide a mobile application for this event. Get up-to-the-minute information for the agenda, updates from the conference planner, speaker information, maps, exhibitor and sponsor details, an attendee list, and more.

An iPhone and iPad app are available in the iTunes app store. Search ASCPT and download the ASCPT 2012 Annual Meeting app. You can also access the app with your BlackBerry, Android or other smart phone. Simply point your mobile browser and bookmark http://ascpt2012.gatherdigital.com.

A feature of the mobile app is that you and other attendees have the option to send messages to each other. It’s a great way to network with fellow attendees up to and during the event. You can also create a profile of yourself that other event attendees can view. To enable these features simply create a password through the app.

We hope you use and enjoy the mobile application.

ASCPT Central
Maryland Lobby
ASCPT Central will be open during the following hours:
Tuesday, March 13  Noon – 5:00 pm
Wednesday, March 14  7:00 am – 8:00 pm
Thursday, March 15  7:00 am – 5:00 pm
Friday, March 16  7:00 am – 5:00 pm
Saturday, March 17  7:00 am – Noon

At ASCPT Central you’ll have the opportunity to:
• Update your membership record
• Speak with a member of the CPT or CPT:PSP Editorial Staff
• Update your Scientific Section designations
• Sign up to participate on various ASCPT Committees
• Volunteer as a CPT or CPT:PSP manuscript reviewer
• Refer a colleague for membership in ASCPT

And much more!

Cyber Café
Maryland Lobby
ASCPT offers the complimentary use of computers with high speed internet access in one centralized location, thanks to the generous support of Duck Flats Pharma. In consideration of your fellow attendees, please limit your internet use to 10 minutes at a time.

The Cyber Cafe will be available during the following hours:
Tuesday, March 13  Noon – 5:00 pm
Wednesday, March 14  7:00 am – 8:00 pm
Thursday, March 15  7:00 am – 8:00 pm
Friday, March 16  7:00 am – 5:00 pm
Saturday, March 17  7:00 am – Noon
EXHIBIT HALL AND POSTER HOURS

Prince George’s Exhibition Hall C

Exhibit Hall and Posters will be open during the following hours:

- **Wednesday, March 14**: 6:00 pm – 8:00 pm (Opening Reception)
- **Thursday, March 15**: 8:00 am – 3:00 pm
- **Friday, March 16**: 8:00 am – 3:00 pm
- **Saturday, March 17**: 7:00 am – 12:30 pm (Posters Only)

SPAKER READY ROOM

Chesapeake A

ASCPT provides technical support through the services available in the Speaker Ready Room, Chesapeake A. Speakers will have the opportunity to review and revise their upcoming presentations. **Speakers are strongly encouraged to check in to the Speaker Ready Room a minimum of 90 minutes in advance of their scheduled presentation.** Our AV staff will be available to make changes to presentations received in advance and assist with technical issues.

The Speaker Ready Room will be available during the following hours:

- **Tuesday, March 13**: Noon – 5:00 pm
- **Wednesday, March 14**: 7:00 am – 8:00 pm
- **Thursday, March 15**: 7:00 am – 5:00 pm
- **Friday, March 16**: 7:00 am – 5:00 pm
- **Saturday, March 17**: 7:00 am – Noon

ASCPT JOB BOARD

Maryland Lobby

Are you looking for a new job in industry, academia, or government? Or are you an employer looking for a prime candidate to fill a position? If so, the ASCPT Job and Volunteer Opportunities Board is the perfect opportunity to reach over 1,000 leading professionals in clinical pharmacology.

The Job Board is located near ASCPT Central and is open during registration hours, from Tuesday, March 13 until Saturday, March 17. Stop by to speak to an ASCPT staff member to post a position or for more information on the Job Board.

ANNUAL MEETING EVALUATIONS

ASCPT is proud to provide its members with the highest quality of care and service. We appreciate all attendees’ feedback to continue to make the Annual Meeting a successful and enjoyable experience. Please take the time to evaluate the 2012 Annual Meeting and its daily sessions through the online evaluation website. All registrants will receive an email prior to the meeting with a link to the evaluation system. If you do not receive the email link, please visit www.ascpt.org.

The online evaluation system will be available from March 12, 2012 - April 30, 2012. Attendees will be able to complete session evaluations as they occur and will be able to save and return to the evaluation as needed. Upon completion of the evaluation, attendees will be able to print their certificate of attendance from their computer or send it directly to their email account.

POLICY ON PHOTOGRAPHY AND PHOTO RELEASE

Attendees at the ASCPT Annual Meeting are asked to refrain from taking photographs of posters and/or PowerPoint presentations during the meeting.

Registrants of the ASCPT Annual Meeting agree to allow ASCPT and its official photographer and/or videographer to photograph or videotape them in the context of the Annual Meeting setting. Footage captured by the official ASCPT photographer/videographer may be used in future print and electronic promotional and archival materials.

POLICY ON CHILDREN, SPOUSES, AND GUESTS

The ASCPT Annual Meeting is geared toward adult participation. For their safety, children under the age of 16 are not permitted in the exhibit hall, session rooms, or receptions for the duration of the meeting. Spouses and guests with a Social registration category are eligible to attend social functions only; admittance to educational programming is not permitted unless the registrant upgrades to a full conference or one-day registration. We appreciate your cooperation and understanding.

If your child(ren) will accompany you to the Annual Meeting and another adult will not be traveling with you, please make arrangements for care while you are attending meeting functions.

Should you need childcare during the ASCPT Annual Meeting we suggest you contact: SeekingSitters – an on-demand babysitting referral service. You can submit requests online for your last minute, one-time, part-time or full-time needs. A local SeekingSitters owner works to schedule a background screened Professional Sitter. SeekingSitters was founded by a licensed private investigator and mother of three young children making security their priority. Every SeekingSitters approved Professional Sitter undergoes an extensive interview process by a local owner and intense background screening before acceptance into the SeekingSitters Babysitting Team. SeekingSitters screen their members for their sitters safety! www.seekingsitters.com

ASCPT has not made any group arrangements or discounts and is not able to endorse the use of this firm; these are informational only.

If your spouse or a guest will accompany you to the Annual Meeting, please note that ASCPT does not offer spouse programs. However, the concierge at the Gaylord National Hotel is adept at making arrangements for dining reservations, excursion reservations, providing shopping and transportation information and answering general questions about local attractions.
CPT offers authors the option to publish their articles with immediate open access upon publication. Authors of original research will have the option to pay a one-time fee for their accepted paper to be made freely available online immediately upon publication. Papers that publish online as open access content will be identified in the journal with an open access image. Open access articles will also be deposited in PubMed Central at the time of publication and will be freely available immediately. This means more exposure for your research!

Contact the Editorial Office staff at cpt@ascpt.org for additional information.
SCIENTIFIC SECTION

Designations

Consistent with the Society's Scientific Section structure, each session presented at the Annual Meeting must also correlate to one or more therapeutic areas. Scientific Sections have been reorganized to increase scientific interaction and reflect the discipline of clinical pharmacology. Sections are grouped into two broad categories: the tools group consists of sections focused on how members do their work, and the applications group consists of sections focused on areas where tools are employed.

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

John Wagner, MD, PhD
Scientific Program Committee Chair
TUESDAY • MARCH 13

Noon - 5:00 pm
ASCPT Annual Meeting Registration Open  Maryland Foyer

WEDNESDAY • MARCH 14

7:00 am - 8:00 pm
ASCPT Registration Open  Maryland Foyer
ASCPT Central Open  Maryland Foyer

7:30 am - 3:00 pm
FDA Pharmaceutical Science and Clinical Pharmacology Advisory Committee Meeting  Maryland C

8:00 am - Noon
CPT Editorial Team Meeting (by invitation only)  Maryland 1

Noon - 1:30 pm
ASCPT Board of Directors and CPT Editorial Team Lunch (by invitation only)  Maryland 2

1:30 pm - 2:30 pm
New Member Welcome  Chesapeake D/E

2:00 pm - 2:45 pm
Award Reception (by invitation only)  Maryland 3

3:00 pm - 4:00 pm
Opening Session  Maryland B/4-6  sponsored by

State of the Society Address  President  Richard L. Lalonde, PharmD

Award Presentations
William B. Abrams Award for Geriatric Clinical Pharmacology
Presenter  Darrell Abernethy, MD, PhD • US Food and Drug Administration
Recipient  Janice B. Schwartz, MD • University of California

Henry E. Elliott Distinguished Service Award
Presenter  Scott A. Waldman, MD, PhD • Thomas Jefferson University
Recipient  Peter K. Honig, MD • AstraZeneca

Gary Neil Prize for Innovation in Drug Development
Presenter  Terrence Blaschke, MD • Stanford University School of Medicine
Recipient  Carl C. Peck, MD • University of California, San Francisco

ASCPT 2011 Young Investigator Awards
Presenter  Richard L. Lalonde, PharmD
Recipients  Landry Kamden Kamden, PharmD, PhD • Harding University School of Pharmacy
Laura Wozinak, MD • University of California, Los Angeles

2011-2012 Top Membership Recruiter
Presenter  Nancy A. Lass, MD • University of Chicago
Recipient  Gregory L. Kearns, PharmD, PhD • Children’s Mercy Hospital and Clinics

2011-2012 Membership Recruiting Honorable Mention
Presenter  Nancy A. Lass, MD • University of Chicago
Recipient  Jason Karnes, PharmD • University of Florida
**WEDNESDAY • MARCH 14**

3:00 pm - 4:00 pm (continued)

**OPENING SESSION - AWARD PRESENTATIONS** (continued)

**David J. Goldstein Trainee Award Winners**
**Presenter** Richard L. Lalonde, PharmD
**Recipients**
- Jason Sprowl, PhD • St. Jude Children's Research Hospital
- Cynthia S. Lancaster, PhD • St. Jude Children's Research Hospital
- Xu Han • Indiana University School of Medicine

**Jason Morrow Trainee Award Winner**
**Presenter** Richard L. Lalonde, PharmD
**Recipient** Qiiping Feng, PhD • Vanderbilt University

**2012 ASCPT Mentor Award**
**Presenter** Richard L. Lalonde, PharmD
**Recipient** Arthur J. Atkinson, Jr., MD • Northwestern University

**PhRMA Foundation Awards**
**Presenter** Darrell Abernethy, MD, PhD • US Food and Drug Administration
**2012 Award in Excellence in Clinical Pharmacology**
**Recipient** Andre Terzic, MD, PhD • Mayo Clinic

**2012 Paul Calabresi Medical Student Fellowship**
**Recipients**
- Jenny Barker • University of Texas Southwestern Medical Center
- Elizabeth Dong • Vanderbilt University

**2012 Faculty Development Award**
**Recipient** Timothy J. Nelson, MD, PhD • Mayo Clinic

**CEO Remarks** Sharon J. Swan, FASAE, CAE

4:00 pm - 5:00 pm

**STATE OF THE ART LECTURE** Maryland B/4-6
**Stephen P. Spielberg, MD, PhD** • Deputy Commissioner for Medical Products and Tobacco, US Food and Drug Administration
**Basic, Applied, Translational, and Regulatory Science: An Interactive Model for the Future of Therapeutics**
**Chair** Richard L. Lalonde, PharmD

5:30 pm - 6:00 pm

**SHOWCASE OF TOP TRAINEE ABSTRACTS** Prince George's Hall C

**ASCPT Presidential Trainee Award Winners**
**Presenter** Richard L. Lalonde, PharmD

**Manuela Vieira, PhD**
US Food and Drug Administration

**SeungHwan Lee, MD**
Seoul National University College of Medicine and Hospital

**J. Kevin Hicks, PharmD, PhD**
St. Jude Children's Research Hospital

**Jessica Lam, BSc**
Hospital for Sick Children

6:00 pm - 8:00 pm

**OPENING RECEPTION AND EXHIBIT HALL OPEN** Prince George's Exhibit Hall C

**sponsored by** Pfizer
SHOWCASE OF TOP TRAINEE ABSTRACTS

PT-1
OXALIPLATIN-INDUCED PERIPHERAL NEUROTOXICITY IS DEPENDENT ON OCT2-MEDIATED TRANSPORT
J.A. Sprowl, C. S. Lancaster, H. Giovinazzo, G. Du, L. Janke, A. Sparreboom; St Jude Children’s Research Hospital, Memphis, TN

PT-2
OATP1B1 POLYMORPHISM AS A DETERMINANT OF ERTHROMYCIN DISPOSITION
C. Lancaster, G. Hoffmann Brun, T. S. Mikkelisen, R. H. Mathijssen, A. Sparreboom; St Jude Children’s Research Hospital, Memphis, TN, Skeyby Hospital, Aarhus University Hospital, Aarhus, Denmark, Erasmus MC, Rotterdam, Netherlands

PT-3
NOVEL TRANSLATIONAL PARADIGM FOR DRUG-DRUG INTERACTION RESEARCH: A COMBINATION OF LITERATURE-BASED DISCOVERY, ELECTRONIC MEDICAL RECORDS AND IN VITRO DDI SCREENING ASSESSMENTS
X. Han, Z. Fang, A. Subhadarsini, S. Karki, R. M. Strother, S. D. Hall, Y. Jin, A. A. Flockhart, S. K. Quinney, J. D. Duke, L. Li, M. D. Roden, J. Smith, M. Rieder; 1Vanderbilt University, Nashville, TN, 2Marshfield Clinic Research Foundation, Marshfield, WI, 3Kaiser Permanente Southeast, Atlanta, GA, 4University of Washington, Seattle, WA, 5Cedars-Sinai Medical Center, Los Angeles, CA, 6Children’s Hospital Oakland Research Institute, Oakland, CA

PT-4
DOSE-RESPONSE CURVES EXTRACTED FROM ELECTRONIC MEDICAL RECORDS IDENTIFY SORT-1 AS A NOVEL GENETIC PREDICTOR OF STATIN POTENCY (ED). Q. Feng, M. S. Waitara, L. Jiang, H. Xu, M. Jiang, C. A. McCarty, R. L. Davis, D. M. Roden, D. A. Nickerson, J. Smith, M. Rieder, J. J. Rotter, R. M. Krauss, R. A. Wilke; 1Vanderbilt University, Nashville, TN, 2Marshfield Clinic Research Foundation, Marshfield, WI, 3Kaiser Permanente Southeast, Atlanta, GA, 4University of Washington, Seattle, WA, 5Cedars-Sinai Medical Center, Los Angeles, CA, 6Children’s Hospital Oakland Research Institute, Oakland, CA

PT-5
PHARMACOKINETIC-PHARMACODYNAMIC MODELING OF ARMODAFINIL: EFFECTS ON ALERTNESS AND ELECTROENCEPHALOGRAM OF SLEEP DEPRIVED ADULTS
D. J. Conrado, M. Bewernitz, M. Ding, J. Cibula, S. Eisenschken, C. Seubert, H. Derendorf; University of Florida, Gainesville, FL

PT-6
EVALUATION OF FDA AND EMA MODELS’ CUT-OFF VALUES FOR CYPIA INHIBITION PREDICTION: A COLLABORATIVE EFFORT AMONG ACADEMIC, REGULATORY AGENCIES, AND INNOVATION AND QUALITY CONSORTIUM (IQC) PHARMACEUTICAL SCIENTISTS

PT-7
INDUCTIVE EFFECT OF RIFAMPIN ON THE PHARMACOKINETICS OF VORICONAZOLE IN HEALTHY SUBJECTS
S. Lee, D. Shin, S. Kim, S. C. Ji, S. H. Toon, J. Y. Cho, S. G. Shin, I. J. Jang, K. S. Yu; Seoul National University College of Medicine and Hospital, Seoul, Republic of Korea

PT-8
AUTOMATED INCORPORATION OF PHARMACOGNOSTIC CONSULTS AND CLINICAL DECISION SUPPORT INTO AN ELECTRONIC MEDICAL RECORD

PT-9
PHARMACOGNOSTIC INSIGHT INTO OXYCODONE: IMPLICATIONS TO BREASTFEEDING MOTHERS AND NEONATES DURING THE POSTPARTUM PERIOD
V. Ancrenaz, Y. Daali, C. Samaer, J. Deglon, C. Staab, P. Dayer, J. Desmeules; Geneva University Hospitals, Geneva, Switzerland

PT-10
DUAL CYTOCHROME P450 3A AND CYP2B6 INHIBITION BY RITONAVIR AFFECTS PRASUGREL PHARMACOKINETICS IN HEALTHY VOLUNTEERS
H. Jong, H. de Loos, K. Verbeke, Y. Vanreentghem, D. R. Kuppers; 1Department of Nephrology and Renal Transplantation, University Hospitals Leuven, Leuven, Belgium, 2Department of Gastrointestinal Research, Catholic University Leuven, Leuven, Belgium

PT-11
IN VIVO CYP3A4-ACTIVITY AND CYP3A5-GENOTYPE PREDICT TACROLIMUS PHARMACOKINETICS IN RENAL TRANSPLANT RECIPIENTS
H. de Jonge, H. de Loos, K. Verbeke, Y. Vanreentghem, D. R. Kuppers; 1Department of Nephrology and Renal Transplantation, University Hospitals Leuven, Leuven, Belgium, 2Department of Gastrointestinal Research, Catholic University Leuven, Leuven, Belgium

PT-12
AZITHROMYCIN (AZI) MODEL TO DESCRIBE BLOOD AND PLASMA CONCENTRATIONS OVER TIME IN HEALTHY SUBJECTS
T. Pene Dumitrescu, T. Anic-Mitic, K. Oreskovic, J. Padovan, K. L. R. Brouwer; 1Division of Pharmacotherapy and Experimental Therapeutics, UNC Eshelman School of Pharmacy, University of North Carolina at Chapel Hill, Chapel Hill, NC, 2GSK Research Center Zagreb Ltd, presently Galapagos istraivački centar d.o.o., Zagreb, Croatia, Clinical Pharmacology Modeling and Simulation, GlaxoSmithKline, Research Triangle Park, NC

PT-13
PHENOBARBITAL CAN REVERSIBLY CONVERT TO ITS PRODRUG PRIMIDONE: A CASE REPORT AND ANIMAL MODEL
R. Tanoshima, G. W. Jong, D. Colantonio, A. Merlocco, J. Simpson, J. N. Friedman, G. Koren; 1Hospital for Sick Children, Toronto, ON, Canada, 2Human Health and Nutritional Sciences, University of Guelph, Guelph, ON, Canada
THURSDAY • MARCH 15

6:45 am - 8:15 am

Scientific Section Leadership Orientation (by invitation only) Chesapeake G/H

6:45 am - 8:00 am

Finance Committee Meeting (by invitation only) Chesapeake 11

7:00 am - 5:00 pm

ASCPT Registration Open Maryland Foyer
ASCPT Central Open Maryland Foyer

7:00 am - 9:00 am

ABCP Board Meeting (by invitation only) Chesapeake 1

8:00 am - 3:00 pm

Exhibits and Posters Open Prince George's Hall C

8:00 am - 9:00 am

Continental Breakfast in Exhibit Hall (all attendees) Prince George's Hall C

8:00 am - 9:30 am

CPT Editorial Board Meeting (by invitation only) Maryland 1 & 2
Poster Session I Prince George's Hall C
Late-Breaking Poster Session I Prince George's Hall C

8:15 am - 9:30 am

CCSS & Scientific Sections (by invitation only) Chesapeake G/H

9:45 am - 11:45 am • 3 Concurrent Symposia

PHATSO: Pharmacologic and Therapeutic Studies in the Obese
endorsed by DDR/SAF/ONC/SPO/PMK Maryland B/4-6

Chairs
Geert W. ’t Jong, MD, PhD • Hospital for Sick Children
Alex Sparreboom, PhD • St. Jude Children's Research Hospital

Speakers
Darrell Abernethy, MD, PhD • US Food and Drug Administration
Pharmacokinetics and Obesity: Historic Perspective
Nicholas Holford, MBChB, FRACP • University of Auckland, New Zealand
Mechanistic Basis of Using Size Metrics to Predict Clearance in the Obese
Gary Rosner, ScD • John Hopkins University
Anticancer Drug Dosing in the Obese: ASCO Guidelines
Catherijne Knibbe, PharmD, PhD • Leiden/Amsterdam Center for Drug Research
Obesity in Children: Dose Considerations and the Role of Population PK-PD Modeling

Learning Objectives
1. To review the influence of obesity on all aspects of pharmacokinetics and dynamics of drugs.
2. To review the application of modeling for understanding alterations in body composition and influences on pharmacokinetic parameters such as clearance and volume of distribution.
3. To discuss the impact of obesity on drug dosing in critical therapeutics like oncology drugs and special populations such as infants and children.
THURSDAY • MARCH 15

9:45 am - 11:45 am • 3 Concurrent Symposia (continued)

Modeling Practical Aspects of Clinical Trials
(Joint Symposium with ASCPT and Model Based Drug Development Consortium)

endorsed by DDR/SAF/PMK  Maryland C

Chairs  Virginia D. Schmith, PhD • GlaxoSmithKline
        Joga Gobburu, PhD • University of Maryland

Speakers  Diane Mould, PhD • Projections Research Inc.
           Modeling Heterogeneity From International Trials
           Huybert Groenendaal, MSc, PhD, MBA • EpiX Analytics LLC
           When There are Differences in Opinions: Expert Modeling
           Brendan Johnson, PhD • GlaxoSmithKline
           Bayesian Model Averaging: Addressing Uncertainty in Final Model Selection,
           When More Than One Model May be Appropriate
           Mats O. Karlsson, PhD • Uppsala University
           The Impact of Decisions by Treating Physicians on Modeling and Simulation of Clinical Trials

Learning Objectives
1. To describe the practical aspects of conducting clinical trials that complicate interpretation of results and modeling
   solutions to these issues.
2. To describe how to handle modeling of heterogeneity in international clinical trials.
3. To describe solutions to incorporating differences in expert opinions using a quantitative approach.
4. To describe how Bayesian Modeling Averaging can be used when there is uncertainty in the final model when more
   than one model may be appropriate.
5. To describe the consequences of physicians or patients making decisions during clinical trials.

Immunomodulatory Therapies and Progressive Multifocal
Leukoencephalopathy (PML): Novel Approaches to Risk Minimization
and Treatment of JC Virus Infection

endorsed by INF/OSD/SPO  Maryland D

Chairs  Juan J.L. Lertora, MD, PhD • NIH Clinical Center
        Dhanesh K. Gupta, MD • Northwestern University Feinberg School of Medicine

Speakers  Eugene O. Major, PhD • National Institute of Neurologic Disorders and Stroke
           PML as a Complication of Immunomodulatory Therapies:
           Clinical Impact and New Antiviral Agents for JC Virus
           Russell R. Lonser, MD • National Institute of Neurologic Disorders and Stroke
           The Challenge of Drug Delivery to the Brain: Convection Perfusion and Other Novel
           Approaches With Potential Application in the Therapy of PML
           Petra Duda, MD, PhD • Biogen Idec
           Clinical Strategies for PML Risk Stratification and Minimization
           Russell Katz, MD • US Food and Drug Administration
           Regulatory Perspectives on Serious Immunomodulatory Therapy: Related Complications

Learning Objectives
1. To inform the clinical significance of PML as a serious complication of effective immunomodulatory therapies and JC
   virus reactivation.
2. To discuss novel approaches to drug discovery and drug delivery to the CNS for the treatment of JC virus infection.
3. To address new strategies for PML risk minimization and related regulatory issues.

Juan J.L. Lertora, MD, PhD
Symposium Chair

Dhanesh K. Gupta, MD
Symposium Chair

Virginia D. Schmith, PhD
Symposium Chair

Joga Gobburu, PhD
Symposium Chair

Juan J.L. Lertora, MD, PhD
Symposium Chair

Dhanesh K. Gupta, MD
Symposium Chair
THURSDAY • MARCH 15

Noon - 1:15 pm

ASCPT Town Hall (box lunch available for attendees) See page 11 for complete details. Maryland A
Trainee Luncheon (ticketed event) See page 10 for complete details. Chesapeake D
Box Lunch (all attendees) Prince George's Exhibit Hall C

1:30 pm - 2:30 pm • 3 Concurrent Sessions

Sheiner-Beal Pharmacometrics Award Lecture Maryland B/4-6
This award is sponsored by the Department of Bioengineering and Therapeutic Sciences
University of California, San Francisco
Malcolm Rowland, DSc, PhD • University of Manchester, United Kingdom
Ask Not What, But Why: A Modeler’s Journey
Chair Leslie Benet, PhD • University of California, San Francisco
The Sheiner-Beal Pharmacometrics Award was established as an ASCPT award by the University of California, San Francisco (UCSF) to acknowledge the pioneering contributions of Drs. Lewis B. Sheiner and Stuart Beal to the field of Quantitative Pharmacology and Pharmacometrics. The Sheiner-Beal Pharmacometrics Award recognizes an investigator or leader who is actively advancing the scientific discipline of pharmacometrics and/or its impact on research, development, regulatory evaluation, or utilization of therapeutic products.

Featured Speaker Maryland C
Alex Sparreboom, PhD • St. Jude Children’s Research Hospital
Transporters and Chemotherapy Toxicity
Honorary Chair Mary V. Relling, PharmD • St. Jude Children’s Research Hospital

Oral Session OI-A: Biomarker Strategies in Neuroscience Maryland D
Chairs Masako P. Nakano, MD, PhD • Eli Lilly and Company
Malle Jurima-Romet, PhD • Celerion Inc.

OI-A-1
TIME-ON-TARGET PET STUDY DEMONSTRATES EQUIVALENT BRAIN NK1-RECEPTOR OCCUPANCY FOLLOWING SINGLE DOSES OF I.V. FOSAPREPITANT AND P.O. APREPITANT
Presenter Craig R. Shadle, MS • Merck and Company

OI-A-2
BNA REVEALS FM-THETA NETWORK IN A WORKING MEMORY TASK PERFORMED UNDER DONEPEZIL AND PLACEBO CONDITIONS
Presenter Keren Ziv, BSc • ElMindA LTD

OI-A-3
EEG EFFECTS OF SCOPOLAMINE IN HEALTHY SUBJECTS: A QEEG AND A SOURCE LOCALISATION STUDY
Presenter Geoffrey Viardot, PhD • Forenap

OI-A-4
PHARMACOKINETIC-PHARMACODYNAMIC MODELING OF ARMODAFINIL: EFFECTS ON ALERTNESS AND ELECTROENCEPHALOGRAM OF SLEEP DEPRIVED ADULTS
Presenter Daniela A. Conrado, MS • University of Florida
2:45 pm - 3:45 pm

**Special Session  Ask the Editors**  Maryland B/4-6

**Chair**  Richard L. Lalonde, PharmD

Introduction and Overview

**Speakers**  CPT:PSP Editor • to be announced

Welcome to the New Journal

Scott Waldman, MD, PhD, FCP • Thomas Jefferson University

CPT...What's New

Questions and Answers  Interactive Q&A with the Audience

Summary and Next Steps

All attendees are invited to participate in this special session where the latest information about *Clinical Pharmacology & Therapeutics* will be presented and ASCPT’s new journal, *CPT: Pharmacometrics & Systems Pharmacology*, will be discussed. The Ask the Editors session will provide a forum for member interaction with the editorial leadership of ASCPT’s journals to discuss the future of these two publications and plans to showcase even more cutting-edge research.

4:00 pm - 5:00 pm

**State of the Art**  Maryland B/4-6

Harvey V. Fineberg, MD, PhD • Institute of Medicine

Vaccines, Devices, Biomarkers, and Evaluation: The Impact of the Institute of Medicine Health Policy

**Chair**  Richard L. Lalonde, PharmD

5:00 pm - 5:15 pm

**Transition to the Future**  Maryland B/4-6

5:30 pm - 7:00 pm  • 3 Concurrent Section Meetings

**Biomarkers and Imaging (BIO)**  Maryland A

**Speakers**  Geoffrey Viardot, PhD • FORENAP, Rouffach, France

EEG Effects of Scopolamine in Healthy Subjects: A QEEG and a Source Localization Study

Kazuyoshi Arao • Oita, Japan

Mirtazapine Suppresses the Increases in Plasma Levels of Adrenocorticotropic Hormone and Neuropeptide Y Under Continual Stress Exposure

Ho-Sook Kim, PhD • Inje University College of Medicine, Busan, Republic of Korea

Both CYP2C19 and PON1 Genotypes are Associated with the Clinical Outcome of Clopidogrel in Patients with Acute Myocardial Infarction but not Angina

Jeremy Matlow, MSc Candidate • Hospital for Sick Children, Toronto, Canada

Ethyl Glucuronide as a Biomarker of Alcohol Consumption During Pregnancy

Aniket Natekar, MSc Candidate • Hospital for Sick Children, Toronto, Canada

Hair Cocaethylene as a Biomarker of Alcohol and Cocaine Co-Exposure

Craig Shadle, MS • Merck, North Wales, PA

Time-On-Target PET Study Demonstrates Equivalent Brain NK1-Receptor Occupancy Following Single Doses of I.V. Fosaprepitant and P.O. Aprepitant
THURSDAY • MARCH 15

5:30 pm - 7:00 pm • 3 Concurrent Section Meetings (continued)

**Molecular Pharmacology and Pharmacogenetics (MOL) • Maryland D**

**Speakers**
Yubo Chai, MD, PhD and Richard M. Weinshilboum, MD • Mayo Clinic, Rochester, MN

Selective Serotonin Reuptake Inhibitor (SSRI) Pharmacogenomics: Identification of Riboflavin Kinase (RFK) as a Novel Candidate Gene for SSRI Response by Genome-Wide Association Study (GWAS) Combined with Functional Genomics

Mingta Michael Lee • Institute of Biomedical Sciences, Academia Sinica, Taipei, Taiwan

A Prospective Study of Hla-B*5801 Genotyping for the Prevention of Allopurinol Induced Severe Cutaneous Adverse Reactions

**Pharmacometrics and Pharmacokinetics (PMK) • Maryland C**

**Speaker**
Ted Grasela, PharmD, PhD • President & CEO, Cognigen Corporation, Buffalo, NY

PMx Saves Pharma: Can It Be a Reality?

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5:30 pm - 7:30 pm

**UCSF Reception (by invitation only) • Maryland 2**

6:00 pm - 7:00 pm

**Donor Reception (by invitation only) • Pose – Lower Level**

**Social for Students and Trainees (students and trainees only) • Chesapeake D**

6:30 pm - 8:00 pm

**PhRMA Foundation Reception (by invitation only) • Maryland 3**

7:00 pm - 8:30 pm

**International Reception (by invitation only) • Maryland 1**

8:30 pm - 9:30 pm

**Gavel Club Dessert Reception (by invitation only) • President’s Suite**

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**Gather Digital Mobile Application**

We're excited to announce that this year ASCPT has collaborated with Gather Digital to provide a mobile application for the event. You will get up-to-the-minute information such as the latest agenda, updates from the conference planner, speaker information, maps, exhibitor and sponsor details, an attendee list and more.

An iPhone and iPad app are available in the iTunes app store. Search ASCPT and download the ASCPT 2012 Annual Meeting app. You can also access the app with your BlackBerry, Android or other smart phone. Simply point your mobile browser to http://ascpt2012.gatherdigital.com (note: omit the www) and bookmark it.

One of the features of the mobile app is that you and other attendees will have the option to send messages to each other through the app. It’s a great way to network with fellow attendees up to and during the event. You can also create a profile of yourself that other event attendees can view. To enable these features you must establish a password which you can do from the app.

We hope you use and enjoy the mobile application.
FRIDAY • MARCH 16

7:00 am - 5:00 pm
ASCPT Registration Open  Maryland Foyer
ASCPT Central Open  Maryland Foyer

7:00 am - 8:00 am
Clinical Pharmacology Program Directors Meeting  (by invitation only)  Maryland 1
Education Committee Meeting  (by invitation only)  Chesapeake D

7:00 am - 8:30 am  6 Concurrent Section Meetings

Drug Development and Regulatory Sciences (DDR)  Maryland A

Infectious Diseases (INF)  Chesapeake 11
Speaker  Craig Hendrix, MD  •  Johns Hopkins University School of Medicine, Baltimore, MD
Pharmacology as an Influential Factor for Understanding Outcomes in HIV Pre-Exposure Prophylaxis Trials

Oncology (ONC)  Maryland D
Speakers  Steven J. Bowlin, DO, MPH, PhD  •  Medco Research Institute, Franklin Lakes, NJ
12-Month Rates of Potential Drug Metabolizing and Transporter Based Drug-Drug Interactions with Enzyme-Targeted Oral Neoplastic Drugs
Weiwei Tan, PhD  •  Pfizer, Inc., San Diego, CA
The Development of Crizotinib in the Treatment of ALK-positive Non-Small Cell Lung Cancer: A Perspective of Clinical Pharmacology

Organ Specific Diseases (OSD)  Chesapeake H
Speaker  Mariellen J. Moore, PharmD  •  University of Florida, College of Pharmacy, Gainesville, FL
Clinical Predictors of Dysglycemic Effects Associated with Use of Beta Blockers and Thiazide Diuretics
Mariellen J. Moore, PharmD  •  University of Florida, College of Pharmacy, Gainesville, FL
Antihypertensive Medication Exposure and Adverse Glycemic Effects: An Evaluation of Fasting and Stimulated Glucose

Drug Safety (SAF)  Maryland C
Speaker  Xu Han  •  Indiana University, School of Medicine, Division of Clinical Pharmacology, Indianapolis, IN
Novel Translational Paradigm for Drug-Drug Interaction Research: A Combination of Literature-Based Discovery, Electronic Medical Records and In Vitro DDI Screening Assays

Special Populations (SPO)  Chesapeake 12
SPO Top Trainee Presentations: A Selection of the Best of ASCPT 2012 Abstracts

8:00 am - 3:00 pm
Exhibits and Posters Open  Prince George's Hall C

8:00 am - 9:00 am
Continental Breakfast in Exhibit Hall  (all attendees)  Prince George's Hall C

8:00 am - 9:30 am
Poster Session II  Prince George's Hall C
Late-Breaking Poster Session II  Prince George's Hall C

9:00 am - 10:00 am
State of the Art Lecture  Maryland B/4-6
Francis Collins, MD, PhD  •  Director, National Institutes of Health
New Partnerships to Accelerate Translation
Chair  Kathleen M. Giacomini, PhD
FRIDAY • MARCH 16

10:15 am - 12:15 pm • 4 Concurrent Symposia

CHINA CLINICAL PHARMACOLOGY TRIALS AND ETHNIC DIFFERENCES IN PK AND PD/New Asian Strategies for Drug Development

endorsed by DDR/PMK/SPO  Maryland B/4-6

Chairs  Feng Guo, PhD • Pfizer China Research and Development Center
        Shiew-Mei Huang, PhD • US Food and Drug Administration

Speakers  Peng Wang, MD • Center for Drug Evaluation (CDE), State of Food & Drug Administration (SFDA), China
        Phase I Trial Regulations in China and Extrapolation of Foreign Trial Data to the Chinese Population

        Pei Hu, MD • Peking Union Medical College Hospital
        Current Status of Phase I Trials in China

        Robert Powell, PharmD • Roche (China) Holding Ltd.
        Ethnicity Considerations on a New Bridging Strategy Driven by Patient Need and Science

        Feng Guo, PhD • Pfizer China R&D Center
        Ethnic Differences in Pharmacokinetics: Analysis of More Than 100 Phase I Studies

LEARNING OBJECTIVES
1. To introduce Phase I trial regulations, challenges, and opportunities for drug development in China and Chinese regulatory agency perspective on extrapolation of foreign trial data to the Chinese population.
2. To discuss mechanistic basis for differences in PK and PD in Chinese subjects, as well as ethnic differences in pharmacokinetics based on an analysis of more than 100 Phase I studies.
3. To provide ethnicity considerations on a new bridging strategy driven by patient need and science.

GAINED IN TRANSLATION: QUANTITATIVE PRECLINICAL AND CLINICAL APPROACHES TO THE DEVELOPMENT OF NEW PAIN MEDICINES

endorsed by OSD/PMK  Maryland C

Chairs  John Roberts, PhD • Novartis Pharmaceuticals
        Donald Mager, PharmD, PhD • University at Buffalo, SUNY

Speakers  Jeffrey Mogil, PhD • McGill University
        Animal Models of Pain as Pharmacodynamic Endpoints: Progress and Challenges

        Anne Estrup Olesen, PhD • Center for Mech-Sense, Aalborg Hospital
        Translational Pain Research: Case Studies in Evaluating PK/PD in Experimental Pain Studies

        Jaap Mandema, PhD • Quantitative Solutions, Inc.
        Model-Based Meta-Analyses for Development of Pain Medicines

        Jianren Mao, MD, PhD • Harvard Medical School
        Achievements and Challenges in Translational Pain Research

LEARNING OBJECTIVES
1. To define currently available preclinical pharmacodynamic models/endpoints for pain research and highlight key assumptions in translating drug pharmacology from the laboratory to the clinic based on these endpoints.
2. To gain an understanding of the current preclinical quantitative translatability of pain (PK/PD) models through several case studies and to convey experimental design implications that follow.
3. To review current clinical pain drugs as a means to understand the ultimate goal of translational PK/PD as related to clinical efficacy and adverse events.
**FRIDAY • MARCH 16**

10:15 am - 12:15 pm • 4 Concurrent Symposia (continued)

**OPTIMIZING PEDIATRIC THERAPEUTICS BY APPLYING LESSONS FROM ADULT DRUG DEVELOPMENT**  
endorsed by DDR/SPO  Maryland A

Chair  Walter K. Kraft, MD, MS • Thomas Jefferson University

Speakers  Gilbert J. Burckart, PharmD • US Food and Drug Administration  
Regulatory Viewpoint of the Use of Adult Data in Pediatric Submissions  
Theoklis E. Zaoutis, MD, MSCE • The Children’s Hospital of Philadelphia  
The Use of Epidemiology in Pediatric Drug Development  
Daniel K. Benjamin, Jr., MD, PhD, MPH • Duke University Medical Center  
Pediatric Trials Network: Optimizing Pediatric Clinical Trial Design  
Walter K. Kraft, MD, MS • Thomas Jefferson University  
Pediatric Drug Development When a Disease Exists in Both Adults and Children

**LEARNING OBJECTIVES**

1. To examine approaches to maximally leveraging adult data and methodologies to pediatric research.
2. To understand the FDA position on the use of adult data in pediatric drug development programs.
3. To identify research approaches for diseases common to adults and children.

**PHARMACOGENETICS IN DRUG DEVELOPMENT: AT THE ACADEMIC-INDUSTRY-REGULATORY CROSSROADS**  
endorsed by BIO/DDR/MOL/ONC  Maryland D

Chairs  Issam Zineh, PharmD, MPH • US Food and Drug Administration  
Yan Jin, MS, MD • Eli Lilly & Company

Speakers  Issam Zineh, PharmD, MPH • US Food and Drug Administration  
Pharmacogenetics in Drug Development and Regulation: The FDA Experience  
Robert L. Becker, Jr., MD, PhD • US Food and Drug Administration  
Development and Validation of Pharmacogenetic Tests During Drug Development: CDRH Points of View  
Michelle Penny, PhD • Eli Lilly and Company  
Genetics-Guided Drug Development: An Industry Perspective  
Michael Bristow, MD, PhD • University of Colorado - Arca Biopharma  
Academic-Based Research to Enhance Pharmacogenetics in Drug Development

**LEARNING OBJECTIVES**

1. To demonstrate enhanced understanding of regulatory guidance and experience in pharmacogenetics.
2. To outline prerequisites for successful development of pharmacogenetic markers to support personalized medicine.
3. To describe how academia based PGx research can inform development of drug therapy in target populations.

12:30 pm - 1:30 pm • 4 Concurrent Sessions

**Box Lunch (all attendees)**  Prince George’s Hall C

**OSCAR B. HUNTER MEMORIAL AWARD IN THERAPEUTICS LECTURE**  Maryland B/4-6

D. Craig Brater, MD • Indiana University School of Medicine  
Making a Career Out of Urine

**Presenter**  Terrence F. Blaschke, MD • Stanford University School of Medicine

The Oscar B. Hunter Memorial Award in Therapeutics Lecture recognizes an individual scientist for outstanding contributions to clinical pharmacology and therapeutics throughout his/her professional career.
12:30 pm - 1:30 pm • 4 Concurrent Sessions (continued)

**Oral Session OII-A**

**Next Generation Physiologically-Based Pharmacoinformatics**  
Maryland D

*Chairs*  
Karthik Venkatakrishnan, PhD • Millennium Pharmaceuticals, Inc.  
Lang Li, PhD • Indiana University

**OII-A-1**  
**Novel Translational Paradigm for Drug-Drug Interaction Research:** A Combination of Literature-Based Discovery, Electronic Medical Records and *In Vitro* DDI Screening Assays

*Presenter*  
Xu Han • Indiana University School of Medicine

**OII-A-2**  
**Application of Physiologically Based Pharmacokinetic (PBPK) Modeling for Prediction of Complex Drug-Drug Interactions (DDIs) Involving OATP1B1-Mediated Uptake and Cytochrome P450 (CYP) Metabolism and Multiple Inhibitors**

*Presenter*  
Karen Rowland Yeo • Simcyp Ltd., Sheffield, United Kingdom

**OII-A-3**  

*Presenter*  
Manuela Vieira, PhD • US Food and Drug Administration

**OII-A-4**  
**Dose-Response Curves Extracted from Electronic Medical Records Identify SORT-1 as a Novel Genetic Predictor of Statin Potency (ED$_{50}$)**

*Presenter*  
Qiping Feng, PhD • Vanderbilt University

**Oral Session OII-B**

**Emerging Genomic Data on CYP-3A4**  
Maryland A

*Chairs*  
Larisa Reyderman, PhD • Eisai Medical Research  
Rebecca Blanchard, PhD • Merck & Co Inc.

**OII-B-1**  
**Association Between the CYP3A4*22 Allele and the Pharmacokinetics of the CYP3A4 Phenotyping Probes Midazolam and Erythromycin in Cancer Patients**

*Presenter*  
Laure Elens, PhD • Erasmus Medical Center

**OII-B-2**  
**Global Analysis of CYP3A4 and CYP3A5 Genotype on *In Vivo* Clearance of CYP3A4 Substrates**

*Presenter*  
Sara K. Quinney, PharmD, PhD • Indiana University School of Medicine

**OII-B-3**  
**In Vivo CYP3A4-Activity and CYP3A5-Genotype Predict Tacrolimus Pharmacokinetics in Renal Transplant Recipients**

*Presenter*  
Hylke de Jonge, MD • University Hospitals Leuven

**OII-B-4**  
**Expression of Drug Metabolizing Enzymes and Transporter Proteins Along the Entire Human Gastrointestinal Tract**

*Presenter*  
Marek Drozdzik, MD • Pomeranian Medical University
FRIDAY • MARCH 16

12:30 pm - 1:30 pm • 4 Concurrent Sessions (continued)

**Oral Session OII-C**
**Targeted Investigation in Vulnerable Populations** Marylnd C

Chairs  
Mara L. Becker, MD, MSCE • Children’s Mercy Hospitals and Clinics  
Raymond J. Hohl, MD, PhD • University of Iowa

**OII-C-1**  
**WITHDRAWN**

**OII-C-2**  
PHARMACOGENETIC INSIGHT INTO OXYCODONE: IMPLICATIONS TO BREASTFEEDING MOTHERS AND NEONATES DURING THE POSTPARTUM PERIOD

Presenter  
Jessica Lam, BSc • Hospital for Sick Children

**OII-C-3**  
USING PBPK MODEL TO GAIN INSIGHT INTO CHANGES IN DISPOSITION OF CYP3A-METABOLIZED DRUGS IN PREGNANT WOMEN: DISCERNING CYP3A INDUCTION IN THE GUT VS. THE LIVER

Presenter  
Ban (Alice) Ke, MS • US Food and Drug Administration

**OII-C-4**  
POPULATION PHARMACOKINETIC MODELING OF PROPOFOL IN OBESE CHILDREN AND ADOLESCENTS

Presenter  
Jeroen Diepstraten • St. Antonius Hospital

1:45 pm - 2:45 pm • 2 Concurrent Sessions

**Rawls Palmer Progress in Medicine Award Lecture** Maryland B/4-6

Scott A. Waldman, MD, PhD • Thomas Jefferson University  
Translational Medicine: From Knowledge Generation to Healthcare Delivery

Presenter  
Howard E. Greenberg, MD, MS, MBA • Thomas Jefferson University

The Rawls Palmer Progress in Medicine Award Lecture recognizes a clinical pharmacologist for significant contributions to drug investigation that incorporate the efforts of modern drug research in the care of patients.

**Featured Speaker** Maryland A

Mary Jeanne Kreek, MD • The Rockefeller University  
Molecular, Neurobiological, and Genetics Studies of Specific Addictive Diseases: Bidirectional Translational Research

Chair  
Arthur J. Atkinson, Jr., MD • Northwestern University

2:45 pm - 3:15 pm

**Afternoon Refreshment Break** Prince George’s Hall C
3:30 pm - 5:30 pm • 3 Concurrent Symposia

New Perspectives in Drug-Induced Renal Injury
endorsed by DDR/SAF/ONC/OSD/SPO Maryland B/4-6
Chair Michael Spigarelli, MD, PhD • University of Utah
Speakers
- Douglas Throckmorton, MD • US Food and Drug Administration
  Drug-Induced Renal Injury: Implications for Drug Development and Regulation
- John van den Anker, MD, PhD • Children's National Medical Center
  Drug-Induced Renal Injury in Special Populations:
  Focus on the Neonate as a Patient Population at Increased Risk for Drug-Induced Renal Injury
- Gideon Koren, MD • Hospital for Sick Children
  Novel Strategies to Prevent Drug-Induced Renal Injury:
  Translation of In Vitro Protective Strategies to Animal Models and Clinical Trials

Learning Objectives
1. To appreciate the importance of drug-induced renal injury in drug development and drug regulation.
2. To appreciate the importance of drug-induced renal injury in special populations such as neonates.
3. To describe new mechanisms of drug-induced renal injury and potential new strategies to reduce the risk of drug-induced renal injury.

Novel Modeling and Simulation Approaches Applied to the Development of Biologics
endorsed by DDR/OSD/PMK Maryland A
Chairs Megan Gibbs, PhD • Amgen, Inc.
Manish Gupta, PhD, FCP • Bristol-Myers Squibb
Speakers
- Jeroen Jansen, PhD • Mapi Values, Inc.
  Network Meta-Analysis to Evaluate the Value of Biologics
- David Salinger, PhD • Amgen, Inc.
  Modeling of Early Biomarker Data in P1a to Inform P2b for a Novel Treatment for Psoriasis
- Jing Yu, PhD • Novartis Institutes for Biomedical Research, Inc.
  Mechanism Based Drug-Target Binding Models for Dose Selection of Biologics:
  From Target Feasibility to Market Support
- Jaap Mandema, PhD • Quantitative Solutions, Inc.
  Relative Effectiveness of Biologics in Rheumatoid Arthritis: A Dose-Response Meta-Analysis

Learning Objectives
1. To identify and evaluate the role of quantitative clinical pharmacology, modeling and simulation in the research and development of new biologics.
2. To appreciate the unique challenges and limitations of model based drug development for biologics.
3. To understand the value of advanced modeling and simulation in evidence-based drug development for therapeutics applied throughout the continuum for biologic drug development.
4. To understand the application of modeling and simulations to impact dose selection, study design, and endpoint selection.
5. To appreciate the application of meta-analysis to inform biologic drug development.
FRIDAY • MARCH 16

3:30 pm - 5:30 pm • 3 Concurrent Symposia (continued)

**CODEVELOPMENT OF INVESTIGATIONAL DRUGS FOR USE IN COMBINATION TO TREAT CANCER AND INFECTIOUS DISEASES**

directed by DDR/INF/MOL/ONC  Maryland C

**Chairs**
- Mark Dresser, PhD • Genentech, Inc.
- Lei Zhang, PhD • US Food and Drug Administration

**Speakers**
- Helen Chen, MD • National Cancer Institute
  - Codevelopment of Investigational Drugs to Treat Cancer: Overview, Background, and Scientific Rationale
- Iris T. Chan, MD, PhD • Genentech, Inc.
  - Novel Combination Drug Development in Oncology: First-In-Human Phase 1b Study of the MEK Inhibitor GDC-0973 and Pan-PI3K Inhibitor GDC-0941
- Patrick Smith, PharmD • Roche, Inc.
  - Addressing Unmet Medical Needs Through Multiple Combination Development: The Infectious Disease Perspective
- Jeffrey Murray, MD • US Food and Drug Administration
  - Regulatory Considerations for the Codevelopment of Unmarketed Investigational Drugs

**LEARNING OBJECTIVES**
1. To describe the scientific rationale and historical context of combining multiple NMEs to maximize cancer and infectious disease treatment outcomes.
2. To understand the potential risks and benefits associated with combining two or more NMEs in drug development, including the relative merits of various clinical development and clinical trial approaches for optimizing combination regimens through presentation of oncology and virology case studies.
3. To understand the regulatory perspective on the codevelopment of investigational agents for use in combination.

6:00 pm - 7:00 pm

**SCIENTIFIC SECTIONS MEET AND GREET** Maryland 2/3

6:30 pm - 7:00 pm

**LEADERSHIP AND MENTOR RECEPTION (by invitation only)** Maryland 1

7:00 pm - 9:00 pm

**PRESIDENT’S RECEPTION** Cherry Blossom Ballroom/Foyer

 sponsored by

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**GATHER DIGITAL MOBILE APPLICATION**

We're excited to announce that this year ASCPT has collaborated with Gather Digital to provide a mobile application for the event. You will get up-to-the-minute information such as the latest agenda, updates from the conference planner, speaker information, maps, exhibitor and sponsor details, an attendee list and more.

An iPhone and iPad app are available in the iTunes app store. Search ASCPT and download the ASCPT 2012 Annual Meeting app. You can also access the app with your BlackBerry, Android or other smart phone. Simply point your mobile browser to http://ascpt2012.gatherdigital.com (note: omit the www) and bookmark it.

One of the features of the mobile app is that you and other attendees will have the option to send messages to each other through the app. It’s a great way to network with fellow attendees up to and during the event. You can also create a profile of yourself that other event attendees can view. To enable these features you must establish a password which you can do from the app.

We hope you use and enjoy the mobile application.
# SATURDAY • MARCH 17

**6:45 am - 9:00 am**

**ASCPT Board of Directors Meeting** *(by invitation only)*  Chesapeake D

**7:00 am - Noon**

**ASCPT Registration Open**  Maryland Foyer  
**ASCPT Central Open**  Maryland Foyer

**7:00 am - 8:00 am**

**Continental Breakfast in Exhibit Hall** *(all attendees)*  Prince George's Hall C  
**Posters Open**  Prince George's Hall C  
**Poster Session III**  Prince George's Hall C  
**Late-Breaking Poster Session III**  Prince George's Hall C

**7:30 am - 2:00 pm**

**Career Bootcamp Half-Day Program** *(Trainees and students only.)*  
Chesapeake H/I  •  See page 40 for program details.  *(Registration is required.)*  
**Chairs**  
Kathleen Neville, MD, MS  •  Children's Mercy Hospitals and Clinics  
Bridgette Jones, MD  •  Children's Mercy Hospitals and Clinics

**8:00 am - 9:30 am**  •  **3 Concurrent Workshops**

**Crossing Over: Innovation and Alternative Trial Designs in Drug Development, Utilization, and Regulation**  
*endorsed by BIO/DDR/MOL/ONC*  Maryland A  
**Chair**  Issam Zineh, PharmD, MPH  •  US Food and Drug Administration  
**Speakers**  
Nicholas Schork, PhD  •  Scripps Research Institute  
Marker-Based Enrichment and N-of-1 Clinical Trial  
Robert Temple, MD  •  US Food and Drug Administration  
Crossover Trials: A Regulatory History and Perspective on Future Utility  
Robert Schmouder, MD, MPH  •  Novartis  
Innovations in early Clinical Trial Designs: Application to New Drug Development

**Learning Objectives**

1. To provide an overview of and rationale for biomarker-restricted clinical trials and discuss the "N-of-1" clinical trial as the "ultimate study design for personalizing medicine."
2. To outline FDA regulatory precedents related to crossover studies.
3. To describe current and future clinical and drug development contexts for innovations in clinical trial designs and discuss innovative ways to conduct trials required to prove that a new medicine is safe, effective, and of superior value to patients.
**SATURDAY • MARCH 17**

8:00 am - 9:30 am • 3 Concurrent Workshops (continued)

### Metabolites in Safety Testing: What Have Clinical Pharmacologists MIST?

*endorsed by DDR/PMK*  Maryland D

**Chair**  
Malle Jurima-Romet, PhD  Celerion, Inc.

**Speakers**  
Mark W. Powley, PhD  US Food and Drug Administration  
FDA MIST and ICH M3(R2) Guidance-Interpretation and Considerations  
R. Scott Obach, PhD  Pfizer, Inc.  
MIST for Clinical Pharmacologist  
Graham Lappin, PhD  University of Lincoln and Xceleron  
Analytical Technologies for Metabolite Identification and Quantitation

**Learning Objectives**

1. To discuss the rationale for the FDA and ICH regulatory guidances pertaining to MIST, areas in common and differences between these guidances, present an update on regulatory perspectives, and review some recent examples of regulatory application of the guidance documents.
2. To discuss the concerns underlying MIST: how can metabolites cause or contribute to toxicity, and the scientific issues involved and strategies for addressing the requirement for profiling of circulating human metabolites early in clinical development.
3. To discuss analytical technologies and strategies to obtain qualitative and quantitative metabolite data from early clinical studies to address MIST issues.

### Should We Tolerate the Maximally Tolerated Dose for Targeted Anti-Cancer Agents?

*endorsed by DDR/ONC/PMK*  Maryland C

**Chairs**  
Keith Orford, MD, PhD  GlaxoSmithKline  
Mark Stroh, PhD  Amgen Inc.

**Speakers**  
Christopher Carpenter, MD, PhD  GlaxoSmithKline  
The Maximally Tolerated Dosing Paradigm: History and Defense  
Michael Maitland, MD, PhD  University of Chicago Medical Center  
Being PC (Pharmacologically and Politically Correct) in Current Cancer Drug Development  
René Bruno, PhD  Pharsight  
The Use of Clinical Endpoints for Dose Selection

**Learning Objectives**

1. To review the rationale for use of maximally-tolerated dosing (MTD) in oncology.
2. To review the rationale for selection of the optimal dose (or dose range) based upon biomarker readout and/or clinical endpoints.
3. To encourage discussion regarding selection of the most appropriate dosing paradigm for targeted anti-cancer agents.

9:45 am - 10:45 am

**Leon I. Goldberg Young Investigator Award Lecture**  Maryland A

Michael Maitland, MD, PhD  University of Chicago Medical Center

**Next Phase, New Wave, Drug Craze, Anyways…**

**Presenter**  
Mark J. Ratain, MD  University of Chicago Medical Center

The Leon I. Goldberg Young Investigator Award Lecture recognizes a young scientist for accomplishments in the field of clinical pharmacology early in his/her career.
10:50 am - 11:50 am • 3 Concurrent Abstract Sessions

**Oral Session OIII-A**
**Innovative Quantitative Approaches in Drug Development and Trial Design**
Maryland D

Chair Amita Joshi, PhD • Genentech, Inc.

**OIII-A-1**
UNDERSTANDING PLACEBO RESPONSES IN ALZHEIMER'S DISEASE CLINICAL TRIALS
FROM THE LITERATURE META-DATA AND CAMD DATABASE
Presenter Kaori Ito, PhD • Pfizer, Inc.

**OIII-A-2**
DEVELOPMENT AND APPLICATION OF A MODEL-BASED DECISION CRITERION FOR A LABORATORY ENDPOINT TO FACILITATE TOFACITINIB (CP-690,550) PHASE 3 DOSE SELECTION
Presenter Pankaj Gupta, BPharm, PhD • Pfizer, Inc.

**OIII-A-3**
A SYSTEMS MODELING APPROACH TO UNDERSTANDING THE MECHANISMS OF RENAL PROTECTION WITH THE DIRECT RENIN INHIBITOR ALISKIREN (ALI)
Presenter K. Melissa Hallow, PhD • Novartis, Inc.

**OIII-A-4**
USE OF THE TARGET-MEDIATED DRUG DISPOSITION (TMDD) MODEL TO SUPPORT DOSE SELECTION OF AN OPTIMAL DOSING REGIMEN IN PHASE III TRIALS FOR GA101, THE FIRST TYPE II GLYCOENGINEERED, HUMANIZED MONOCLONAL ANTI-CD20 ANTIBODY
Presenter Florence Hourcade-Potelleret, PharmD • F. Hoffman-LaRoche, LTD

**Oral Session OIII-B**
**Application of Biomarkers in Oncology: from Discovery to Utilization**
Maryland C

Chairs Jerry Collins, PhD • National Cancer Institute, NIH
Sarah Holstein, MD, PhD • University of Iowa

**OIII-B-1**
A GENOME WIDE APPROACH FOR DISCOVERING POTENTIAL BIOMARKERS OF CHEMOTHERAPEUTIC AGENTS SUSCEPTIBILITY
Presenter Yujia Wen, PhD • The University of Chicago

**OIII-B-2**
IDENTIFICATION OF TRANSPORTERS AND KINASE TARGETS INVOLVED IN SORAFENIB SKIN TOXICITY
Presenter Sharyn D. Baker, PharmD, PhD • St. Jude Children's Research Hospital

**OIII-B-3**
PHARMACOGENOMICS OF BREAST CANCER ENDOCRINE THERAPY: TSPLY5 SNPS ARE ASSOCIATED WITH PLASMA ESTRADIOL (E2) CONCENTRATIONS AND THE REGULATION OF AROMATASE
Presenter Mohan Liu, PharmD • Mayo Clinic

**OIII-B-4**
ASSOCIATION BETWEEN TUMOR SIZE DYNAMICS AND TREATMENTS, PROGNOSTIC FACTORS AND CLINICAL OUTCOMES IN 2ND LINE NSCLC
Presenter Kelong Han • Genentech, Inc.
10:50 am - 11:50 am • 3 Concurrent Abstract Sessions (continued)

**Late-Breaking Oral Session**  Maryland A

These late-breaking abstracts will be presented as oral and poster presentations. See page 74 for complete abstract information.

**Chairs**  Kellie S. Reynolds, PharmD • US Food and Drug Administration  
Susan Shoaf, PhD • Otsuka Pharmaceutical Development and Commercialization

**LB-A-1**  
**AGE-RELATED DIFFERENCES IN PLASMA AND INTRACELLULAR (IC) TENOFOVIR (TFV) CONCENTRATIONS**  
**Presenter**  Gautam Baheti, MSc • University of Nebraska Medical Center

**LB-A-2**  
**PHARMACOKINETICS AND SAFETY OF METRONIDAZOLE IN PRETERM INFANTS: VALIDATION OF DRIED BLOOD SPOT SAMPLING**  
**Presenter**  Mario Sampson • Duke Clinical Research Institute

**LB-A-3**  
**EFFECT OF THE NOVEL CYP3A4 INTRON 6 POLYMORPHISM (CYP3A4*22) AND CYP3A COMBINED GENOTYPES ON TACROLIMUS DOSING REQUIREMENTS AND BLOOD CONCENTRATIONS IN PEDIATRIC HEART TRANSPLANT RECIPIENTS**  
**Presenter**  Violette M. Gijsen, MSc • Erasmus MC-Sophia Children’s Hospital

**LB-A-4**  
**INTRAVENOUS PARACETAMOL REDUCES MORPHINE REQUIREMENTS IN NEONATES AND YOUNG INFANTS UNDERGOING MAJOR NON-CARDIAC SURGERY: RESULTS OF A RANDOMIZED CONTROLLED TRIAL**  
**Presenter**  Saskia N. de Wildt, MD, PhD • Erasmus MC-Sophia Children’s Hospital

Noon - 1:30 pm • 3 Concurrent Workshops

**Evaluation of Concentration-QT Relationship in Early Clinical Development: Is a Thorough QT Study Necessary?**  
**endorsed by SAF/PMK**  Maryland A

**Chairs**  Venkat Jarugula, PhD • Novartis Institutes for Biomedical Research  
Joga Gobburu, PhD • University of Maryland

**Speakers**  Venkat Jarugula, PhD • Novartis Institutes for Biomedical Research  
*QT Evaluation in Early Clinical Development and Impact on Thorough QT Study*  
Brian Smith, PhD • Amgen, Inc.  
*Statistical Considerations in Characterizing Exposure: QTc Relationship in Drug Development*  
Christine Garnett, PharmD • US Food and Drug Administration  
*Value of Evaluation Concentration: QTc Relationship in Regulatory Decision Making*

**Learning Objectives**

1. To review and understand the role of concentration-QT relationship evaluation in drug development and its impact on regulatory decision making.
2. To discuss if a well characterized concentration-QT relationship during early clinical development can obviate the need to conduct a thorough QT study.
SUNDAY • MARCH 17

Noon - 1:30 pm • 3 Concurrent Workshops (continued)

**Imaging Studies of Drug Transport and Response**
*Endorsed by BIO/MOL, Maryland C*

**Chairs**
- John Mendelson, MD • California Pacific Medical Center Research Institute
- Kim L. R. Brouwer, PharmD, PhD • University of North Carolina

**Speakers**
- J. James Frost, MD, PhD, MBA • BioMolecular Imaging, LLC
- Imaging CNS Drug Transporters: From Early Development to Novel Market Opportunities
- Bertha Madras, PhD • Harvard Medical School
- Imaging Drug Occupancy of the Dopamine Transporter
- Kim L.R. Brouwer, PharmD, PhD • University of North Carolina at Chapel Hill
- Technetium-Labeled Probes to Assess Hepatic Transporter Activity and Drug-Drug Interactions in Humans

**Learning Objectives**
1. To be able to describe the use of imaging probes in the measurement of transport activity in the brain and liver, and in cocaine addiction.
2. To list potential sites of drug-drug interactions (DDIs) in hepatobiliary transport and describe how imaging agents can be used to assess hepatic transport-mediated DDIs.

**Novel Protein Therapeutics: Delivering Toxins to Tumors and mAbs to Patients to Improve Therapeutic Benefit**
*Endorsed by ONC, Maryland D*

**Chairs**
- Richard Graham, PhD • Genentech, Inc.
- Stacy Shord, PharmD • US Food and Drug Administration

**Speakers**
- Christine McIntyre, PhD • F. Hoffman-La Roche AG
- Enhancing Therapeutic Benefit of Monoclonal Antibodies Through Subcutaneous Administration
- Manish Gupta, PhD, FCP • Bristol-Myers Squibb
- Clinical Pharmacology of Antibody Drug Conjugates
- Stacy Shord, PharmD • US Food and Drug Administration
- Regulatory Commentary on Clinical Pharmacology of Novel Protein Therapeutics

**Learning Objectives**
1. To understand how delivery of monoclonal antibodies by subcutaneous administration may improve patient convenience and therapeutic benefit.
2. To diagram how each of the structural components of an ADC, including the monoclonal antibody or fragment, the linker, and the small molecule (payload), influence the nonclinical/preclinical and clinical pharmacology development study of a proposed drug product using examples of currently approved ADCs or those undergoing development.
3. To illustrate approaches within the US FDA to support the development of drug products in which the benefits outweigh the risks.

**Gather Digital Mobile Application**

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We hope you use and enjoy the mobile application.
CAREER BOOTA CAMP
HALF-DAY PROGRAM FOR TRAINEES & STUDENTS
SATURDAY, MARCH 17 • Chesapeake H/I

CHAIRS

Kathleen Neville, MD, MS
Bridgette Jones, MD

SPEAKERS

Gregory L. Kearns, PharmD, PhD
Jun Yang, PhD
Bert L. Lum, PharmD
David Katz, PhD
Deanna Kroetz, PhD
Anne Zajicek, MD, PharmD

7:30 am - 8:00 am  **Continental Breakfast**

8:00 am - 8:30 am  **How to Find a Mentor**
Kathleen Neville, MD, MS
This session will instruct trainees and those who are early in their career on how to find an appropriate mentor. Included will be expectations of a mentor/mentee relationship and how to foster highly productive lifelong mentor relationships.

8:30 am - 9:00 am  **A Five Year Plan to Jump Start a Career in Academia**
Gregory L. Kearns, PharmD, PhD
This session will provide trainees and those who are early in their career with instructions on how to develop a five year strategy for starting a successful career. Topics covered will include: 1) obtaining and maintaining funding; 2) considerations regarding tenure/promotion; and 3) how to develop and stay on track with career goals, including how to choose high yield projects and how/when to skillfully say no.

9:00 am - 9:30 am  **Negotiating a Starting Package**
Jun Yang, PhD
This session will provide valuable instructions on negotiating salary, lab/office space, faculty development and educational support, as well as other support infrastructure to ensure a successful start to a career.

9:30 am - 10:00 am  **Practical Points in Finding/Evaluating/Applying for Biotech/Pharma Positions**
Bert L. Lum, PharmD
This session will cover integrating the biotech revolution and clinical pharmacology into a career path that makes a difference. It will also cover how to showcase your skills (technical, research, general talents) and ambitions when applying for a position. Types of positions available (small vs. large pharma, biotech vs. pharma) will also be discussed.

10:00 am - 10:30 am  **Considerations Unique to Early Career Decisions in the Biotech/Pharma Industry**
David Katz, PhD
This session will cover the how/when/why to move within a company/between companies/between subspecialties in the biotech/pharma industry.

10:30 am - 10:45 am  **Break**

10:45 am - 11:45 am  **Ask the Experts: Getting Real Answers to Your Most Difficult Questions**
Kathleen Neville, MD, MS, Gregory L. Kearns, PharmD, PhD, and Jun Yang, PhD
This panel discussion will more fully elaborate on topics covered in the previous sessions, specifically in the areas of Academia and Industry. This session is designed to be an interactive discussion with attendees and between panelists and is intended to stimulate discourse around topics not routinely covered during training.

11:45 am - Noon  **Working Lunch Grab-n-Go**

Noon - 12:45 pm  **Grants 101/Non-NIH Funding**
Deanna Kroetz, PhD
This session will cover the basic components of every grant application and will briefly discuss resources in addition to NIH that are available for extramural funding.

12:45 pm - 1:45 pm  **Meet the NIH**
Anne Zajicek, MD, PharmD
This session will provide insight into navigating the NIH. A representative from the NIH will discuss award mechanisms through the NIH (K awards, R awards, early investigator status), organization structure, what do the acronyms mean, and how to navigate through the system.

1:45 pm - 2:00 pm  **Questions/Wrap-up**

40  Invited Chairs and Speakers are subject to change.
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### Accel Research Sites

- **Booth 112**
- **Address:** 860 Peachwood Drive, DeLand, FL 32720, USA
- **Phone:** 919.342.6512
- **Email:** scalandra@accelclinical.com
- **Website:** 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.

### Advanced Pharma CR, LLC

- **Booth 103**
- **University of Miami**
- **Address:** 1951 NW 7th Avenue, Miami, FL 33136 USA
- **Phone:** 305.220.2727
- **Fax:** 305.220.2730
- **Email:** samaba@advancedpharmacr.com
- **Website:** www.advancedpharmacr.com

Advanced Pharma CR is a dedicated Phase I-IV Clinical Research Facility located in the densely populated South Florida area at the state-of-the-art University of Miami Life Science & Technology Park. Our facility includes a 24-bed dedicated Phase I Unit, which will soon expand to a dedicated 125-bed Phase I Unit. APCR conducts clinical trials in ALL Specialties and ALL Indications.

### Algorithmhe Pharma

- **Booth 140**
- **Address:** 575, Armand-Frappier Blvd. Moskauer Str. 25, Laval, Quebec Canada, H7V 4B3
- **Phone:** 450.973.6077
- **Fax:** 1.888.267.7449
- **Email:** contact@algopharm.com
- **Website:** www.algopharm.com

Algorithmhe Pharma, a member of Altasciences, is an early stage clinical CRO with a full service offering, from study design to study conduct, PK/PD analysis and bioanalysis. Working along with their sister company, Simbec Research in the UK, they have been servicing international pharmaceutical, biotechnology and generic drug companies for over 35 years.

Algorithmhe Pharma’s GLP-compliant bioanalytical facilities perform large and small molecule bioanalysis on samples from preclinical to Phase IV studies.

The team is made up of almost 500 professionals from the medical and scientific fields who work together to conduct Phase I/IIa, Bioequivalence and 505(b)(2) studies, involving over 5,000 participants including patient populations.

### American College of Clinical Pharmacology

- **Booth 235**
- **Address:** PO Box 1637, Rockville, MD 20849, USA
- **Phone:** 240.399.9070 / 240.399.9076
- **Fax:** 240.399.9071
- **Email:** TStevens@ACCP1.org
- **Website:** www.ACCP1.org

American College of Clinical Pharmacology (ACCP) is a non-profit organization comprised of a wide spectrum of health care professionals devoted to improving health by optimizing therapeutics and providing innovative leadership and interdisciplinary education that will enable the generation, integration and translation of scientific knowledge to optimize research, development and utilization of medication for the benefit of all.

### Anaheim Clinical Trials

- **Booth 105**
- **Address:** 1085 N. Harbor Boulevard, Anaheim, CA 92801, USA
- **Phone:** 714.774.7777
- **Fax:** 714.399.4135
- **Email:** pm@act-trials.com
- **Website:** www.act-trials.com

Anaheim Clinical Trials (ACT) is a research center of excellence for the administration of PHASE I clinical trials.

ACT is one of the largest independently owned Research Sites in the United States. It is an organization committed to exceeding the needs and expectations of our clients by providing innovative, professional and superior quality service with integrity and reliability. Our mission is to advance science and ensure the protection and safety of all patients who choose to participate in our clinical trials, ensure compliance with government regulations, recognize the value of our client, subject, and employee partnerships, exceed customer expectations through a combination of dedication, hard work and perseverance without compromise, and champion solutions through innovative thinking.

### ARENSIA Exploratory Medicine

- **Booth 200**
- **Address:** 11491 Woodside Avenue, Anaheim, CA 92101, USA
- **Phone:** 619.469.0108
- **Fax:** 619.469.4108
- **Email:** john@aspire-irb.com
- **Website:** www.aspire-irb.com

AREN SIA EXPLORATORY MEDICINE is expert in performing EARLY PATIENT STUDIES in various therapeutic areas. We run modern Phase I units located in Eastern European university clinics.

Our projects imply a high degree of scientific and logistical features (e.g. sophisticated designs, biomarkers), within a fast regulatory approval environment.

AREN SIA’s competitive edge are unmatched recruitment speed in numerous patient populations and a spotless quality record for complex Phase I / II / POC studies.

Working with ARENSIA results in major savings because the Sponsor can reduce the number of sites, as we are able to deliver faster and in a single site.

### AspireIRB

- **Booth 134**
- **Address:** 11491 Woodside Avenue, Anaheim, CA 92104, USA
- **Phone:** 619.469.0108
- **Fax:** 619.469.4108
- **Email:** john@aspire-irb.com
- **Website:** www.aspire-irb.com

Aspire IRB is a fully AAHRPP accredited Independent Review Board (IRB), based in San Diego, CA, providing full IRB review and approval services for clinical trials in all therapeutic areas and Phases I-IV.

Aspire has a specialized Phase I team to assist with the unique requirements faced by early drug development clinical trials.

Aspire offers rapid and efficient turnaround, unparalleled customer support and 24/7 web based access to all documents via our ASAP web portal.
Bayer Technology Services GmbH

Building K-9
D-51368 Leverkusen
Germany

Phone +49 (0) 214 30-1
Email info@bayertechnology.com
Web www.bayertechnology.com

Bayer Technology Services GmbH, a Bayer AG company, is a capable supplier of technology solutions for the chemical and pharmaceutical industries. With the aim of supporting decision making along the pharma research and development process, our Systems Pharmacology Group offers software products for predictive simulation of drug behavior and modeling of cellular pathways (Computational Systems Biology Software Suite with PK-Sim* and MoBi*) as well as professional application and consulting services, integrating many years of in-house and external market experience.

Bio Pharma Services Inc.

4000 Weston Road
Toronto Ontario
Canada M9L3A2

Phone 416.747.8484
Fax 416.747.8480
Email t foster@biopharmaservices.ca
Web www.biopharmaservices.ca

BioPharma Services Inc. is an FDA-inspected, physician-owned, Contract Research specializing in Phase I/IIa clinical trials in healthy volunteers, special populations, and patient populations. Founded in 2006, we currently work with 40 pharmaceutical companies to conduct clinical trials for US, Canadian, and European submission. Bio Pharma’s modern Toronto-based Clinical Facility and Headquarter’s has 50,000 square feet in space and a 174-bed capacity comprised of three 48-64 bed BA/BE study clinics and one 14 bed ICU unit for first-in-man and first-in-patient clinical trials. This facility has also been inspected by Health Canada and UK MHRA.

Biotrial

7-9 rue Jean-Louis Bertrand
35000 Rennes
France

Phone +33 0 2 99 599 191
Fax +33 0 2 99 599 197
Email smarin@biotrial.com
Web 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, and Belgium, Biotrial performs hundreds of studies a year and offers tailor-made solutions to Pharma and Biotech companies. In the past year Biotrial expanded its Paris Unit, has opened a new 50,000 sq. ft. extension in Rennes and has announced the location of the new 100-bed Phase I Clinic in Newark, NJ, USA. In 2012 Biotrial continues to develop new partnerships in India as well as will be increasing bed capacity in the Rennes Phase I Clinic.

Ce3 Inc.

246 Goose Lane
Suite 202
Guilford, CT 06437
USA

Phone 203.252.7594
Fax 203.646.9919
Email mforgione@ce3inc.com
Web www.ce3inc.com

Ce3 is a full service contract research organization focused on providing biotechnology companies with Phase 1 – 3 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.

CMA, a Division of IDT Australia Limited

Level 5 East Wing
Royal Adelaide Hospital
North Terrace
Adelaide, SA, 5000
Australia

Phone +61 8 82222 3923
Fax +61 8 8223 3475
Email jane.kelly@cmax.com.au
Web www.cmax.com.au

CMA, a Division of IDT Australia Limited, has been established as a Phase I clinical research facility since December 1993, making it the longest-running in Australia. The facility has 50 beds, housed within a self-contained unit co-located within the Royal Adelaide Hospital, which is the largest public, teaching hospital in South Australia.

CMA specializes in the conduct of Phase I studies including first-time-in-man studies, as well as participating in Phase II-IV studies as an investigative site. CMA provides services to both local and international clients. We pride ourselves on the provision of high quality data and responsiveness to our clients.

CNS Network, Inc.

12772 Valley View Street
Garden Grove, CA 92845
USA

Phone 714.799.7799
Fax 714.799.1633
Email clinicaltrials@cnstrial.com
Web 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 14 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. For more information please access our web-site at www.cnstrial.com or contact Bobbie Theodore at 916-939-6696.

CPR Pharma Services Pty Ltd.

Suite C
32 West Thebarton Road
Thebarton, South Australia
5031
Australia

Phone 1 514 441 2313 (NA)
Fax +61 8 8125 1900 (AUS)
Email jannmarie.houle@cprservices.com.au
Web www.cprservices.com.au

CPR Pharma Services Pty Ltd. is an Australian and Singapore-based full-service CRO with a focus on early-stage clinical research, due to its unique combination of clinical trial, data management and accredited GLP bioanalytical services.

CPR expertise is recognized globally. CPR’s experienced staff and quality processes are confirmed by a successful FDA audit in 2011 and >85% rate of repeat business.
CRI Lifetree

16000 Horizon Way
Suite 100
Mount Laurel, NJ 08054
USA

CRI Lifetree is a leader in specialized, multi-therapeutic early stage research. The company has significant expertise in psychiatry, pain, neurology, pediatrics, and patient population trials, as well as widely recognized clinical trial expertise in Phase I-III pain management and abuse liability studies. CRI Lifetree offers a broad range of Phase 1-IV services and rapid access to specific patient populations to meet the requirements of complex clinical research programs. With sites in Philadelphia, New Jersey, and Salt Lake City, the company conducts inpatient and outpatient clinical research in special populations and healthy volunteers.

CRS - Clinical Research Services

Lohmannstraße 2
36626 Andernach
Germany

CRS is a leading European full-service CRO (Phase I-IIa, Phase Ib-IV, Bioanalytic, CDM/Statistics and CTSM services) with more than three decades experience in clinical trials. We have 200 beds amongst our three own clinical pharmacology units all of which function under a centralized common SOP system maintaining rigorous adherence to GCP, GLP, and GMP guidelines. These units are located in metropolitan areas providing facilitated recruitment of either healthy volunteers or patients. CRS offers the conduct of a complete range of high-quality clinical trials including FIM, POC, interaction trials, patient trials, and specialities like TQT, skin safety, respiratory research and renal/hepatic insufficiency studies.

Celerion

621 Rose Street
Lincoln, Nebraska 68502
USA

Celerion is the premier provider of innovative early stage clinical research solutions. From facilities strategically located around the world, advanced scientific and technological expertise is applied to global clinical research (over 730 beds (24 in-hospital) in Phases 0, I and IIa, NDA-enabling clinical pharmacology, ADME), clinical pharmacology sciences, global bioanalytical services (discovery through late stage), and drug development services. Celerion has a full spectrum of resources to meet the needs of the pharmaceutical, biotechnology and generic industries for Phase 0 through IIa proof-of-concept studies.

Cetero Research (i.e. CRS Management, Inc.)

2000 Regency Parkway
Suite 255
Cary, NC 27518
USA

Cetero is the industry's leading early-phase CRO, specializing in full-service clinical pharmacology, bioanalytical and scientific affairs services. With nearly 30 years of experience, we have conducted more than 20,000 clinical pharmacology studies – more than any other CRO.

Cetero's proven track record allows us to provide flexible and high-quality, drug-development services, and our time-tested systems produce consistent and reliable data you can trust.

With five clinical sites across North America, Cetero is the leader in early-stage development. Our repertoire of clinical-pharmacology study experience includes first-in-human, accelerated proof-of-concept, interaction, bioavailability, PK/PD and Thorough QT studies.

Clinical Pharmacology of Miami, Inc.

550 West 84 Street
Miami, Florida 33014
USA

Clinical Pharmacology of Miami, Inc. is a private pharmaceutical research organization dedicated to the conduct of clinical trials (Phase I-IV) in the South Florida area. Kenneth C. Lasseter, MD, Stacy C. Dilzer, RN, BSN, and E Cooper Shamblen are the principals who make up our experienced management team. We have the experience, expertise and facility to conduct safe, well controlled clinical research with new and existing drugs. Our research facility is state of the art and fully equipped with 120 beds. Our local subject population includes healthy males and females, Hepatically Impaired, Renal insufficiency, Hypertensive, Geriatric, Diabetic and Obese volunteers.

CRI Lifetree

16000 Horizon Way
Suite 100
Mount Laurel, NJ 08054
USA

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Clinilabs

Clinilabs is a full-service contract research organization (CRO) that provides early-phase and specialty clinical drug development services to industry. We offer teams, processes, and technology solutions designed to serve single center and multicenter early-phase or specialty patient studies – these services can be scaled as needed to meet the requirements of any clinical development program. Clinilabs is recognized globally as a leading specialty CRO, and has made important contributions to eleven successful new drug applications (NDAs) since 2001.

Community Research

Community Research is an independent, full-service contract research organization (CRO) providing comprehensive, life-cycle drug development services to biotechnology and pharmaceutical clients. With the most comprehensive portfolio of preclinical, clinical development and commercialization services, Covance provides industry-leading services, the world’s largest central laboratory network, and a global team of clinical trial and commercialization experts.

Covance, Inc.

Covance, with headquarters in Princeton, New Jersey, is one of the world’s largest and most comprehensive drug development services companies with more than 10,500 employees in over 60 countries.

CoreLab Partners Inc.

CoreLab Partners is a leading, independent core lab providing best-in-class centralized cardiac safety services and medical imaging assessment solutions for pharmaceutical, biotechnology, and medical device sponsors of Phase I-V studies. Our commitment to service quality and scientific excellence is focused on expediting our clients’ drug development programs.

By combining proven operational processes, experienced project teams and full-time, board-certified, sub-specialty trained radiologists, cardiologists, nuclear medicine physicians and oncologists, we deliver accurate, credible trial data on-time and on-budget.

CoreLab Partners boasts a truly global footprint with more than 325 employees and operational offices in North America, Europe and Asia.

Comprehensive Clinical Development

Comprehensive Clinical Development is a leading provider of premium early phase pharmacology and specialty trials. Concentrating in Phase 0-4 studies in three clinical pharmacology units and coast to coast patient-focused research centers, our expertise spans standard through complex studies, including radiolabelled and cardiac safety.

With access to healthy volunteers and special populations nationwide, we deliver a full range of clinical development services across an array of therapeutic areas, consistently delivering on time and within budget.

DaVita Clinical Research

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.

Duke Clinical Research

The Duke Clinical Research Unit combines the clinical expertise and academic leadership of one of the most prestigious university medical centers in the world with the operational capabilities of a full-service contract research organization, giving us the resources to conduct truly science driven global proof-of-concept studies in both adults and children. We offer rapid start-up, experienced thought leadership, direct access to patients, cutting-edge technologies, and first rate facilities. Combined with extensive operational capabilities, we offer a unique model for conducting early phase global clinical research that accelerates the development of new medical therapies and their translation into patient care.
ERT, Inc.  
1818 Market Street  
Suite 1000  
Philadelphia, PA 19103  
USA  
Phone 215.972.0420  
Fax 215.972.0414  
Email eresearch@ert.com  
Web 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.

ERT is the industry leader in centralized cardiac safety and respiratory efficacy services and also provides electronic patient reported outcomes (ePRO) for multiple modalities across all phases.

EUROFINS OPTIMED  
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Web www.optimed.fr

A French company founded in 1990, EUROFINS OPTIMED provides services for Early Clinical Development (First into Human and First into Patient studies, PK/PD studies, Proof of concept etc).

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MOLECULAR PHARMACOLOGY AND PHARMACOGENETICS (MOL)

PI-26
THE ASSOCIATION BETWEEN THE CYP2C19 GENOTYPE AND CLOBAZAM DOSE REQUIREMENTS IN JAPANESE PATIENTS WITH EPILEPSY
J. Saruwatari,1 N. Ogusu,1 M. Shimomasa,2 T. Sio,1 R. Nagata,2 S. Yoshida,3 K. Oniki,4 N. Yari-Furukori,5 S. Kaneko,5 T. Ishitani,5 K. Nakagawa;6 Division of Pharmacology and Therapeutics, Graduate School of Pharmaceutical Sciences, Kumamoto University, Kumamoto, Japan, 1Department of Neuropharmacology, Hirotsuki University School of Medicine, Hirotsuki, Japan, 2Kamamoto Saishunso National Hospital, Kumamoto, Japan, 3Division of Pharmacology and Therapeutics, Graduate School of Pharmaceutical Sciences, and Center for Clinical Pharmaceutical Sciences, Kumamoto University, Kumamoto, Japan.

PI-27
PROGRESSIVE DECLINE IN IN VIVO CYP1A4 ACTIVITY EXPLAINS TIME-RELATED INCREASE IN DOSE CORRECTED TACROLIMUS EXPOSURE AFTER RENAL TRANSPLANTATION
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PI-28
SYSTEMATIC EVALUATION OF PHARMACOGENOMIC ASSOCIATED ADVERSE EVENTS IN THE LITERATURE AND THE LABELING
S. S. Shord,1 P. Mummnenani,1 J. Vaidyanathan,1 G. Gieser,2 S. Amur,1 A. Adebowale; U.S. Food and Drug Administration, Silver Spring, MD.

PI-29
THE CONTRIBUTION OF GENETIC VARIATIONS ASSOCIATED WITH FKBPS EXPRESSION IN PREDICTION OF CLINICAL OUTCOMES IN DEPRESSION PATIENTS
K. A. Ellsworth,1 I. Moon,2 L. L. Pelleymounter,1 B. W. Eckloff,3 B. L. Fridley,3 G. D. Jenkins,4 A. Batzler,5 J. Biernacka,1 E. D. Wieben,3 T. Mushiroda,2 M. Kubo,2 Y. Nakamura,2 N. Kamatani,6 D. A. Mrazek,1 R. M. Weinsilboum,1 L. Wang,7 Mayo Clinic, Rochester, MN, 8RIKEN Center for Genomic Medicine, Yokohama, Japan.

PI-30
FUNCTIONAL ACTIVITY OF HUMAN HEART MICROSOMES EXPRESSING CYP2E1
J. Huguet,1 E. Chehade,1 V. Michaud,1 F. Gaadette,1 J. Turgeon1; 1University of Montreal - CRCHUM, Montreal, QC, Canada, 2University of Indianapolis, Indianapolis, IN.

PI-31
CYP450 FUNCTIONAL ACTIVITIES IN HUMAN HEART MICROSOMES
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PI-32
STEREOSELECTIVE CONJUGATION OF 4'-METHOXYPHENOTEROL STEROISOMERS BY SULFOTRANSFERASES
L. V. Iyer,1 A. Ramamoorthy,1 A. M. Purimsky,1 L. Tang,1 P. Catz,2 C. E. Green,1 I. W. Wainer1; 1SRI International, Menlo Park, CA, 2National Institute on Aging, Baltimore, MD.

PI-33
DEXMEDETOMIDINE DECREASES SERUM INSULIN CONCENTRATIONS AND THIS RESPONSE IS INFLUENCED BY ALPHA2A ADRENOCEPTOR GENETIC VARIATION
L. V. Ghimire,1 D. Kurnik,1 M. Muszkat,1 G. G. Sofowora,1 M. Scheinin,2 A. J. Wood,1 C. Stein; 1Vanderbilt University, Nashville, TN, 2University of Turku, Turku, Finland.

Molecular Pharmacology and Pharmacogenetics (MOL)

PI-34
IN VITRO METABOLISM STUDY OF EBASTINE AND 7-ETHOXYRESORUFIN IN BREAST CANCER CELL LINES
C. Armstrong,1 J. Huguet,1 F. Gaadette,1 F. Belanger,2 D. Balicki,1 J. Turgeon1; 1University of Montreal - CRCHUM, Montreal, QC, Canada, 2CRCHUM, Montreal, QC, Canada, 3University of Montreal, Montreal, QC, Canada.

PI-35
NON-SYNONYMOUS SNPS IN SELF, SELP, AND SIGLEC12 ASSOCIATE WITH CARDIOVASCULAR (CV) OUTCOMES IN THE INTERNATIONAL VERAPAMIL SR-TRANDOLAPRIL STUDY GENETIC SUBSTUDY (INVEST-GENES)
C. W. McDonough,1 B. Burkle,1 Y. Gong,1 T. Y. Langae,2 C. J. Pepine,2 R. M. Cooper-DeHoff1; 1University of Florida College of Pharmacy, Gainesville, FL, 2University of Florida College of Medicine, Gainesville, FL.

PI-36
ALPHA ADDUCIN-1 (ADD1) SINGLE NUCLEOTIDE POLYMORPHISM (SNP) ASSOCIATED WITH NEW ONSET DIABETES RISK WITH HYDROCHLOROTHIAZIDE (HCTZ) THERAPY IN THE INTERNATIONAL VERAPAMIL SR TRANDOLAPRIL GENETIC SUBSTUDY (INVEST-GENES)
J. H. Karnes,1 C. W. McDonough, Y. Gong, T. Y. Langae, C. J. Pepine, J. A. Johnson, R. M. Cooper-DeHoff; University of Florida College of Pharmacy, Gainesville, FL.

PI-37
SULFONYLUREA RECEPTOR POLYMORPHISMS IN ABCG8 AFFECT THE RESPONSE TO SULFONYLUREA TREATMENT IN PATIENTS WITH TYPE 2 DIABETES MELLITUS

PI-38
PON-1 IS NOT THE MAJOR BIOACTIVATION PATHWAY OF CLOPIDOGREL IN-VITRO
V. Ancrenaz1; 1Clinical Pharmacology Service, Geneva University Hospitals, Geneva, Switzerland, 2Geneva University Hospitals, Geneva, Switzerland.

Oncology (ONC)

PI-39
MULTIPLE DOSES (MD) OF RIDAFOROLIMUS (RIDA) DO NOT HAVE A CLINICALLY IMPORTANT IMPACT ON THE SINGLE DOSE (SD) PHARMACOKINETICS (PK) OF MIDAZOLAM (MDZ)
A. Patnaik,1 A. Tolcher,1 J. E. Talaty2; 2M. A. Stroh,1 J. B. McCrea,1 M. Truksis,1 J. Palcza,2 K. Orford,3 K. Cerchioro,1 S. Breidinger,1 D. Panebianco,1 J. A. Wagner,2 N. Agrawal,3 G. Carrizales,4 R. Lush,4 K. Papadopoulos4; 4South Texas Accelerated Research Therapeutics, San Antonio, TX, 5Clinical Pharmacology, Merck & Co., Inc., North Wales, PA, 6Clinical Pharmacology, Merck & Co., Inc., West Point, PA, 7Clinical Pharmacology and Therapeutics, Catholic University Leuven, Leuven, Belgium, 8Clinical Pharmacology, Merck & Co., Inc., Boston, PA, 9H. Lee Moffit Cancer Center and Research Institute, Tampa, FL.
ONCOLOGY (ONC)

PI-40
THE BIOAVAILABILITY OF AN ORAL LIQUID FORMULATION (OLF) RELATIVE TO A FORMULATED CAPSULE (FC) OF CRIZOTINIB, A DUAL ALK/MET INHIBITOR, IN HEALTHY SUBJECTS

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PI-41
ASSOCIATION OF ABCG2 POLYMORPHISMS WITH CISPLATIN DISPOSITION AND EFFICACY

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PI-42
CONTRIBUTION OF P53 SIGNALING TO CISPLATIN NEPHROTOXICITY IN OCT1/2-DEFICIENT MICE

C. S. Lancaster, J. A. Sprowl, R. M. Franke, A. A. Gibson, L. Li, D. Finkelstein, L. Janke, A. Sparreboom; St Jude Children’s Research Hospital, Memphis, TN.

PI-43
CONTRIBUTION OF METABOLISM TO SORAFENIB PHARMACOKINETIC VARIABILITY

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ORGAN SPECIFIC DISEASES (OSD)

PI-44
MANAGING ACUTE DEXMEDETOMIDINE WITHDRAWAL SYNDROME: A NOVEL MECHANISM BASED USE OF ORAL CLONIDINE

A. T. Kukoyi,1 S. A. Coker,1 L. D. Lewis,2 D. W. Nierenberg2; Albert Einstein Hospital, Philadelphia, PA, Dartmouth Hitchcock Medical Center, Lebanon, NH.

PI-45
CLINICAL PREDICTORS OF DYSGLYCEMIC EFFECTS ASSOCIATED WITH USE OF BETA BLOCKERS AND THIAZIDE DIURETICS

M. Moore,1 G. Yan,1 W. Hou,1 A. B. Chapman,1 T. Langaee,1 G. L. Schwartz,3 S. T. Turner,1 J. G. Gums,1 K. Bailey,1 E. Boerwinkle3, A. L. Bettelheims3, R. M. Cooper-DeHoff3, J. A. Johnson3; University of Florida, College of Pharmacy, Gainesville, FL, Emory University School of Medicine, Atlanta, GA, Mayo Clinic College of Medicine, Rochester, MN, Mayo Clinic College of Medicine, Rochester, GA, University of Florida, Colleges of Pharmacy and Medicine, Gainesville, FL, University of Texas at Houston Center for Human Genetics, Houston, TX, University of Maryland College of Medicine, Baltimore, MD.

PI-46
ANTIHYPERTENSIVE MEDICATION EXPOSURE AND ADVERSE GLYCEMIC EFFECTS: AN EVALUATION OF FASTING AND STIMULATED GLUCOSE

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PI-47
WITHDRAWN

PHARMACOMETRICS AND PHARMACOKINETICS (PMK)

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Y. Huh, D. E. Smith, M. R. Feng; University of Michigan, Ann Arbor, MI.

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M. E. Thomas, Jr, A. Wu, L. Liu, L. Kong, S. Choudhury, Y. Ye, M. Palmisano, O. L. Laskin; Celgene Corporation, Summit, NJ.

PI-51
SAFETY/TOLERABILITY AND PHARMACOKINETICS OF MULTIPLE ORAL DOSES OF APRILIMAST IN HEALTHY MALE SUBJECTS

A. Wu1, R. Bohane2, J. Ng2, B. DeGroot3, R. Colgan3, O. L. Laskin3; Celgene Corp., Summit, NJ, Celeron, Inc., Lincoln, NE.

PI-52
POPULATION PHARMACOKINETIC ANALYSIS OF (R)- AND (S)-KETAMINE AND NORKETAMINE IN RATS ON AD LIB AND CALORIE RESTRICTED DIETS

A. Ramamoorothy3, S. Van Wart1, R. de Cabo1, D. Mager3, I. Wainer1; National Institute on Aging (NIA/NIH), Baltimore, MD, University at Buffalo, Buffalo, NY.

PI-53
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M. Sanghvi1, R. Moaddel1, K. O’Loughlin1, C. Green2, A. Ramamoorothy3, I. Wainer1; NIA/NIH, Baltimore, MD, SRI International, Menlo Park, CA.

PI-54
POPULATION PHARMACODYNAMICS OF NADROPARIN IN MORBIDLY OBESE PATIENTS USING ANTI-XA LEVELS AS PHARMACODYNAMIC ENDPOINT

J. Diepstraten, E. J. Janssen, C. M. Hacking, S. van Kralingen, M. Y. Peeters, E. P. van Dongen, R. J. Wiezer, B. van Ramshorst, C. A. Knibbe; St. Antonius Hospital, Nieuwegein, Netherlands.

PI-55
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R. F. De Cock1, K. Allegaert2, A. Kulo1, J. de Hoon1, R. Verbesselt1, M. Danhof3, C. A. Knibbe4; Leiden University (LACDR), Leiden, Netherlands, University Hospital Leuven, Leuven, Belgium, University of Sarajevo, Sarajevo, Bosnia Herzegovina and University Hospital Leuven, Leuven, Belgium, Leiden University (LACDR), Leiden, Netherlands and St. Antonius Hospital, Nieuwegein, Netherlands.

PI-56
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R. F. De Cock1, K. Allegaert1, C. M. Sherwin1, M. de Hoog2, J. N. van den Anker3, M. Danhof3, C. A. Knibbe3; Leiden University (LACDR), Leiden, Netherlands, University Hospital Leuven, Leuven, Belgium, University of Utah School of Medicine, Salt Lake City, UT, Erasmus MC - Sophia Children’s Hospital, Rotterdam, Netherlands, Erasmus MC - Sophia Children’s Hospital, Rotterdam, Netherlands and Children’s National Medical Center, Washington, WA, Leiden University (LACDR), Leiden, Netherlands and St. Antonius Hospital, Nieuwegein, Netherlands.
PI-57 MODEL-BASED LITERATURE META-ANALYSIS OF LONGITUDINAL MATRICES CONSENSUS COGNITIVE BATTERY (MCCB) IN COGNITIVE IMPAIRMENT ASSOCIATED WITH SCHIZOPHRENIA (CIA)
B. Tan, S. Ahadieh, D. Palumbo, A. Banerjee, N. DeMartinis, J. Liu; Pfizer, Groton, CT.

PI-58 PHARMACOKINETICS AND PHARMACODYNAMICS OF MLTA3698A, A NOVEL ANTI-LYMPHOPOXIN-a MONOCLONAL ANTIBODY, IN A PHASE I STUDY WITH RHEUMATOID ARTHRITIS PATIENTS

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H. Sun1, D. Kennedy1, N. Lewis1, T. Latham2, K. Yee1, L. Van Bortel3, L. Rosen3, J. Chodakewitz1, J. Wagner1, G. Murphy1; Merck, North Wales, PA, 2Genentech, South San Francisco, CA, 3Merk, Brussels, Belgium.

PI-60 NO ADVERSE IMPACT OF REPEATED ORAL DOSES OF TERIFLUNOMIDE ON THE PHARMACOKINETICS OF ORAL CONTRACEPTIVE STEROIDS (ETHINYLESTRADIOL AND LEVONORGESTREL) IN YOUNG HEALTHY FEMALE SUBJECTS
S. Turpault1, B. Miller2, F. Menguy-Vacheron3, Sanofi-Aventis, Bridgewater, NJ, 2Sanofi-Aventis, Chilly-Mazarin, France.

PI-61 GENOTYPE-BASED IN VITRO-IN VIVO EXTRAPOLATION (IVIVE) OF EFAVIRENZ PHARMACOKINETICS USING A PHYSIOLOGICALLY-BASED PHARMACOKINETIC MODEL
C. Xu1, S. Quinney1, Y. Guo1, Z. Desta1; 1Division of Clinical Pharmacology, Indiana University School of Medicine, Indianapolis, IN, 2Department of Obstetrics and Gynecology, Indiana University School of Medicine, Indianapolis, IN, 3Drug Disposition, Lilly Research Laboratories, Indianapolis, IN.

PI-62 POPULATION PHARMACOKINETICS OF SM-26000, LIPOSOMAL AMPHOTERICIN B, IN JAPANESE PEDIATRIC PATIENTS WITH INVASIVE FUNGAL INFECTION
Y. Ohata1, Y. Tomita1, K. Suzuki2, T. Maniwa1, Y. Yano1, K. Sunakawa1; 1Dainippon Sumitomo Pharma Co., Ltd., Osaka, Japan, 2Kyoto Pharmaceutical University, Kyoto, Japan, 3Kitasato University, Tokyo, Japan.

PI-63 LOW DENSITY LIPOPROTEIN (LDL-C) EXPOSURE-RESPONSE ANALYSIS FOR TOFACITINIB (CP-690,550) IN PATIENTS WITH RHEUMATOID ARTHRITIS
S. P. Riley, M. G. Boy, R. Riese, S. Krishnaswami; Pfizer Inc, Groton, CT.

PI-64 A PHASE I STUDY TO ESTIMATE THE EFFECT OF KETOCONAZOLE ON THE PHARMACOKINETICS OF TOFACITINIB (CP-690,550) IN HEALTHY VOLUNTEERS
P. Gupta1, R. Wang1, I. Kaplan2, C. W. Alvey3, M. Ndongo4, S. Krishnaswami4; Pfizer Inc, Groton, CT, 2Pfizer Clinical Research Unit, Brussels, Belgium.
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THE EFFECT OF RIFAMPIN ON THE PHARMACOKINETICS OF TOFACITINIB (CP-690,550) IN HEALTHY VOLUNTEERS
M. Lamba, R. Wang, I. Kaplan, J. Salageanu, S. Tarabar, S. Krishnaswami; Pfizer, Groton, CT, Pfizer Clinical Research Unit, New Haven, CT.

PI-74
THE EFFECT OF FOOD ON THE PHARMACOKINETICS OF TOFACITINIB (CP-690,550)
M. Lamba, R. Wang, T. Stock, M. O’Gorman, S. Krishnaswami; Pfizer Inc, Groton, CT, Pfizer Inc, Collegeville, PA.

PI-75
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PI-78
POPULATION MODELING OF THE PHARMACOKINETICS AND PHARMACODYNAMICS OF PONESIMOD, A SELECTIVE S1P1 RECEPTOR AGONIST
A. Krause, P. Brossard, D. D’Ambrosio, J. Dingemans; Actelion Pharmaceuticals, Allschwil, Switzerland.

PI-79
MODEL-BASED META-ANALYSIS (MBMA) OF TOTAL MOTOR SCORE, CHOREA SCORE, AND TOTAL FUNCTIONAL CAPACITY FOR PATIENTS WITH HUNTINGTON’S DISEASE (HD)
Y. Jin, S. Ahadieh, E. Pickering, R. Evans, J. Liu; Pfizer Inc, Groton, CT.

PI-80
IMPORTANCE OF PK VARIABILITY ON DOSE SELECTION FOR COMPOUNDS WITH POTENTIAL INVERTED U SHAPE DOSE RESPONSE
Y. Jin, J. Liu, D. Nichols; Pfizer Inc, Groton, CT, Pfizer Inc, Sandwich, United Kingdom.

PI-81
CHARACTERIZATION OF GUINEA PIG MDRI/P-GP FUNCTION
I. Hasibou, D. Patoine, S. Pilote, B. Drolet, C. Simard; Institut Universitaire de Cardiologie et de Pneumologie de Quebec, Quebec, QC, Canada.

PI-82
CHARACTERIZATION OF GUINEA PIG CYP2C FUNCTION
I. Hasibou, S. Pilote, D. Patoine, B. Drolet, C. Simard; Institut Universitaire de Cardiologie et de Pneumologie de Quebec, Quebec, QC, Canada.

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A NEWLY DEVELOPED PEDIATRIC FORMULATION OF REVATIO FOR PEDIATRIC PULMONARY ARTERIAL HYPERTENSION PATIENTS IS BIOEQUIVALENT TO THE 1X20 MG REVATIO COMMERCIAL TABLET AND TO THE 2X10 MG SILDENAFIL CITRATE CLINICAL TRIAL TABLETS IN HEALTHY ADULT VOLUNTEERS
X. Gao, L. Robert, M. O’Gorman, J. Cook; Pfizer, Inc, Groton, CT.

PI-84
A PHASE I STUDY TO ASSESS THE EFFECT OF LU AA21004 ON THE STEADY-STATE PHARMACOKINETICS OF LITHIUM IN HEALTHY MALE SUBJECTS
G. Chen, R. Lee, Z. Zhao, M. Serenko; Takeda Global Research and Development Center, Deerfield, IL.

PI-85
A POPULATION ANALYSIS OF UNBOUND MYCOPHENOLIC ACID PHARMACOKINETICS AND PHARMACOGENETICS IN ADULT ALLOGENEIC HEMATOPOIETIC CELL TRANSPLANTATION
A. Frymoyer, D. Verotta, P. A. Jacobson, J. Long-Boyle; University of California, San Francisco, San Francisco, CA, University of Minnesota, Minneapolis, MN.

PI-86
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S. Misaka, N. Miyazaki, J. Yatabe, K. Kawabe, K. Takano, T. Ono, S. Onoue, T. Fukushima, S. Yamada, J. Kimura; Fukushima Medical University, Fukushima, Japan, University of Shizuoka School of Pharmaceutical Sciences, Shizuoka, Japan, Hamamatsu University School of Medicine, Hamamatsu, Japan.

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C. Tang, S. Saito, J. Satterwhite, G. Cameron, S. Banerjee, L. Tham; Lily-NUS Centre for Clinical Pharmacology Pte Ltd, Singapore, Singapore, Eli Lilly and Company, Indianapolis, IN.

PI-90
EFFECT OF ACTIVATED CHARCOAL ON THE PHARMACOKINETICS OF APIXABAN IN HEALTHY SUBJECTS
X. Wang, G. Tirucherrai, N. Panammi, J. Wang, A. Elsrouy, V. Teslenko, M. Chang, D. Zhang, C. Frost; Bristol-Myers Squibb, Princeton, NJ.
PI-91
A CLINICAL STUDY TO ASSESS EFFECT OF RIFAMPIN ON THE PHARMACOKINETICS (PK) OF NEBATTIN (HKI-272), A PAN-ERBB RECEPTOR TYROSINE KINASE INHIBITOR, WHEN ADMINISTERED CONCOMITANTLY IN HEALTHY SUBJECTS
R. Abbas, B. Hug, C. Leister, D. Sonnichsen; Pfizer, Collegeville, PA.

PI-92
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A. Grover, L. Z. Benet; University of California, San Francisco, San Francisco, CA.

PI-93
ORAL MIDAZOLAM (MDZ) PARTIAL AREA UNDER-CURVE (AUC) DOES NOT RELIABLY PREDICT CYTOCHROME P450 (CYP) 3A BASELINE ACTIVITY IN HEALTHY SUBJECTS
W. Tai, S. L. Gong, S. M. Tsunoda, H. E. Greenberg, J. C. Gorski, S. R. Penzak, S. A. Stock, J. D. Ma; UCSI, Skaggs School of Pharmacy & Pharmaceutical Sciences, La Jolla, CA, 3Department of Pharmacology and Experimental Therapeutics, Thomas Jefferson University, Philadelphia, PA, 4Mylan Pharmaceuticals, Morgantown, WV, 5Pharmacy Department, National Institutes of Health, Bethesda, MD, 6Mercy, Rahway, NJ.

PI-94
ORAL MIDAZOLAM (MDZ) PARTIAL AREA UNDER-CURVE (AUC) DOES NOT RELIABLY PREDICT CYTOCHROME P450 (CYP) 3A INHIBITION/ACTIVATION IN HEALTHY SUBJECTS
S. L. Gong, W. Tai, S. M. Tsunoda, H. E. Greenberg, J. C. Gorski, S. R. Penzak, S. A. Stock, J. D. Ma; UCSI, Skaggs School of Pharmacy & Pharmaceutical Sciences, La Jolla, CA, 3Department of Pharmacology and Experimental Therapeutics, Thomas Jefferson University, Philadelphia, PA, 4Mylan Pharmaceuticals, Morgantown, WV, 5Pharmacy Department, National Institutes of Health, Bethesda, MD, 6Mercy, Rahway, NJ.

PI-95
POPULATION PHARMACOKINETIC ANALYSIS OF DAPAFLIFLOZIN IN PATIENTS WITH TYPE 2 DIABETES MELLITUS
Y. Hong, A. Ropj; D. Boulton, F. LaCreta, S. Parikh; UCSD, Skaggs School of Pharmacy & Pharmaceutical Sciences, La Jolla, CA, 3Department of Pharmacology and Experimental Therapeutics, Thomas Jefferson University, Philadelphia, PA, 4Mylan Pharmaceuticals, Morgantown, WV, 5Pharmacy Department, National Institutes of Health, Bethesda, MD, 6Mercy, Rahway, NJ.

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PI-97
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X. Chen, X. Liu, S. Peng, W. V. Williams, V. Sandor, S. Yeleswaram; Incyte Corp., Wilmington, DE.

PI-98
POPULATION PK/PD ANALYSIS OF SPLEEN VOLUME IN SUBJECTS WITH MYELOFIBROSIS (MF) ADMINISTERED WITH RUXOLITINIB
X. Chen, X. Liu, S. Peng, W. V. Williams, V. Sandor, S. Yeleswaram; Incyte Corp., Wilmington, DE.

PI-99
POPULATION PK/PD ANALYSIS OF TOTAL SYMPTOM SCORE (MFSAF) IN SUBJECTS WITH MYELOFIBROSIS (MF) TREATED WITH RUXOLITINIB
X. Chen, X. Liu, S. Peng, W. V. Williams, V. Sandor, S. Yeleswaram; Incyte Corp., Wilmington, DE.

PI-100
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F. Khalil, F. Lacer; Department of Clinical Pharmacy and Pharmacotherapy, Heinrich-Heine-University of Duesseldorf, Duesseldorf, Germany.

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POPULATION PHARMACOKINETICS OF VORICONAZOLE IN HUMAN PLASMA AND AQUEOUS HUMOUR AFTER ORAL ADMINISTRATION
Y. Daali, L. Cottet, M. Gex-Fabry, P. Dayer, E. Baglivo, J. Desmeules; Geneva University Hospitals, Geneva, Switzerland.

PI-103
PAIN PERCEPTION AND PROCESSING IN A MEDICATED STATE: A PILOT STUDY IN AN ELDERLY COHORT
A. Edginton, K. Schaffler; University of Waterloo, Waterloo, ON, Canada, 3HPR Dr. Schaffler GmbH, Munich, Germany.

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A PROBABILISTIC RISK ASSESSMENT OF BREAST CANCER TREATMENT FAILURE DURING CO-ADMINISTRATION OF TAMOXIFEN AND PAROXETINE AS IT RELATES TO CYP2D6 GENOTYPE
A. Edginton, M. Sevestre, J. Stingl; University of Waterloo, Waterloo, ON, Canada, 3Design2Code, Waterloo, ON, Canada, 4University of Ulm, Ulm, Germany.

PI-105
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J. Lee, V. Crentsil; U.S. Food and Drug Administration, Silver Spring, MD.

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V. Crentsil, J. Lee, A. Jackson; U.S. Food and Drug Administration, Silver Spring, MD.
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THE PHARMACOKINETICS OF BRENTUXIMAB VEDOTIN (SGN-35), AN ANTIBODY-DRUG CONJUGATE (ADC)
T. H. Han,1 D. Kennedy,1 S. Hayes,1 C. M. Lynch;1 Seattle Genetics, Inc., Bothell, WA, 2ICON Development Solutions, Ellicot City, MD.

PII-2
BRENTUXIMAB VEDOTIN (SGN-35), AN ANTIBODY-DRUG CONJUGATE, DOES NOT AFFECT MIDAZOLAM PHARMACOKINETICS
T. H. Han, L. E. Grove, C. M. Lynch; Seattle Genetics, Inc., Bothell, WA.

PII-3
EFFECT OF DISCONTINUING ORAL ANTI-DIABETIC DRUGS (OAD) PRIOR TO ENROLLMENT IN A PHASE I TRIAL
R. J. Schott,1 J. E. Angeles,2 H. Larrabee,2 C. Humphreys,2 K. M. Schott,2 L. A. Morrow,2 M. Hompesch;1 Profoil Institute for Clinical Research, Chula Vista, CA, 2Profil Institute for Clinical Research, Chula Vista, CA.

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PII-5
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S. Raja, N. Buidha, M. Dresser; Genentech, South San Francisco, CA.

PII-6
PREDICTING CYP3A4 INHIBITION IN CYP2D6 POOR METABOLIZERS USING PBPK MODELING AND SIMULATION: FESOTERODINE AS AN EXAMPLE
M. L. Vieira, P. Zhao, M. Kim, S. Apparaju, S. Huang; Food and Drug Administration, Silver Spring, MD.

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J. Vaidyanathan, V. Arya, S. Agarwal, M. de L T Vieira, P. Zhao, S. Huang, L. Zhang; FDA, Silver Spring, MD.

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J. Cho,1 H. Kim,1 S. Back,2 J. Choi,1 I. Jang,1 G. Bae,1 J. Shin;1 Department of Pharmacology and Clinical Pharmacology, Inje University College of Medicine and Busan Paik Hospital, Busan, Korea, Republic of, 2Clinical Trial Center, Busan Paik Hospital, Busan, Korea, Republic of.

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P. Statkevich, T. Kosogolou, B. Kumar, J. Li, F. Xuan, Z. Wang, A. G. Meehan, D. I. Cutler; Merck Sharp & Dohme Corp., Whitehouse Station, NJ.

DRUG SAFETY (SAF)

PII-10
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I. R. Youngs, T. P. Laughren, Y. Wang, M. Mathis, J. V. Gobburu; FDA, Silver Spring, MD.

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THE PHARMACOKINETIC PARAMETERS OF A NOVEL, NANO-FORMULATED LOWER DOSE ORAL DICLOFENAC
G. Manvelian, S. Daniels, A. Gibofsky; Iroko Pharmaceuticals, LLC, Philadelphia, PA, 2Premier Research Group, Austin, TX, 3Hospital for Special Surgery, New York, NY.

PII-12
ACUTE PAIN RELIEF BY A PROPRIETARY, NANO-FORMULATED LOWER DOSE ORAL DICLOFENAC
G. Manvelian, S. Daniels, A. Gibofsky; Iroko Pharmaceuticals, LLC, Philadelphia, PA, 2Premier Research Group, Austin, TX, 3Hospital for Special Surgery, New York, NY.

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B. L. Stangl, M. Zametkin, V. Vatsalya, V. A. Ramchandani; NIAAA, Bethesda, MD.
MOLECULAR PHARMACOLOGY AND PHARMACOGENETICS (MOL)

PII-19
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Z. Jiao1, P. Sun, X. Qiu, M. Zhong; Huashan Hospital, Fudan University, Shanghai, China.

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Y. Wang1, M. Trucksis1, J. McElwee1, P. Wong1, C. Macingol1, C. Thompson1, T. Prueksaritanont1, C. Gibson1, G. Garrett1, R. Deleroq1, E. Vets1, K. Willson1, R. Smith, J. Clappensbach1, G. Opietek1, T. Tsou1, T. Laethem1, P. Panorchan1, L. Maganti1, M. Ivamoto1, R. Rippley1, P. Shaw1, J. Wagner1, J. Harrelson1; 1Merck & Co., Inc., Whitehouse Station, NJ, 2SGS Life Science Services, Antwerp, Belgium.

PII-21
ASSOCIATION OF FTO WITH HYDROCHLOROTHIAZIDE (HCTZ)-INDUCED ELEVATION IN URIC ACID (UA) IN AFRICAN AMERICAN (AA) HYPERTENSIVES IN THE PHARMACOGENOMIC EVALUATION OF ANTIHYPERTENSIVE RESPONSE (PEAR) STUDY
A. G. Vander1, C. W. McDonough1, T. Y. Langsee1, B. Burkley1, Y. Gong1, S. T. Turner1, J. G. Gums1, A. B. Chapman1, A. L. Beitelshiese1, K. R. Bailey2, E. Boerwinkle1, R. M. Cooper-DeHoff1, J. A. Johnson1; 1University of Florida, Gainesville, FL, 2Mayo Clinic, Rochester, MN, 3Emory University, Atlanta, GA, 4University of Maryland, Baltimore, MD, 5University of Texas, Houston, TX.

PII-22
A TRANSLATIONAL APPROACH TO LINK CLINICAL OBSERVATIONS WITH MECHANISMS OF ACTION FOR FENOBRIBATE
R. A. Farris, C. A. Wiley, E. T. Price; University of Arkansas for Medical Sciences, Little Rock, AR.

PII-23
DRUG-DRUG INTERACTIONS BETWEEN ROSUVASTATIN AND β-BLOCKERS THROUGH THE OATP1A2 TRANSPORTER
J. Lu1, F. Gaudette1, Y. Leung1, J. Turgeon1; 1Montreal University, Montreal, QC, Canada, 2CRCHUM, Centre de Recherche du Centre Hospitalier de l’Universite de Montreal, Montreal, QC, Canada.

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DRUG-TRANSPORTER INTERACTIONS: INHIBITION OF MCT1 AND MCT4 BY STATINS
Y. Leung1, F. Blanger1, C. Armstrong1, J. Lu1, J. Turgeon1; 1University of Montreal (CRCHUM), Montreal, QC, Canada, 2CRCHUM, Montreal, QC, Canada.

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GENOME-WIDE GENETIC ASSOCIATION STUDIES OF SSRI SIDE EFFECTS
C. C. Wen1, L. Shen1, K. M. Giacomini1, N. Risch1, C. Schafer2; 1Department of Bioengineering and Therapeutic Sciences, University of California, San Francisco, San Francisco, CA, 2Kaiser Permanente Northern California Division of Research, Oakland, CA, 3Department of Epidemiology and Biostatistics, University of California, San Francisco, San Francisco, CA.

PII-26
MIDAZOLAM PHARMACOKINETICS ARE NOT INFLUENCED BY POLYMORPHISMS OF HEPATIC OATP1B1 IN HEALTHY VOLUNTEERS
V. C. Ziesenitz1, S. K. Koenig1, J. Weiss1, J. Burhennne1, W. E. Haefeli1, G. Mikus1; 1Department of Clinical Pharmacology and Pharmacopmdemiology, University Hospital Heidelberg, Heidelberg, Germany and Center for Clinical and Community Research, Children’s National Medical Center, Washington, DC, 2Department of Clinical Pharmacology and Pharmacoepidemiology, University Hospital Heidelberg, Heidelberg, Germany, 3Department of Clinical Pharmacology and Pharmacopmdemiology, University Hospital Heidelberg, Heidelberg, Germany.

PII-27
EFFECT OF OATP INHIBITION BY RIFAMPICIN ON THE PHARMACOKINETICS OF FENTANYL IN HEALTHY VOLUNTEERS GENOTYPED FOR ORGANIC ANION-TRANSLOCATING POLYPEPTIDE 1B1
V. C. Ziesenitz1, N. Mahlke1, S. K. Koenig1, G. Skopp1, J. Weiss2, J. Burhennne1, W. E. Haefeli1, G. Mikus1; 1Department of Clinical Pharmacology and Pharmacopmdemiology, University Hospital Heidelberg, Heidelberg, Germany and Center for Clinical and Community Research, Children’s National Medical Center, Washington, DC, 2Institute of Legal Medicine, University Hospital Heidelberg, Heidelberg, Germany, 3Department of Clinical Pharmacology and Pharmacopmdemiology, University Hospital Heidelberg, Heidelberg, Germany.

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Y. Liu1, J. Tian1, H. Kuo1, S. Liu1, S. Lu1, K. Lin1, Y. Chen2; 1National Health Research Institutes, Miaoli County, Taiwan, 2College of Medicine, National Taiwan University, Taipei, Taiwan.

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T. Rusdiana1, T. Araki1, T. Nakamura1, A. Subarnas1, K. Yamamoto1; 1Department of Clinical Pharmacology, Gunma University Graduate School of Medicine, Maebashi, Japan, 2Faculty of Pharmacy, Padjadjaran University, 3J. Raya Bandung-Sumedang km 21 Jatinangor, Indonesia.

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

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R. Harrell, Jr., A. Karim,1 W. Zhang,1 C. Dudkowski2; 1Arkansas Research Medical Testing, Little Rock, AR, 2AzK Consulting, Skokie, IL, 3Takeda Global Research and Development, Deerfield, IL.

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S. Tse1, S. Raje,2 M. Seymour,3 Y. Shishikura,3 R. S. Obach1; 1Pfizer Inc, Groton, CT, 2Pfizer Inc, Collegeville, PA, 3Xceleron, LLC, Heslington, York, United Kingdom.

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S. Tse,1 K. Powell,2 S. Fournier,3 S. J. MacLennan,1 A. R. Moorman,1 C. Paterson,1 R. Bell1; 1Pfizer Inc, Groton, CT, 2Tandem Lab., Durham, NC, 3CiTox LAB Research, N.A., Laval, QC, Canada, 4Pfizer Inc., Cary, NC. Currently BioCryst Pharmaceuticals, Inc., Durham, NC, 5Pfizer Inc., Cary, NC. Currently Alta Vetta Pharmaceutical Consulting LLC, Durham, NC, 6Pfizer Inc., Cary, NC. Currently Salix Pharmaceuticals Inc., Raleigh, NC, 7Pfizer Inc, Groton, CT.

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P. T. Pollak, R. J. Herman, K. B. Zarnke; University of Calgary, Calgary, AB, Canada.

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T. Kim1, J. Kim1; 1University of North Carolina-Chapel Hill, Chapel Hill, NC, 2Clinical Pharmacology Modeling and Simulation, GlaxoSmithKline, Research Triangle Park, NC.

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Y. Kim,1 H. Yoon,2 B. Choi,2 G. Noh1; 1Department of Clinical Pharmacology and Therapeutics, Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea, Republic of, 2Department of Anesthesiology and Pain Medicine, Chungnam National University College of Medicine, Daejeon, Korea, Republic of, 3Department of Anesthesiology and Pain Medicine, Asan Medical Center, University of Ulsan College of Medicine, Seoul, Republic of Korea, 4Department of Clinical Pharmacology and Therapeutics, Department of Anesthesiology and Pain Medicine, Asan Medical Center, University of Ulsan College of Medicine, Seoul, Republic of Korea.

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R. P. Singh,1 M. D. Sahre,2 H. Derendorf,1 V. D. Schmith1; 1University of Florida, Gainesville, FL, 2Food and Drug Administration, Silver Spring, MD, 3GlaxoSmithKline, RTP, NC.
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J. Lee,1 S. Park,1 S. Seong,1 S. Han,2 M. Lim,2 J. Park,1 J. Seo,1 H. Lee,1 Y. Yoon1; 1Kyungpook National University Hospital Clinical Trial Center, DAEGU, Korea, Republic of, 2Department of Pharmacology, College of Medicine, the Catholic University of Korea, Seoul, Korea, Republic of, 2Yuhan Corporation, Republic of, 2Department of Pharmacology, College of Medicine, the Catholic University of Korea, Seoul, Republic of, 2Yuhan Corporation, Republic of.

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H. Sung, Y. Kim, S. Jin, Y. Noh, H. Choi, M. Kim, K. Bae; Department of Clinical Pharmacology and Therapeutics, Asan Medical Center and University of Ulsan College of Medicine, Seoul, Republic of Korea.

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N. Gupta,1 C. Lu, K. Venkatakrishnan; Millennium Pharmaceuticals, Inc., Cambridge, MA.

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N. Gupta, M. Saleh, K. Venkatakrishnan; Millennium Pharmaceuticals, Inc., Cambridge, MA.

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S. Han, J. Lee, S. Jeon, T. Hong, D. Yim; The Catholic University of Korea, Seoul, Republic of Korea.

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S. Seong,1 J. Lee, S. Park, M. Lim, J. Park, J. Seo, H. Lee,1 Y. Yoon; Kyungpook National University Hospital Clinical Trial Center, Daeug, Republic of Korea.

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M. Dostalek,1 R. Y. Gohh,2 F. Akhlaghi1; 1University of Rhode Island, Kingston, RI, 2Brown University Medical School, Rhode Island Hospital, Providence, RI.

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M. Dostalek, W. Sam, F. Akhlaghi; University of Rhode Island, Kingston, RI.

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W. Chandranapongse, S. Ito; The Hospital for Sick Children, University of Toronto, Toronto, ON, Canada.
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L. P. James,1 L. Letzig,1 D. W. Roberts,1 J. E. Sullivan,1 K. Yan,1 P. M. Simpson2; 1Arkansas Children’s Hospital Research Institute, Little Rock, AR, 2Medical College of Wisconsin, Milwaukee, WI.

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R. Preston,1 A. Karim,1 D. Garg,1 Z. Zhao,1 C. Dudkowski1; 1Miller School of Medicine, University of Miami, Miami, FL, 2AzK Consulting, Skokie, IL, 3Clinical Research Services, Boynton Beach, FL, 4Takeda Global Research and Development, Deerfield, IL.

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S. N. de Wildt,1 M. Koninckx,1 U. Kraemer,1 E. A. Buijs,1 I. Reiss,1 D. Tibboel; Erasmus MC-Sophia Children’s Hospital, Rotterdam, Netherlands.

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C. Nanavati,1 B. Xia,1 T. Heimbach,1 H. He1; 1Department of Pharmaceutical Sciences, University at Buffalo, State University of New York, Buffalo, NY, 2Novartis Institute for Biomedical Research, East Hanover, NJ.

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A. M. Cressman,1 K. L. Silver,1 K. C. Kain,1 M. Piquette-Miller1; 1University of Toronto, Department of Pharmacology and Toxicology, Toronto, ON, Canada, 2University of Toronto, McLaughlin-Rotman Centre for Global Health, Toronto, ON, Canada, 3University of Toronto, Leslie Dan Faculty of Pharmacy, Toronto, ON, Canada.

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G. D. Dai, T. Sing, W. Sallas, O. Chiparas, K. Gillis, S. Novick, Y. Wang; Novartis Oncology, East Hanover, NJ.
POSTER SESSION III
PRINCE GEORGE'S EXHIBIT HALL C  ★  Saturday, March 17  |  7:00am-12:30pm  |  Attended Poster 7:00am-8:00am

DRUG DEVELOPMENT AND REGULATORY SCIENCES (DDR)

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A. M. Abdelhady1 Z. Desta1 F. Jiang1 C. W. Yeo1 J. Shin1 B. R. Overholser2 Purdue University College of Pharmacy, West Lafayette, IN, 2Indiana University School of Medicine, Indianapolis, IN, 3Inje University College of Medicine, Busan, Republic of Korea.
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PHARMACOKINETICS OF ORAL 3,4-METHYLENEDIOXYAMPHETAMINE IN HUMANS
DR. WILLIAM B. ABRAMS LECTURE

INTEGRATING MULTIPLE SOURCES OF INFORMATION TO UNDERSTAND DRUG ACTION:
FROM MOLECULAR STRUCTURE TO CLINICAL POPULATION DATA

DATE
MAY 23, 2012
1:30 pm – 2:30 pm

LECTURER
RUSS B. ALTMAN, MD, PHD
Professor of Bioengineering, Genetics and Medicine
Stanford University

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White Oak Campus
Shared Use Facility / Room 2047
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Silver Spring, MD

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LB-A-1

AGE-RELATED DIFFERENCES IN PLASMA AND INTRACELLULAR (IC) TENOFOVIR (TFV) CONCENTRATIONS

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BACKGROUND
To use population pharmacokinetic (PK) modeling to investigate apparent differences in plasma TFV and IC TFV-diphosphate (TFV-DP) concentrations (conc) in children and adolescents compared with adults following tenofovir disoproxil fumarate (TDF) dosing.

METHODS
Data were pooled from 3 different studies in HIV-infected children, adolescents, and adults receiving TDF 300 mg daily. TFV plasma conc were measured 6-8 times and IC TFV-DP 2-3 times in each subject. Data analysis began in October, 2011. A 2-compartment model (NONMEM® 7.2) subdivided by age, allometrically scaled for children and adolescents and partitioned for slow and fast absorbers (Tmax either <2 or >2 hrs, respectively) was utilized for plasma TFV. IC conc were modeled using an indirect response model: EC50 (plasma conc producing 50% of maximum effect [Emax]); kin (0 order rate constant for TFV-DP production); kout (IC elimination rate constant); partitioned by age (>25 or <25 years). kout for adults was fixed to a previous estimate. Covariates included age, sex, weight, race, creatinine clearance (CRCL), Tanner stage (adolescents), total bilirubin, and concomitant protease inhibitor.

RESULTS
Subjects: N=102 (61 male/41 female), 88 with IC conc. Median (range) age and CRCL were: 21 (9-60) years and 128 (43.3-267.6) ml/min, respectively. In final plasma model (FOCEI), oral clearance (CL/F) was significantly faster in those < vs. > 25 years. CRCL was the most significant covariate on CL/F and central distribution volume. IC TFV-DP EC50 was 69 vs 116 ng/mL, and t1/2 (= to 0.693/kout) was 70 h vs 86 hrs for those < vs > 25 yrs; Emax was fixed at 1200 fmol/106 cells.

CONCLUSION
Children and adolescents achieve higher IC TFV-DP conc than adults despite lower plasma conc. This analysis suggests a mechanism of greater phosphorylation sensitivity (quantified as lower EC50) vs. slower IC elimination. Additional mechanistic studies are needed to understand fully the clinical pharmacology of IC TFV.

LB-A-2

PHARMACOKINETICS AND SAFETY OF METRONIDAZOLE IN PRETERM INFANTS: VALIDATION OF DRIED BLOOD SPOT SAMPLING

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BACKGROUND
Metronidazole is routinely used to treat intra-abdominal infections in preterm infants. Pharmacokinetic (PK) data for this drug in this population are virtually absent. Dried blood spot (DBS) technology has the potential to enable appropriate PK studies in this population necessary to define age-appropriate dose.

METHODS
A prospective, open-label, multicenter study of 24 infants (<32 weeks gestation and 15 days postnatal age) was performed. Sparse plasma and DBS samples were obtained around the first dose, at doses 3-5, and with the last dose. Concentrations were determined by HPLC/MS/MS (LLOQ 50 ng/mL). Population nonlinear mixed effect modeling was used to analyze the PK data, and plasma vs. DBS concentration association was evaluated using linear regression techniques. Last infant was enrolled November 1, 2011, and data were subsequently analyzed.

RESULTS
24 infants (median [range] gestational age at birth 25 [23-31] weeks, postnatal age 27 [1-82] days) provided 101 plasma and 50 DBS samples for analysis. Metronidazole population PK was described by a 1-compartment model: mean clearance (CL, liter/kg/h) = 0.042 x (postnatal age/27)^0.45. Apparent volume of distribution (V) was 0.95 L/kg. The relative standard errors around CL and V estimates were 10% and 3%, respectively. The median (range) ratio of metronidazole DBS to plasma concentrations was 88% (39-112%). DBS and plasma concentrations were highly correlated (r2 0.85, P<0.001), and no significant differences were found when metronidazole PK were calculated from plasma vs. DBS concentrations.

CONCLUSION
Metronidazole CL increased as a function of postnatal age as expected with development. DBS sampling offers an avenue to critically evaluate the PK of metronidazole and potentially other drugs in neonates and young infants.
**LB-A-3**

**EFFECT OF THE NOVEL CYP3A4 INTRON 6 POLYMORPHISM (CYP3A4*22) AND CYP3A COMBINED GENOTYPES ON TACROLIMUS DOSING REQUIREMENTS AND BLOOD CONCENTRATIONS IN PEDIATRIC HEART TRANSPLANT RECIPIENTS**

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**BACKGROUND**

Both CYP3A4 and CYP3A5 are involved in the metabolism of tacrolimus, an immunosuppressant. We aimed to determine the influence of the newly recognized CYP3A4*22 polymorphism, and the CYP3A5*3 polymorphism. In addition, we clustered CYP3A4 and CYP3A5 genotypes to study the effect of clustered CYP3A genotype on tacrolimus dosing requirements in pediatric heart transplant recipients.

**METHODS**

Thirty-nine pediatric heart transplant recipients (median age 6.0 [IQR: 13.75] years) were included. Tacrolimus doses and trough concentrations collected in the first 14 days post-transplantation were compared between patients and correlated with CYP3A4*22 and CYP3A5*3 genotype. Clustered CYP3A genotypes were extensive metabolizers (CYP3A5*1 carriers + CYP3A4*1/*1), intermediate metabolizers (CYP3A5*3/*3 + CYP3A4*1/*1), and poor metabolizers (CYP3A5*3/*3 + CYP3A4*22 carriers). All analyses were done in November 2011.

**RESULTS**

CYP3A poor metabolizers had significantly lower median (day4-14) dosing requirements (0.040 [range: 0.018-0.053] mg/kg/day) compared to intermediate metabolizers (0.062 [IQR: 0.047] mg/kg/day) and extensive metabolizers (0.123 [IQR: 0.086] mg/kg/day), P = 0.001. Age and CYP3A genotype clusters were independently associated with median tacrolimus dosing requirements (R² = 0.507, p<0.001) and concentration/dose ratio (R² = 0.415, p<0.001). No significant differences in tacrolimus dosing requirements (p = 0.062) or trough concentrations (p = 0.128), and concentration/dose ratio (p = 0.057) were found between patients carrying at least one CYP3A4*22 allele carriers compared to CYP3A4*1/*1 patients. No relationship was found between the genetic variability and estimated glomerular filtration rate.

**CONCLUSION**

Despite the small sample size, this novel report shows that clustered CYP3A genotypes show promising results for further individualization of tacrolimus therapy in pediatric heart transplant patients.

**LB-A-4**

**INTRAVENTOUS PARACETAMOL REDUCES MORPHINE REQUIREMENTS IN NEONATES AND YOUNG INFANTS UNDERGOING MAJOR NON-CARDIAC SURGERY: RESULTS OF A RANDOMIZED CONTROLLED TRIAL**

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**BACKGROUND**

Continuous morphine infusion as standard postoperative analgesic therapy in neonates and infants is associated with side effects such as respiratory depression. We aimed to assess whether intermittent intravenous paracetamol administration would significantly (>30%) reduce morphine requirements.

**METHODS**

In this single-center prospective, randomized double-blind study, infants under the age of 1 year were randomized to receive either continuous morphine or intermittent intravenous paracetamol after major surgery. Infants in both study groups received morphine (boluses and/or continuous infusion) as rescue medication on the guidance of the validated pain assessment instruments. Endpoints in the first 48 hours post-operatively were: 1) cumulative morphine dose (study and rescue dose) (mcg/kg); 2) morphine rescue dose (mcg/kg); 3) morphine-related side effects. Analysis was by intention to treat. www.trialregister.nl: number NTR1438. Final data analyses were performed after September 20, 2011.

**RESULTS**

Between March 2008 and July 2010, 71 of 74 patients were included in the primary analysis (paracetamol (P), n=33 vs. morphine (M), n=38). Patients in the paracetamol group received 66% less morphine than patients in the morphine group [121 (IQR 99-264) vs. 357 (IQR 220-605) mcg/kg, p< 0.001]. The median rescue dose of morphine (P; 25 (0-164) mcg/kg vs. M; 20 (IQR 0-226), p=0.99), incidences of morphine-related side effects (P; 27.3 % vs. M; 34.2 %), RR 1.4, 95% CI 0.5-3.8) and levels of pain scores did not differ between study groups.

**CONCLUSION**

Intravenous paracetamol reduces morphine requirements in neonates and young infants after major surgery, thereby potentially reducing the risk for opioid-related side effects with similar validated pain scores demonstrating identical pain levels.
**LBI-1**

**PHARMACOKINETIC/PHARMACODYNAMIC (PK/PD) MODELING OF INTRAVENOUS AND ORAL TOPIRAMATE (TPM) AND ITS EFFECTS ON PHONEMIC FLUENCY (PF) IN ADULT HEALTHY VOLUNTEERS**

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**BACKGROUND**

TPM affects PF as measured by the controlled oral word association test (COWA), but the relationship to drug exposure has not been evaluated. Objectives were to: 1) characterize TPM PK; 2) develop a PK/PD model to quantify effects of TPM on PF; 3) simulate effects of TPM at higher doses.

**METHODS**

Subjects were healthy volunteers (n=32, 18-65 yrs) not taking interacting medications. Three randomized crossover studies were conducted: I) 50 and 100 mg TPM given orally and intravenously; II&III) 100 mg oral TPM versus placebo. COWA was assessed pre and post-treatment baselines (BL), at 0.25, 2.5, 6 h (study I), or at 2.5 h after dose (studies II&III). Blood was collected until 120 h after dose (study I) or immediately after COWA (studies II&III). Linear and nonlinear PK/PD links of TPM concentration (Cp) to COWA under 3 distributions (normal, negative binomial, and Poisson) were explored. The final model was used to simulate the effect of a 200 mg daily dose of TPM on COWA. PK/PD data were available for analysis 9/26/2011. Data analysis was finalized 11/30/2011.

**RESULTS**

A 2-compartment model first order absorption and elimination described TPM PK. Estimates (95% CI) were: CL, 1.3 L/h (1.2, 1.5); Vc, 58.8 L (50.6, 67); Vp, 12.8 L (10.2, 15.4); Q, 1.27 L/h (0.3, 2.3); Ka, 2.9 h⁻¹ (1.9, 3.9); and oral bioavailability, 1.08 (1.03, 1.13). Interindividual variances (IIV) were estimated for CL (19.6% CV), and Vc (23.3% CV). Body weight was a predictor of Vc. PD model estimates and intervals were similar for all distributions. Mean COWA-Cp profiles fit an exponential decline function. Estimate (95% CI) for BL was 42.7 words/3 min (39.9, 45.5); learning effect on repeated testing was 10% (5%, 15%) of BL. TPM at 4.47 mg/L (3.9, 5.2) reduced BL COWA by half. The IIV for BL was 16.7% CV. The median simulated COWA score after a daily dose of 200 mg of TPM was ~15 words/3 min.

**CONCLUSION**

PF declined exponentially with rise in TPM Cp. Simulations showed an increased effect of TPM on PF after a daily dose of 200 mg.

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**LBI-2**

**MODEL-BASED META-ANALYSIS FOR COMPARATIVE EFFICACY OF OSTEOPOROSIS AGENTS: DENOSUMAB VS. OTHER TREATMENT OPTIONS**

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**BACKGROUND**

Bone mineral density (BMD) changes are critical for evaluating the efficacy of osteoporosis agents. Many osteoporosis agents are clinically available but comparisons in BMD response among those agents are lacking. This model-based meta-analysis allows the comparisons of BMD changes at both lumbar spine and total hip after various treatment durations of different osteoporosis agents at different doses.

**METHODS**

Data were obtained from randomized controlled clinical trials in postmenopausal women available in the public domain. The longitudinal BMD changes from baseline at lumbar spine and total hip were analyzed using a nonlinear least square random effect regression analysis in October 2011.

**RESULTS**

Data from 72 trials, representing over 96,000 patients and 13 drugs including denosumab, bisphosphonates, selective estrogen receptor modulators, and parathyroid hormone, were analyzed. The dose response relationship of BMD changes was well characterized by an Emax model with a different Emax for lumbar spine and total hip for each drug class. The ratio of lumbar spine and total hip BMD changes was significantly different across the different drug classes. The potency, dose achieving 50% Emax, was different for each drug. The time course of BMD changes was well characterized by an exponential onset with different rate constant for lumbar spine and total hip for each class. Difference in baseline BMD was an important factor explaining between trial variability in treatment effect.

**CONCLUSION**

Denosumab at 60 mg Q6M SC administration provided the greater improvement in total hip and lumbar spine BMD throughout 36 months of treatment when compared with 10 mg/day oral alendronate, 5 mg/year iv zoledronic acid, 5 mg/day oral risedronate, 150 mg/month oral ibandronate, 3 mg Q3M iv ibandronate, and 60 mg/day oral raloxifene. The dose response relationship of denosumab indicated that dose greater than the current registered dose would provide limited additional benefit.
**LBI-3**

A POPULATION (POP) PHARMACOKINETIC (PK)/PHARMACODYNAMIC (PD) ANALYSIS OF MIPOMERSEN (MIPO)

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**BACKGROUND**

Mipo, an antisense oligonucleotide, is an apoB 100 synthesis inhibitor and has completed Phase 3 trials in hypercholesterolemia. ApoB 100 is the structural core of all atherogenic lipoproteins and required for hepatic secretion of VLDL. The objective was to develop pop PK and PD models for Mipo and to identify any influential covariates for PK or PD.

**METHODS**

NONMEM 7.2 was used to describe data from 17 clinical trials. Most patients had > 4 plasma samples taken; and most were taken 120-240 hours post last dose. The log transform both sides approach and evaluated using FOCE method were used. Model building and covariate assessments were conducted using standard methods. Final models were evaluated with several tests, including evaluation of an internal validation database, and visual predictive checks. The data analyses were complete on September 28, 2011.

**RESULTS**

Mipo PK was best described by a 2-compartment model with a time dependent clearance (TDCL), described via exponential asymptotic decrease. A mixture model found two TDCL groups: SLOW (88.6% patients) and FAST (11.4% patients) with 25% and 86% decrease in CL, respectively, after 1 year of dosing. Creatinine CL was found to be a covariate for CL. The significance of this finding is limited by the small number of patients with low CrCL (<60 mL/min). Route of administration was predictive of central volume of distribution (Vc), with Vc for IV 25% lower than SC. ApoB PD was described with an indirect effect model with Mipo nearly completely inhibiting ApoB formation. The SLOW group had a 10-fold lower IC50 for ApoB production (91 vs 1080 ug/L, respectively).

**CONCLUSION**

The PK and PD of Mipo have been well described by the models. Model based simulation has indicated TDCL occurs within first 6 months of dosing and plateaus thereafter. A 200 mg Mipo weekly SC dose for 1 year would reduce ApoB 46% for SLOW and 27% for FAST subpopulation with commensurate reduction in LDL-C. Underlying etiology of the two populations is not yet understood.

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**LBI-4**

FIRST APPLICATION OF A DIFFERENTIAL ORDERED CATEGORICAL MODEL FOR ORDERED EFFICACY ENDPOINTS OF TOFACITINIB IN PATIENTS WITH RHEUMATOID ARTHRITIS (RA)

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**BACKGROUND**

Tofacitinib (CP-690,550) is a novel oral Janus kinase inhibitor being investigated as a targeted immunomodulator for the treatment of RA. Objective was to jointly characterize the dose-time-response (efficacy) of tofacitinib across the American College of Rheumatology (ACR) response thresholds of 20, 50, and 70% improvements (ACR20/50/70).

**METHODS**

Data were pooled from two randomized, double-blind, monotherapy, dose-ranging studies (N=642) in RA patients. Treatments included placebo, 1, 3, 5, 10, and 15 mg BID doses of tofacitinib for 12 or 24 weeks. Binary ACR responses were combined into a 4-level ordered categorical endpoint. Pharmacologically-based logistic longitudinal models with proportional odds (PO) and differential odds (DO) assumptions were evaluated (analysis completed October 2011).

**RESULTS**

A DO model with an effect compartment provided the best description of the data with statistically significant and clinically important improvements over the PO model, particularly in predicting the magnitude and time course of ACR70. The DO model predicted that steady state response was achieved by 10, 11, and 24 weeks for ACR20, ACR50, and ACR70 respectively. Common estimates of Emax and ED50 for all categories resulted in improved precision of the dose-response (D-R) curves (90% confidence interval width 7-9%). Important differences were noted in the estimation of the probability of exceeding clinically meaningful response rates between the DO and PO models and between week 12 and 24 for ACR70, while results were similar when compared to binary models for each endpoint.

**CONCLUSION**

This first application of a semi-mechanistic DO model for tofacitinib provides potential for increased accuracy and precision of the D-R relationship. By allowing for different rate-constants with common drug parameter estimates, the DO model provides an integrated estimation of probability of success for all ACR endpoints to inform dose-selection decisions.
LBI-5

POPULATION PHARMACOKINETIC MODELING OF BUPRENORPHINE IN NEWBORNS WITH NEONATAL ABSTINENCE SYNDROME

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BACKGROUND
About 55 to 94% of infants born to opioid dependent mothers have neonatal abstinence syndrome (NAS). Buprenorphine (BUP) is currently used in clinics as a detoxification and maintenance treatment for opioid dependence. No pharmacokinetic (PK) data of BUP is available to newborns following sublingual administration of BUP.

METHODS
Population PK were estimated using NONMEM in 25 newborns in NAS sublingually administered with BUP in an open labeled study, with 4 co-treated with phenobarbital within a certain period of time after treatment started. PK parameters, obtained using published 3-CMT model in adults administered with BUP intravenously and 2-CMT model constructed using published plasma concentrations -time data in adult using sublingual administration, were extrapolated to those in neonate using allometric scaling. The predicted plasma concentration-time data obtained by extrapolation under-predicted our BUP-Norbuprenorphine (NorBUP) data profile. 1-CMT model with 1st-order absorption and 1st order elimination was used to describe data. (Half data were analyzed on December 15).

RESULTS
The population mean of total CL of BUP including metabolism is approximately 12.0 L/hr. The volume of distribution of BUP is approximately 145 L. The estimated metabolism of BUP to NorBUP accounts for approximately 23% of the total CL of BUP. A 56% of increase in metabolism and total CL for patients co-treated with phenobarbital was observed.

CONCLUSION
The population PK 1-CMT model with 1st-order absorption, metabolism, and elimination developed on sparse data was adequate in describing the PK of BUP and NorBUP in neonates. Difference in PK between neonates and adults were demonstrated, suggesting that special attention should be paid if allometric scaling is adopted to apply PK results from adults to neonates. The results would be used to guide the dose selection and titration in the ongoing larger trials of buprenorphine in newborns.

LBI-6

PREDICTION OF CYP3A4-MEDIATED DRUG-DRUG INTERACTION POTENTIAL BETWEEN PI3K INHIBITOR GDC-0941 AND KETOCONAZOLE THROUGH PHYSIOLOGICALLY-BASED PHARMACOKINETIC (PBPK) MODELING

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BACKGROUND
GDC-0941 is a potent, selective pan-inhibitor of class I PI3K which has good activity in xenograft models and is being investigated for oncology. Human liver microsomes and recombinant cytochrome P450s (CYPs) studies identified CYP3A4 as the major enzyme contributing to GDC-0941 oxidative metabolism. The aim of this study was to assess the effect of ketoconazole (KTZ) co-administration on GDC-0941 pharmacokinetics (PK), and to evaluate the ability of Simcyp to predict the drug-drug interaction (DDI) potential.

METHODS
This was a single center, open label, randomized study conducted in healthy volunteers (n=20). All subjects received 60 mg GDC-0941 alone or with 200 mg KTZ twice daily. Simcyp was used prospectively to assess the CYP3A4-mediated DDI potential, and the predictions were retrospectively evaluated and refined en light of the observed results (not available until after abstract deadline).

RESULTS
The geometric mean ratios (90% CI) of Cmax and AUC0-inf were 1.04 (0.88, 1.24; P = 0.67) and 1.43 (1.24, 1.64; P < 0.0005), when comparing GDC-0941 alone to KTZ co-administration, respectively. Increased GDC-0941 half-life in the presence of KTZ suggested that the impact of KTZ was on GDC 0941 elimination. Prospective Simcyp simulations reasonably predicted the DDI risk (1.8-fold AUC change), assuming 50% CYP3A4 metabolic contribution (fm). Evaluation of CYP3A4 fm based on the clinical DDI result using Simcyp suggested fm of 40%. Overall, retrospective refinement of Simcyp simulations allowed for more accurate prediction of PK attributes and DDI risk.

CONCLUSION
Concomitant administration of the CYP3A4 inhibitor KTZ with GDC-0941 resulted in a mean exposure increase of 43%, and was well-predicted by Simcyp simulation assuming 40% CYP3A4 contribution. Simcyp simulations can be used prospectively to assess DDI risk and assist clinical study design, and should be iteratively refined to optimize predictability.
LONGITUDINAL POPULATION PHARMACOKINETIC/PHARMACODYNAMIC (PK/PD) ANALYSIS FOR PF-02545920 EXPOSURE AND POSITIVE AND NEGATIVE SYNDROME SCALE (PANSS) TOTAL RESPONSE IN PATIENTS WITH ACUTE EXACERBATION OF SCHIZOPHRENIA
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BACKGROUND
PF-02545920 is a highly selective phosphodiesterase 10A inhibitor (PDE10Ai) that has been evaluated for the treatment of acute schizophrenia. Presented here is the result of modeling and simulation activity (final data delivered on September 27, 2011) that aimed to: 1) develop a model that characterizes the time course of placebo response and the effect of PF-02545920 on PANSS total scores (PANSS hereafter); and 2) assess the probability of achieving the target value (PTV) of -10 points on PANSS for PF-02545920 vs. placebo at week 4.

METHODS
A total of 1263 observations from 222 patients were obtained from a 4-week double-blind, placebo & positive-controlled, randomized, inpatient phase 2a study investigating 5 and 15 mg BID of PF-02545920, placebo, and 3 mg risperidone (risperidone data was excluded from the analysis). The model development consisted of describing placebo response, characterizing treatment effects, evaluating the model, and assessing the PTV. NONMEM 7.1.2 and R 2.10.1 were the main analysis tools.

RESULTS
An exponential model was used to describe placebo response that tended to asymptotically decrease over time. Typical maximum placebo response (P_{max}) was estimated to be a decrease in PANSS by 12.2 (17.5% RSE) points (9.56 points drop at week 4), with a half life of ~11 days to reach P_{max}. A slight and time-dependent trend of improvement in PANSS with increase in average steady-state concentration (C_{avg}) was also characterized. The slope estimate of C_{avg} dependency in PANSS was 0.0476 points per ng/mL (66.6% RSE) at week 4, which corresponds to ~2 points drop in PANSS at the median C_{avg} of 42.5 ng/mL. The model predicted 90% CI for placebo adjusted mean was [-4.2, 0.13], which was not significantly different from 0.

CONCLUSION
Longitudinal exposure response analysis on PANSS was performed to characterize placebo and treatment effect of PF-02545920. The model concluded a minimal treatment effect on PANSS and near 0% PTV at either dose of PF-02545920.
LBII-1

THE EFFECT OF MATE2K GENOTYPE ON METFORMIN DISPOSITION AND RESPONSE IN ASIANS AND CAUCASIANS

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BACKGROUND
Metformin is the first line therapy for the treatment of type II diabetes. The disposition and response to metformin varies significantly. The aims of this study were to examine the effect of genotype of the kidney transporter, MATE2K, on the pharmacokinetics and pharmacodynamics of metformin in Asian and Caucasian healthy volunteers. A gain of function variant of MATE2K, -130G>A, identified in previous studies was the focus of the study.

METHODS
Healthy Asian (n=18) and Caucasian (n=6) volunteers with known MATE2K (-130G>A) genotype were recruited into an open label study. A 3-hour oral glucose tolerance test, OGTT (75g glucose), was conducted in the morning on Day 1 and Day 2. Metformin was administered in the evening of Day 1 (850 mg) and the morning of day 2 (1000 mg). Blood and urine were collected for determination of metformin, glucose and creatinine. Data were analyzed using WinNonLin (12/9/11) and unpaired t-test.

RESULTS
The metformin half-life was significantly greater in Asians (3.9±0.8h) compared to Caucasians (3.0±0.3h; p<0.01). Consistent with the shorter half-life, Caucasians had a higher metformin renal clearance (1056±301 versus 663±310 mL/min, respectively; p<0.01) and renal secretion (967±281 versus 554±301 mL/min, respectively; p<0.001) compared to Asians. The Vd and AUC were similar for Asians and Caucasians. However, the glucose lowering effect of metformin was greater in Caucasians compared to Asians (pA, Asian subjects homozygous for the MATE2K variant, -130A, (n=4) had a significantly greater renal clearance (973±422 versus 510±148mL/min; p<0.01) and renal secretion (512±356 versus 452±228mL/min; p<0.05) than those carrying one reference allele of MATE2K (n=8).

CONCLUSION
Our data indicate that ethnicity and genetic variation in MATE2K influence the pharmacokinetics of metformin. Furthermore, metformin response was greater in Caucasians compared to Asians.

LBII-2

METABOLIC RATIO OF OPIOIDS IN HAIR: A NOVEL METHOD TO STUDY POPULATION GENETIC POLYMORPHISMS

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BACKGROUND
Codeine, still widely prescribed for its analgesic effects, is subject to CYP2D6 polymorphisms affecting its metabolism. Metabolic ratio (MR) of morphine to codeine represents the extent of codeine metabolism to its active metabolite. MR has previously been studied in blood, and urine. However, these compounds can be found in hair, which has never been used as a matrix to study MR. Studying MR in hair can provide a simple method to evaluate population variability obviating the need for blood.

METHODS
Hair samples were collected from the Motherisk Laboratory for testing as per request by social workers, lawyers and other agencies. Since July 2010, 1468 samples were tested for codeine and morphine through GC-MS analysis. All codeine positive samples (n=214) and respective morphine results were used to calculate metabolite-to-parent MR. Frequencies of MR were graphed to assess population distribution. Data was analyzed on October 4th because trainee began graduate program on September 6th.

RESULTS
The distribution of MR frequency illustrated in Figure 1 shows similarities to distributions using blood samples. Similar to blood, hair appears to exhibit large inter-individual variability of MR.

CONCLUSION
With better understanding of codeine and morphine incorporation into human hair, polymorphisms can be studied in hair using MR. Unlike blood, hair collection is non-invasive and shows previous use. This is the first study to assess the use of human hair as a matrix to study CYP2D6 polymorphisms.
A SEMI-MECHANISTIC PHARMACOKINETIC/PHARMACODYNAMIC (PK/PD) MODEL FOR IMIPENEM (IMP)/MK-7655 COMBINATION THERAPY AGAINST RESISTANT PSEUDOMONAS AERUGINOSA (PA)

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BACKGROUND
MK-7655 (beta-lactamase inhibitor) is under development as a combination therapy to restore IMP's activity against resistant PA. Objectives of this study were to: (1) build a PK/PD model that describes time-kill (TK) curves of resistant PA after treatment, and (2) translate the model to an in vivo species.

METHODS
Three studies were conducted: (I) a TK and PK study in an in vitro hollow fiber, (II) an in vitro study of minimum inhibitory concentration (MIC) of IMP against PA at varying concentrations of MK-7655 (C of MK-7655) and (III) an in vivo TK and PK study in a mouse model of lung infection. Model fitting and simulations were performed in NONMEM 7. Precision of parameter estimates was evaluated using bootstrapping. The model was tested in mice and evaluated by simulations. All data were available for analysis 9/25/2011. Data analysis was finalized 11/22/2011.

RESULTS
PK (n=32)/TK (n=16), and MIC-C of MK-7655 (n=93) profiles were collected from studies I and II, respectively. PK (n=17) and TK curves (n=9) were generated from study III. The PK/PD model and assumptions for the mouse model are shown in the figure. Simulations in mice showed that 94% of the observed CFU/lung fell within the 5th, 95th percentiles of the simulated profiles.

CONCLUSION
A semi-mechanistic PK/PD model that describes the in vitro TK profiles of PA after treatment with IMP or IMP+MK-7655 was developed and successfully translated into mice. Simulation studies in humans are planned for optimal dose selection in clinical trials.

GENETIC POLYMORPHISM OF CYTOCHROME P450 2D6 AND PAROXETINE INFLUENCE FORMATION OF THE ACTIVE METABOLITES OF THE 1ST LINE INFERTILITY DRUG CLOMIPHENE

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BACKGROUND
Ovulation induction with clomiphene (CLOM) is the first-line treatment in women with polycystic ovarian syndrome and unexplained infertility. While CLOM provides safe and effective medication, up to 30% of women fail to respond despite dose triplication. CLOM is structurally similar to tamoxifen, which is predominantly bio-activated by the polymorphic cytochrome P450 (CYP) 2D6 suggesting that CYP2D6 poor (PM) or extensive metabolism (EM) may predict individual success of CLOM.

METHODS
Incubations with pooled human liver microsomes from 150 donators of known CYP geno- and phenotype, from 8 PM donators, and from recombinant CYP (supersomes). The capacity of CLOM and its metabolites to inhibit oestrogen at its receptor was tested using an oestrogen response element reporter assay. CLOM and metabolites were quantified by LC-MS/MS. An in vivo metabolic drug-drug interaction study was performed in 7 healthy female volunteers selected according to their CYP2D6 genotype. Two single doses of 100 mg CLOM were applied with and without co-administration of 2-days paroxetine 40 mg qd (analysis from December 2011).

RESULTS
Incubation experiments identified CYP2D6 as major enzyme to form (E)-4-hydroxyclomiphene (OHCLOM) and (E)-4-hydroxy-N-desethylclomiphene (OHDECLOM). Formation rate of hydroxyl-metabolites in 30 human liver donors correlated with CYP2D6 genotype showing a distinct gene-dose effect. OHCLOM and OHDECLOM were identified as active metabolites with strongest inhibition of the oestrogen receptor activity. In the clinical study Cmax of OHCLOM and OHDECLOM showed 8- and 12-times lower concentrations in PM. Co-administration of paroxetine significantly decreased formation of hydroxyl-metabolites in EM, while metabolic profile in PM remained unaffected.

CONCLUSION
Data provide proof-of-concept that polymorphic CYP2D6 influences bio-activation of CLOM and that response to CLOM may be prone to drug-drug interaction by CYP2D6 inhibitors.
LBII-5
WITHDRAWN

LBII-6
CLINICAL PHARMACOLOGY STUDY INVESTIGATING THE PESSOR RESPONSE TO ORAL TYRAMINE DURING CO-ADMINISTRATION WITH SAFINAMIDE IN HEALTHY VOLUNTEERS
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BACKGROUND
Safinamide is an alpha-aminoamide with dopaminergic (potent, selective, reversible MAO-B inhibition) and non-dopaminergic activities in phase 3 development for Parkinson’s disease. This controlled study investigated pressor response to oral tyramine during co-administration with safinamide to assess need for dietary restrictions.

METHODS
Design was a randomized, double-blind, placebo-, comparator (selegiline 10 mg/day)- and active (phenelzine 30 mg/day)-controlled multiple-dose study in 90 healthy subjects aged 18 to 70 years, evaluating safinamide at therapeutic (100 mg/day) and supratherapeutic (350 mg/day) doses. Response was characterized by Tyr30, defined as dose of oral tyramine producing a sustained increase of Systolic Blood Pressure (SBP) ≥30 mmHg compared to a daily-defined baseline SBP. During the treatment period, daily tyramine pressor tests (with escalating tyramine doses) were conducted on Days 7 through 16 or until Tyr30 was reached. Primary endpoint was Tyramine Sensitivity Factor (TSF), defined as subject-specific Tyr30 at screening divided by subject-specific Tyr30 under treatment. Complete analyses were not released before October.

RESULTS
TSF geometric means were: placebo: 1.52, safinamide 100 mg: 2.15, safinamide 350 mg: 2.74, selegiline 10 mg: 3.12, phenelzine 30 mg: 9.98. ANOVA analysis of log-transformed TSF showed consistent results, with treatment ratios versus placebo (90% CI) of: safinamide 100 mg: 1.6 (1.2-2.4), safinamide 350 mg: 1.8 (1.1-2.7), selegiline 10 mg: 2.2 (1.4-3.3), phenelzine 30 mg: 6 (3.9-9.1).

CONCLUSION
Safinamide induced a mild increase in TSF. However, its pressor effect at both doses remained lower than that of selegiline, which is devoid of a label warning for tyramine at the tested dose level. This study confirms that safinamide is a highly selective MAO-B inhibitor, even at supratherapeutic doses, and supports its administration without tyramine-related dietary restrictions.

LBII-7
D-LIMONENE MODULATES T LYMPHOCYTE ACTIVITY AND VIABILITY
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BACKGROUND
d-limonene is a cyclic terpene that possesses chemopreventative and chemotherapeutic activity. Treatment with d-limonene and related monoterpenes inhibits the development of mammary carcinomas, lung neoplasms, pancreatic tumors, liver cancer, pulmonary adenomas and forestomach tumors in rodent models. Phase I and II human clinical trials of d-limonene and d-limonene metabolites indicate that these agents show promise in the treatment of breast and colorectal cancers. Given the integral role the immune system plays in tumor surveillance, it is surprising that only a limited number of studies have been conducted investigating the effects of d-limonene on immune system function.

METHODS
CD3+ T lymphocytes (>94% pure) were purified from the spleens of C57BL/6 mice and activated by incubation in 96-well plates coated with 2-10 µg/ml immobilized anti-CD3 mAb for 24 hours at 37°C in 5% CO₂. Cells were co-cultured with 0.5-8 mM d-limonene or vehicle control. TH1 and TH2 cytokine production was measured by ELISA, cell proliferation was measured by CFSE staining, activation marker expression was measured by flow cytometry and cell viability was measured via annexin V and propidium iodide staining.

RESULTS
Exposure to d-limonene inhibited the production by activated T lymphocytes of IFN-γ (EC50 = 2.03 ± 0.35 mM); IL-2 (EC50 = 2.62 ± 0.52 mM); TNF-α (EC50 = 4.22 ± 0.85 mM); IL-4 (EC50 = 2.30 ± 0.29 mM); and IL-13 (EC50 = 1.26 ± 0.30 mM). The expression of CD40L was inhibited by up to 44.13 ± 8.42% as a result of exposure to 2-8 mM d-limonene, while no significant effect on T cell proliferation was observed. An approximate 14 fold increase in T cell death was induced by treatment with 8 mM d-limonene, with lower doses having no significant effect on cell viability. (analyzed 10/11-12/11)

CONCLUSION
d-limonene possesses immunosuppressant and cytotoxic potential. These immunomodulatory activities must be considered when evaluating therapeutic applications of the compound.
NO CLINICALLY RELEVANT INTERACTION BETWEEN SUGAMMADEX AND ACETYLSALICYLIC ACID ON PLATELET AGGREGATION

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BACKGROUND
This study evaluated a potential interaction between sugammadex and acetylsalicylic acid (ASA) on whole blood platelet aggregation.

METHODS
A randomized, double-blind, placebo-controlled, 4-way crossover study in 26 healthy males (18-45 yr). Subjects received intravenous (IV) placebo or sugammadex 4 mg/kg in the absence (periods 1 and 2) or presence (periods 3 and 4) of background daily oral ASA 75 mg. Primary assessment: potential interaction between sugammadex and ASA on whole blood collagen-induced platelet aggregation. Secondary assessments: activated partial thromboplastin time (APTT); bleeding time; safety. Platelet aggregation and APTT were evaluated by geometric mean ratios, using area under effect curves from 3-30 min after dosing. Non-inferiority margins were determined via thorough literature review. Type I error was controlled using a hierarchical strategy. Data became available for analysis on October 17, 2011.

RESULTS
There was no clinically relevant interaction between sugammadex and ASA on platelet aggregation. Interactions and/or effects on APTT and bleeding time did not exceed pre-specified non-inferiority margins (Table). Sugammadex (alone or with ASA) was generally well tolerated.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Treatment comparison</th>
<th>Geometric mean ratio</th>
<th>One-sided 95% confidence limit</th>
<th>Non-inferiority margin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole blood platelet aggregation</td>
<td>ASA + sugammadex vs ASA alone</td>
<td>1.01</td>
<td>0.01</td>
<td>&lt;0.75</td>
</tr>
<tr>
<td>Bleeding time (test at 3-5 min)</td>
<td>ASA + sugammadex vs ASA alone</td>
<td>1.20</td>
<td>1.45</td>
<td>&lt;1.5</td>
</tr>
<tr>
<td>APTT</td>
<td>Non-interaction ASA by sugammadex</td>
<td>1.01</td>
<td>1.04</td>
<td>&lt;1.5</td>
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<tr>
<td></td>
<td>Sugammadex alone vs placebo alone</td>
<td>1.06</td>
<td>1.07</td>
<td>&lt;1.5</td>
</tr>
</tbody>
</table>

CONCLUSION
There was no clinically relevant reduction in platelet aggregation with the addition of sugammadex to ASA treatment. Furthermore, the pre-specified non-inferiority margins were not exceeded for bleeding time and APTT.
**LBIII-1**

**AGE-RELATED DIFFERENCES IN PLASMA AND INTRACELLULAR (IC) TENOFOVIR (TFV) CONCENTRATIONS**

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**BACKGROUND**

To use population pharmacokinetic (PK) modeling to investigate apparent differences in plasma TFV and IC TFV-diphosphate (TFV-DP) concentrations (conc) in children and adolescents compared with adults following tenofovir disoproxil fumarate (TDF) dosing.

**METHODS**

Data were pooled from 3 different studies in HIV-infected children, adolescents, and adults receiving TDF 300 mg daily. TFV plasma conc were measured 6-8 times and IC TFV-DP 2-3 times in each subject. Data analysis began in October, 2011. A 2-compartment model (NONMEM® 7.2) subdivided by age, allometrically scaled for children and adolescents and partitioned for slow and fast absorbers (Tmax either <2 or >2 hrs, respectively) was utilized for plasma TFV. IC conc were modeled using an indirect response model: EC50 (plasma conc producing 50% of maximum effect [Emax]); kin (0 order rate constant for TFV-DP production); kout (IC elimination rate constant); partitioned by age (>25 or <25 years). kout for adults was fixed to a previous estimate. Covariates included age, sex, weight, race, creatinine clearance (CRCL), Tanner stage (adolescents), total bilirubin, and concomitant protease inhibitor.

**RESULTS**

Subjects: N=102 (61 male/41 female), 88 with IC conc. Median (range) age and CRCL were: 21 (9-60) years and 128 (43.3-267.6) ml/min, respectively. In final plasma model (FOCEI), oral clearance (CL/F) was significantly faster in those < vs. > 25 years. CRCL was the most significant covariate on CL/F and central distribution volume. IC TFV-DP EC50 was 69 vs 116 ng/mL, and t1/2 (= to 0.693/kout) was 70 h vs 86 hrs for those < vs > 25 yrs; Emax was fixed at 1200 fmol/10^6 cells.

**CONCLUSION**

Children and adolescents achieve higher IC TFV-DP conc than adults despite lower plasma conc. This analysis suggests a mechanism of greater phosphorylation sensitivity (quantified as lower EC50) vs. slower IC elimination. Additional mechanistic studies are needed to fully understand the clinical pharmacology of IC TFV.

**LBIII-2**

**PHARMACOKINETICS AND SAFETY OF METRONIDAZOLE IN PRETERM INFANTS: VALIDATION OF DRIED BLOOD SPOT SAMPLING**

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**BACKGROUND**

Metronidazole is routinely used to treat intra-abdominal infections in preterm infants. Pharmacokinetic (PK) data for this drug in this population are virtually absent. Dried blood spot (DBS) technology has the potential to enable appropriate PK studies in this population necessary to define age-appropriate dose.

**METHODS**

A prospective, open-label, multicenter study of 24 infants (<32 weeks gestation and 15 days postnatal age) was performed. Sparse plasma and DBS samples were obtained around the first dose, at doses 3-5, and with the last dose. Concentrations were determined by HPLC/MS/MS (LLOQ 50 ng/mL). Population nonlinear mixed effect modeling was used to analyze the PK data, and plasma vs. DBS concentration association was evaluated using linear regression techniques. Last infant was enrolled November 1, 2011, and data were subsequently analyzed.

**RESULTS**

24 infants (median [range] gestational age at birth 25 [23-31] weeks, postnatal age 27 [1-82] days) provided 101 plasma and 50 DBS samples for analysis. Metronidazole population PK was described by a 1-compartment model: mean clearance (CL, liter/kg/h) = 0.042 x (postnatal age/27)^0.45. Apparent volume of distribution (V) was 0.95 L/kg. The relative standard errors around CL and V estimates were 10% and 3%, respectively. The median (range) ratio of metronidazole DBS to plasma concentrations was 88% (39-112%). DBS and plasma concentrations were highly correlated (r^2 0.85, P<0.001), and no significant differences were found when metronidazole PK were calculated from plasma vs. DBS concentrations.

**CONCLUSION**

Metronidazole CL increased as a function of postnatal age as expected with development. DBS sampling offers an avenue to critically evaluate the PK of metronidazole and potentially other drugs in neonates and young infants.
EFFECT OF THE NOVEL CYP3A4 INTRON 6 POLYMORPHISM (CYP3A4*22) AND CYP3A COMBINED GENOTYPES ON TACROLIMUS DOSING REQUIREMENTS AND BLOOD CONCENTRATIONS IN PEDIATRIC HEART TRANSPLANT RECIPIENTS

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BACKGROUND
Both CYP3A4 and CYP3A5 are involved in the metabolism of tacrolimus, an immunosuppressant. We aimed to determine the influence of the newly recognized CYP3A4*22 polymorphism, and the CYP3A5*3 polymorphism. In addition, we clustered CYP3A4 and CYP3A5 genotypes to study the effect of clustered CYP3A genotype on tacrolimus dosing requirements in pediatric heart transplant recipients.

METHODS
Thirty-nine pediatric heart transplant recipients (median age 6.0 [IQR: 13.75] years) were included. Tacrolimus doses and trough concentrations collected in the first 14 days post-transplantation were compared between patients and correlated with CYP3A4*22 and CYP3A5*3 genotype. Clustered CYP3A genotypes were extensive metabolizers (CYP3A5*1 carriers + CYP3A4*1/*1), intermediate metabolizers (CYP3A5*3/*3 + CYP3A4*1/*1), and poor metabolizers (CYP3A5*3/*3 + CYP3A4*22 carriers). All analyses were done in November 2011.

RESULTS
CYP3A poor metabolizers had significantly lower median (day4-14) dosing requirements (0.040 [range: 0.018-0.053] mg/kg/day) compared to intermediate metabolizers (0.062 [IQR: 0.047] mg/kg/day) and extensive metabolizers (0.123 [IQR: 0.086] mg/kg/day), P = 0.001. Age and CYP3A genotype clusters were independently associated with median tacrolimus dosing requirements (R² = 0.507, p<0.0001) and concentration/dose ratio (R² = 0.415, p<0.0001). No significant differences in tacrolimus dosing requirements (p = 0.062) or trough concentrations (p = 0.128), and concentration/dose ratio (p = 0.057) were found between patients carrying at least one CYP3A4*22 allele carriers compared to CYP3A4*1/*1 patients. No relationship was found between the genetic variability and estimated glomerular filtration rate.

CONCLUSION
Despite the small sample size, this novel report shows that clustered CYP3A genotypes show promising results for further individualization of tacrolimus therapy in pediatric heart transplant patients.

INTRAVENOUS PARACETAMOL REDUCES MORPHINE REQUIREMENTS IN NEONATES AND YOUNG INFANTS UNDERGOING MAJOR NON-CARDIAC SURGERY: RESULTS OF A RANDOMIZED CONTROLLED TRIAL

I. Ceelie, S. N. de Wildt, M. van Dijk, M. M. van den Berg, G. E. van den Bosch, H. J. Duivenvoorden, T. G. de Leeuw, R. A. Mathôt, C. A. Knibbe, D. Tibboel; Erasmus MC-Sophia Children’s Hospital, Rotterdam, Netherlands, Academic Medical Center, Rotterdam, Netherlands, Leiden University, Leiden, Netherlands

BACKGROUND
Continuous morphine infusion as standard postoperative analgesic therapy in neonates and infants is associated with side effects such as respiratory depression. We aimed to assess whether intermittent intravenous paracetamol administration would significantly (>30%) reduce morphine requirements.

METHODS
In this single-center prospective, randomized double-blind study, infants under the age of 1 year were randomized to receive either continuous morphine or intermittent intravenous paracetamol after major surgery. Infants in both study groups received morphine (boluses and/or continuous infusion) as rescue medication on the guidance of the validated pain assessment instruments. Endpoints in the first 48 hours post-operatively were: 1) cumulative morphine dose (study and rescue dose) (mcg/kg); 2) morphine rescue dose (mcg/kg); 3) morphine-related side effects. Analysis was by intention to treat. www.trialregister.nl: number NTR1438. Final data analyses were performed after September 20, 2011.

RESULTS
Between March 2008 and July 2010, 71 of 74 patients were included in the primary analysis (paracetamol (P), n=33 vs. morphine (M), n=38). Patients in the paracetamol group received 66% less morphine than patients in the morphine group [121 (IQR 99-264) vs. 357 (IQR 220-605) mcg/kg, p< 0.001]. The median rescue dose of morphine (P; 25 (0-164) mcg/kg vs. M; 20 (IQR 0-226), p=0.99), incidences of morphine-related side effects (P; 27.3 % vs. M; 34.2 %), RR 1.4, 95% CI 0.5-3.8) and levels of pain scores did not differ between study groups.

CONCLUSION
Intravenous paracetamol reduces morphine requirements in neonates and young infants after major surgery, thereby potentially reducing the risk for opioid-related side effects with similar validated pain scores demonstrating identical pain levels.
LBIII-5

EVIDENCE OF DISTINCT HISTAMINE PHARMACODYNAMIC PHENOTYPES IN CHILDREN

B. L. Jones,1 C. M. Sherwin,2 K. A. Neville,1 M. G. Spigarelli,2 G. L. Kearns,1 J. S. Leeder1; 1Children’s Mercy Hospital and Clinics, Kansas City, MO, 2University of Utah, Salt Lake City, UT

BACKGROUND

Histamine iontophoresis with laser Doppler monitoring (HILD) provides a surrogate endpoint of histamine microvasculature response which is more dynamic and robust than classical epicutaneous histamine challenge. The purpose of this study was to characterize the pharmacodynamics (PD) of histamine in children using HILD.

METHODS

HILD was performed in children with allergic rhinitis (n=54). PD data were analyzed with a non-linear mixed-effects model (NONMEM v7.2). Effect data (relative maximal response over baseline; \( Eff_{\text{max}} \)) and time of \( Eff_{\text{max}} \) were initially evaluated by visualization of time vs. response relationships which revealed apparent sub-groups within the cohort. Differences in model parameters between groups were determined using ANOVA and post-hoc analysis using Tukey’s HSD. Linear regression was used to explore associations between parameters to validate apparent sub-group differences in PD. Data analysis was completed 12/15/11.

RESULTS

Evaluable data were obtained for N=43 participants 7-17 years of age (mean 12.2 yr). Three distinct histamine response phenotypes were identified; one group (n=7) demonstrated a pattern consistent with an apparent hyper-responsive phenotype that was characterized by significantly higher \( T_{\text{max}} \), \( Eff_{\text{max}} \), and AUEC with respect to microvascular blood flow as a function of time \((p<.007)\). There were no significant differences observed for \( E_{50} \) and \( K_0 \). Identification of the hyper-responsive subgroup was further validated by a stronger association between AUEC and \( Eff_{\text{max}} \) \((r^2 =0.86)\) when compared to the entire cohort \((r^2 = 0.005)\).

CONCLUSION

Our data demonstrate the presence of an apparent hyper-responsive phenotype for histamine effect as reflected by HILD monitoring. This “effect phenotype” must be considered in future pediatric studies which are designed to assess the PK-PD relationship for antihistamines, either as a function of age or disease state.

LBIII-6

ANALYSIS OF FAILED PEDIATRIC STUDIES CONDUCTED UNDER THE FDA AMENDMENTS ACT (FDAAA) OF 2007

J. D. Momper,1 Y. Mulugeta,1 C. S. Lee,2 G. J. Burckart1; 1Office of Clinical Pharmacology, Center for Drug Evaluation and Research, US Food and Drug Administration, Silver Spring, MD, 2Office of Pediatric Therapeutics, Office of the Commissioner, US Food and Drug Administration, Silver Spring, MD

BACKGROUND

Since 2007, over 130 drugs and biologics have been studied in pediatric patients under the renewed PREA and BPCA sections of FDAAA. The goal of these studies is to achieve labeling for an approved indication in the pediatric population. The objective of this study was to analyze all pediatric drug trials under FDAAA, and to determine the causes of the failed or incomplete trials.

METHODS

Design: Retrospective analysis of all products studied under FDAAA since the 2007 reauthorization. Data collection: The FDA labels and medical, statistical, and clinical pharmacology reviews were evaluated, and the principal reason for failure or lack of completion was identified. These data were analyzed in December 2011 in preparation for the FDA Advisory Committee meeting in March 2012.

RESULTS

A total of 137 products were reviewed. Overall, 25% of BPCA and PREA studies did not achieve a new pediatric indication. Of the 89 products studied under PREA, 76 (85%) obtained a new pediatric indication. Of the 21 products studied under BPCA, 8 (38%) were given a new pediatric indication. For products studied under both PREA and BPCA (n=27), a new pediatric indication was achieved in 19 cases (70%). The reasons that pediatric studies did not achieve a labeled indication are shown in the Figure.

CONCLUSION

We conclude that (1) pediatric trial failures or delays in completion are still common, and (2) improved methods of selecting drug doses and outcome measures for pediatric drug approval trials are critically needed.
IMMUNOPHENOTYPING PEDIATRIC LIVER TRANSPLANT RECIPIENTS TO ASSESS THE PHARMACODYNAMICS OF TACROLIMUS

L. J. Wozniak, Y. Korin, T. Smith, G. Lopez, R. Venick, S. V. McDiarmid, E. F. Reed; University of California, Los Angeles, CA

BACKGROUND

In liver transplantation, therapeutic drug monitoring is based on serum trough tacrolimus levels which can be variable, may not reflect cellular concentration, and have not been established to correlate with inhibition of immune cells involved in rejection. Few studies have correlated pharmacodynamic marker assay results with immunosuppressive efficacy. Our objective was to characterize peripheral blood mononuclear cell (PBMC) immunophenotypes associated with tacrolimus use in pediatric liver transplant recipients.

METHODS

100 peripheral blood samples were collected in CPT tubes from 58 pediatric liver transplant recipients and 3 normal healthy controls. Starting December 2011, immunophenotyping of T, B, NK, and dendritic cells was performed with multi-color monoclonal antibody panels. Cell fluorescence was acquired on an LSR Fortessa, and population measurements were determined using FCS Express V3 analysis software.

RESULTS

6 samples from 4 stable recipients on tacrolimus monotherapy and 2 control samples have been analyzed to date. Compared to controls, the liver recipients have a higher percentage of CD4 and CD8 memory effector cells, as determined by CD45RA-/CD27- surface markers (40% vs 20%). The liver recipients also have an increased ratio of monocytoid to plasmacytoid dendritic cells (2.1 vs 0.7), a pattern that has previously been associated with non-tolerogenic states. The remaining samples are currently being analyzed, including those from liver transplant recipients on no immunosuppression versus dual or triple immunosuppression.

CONCLUSION

This is the first study to assess variations in PBMC immunophenotypes associated with tacrolimus use in pediatric liver transplant recipients. By comparing these immunophenotypes to allograft function, we hope to develop a pharmacodynamic assay that can better assess the therapeutic effects of tacrolimus and ultimately enable clinicians to individualize immunosuppression.

ENDOMYOCARDIAL, INTRALYMPHOCYTE AND WHOLE BLOOD CONCENTRATIONS OF CYCLOSPORINE A IN HEART TRANSPLANT RECIPIENTS

I. Robertsen,1 P. Falck,1 N. Naess,1 A. Andreassen,2 L. Gullestad,1 H. Christensen,1 A. Åsberg1; 1School of Pharmacy, University of Oslo, Oslo, Norway, 2Department of Cardiology, Oslo University Hospital, Rikshospitalet, Oslo, Norway

BACKGROUND

Previous studies indicate that intracellular cyclosporine A (CsA) concentration may be a more sensitive monitoring tool for acute rejections in renal transplant recipients. In the present study we investigated CsA concentrations in isolated T-lymphocytes from heart transplant recipients. In addition, concentration of CsA and its metabolites were measured in endomyocardial biopsies to elucidate its association with rejections and side effects.

METHODS

Ten heart transplant recipients (8 men, 2 women) on CsA-based immunosuppression were enrolled in this prospective single-center pilot study. Blood samples were obtained twice weekly initially, and thereafter weekly for up to 12 weeks after transplantation. One of the weekly routine biopsies was allocated to this study. Whole blood, intralymphocyte and biopsy CsA concentrations were determined with a validated high-performance liquid chromatography-tandem mass spectrometry method. Due to analytical challenges, the analysis of CsA concentrations in endomyocardial biopsies was delayed and finalized mid-November 2011.

RESULTS

The average (range) intralymphocyte CsA trough concentrations were 10.6 (1.5-39.3) and 7.4 (1.3-25.2) ng/10⁶ cells in the rejection and non-rejection group, respectively (P=0.70). The corresponding whole blood CsA concentrations were 321 (153-941) and 308 (152-847) ng/mL, respectively (P=0.26). There were no correlation between whole blood and intralymphocyte CsA concentration (r²=0.03) and no correlations were found between endomyocardial CsA concentrations and whole blood (r²=0.065) or intralymphocyte concentrations (r²=0.072).

CONCLUSION

The present study did not reveal any correlation between CsA concentrations in whole blood, T-lymphocytes or endomyocardial tissue. The study could not support previous findings, as no association between intralymphocyte CsA concentrations and acute rejections was present.
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2011
Landry Kamdem Kamdem, PharmD, PhD
Pediatric Gastroenterology Fellow / Assistant Professor
Pharmaceutical Sciences
Harding University College of Pharmacy
Research Project
The Impact of UGT2B17 Genetic Polymorphisms on the Disposition and Action of Exemestane in Healthy Volunteers

Laura J. Wozniak, MD
Pediatric Gastroenterology Fellow • Department of Pediatrics
University of California, Los Angeles • Los Angeles, CA
Research Project
Development of Immune Profiles as Tools for Individualization of Immunosuppression in Pediatric Liver Transplant Recipients

2010
David S. Lee, PharmD, PhD
Department of Internal Medicine
Yale School of Medicine
Research Project
Development of Risk Prediction Models in Older Adults on Antihypertensive Medications for Cardiovascular and Falls Outcomes

2009
Jun J. Yang, PhD
Department of Pharmaceutical Sciences
St. Jude Children's Research Hospital
Research Project
Genetic Polymorphisms of 5-aminoimidazole-4-carboxamide ribonucleotide formyltransferase/IMP cyclohydrolase and In Vivo Response to Methotrexate

2008
Satsuki Yamada, MD, PhD
Departments of Clinical Pharmacology/Molecular Pharmacology & Experimental Therapeutics
Cardiovascular Diseases/Medicine
Mayo Clinic
Research Project
Clinical Pharmacology of Patient-Derived Stem Cells for Cardiac Repair

2007
Candace Y.W. Lee, MD, PhD, FRCPC
Departments of Medicine and Physiology / Cardiorenal Research Laboratory
Department of Molecular Pharmacology and Experimental Therapeutics
Clinical Pharmacology Fellowship Program
Mayo Clinic
Research Project
Discovery and Development of Novel Designer Natriuretic Peptides for the Treatment of Heart Failure

2006
Ying-Jun Cao, MB
Division of Clinical Pharmacology
Johns Hopkins University
Research Project
Distribution of Indinavir in Male Genital Tract
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