



# American Thoracic Society International Conference



*Where today's science meets tomorrow's care™*

# Final Program



**ATS 2016**  
*Where today's science  
meets tomorrow's care™*

May 13 - May 18, 2016  
San Francisco, California  
[conference.thoracic.org](http://conference.thoracic.org)



**U.S. FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH**

**L1 GENERIC DRUG DEVELOPMENT FOR  
RESPIRATORY PRODUCTS: U.S. FOOD AND DRUG  
ADMINISTRATION UPDATE**

**12:15 p.m. - 1:15 p.m.**

**MOSCONE CENTER**

**Room 3016/3018 (West Building, Level 3)**

**Target Audience**

Clinicians in practice, researchers, pharmaceutical industry representatives, international drug regulators.

**Objectives**

At the conclusion of this session, the participant will be able to:

- recognize key aspects of the generic drug regulatory approval process, and their impact on inhaled generic drug products;
- describe how the Office of Generic Drugs (OGD) evaluates bioequivalence for complex inhaled generic drug products, using a weight-of-evidence approach, and how pharmacodynamic (PD) studies are used to establish equivalent local delivery;
- articulate how device and formulation similarity, in vitro performance studies, and pharmacokinetic (PK) studies are utilized within the weight-of-evidence approach to establish bioequivalence for generic inhaled drug products.

This session will describe respiratory product development of generic drugs within the U.S., focusing on paths forward to bring safe and effective generic respiratory products to the American public. History of the generic drug approval process will be explored, distinguishing generic approval from new drug approvals, and identifying key regulations by which approvals are governed. Generic drug program requirements including bioequivalence, pharmaceutical equivalence, and product performance will be discussed, including the role of clinical endpoint studies, recommendations for combination drug products, and drug-device issues specific for metered dose inhaler (MDI) and dry powder inhaler (DPI) products.

**Chairing:** K.A. Witzmann, MD, Silver Spring, MD

**12:15 Introduction**

K.A. Witzmann, MD, Silver Spring, MD

**12:18 Overview of FDA Generic Inhaled Drug Approval Process**

L. Lapteva, MD, MHS, Silver Spring, MD

**12:35 Discussion of the Generic Approval Process, Specific to Inhaled Drug Products**

K.A. Witzmann, MD, Silver Spring, MD

**12:52 Bioequivalence for Complex Inhaled Generic Drug Products: Formulation Similarity, In Citro Studies and Pharmacokinetics (PK)**

B. Saluja, PhD, Silver Spring, MD

**1:09 Questions and Answers**

K.A. Witzmann, MD, Silver Spring, MD

**NATIONAL INSTITUTE OF ALLERGY  
AND INFECTIOUS DISEASES, NIH**

**L2 INSIGHTS INTO ASTHMA SEVERITY FROM THE  
INNER-CITY ASTHMA CONSORTIUM**

**12:15 p.m. - 1:15 p.m.**

**MOSCONE CENTER**

**Room 3006/3008 (West Building, Level 3)**

**Target Audience**

Clinicians, researchers, health care administrators, public health specialists, asthma educators.

**Objectives**

At the conclusion of this session, the participant will be able to:

- understand how host and environmental factors work in concert to determine asthma severity;
- learn how IgE levels influence viral infection and illness;
- learn how lowering IgE levels restores anti-viral immunity focusing on the dendritic cell.

The Inner City Asthma Consortium (ICAC) has over 20 years experience studying asthma morbidity among inner city children and adolescents. This session will present data from two recently completed ICAC studies demonstrating the complex interaction of host and environmental factors on asthma severity and the impact of IgE level on viral respiratory infections and subsequent exacerbations.

**Chairing:** P.J. Gergen, MD, MPH, Rockville, MD

**12:15 Risk Pathways Determining Asthma Severity**

A. Liu, MD, Denver, CO

**12:35 How Does Omalizumab Affect Viral Respiratory Infections and Illnesses in Asthma?**

J.E. Gern, MD, Madison, WI

**12:55 Understanding the Role of Dendritic Cells in Anti-Viral Immunity**

M. Gill, MD, Dallas, TX

**NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES  
50TH ANNIVERSARY SESSION**

**L3 INDOOR EXPOSURE TO BIOMASS/WOODSMOKE  
EXPOSURE AND PULMONARY HEALTH**

**12:15 p.m. - 1:15 p.m.**

**MOSCONE CENTER**

**Room 3010/3012 (West Building, Level 3)**

**Target Audience**

Basic and clinical researchers, physicians, pulmonologists and community and public health specialists.

**Objectives**

At the conclusion of this session, the participant will be able to:

- understand the levels and potential effects of indoor air pollution on pulmonary health;



- gain knowledge on biochemical and molecular pathways involved in exposure to particulates from biomass combustion;
- understand current efforts on developing potential interventions strategies.

Globally half of the population relies on solid fuels for their everyday energy requirements. The rural households in developing and underdeveloped countries mainly use biomass fuels (wood, dung, crop wastes) that are typically burned in inefficient, poorly ventilated homes (often open fires). Women and infants in these homes have very high exposures to smoke, typically levels that are considered harmful to health by the U.S. Environmental Protection Agency (EPA) and the World Health Organization (WHO). The presentations at this session will highlight our current efforts in addressing these issues from monitoring exposure to developing preventive and intervention measures.

**Chairing:** S.S. Nadadur, PhD, Durham, NC  
J.R. Balmes, MD, San Francisco, CA

**12:15 Introduction**  
S.S. Nadadur, PhD, Durham, NC

**12:20 Use of the MicroPEM to Support Biomass Cookstove Exposure and Health Outcome Studies**  
J. Thornburg, PhD, Durham, NC

**12:37 Household Air Pollution: A Major Preventable Cause of COPD**  
J.R. Balmes, MD, San Francisco, CA

**12:54 Development of Interventions for PM Induced Airway and Systemic Diseases**  
D. Peden, MD, Chapel Hill, NC

## PATIENT CENTERED OUTCOME RESEARCH INSTITUTE

### L4 UPDATES ON PATIENT-CENTERED OUTCOME RESEARCH INSTITUTE (PCORI): PCORNET AND EVIDENCE TO ACTION NETWORKS

12:15 p.m. - 1:15 p.m. MOSCONE CENTER

Room 3020/3022 (West Building, Level 3)

#### Target Audience

Clinicians (physicians, nurses, fellows, residents), researchers, administrators and policymakers; anyone involved in delivery of care and the science of patient-centered research.

#### Objectives

At the conclusion of this session, the participant will be able to:

- understand the role of Patient Centered Outcomes Research Institute in funding comparative effectiveness research;
- understand how a patient stakeholder is engaged in PCORI projects;
- learn from PCORI researchers what network activities are ongoing.

A PCORI official will introduce summaries of PCORI funded projects in pulmonary, critical care and sleep disorders and the presenters will expand on this by introducing the unique network activities in asthma, COPD and transition of care. A patient stakeholder/reviewer will also discuss their involvement in PCORI funded projects and their view as a patient grant reviewer. The purpose of the session will be to raise awareness of PCORI activities relevant to patient centered care for patients with pulmonary, critical care, and sleep disorders.

**Chairing:** J.V. Selby, MD, MPH, Washington, DC  
K. Sumino, MD, MPH, St. Louis, MO

**12:15 Patient Centered Outcome Research Institute in Thoracic Disease**  
J.V. Selby, MD, MPH, Washington, DC

**12:25 Lay PCORI Grant Reviewer Perspective**  
J. Sullivan, MPH, Washington, DC

**12:30 Update on COPD Patient-Powered Research Network and PCORnet**  
R.A. Mularski, MD, MSHS, Portland, OR

**12:40 Update in Evidence to Action Network in Asthma**  
K. Sumino, MD, MPH, St. Louis, MO

**12:50 Update on PCORI Evidence to Action Network for Transitions in Care**  
J.A. Krishnan, MD, PhD, Chicago, IL

**1:00 Panel Discussion**  
J.V. Selby, MD, MPH, Washington, DC

## NATIONAL HEART, LUNG, AND BLOOD INSTITUTE, DIVISION OF LUNG DISEASES, NIH

### L5 PREMATURETY AND RESPIRATORY OUTCOMES PROGRAM (PROP): RESPIRATORY OUTCOMES AT ONE YEAR

12:15 p.m. - 1:15 p.m. MOSCONE CENTER  
Room 2002/2004 (West Building, Level 2)

#### Target Audience

Pediatric providers of lung health, basic and clinical researchers interested in neonatal lung diseases, including pediatric, pulmonologists, neonatologists and basic pulmonary biology researchers.

#### Objectives

At the conclusion of this session, the participant will be able to:

- understand that respiratory outcomes of the premature can persist beyond the NICU period;
- learn and understand how to measure respiratory morbidity of extremely premature infants after the NICU;
- learn that objective measures of respiratory physiology can detect consequences of extremely premature birth.

PROP is a multicenter, observational cohort of extremely low birth weight infants at high risk of bronchopulmonary dysplasia (BPD) and long-term respiratory morbidity. Infants 29 weeks gestation were enrolled and reached a neonatal outcome at 12 months corrected age (n = 765). PROP prospectively collected standardized clinical data to test for associations between neonatal clinical parameters, respiratory physiology at 36 weeks postmenstrual age, and respiratory status at one-year corrected age. This session will focus on presentations of the 12 month corrected age outcomes of the PROP cohort including respiratory symptoms, respiratory medication use, and infant pulmonary function.

**Chairing:** L.M. Taussig, MD, Denver, CO  
C.J. Blaisdell, MD, Bethesda, MD