



COLUMBIA UNIVERSITY

*College of Physicians
and Surgeons*

NewYork-Presbyterian
The University Hospital of Columbia and Cornell

*Clinical Trials in
Pulmonary Arterial Hypertension:
Past, Present, and Future*

Friday & Saturday, October 5 & 6, 2007






Program Description & Objectives

This conference brings together expert speakers for a highly-interactive meeting to elucidate critical topics in the development and refinement of the methodology of clinical trials in pulmonary arterial hypertension (PAH). Specific areas of focus will include standard principles of clinical trial design in cardiopulmonary medicine, definitions and criteria of valid end points in PAH and other conditions, the assessment of hemodynamics, cardiac imaging, exercise, biomarkers, and quality of life in PAH clinical trials, and the ethics of trial conduct. Course participants will be expected to contribute to open forum discussions of these topics as a means to improve the yield of clinical trials in PAH.

The objective of this meeting is to educate participants in the principles of rigorous clinical trial design and to stimulate discussion of how to produce safe, high-quality, and efficient PAH clinical trials in the future. Such discussion will allow for a more uniform understanding of the relevance of particular diagnostic, therapeutic, and prognostic outcomes in PAH. Investigators, clinicians, sponsors and regulatory boards who study, utilize and review therapeutic agents in the treatment of PAH should find this course informative and stimulating.



Course Directors

Ramona Doyle, M.D., *Associate Professor of Medicine*, Stanford University School of Medicine, Palo Alto, California

Steven M. Kawut, M.D., M.S., *Herbert Irving Assistant Professor of Clinical Medicine (in Epidemiology)*, Columbia University College of Physicians & Surgeons, New York, New York

Faculty

David Badesch, M.D., *Professor of Medicine*, University of Colorado, Denver, Colorado

Raymond L. Benza, M.D., *Associate Professor of Medicine*, University of Alabama, Birmingham, Alabama

Mardi Gomberg-Maitland, M.D., M.S., *Assistant Professor of Medicine*, University of Chicago, Chicago, Illinois

Scott Halpern, M.D., Ph.D., *Fellow*, Division of Pulmonary, Allergy, and Critical Care Medicine; Senior Scholar, Center for Bioethics, University of Pennsylvania School of Medicine, Philadelphia, Pennsylvania

Nicholas Hill, M.D., *Professor of Medicine*, Tufts University School of Medicine, Boston, Massachusetts

Mark A. Hlatky, M.D., *Professor of Health Research and Policy and Professor of Medicine*, Stanford University School of Medicine, Palo Alto, California

Harrison W. Farber, M.D., *Professor of Medicine*, Boston University School of Medicine, Boston, Massachusetts

James E. Loyd, M.D., *Rudy W. Jacobson Professor of Medicine*, Vanderbilt University School of Medicine, Nashville, Tennessee

Andrew Peacock, M.D., FRCP, *Professor of Medicine*, Western Infirmary, Glasgow, Scotland

Ileana L. Piña, M.D., *Professor of Medicine*, Case Western Reserve University, Cleveland, Ohio

Lewis J. Rubin, M.D., *Professor of Medicine*, University of California San Diego, La Jolla, California

Olivier Sitbon, M.D., *Consultant*, Service de Pneumologie Réanimation Respiratoire, Hôpital Antoine Bécclère, Clamart, France

Norman L. Stockbridge, M.D., Ph.D., *Director*, Division of Cardiovascular and Renal Products, Center for Drug Evaluation and Research, Food and Drug Administration, Silver Spring, Maryland



October 5, 2007

7:15 a.m. *Registration; Continental Breakfast*

Background

8:15 a.m. Welcome and Introduction
Lewis J. Rubin, M.D.

8:30 a.m. Principles of Clinical Trials in
Cardiopulmonary Medicine
Mark A. Hlatky, M.D.

9:15 a.m. Modern Trial Design: Lessons from New Drugs
and Novel Endpoints
Ileana L. Piña, M.D.

10:00 a.m. *Break*

10:30 a.m. Drug and Non-Drug Interventions in PAH
Harrison W. Farber, M.D.

11:15 a.m. What the FDA Wants/Needs from Clinical
Trials in PAH
Norman L. Stockbridge, M.D., Ph.D.

12:00 p.m. *Lunch*

Current Controversies in PAH Clinical Trials

1:30 p.m. Is it Ethical to Perform Clinical Trials in PAH?
Scott Halpern, M.D., Ph.D.

2:15 p.m. PAH Patients in Clinical Trials: WHO Are You?
Nicholas Hill, M.D.

3:00 p.m. *Break*

3:15 p.m. Traditional and Alternative Approaches to
Phase III Trials in PAH
Mardi Gomberg-Maitland, M.D., M.S.

4:00 p.m. Discussion

4:15 p.m. *Adjourn*

October 6, 2007

7:00 a.m. *Registration; Continental Breakfast*

The Future of Assessment in PAH Clinical Trials

8:00 a.m. Surrogate and Combined Endpoints:
The Good, The Bad, and The Good Enough
Andrew Peacock, M.D., FRCP

8:45 a.m. Hemodynamics-Are They the (Fool's) Gold Standard?
David Badesch, M.D.

9:30 a.m. Cardiac Imaging: Is a Picture Worth 1000 Words?
Raymond L. Benza, M.D.

10:15 a.m. *Break*

10:30 a.m. Exercise-Walk, Run, or Ride?
Olivier Sitbon, M.D.

11:15 a.m. Biomarkers
James E. Loyd, M.D.

12:00 p.m. Quality of Life
Ramona Doyle, M.D.

12:45 p.m. Summary
Steven M. Kawut, M.D., M.S.

1:00 p.m. *Adjourn*

Meeting Location

Arizona Biltmore Resort & Spa
2400 East Missouri Avenue
Phoenix, Arizona 85016
Telephone: (602) 955-6600

Hotel Accommodations

A block of rooms has been reserved at the Arizona Biltmore Resort & Spa, at the special rate of \$279 per night, plus state & local taxes. These special room rates are available to the course attendees from October 4-7, 2007. Other rates and conditions may apply. Additional information can be obtained by calling the Arizona Biltmore Resort & Spa directly.

Reservations must be made directly with the Arizona Biltmore Resort & Spa. To receive this room rate remember to mention that you are a registrant of the Columbia University course.

Rooms will be held until September 4, 2007 or until the room block has been exhausted, whichever comes first. Reservations received after the cut-off date are subject to availability and prevailing rates.

Arizona Biltmore Resort & Spa

2400 East Missouri Avenue
Phoenix, AZ 85016

(800) 950-2575

(602) 955-6600

Cut-Off: September 4, 2007

Additional Information

Contact: Center for Continuing Medical Education
Columbia University College of Physicians & Surgeons
630 West 168th Street, Unit 39
New York, NY 10032
Telephone: (212) 305-3334
Fax: (212) 781-6047
e-mail: cme@columbia.edu
<http://columbiacme.org>

Accreditation/Designation of Credit

The College of Physicians and Surgeons of Columbia University is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians.

The College of Physicians and Surgeons designates this educational activity for a maximum of 10.5 *AMA PRA Category 1 Credit(s)*[™]. Physicians should only claim credit commensurate with the extent of their participation in the activity.

The American College of Nurse Practitioners (ACNP) and the American Academy of Physician Assistants (AAPA) accept AMA/PRA category 1 credit from organizations accredited by the ACCME.

The American Nurses Credentialing Center (ANCC) accepts AMA/PRA category 1 credit toward recertification requirements.

Disclosure

Before the program, all faculty will disclose the existence of any financial interest and/or other relationship(s) (e.g. employee, consultant, speaker's bureau, grant recipient, research support, stock ownership or any other special relationship) they might have with a) the manufacturer(s) of any commercial product(s) to be discussed during their presentation and/or b) any commercial contributor to this activity. When unlabeled uses are discussed, these will also be indicated.

Acknowledgements

This course was supported by generous, unrestricted educational grants from:

Actelion Pharmaceuticals, Encysive, Pfizer

Gilead Sciences

United Therapeutics

Tuition

Physicians: \$175; Other Health Professionals: \$125; Fellows & Residents: \$95 (with a letter from program director certifying status). The fee includes the academic presentations, daily continental breakfast, one lunch, refreshments and a course syllabus. Confirmation of registration and directions to the meeting location will be sent upon receipt of the registration form.

Refund of registration fee, less a \$25 administrative charge, will be made if written notice of cancellation is received by September 25, 2007. No refunds can be made thereafter.

Registration

Space is Limited. Early Registration is Encouraged.

By Mail:

Complete the registration form and mail with full payment to:

**Columbia University
College of Physicians & Surgeons
Center for Continuing Medical Education
630 West 168th Street, Unit 39
New York, NY 10032**

By Fax:

Registrants may fax the registration form with credit card information to:

(212) 781-6047

On-Line:

<http://columbiacme.org>

**Telephone registrations and/or
cancellations are not accepted.**

Americans with Disabilities Act

The Columbia University College of Physicians and Surgeons fully complies with the legal requirements of the ADA and the rules and regulations thereof. Any participant with special needs must submit a written request to our office at least one month prior to the course date.

Registration Form

COLUMBIA UNIVERSITY

Pulmonary Hypertension

(Please print or type)

Last Name

Degree

First Name

Middle Initial

Address

City

State

Zip

Daytime Phone

Daytime Fax

e-mail

Institution

Specialty/Area of Interest

\$175 Physicians

\$125 Other Health Professionals

\$95 Fellows & Residents
(with letter from program director).

Medicine PM 117
October 5 & 6, 2007
58404/10.5

Enclosed is a check or money order made payable to
Columbia University.
Checks must be in U.S. Dollars drawn on a U.S. bank.
Money orders must be in U.S. Dollars.

Please charge to: MasterCard Visa

Exp. Date _____

Card Number _____

Cardholder's Name _____

Cardholder's Signature _____



Columbia University
College of Physicians & Surgeons
630 West 168th Street, Unit 39
New York, New York 10032

NON-PROFIT ORG.
U.S. POSTAGE
PAID
WHITE PLAINS, N.Y.
PERMIT NO. 5198

Clinical Trials in Pulmonary Arterial Hypertension: Past, Present, and Future

Friday & Saturday, October 5 & 6, 2007