



New England Chapter

12th Annual ACRP New England Chapter Fall Symposium

Clinical Research Effectiveness: Foundation for Success

Friday, November 4, 2011

8:00 AM – 4:30 PM

Westin Hotel, Waltham MA

*Space is Limited
Register Early*

Agenda

Goals and Objectives:

Attendance at this symposium will provide the attendees with:

1. An FDA perspective on Investigator Initiated Trials
2. An Update on the FDA Guidance regarding Pharmacovigilance Reporting
3. Knowledge about the Physician Payment Act
4. An Update on US Healthcare Reform
5. Managing multicenter trials in an academic setting
6. Current GCP compliance trends and issues.

7:15 AM – 8:00AM

Breakfast and Registration

8:00 AM – 8:10 AM

Susan Flint, President New England Chapter ACRP
Welcome

8:10 AM- 8:15 AM

Jessica Hyacinthe, 2011 Symposium Chairman
Speaker Introductions

8:15 AM – 9:00 AM

**Joel Moss, M.D., Deputy Chief of the Cardiovascular and Pulmonary
Branch, National Heart, Lung and Blood Institute, National Institutes of
Health**

*Lymphangiomyomatosis (LAM): Molecular Insights
Lead to Targeted Therapies*

9:00 AM – 9:45 AM

Keynote Speaker

**Ken Getz, MBA, Senior Research Fellow, Tufts Center for the Study of Drug
Development**

Transforming Legacy R & D Through Open Innovation



New England Chapter

- 9:45 AM – 10:00 AM **Networking Break**
- 10:00 AM – 10:45 AM **Christine Drabick, FDA Consumer Safety Office**
Investigator-Sponsored Research: An FDA Perspective
- 10:45 AM – 11:30 AM **David Vulcano, LCSW, MBA, CIP, RAC, VP and Responsible Executive
Clinical Research, Clinical Services Group**
*US Healthcare Reform and Human Subject Protection: Opportunities and
Challenges*
- 11:30 AM – 12:15 PM **Colleen Sproul, JD, Principal Contracts Associates**
*The Physician Payment Sunshine Act and its Impact On Clinical Trial
Agreements*
- 12:15PM – 1:15PM **Lunch**
- 1:15 PM – 2:15 PM **Panel Discussion: New FDA safety reporting guidance and the impact on
pharmacovigilance reporting**
**Panelists: Marianne Savage, Senior Product Manager/Strategy, Oracle; Jun
Kawashima, MD; Gillian Black-Noller, MD, Senior Director, CV/Metabolic,
Pfizer**
- 2:15 PM – 2:30 PM **Networking Break**
- 2:30 PM – 3:15 PM **Marianne Kearney, MGH Director of Project Management Neurology
Clinical Trials Unit**
*Managing Multicenter Clinical Trials in an Academic
Setting: Project Manager Roles and Responsibilities*
- 3:15 PM – 4:00 PM **Christine H. Wang, MS, Executive Director of ClinPath™
BioBridges LLC**
Current GCP Compliance Trends and Issues
- 4:00 PM – 4:30 PM **Susan Flint and Jessica Hyacinthe**
Grand Prize Drawing and Closing Remarks