

THREE-PART WEBINAR SERIES

Pharmacovigilance Webinar Series

OCTOBER 19, 26, and NOVEMBER 2, 2011

11:00 AM-12:30 PM ET

9:00 AM-10:30 AM MT

10:00 AM-11:30 AM CT

8:00 AM-9:30 AM PT



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WHO SHOULD ATTEND

Professionals involved in:

- Pharmacovigilance
- Drug safety
- Signal detection

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See page 4 for the registration form for a single webinar.

This webinar series will provide you with a better understanding of operational implications of the new European pharmacovigilance legislation, safety signaling and confirmatory studies, and pharmacovigilance for co-marketed products.

WEBINAR SCHEDULE AND DESCRIPTIONS

■ PART 1 WEBINAR #11248 OCTOBER 19, 2011

Out with the Old, In with the New: Operational Implications for the New European Pharmacovigilance Legislation

MODERATOR

ANGELA PITTWOOD

Pharmacovigilance Advisor and Consultant

PRESENTERS

VERONIQUE BASCH

Executive Director, Safety, Europe
United BioSource Corporation

KLAUS JAKOBSEN

Senior Director Head of International Safety
Nycomed

The new European legislation on pharmacovigilance will take effect in July 2012. This webinar will discuss the operational changes you will need to implement to support the new legislation, including:

- Streamlining or increasing certain activities
- Identifying a project plan and calendar to implement changes
- Prioritization of short- and long-term activities to maintain compliance.

(continued on page 2)

LEARNING OBJECTIVES

At the conclusion of this webinar, participants should be able to:

- Describe an overview of the legislation and its implementation schedule
- Identify main areas where operational changes will be required at the level of the MAH
- Explain what to implement first and how to prioritize and develop a project plan and calendar for implementation
- Discuss the challenges and uncertainties of the New European Pharmacovigilance Legislation

■ PART 2 WEBINAR #11250 OCTOBER 26, 2011

Pharmacovigilance for Co-marketed Products: Identifying and Overcoming Potential Obstacles

MODERATOR

ANGELA PITTWOOD

Pharmacovigilance Advisor & Consultant

PRESENTERS

WENDA BRENNAN

Director, Pharmacovigilance
United BioSource Corporation

ROY BRISENDINE, MBA

Pharmacovigilance Agreement Specialist
Teva Pharmaceuticals USA, Inc.

A co-licensing agreement creates legal requirements for safety data exchange. A Pharmacovigilance Agreement (PVA) is an integral part of maintaining compliance in an ever-changing and complex Regulatory environment. Careful planning is key to establishing a successful working partnership, especially taking into consideration the size and scope of countries where reporting is required.

This webinar will review the complexities of global and local co- and multi-licensing agreements, provide examples of what “good” looks like, discuss the top five pitfalls, share an outline for a common approach to ensure success.

LEARNING OBJECTIVES

At the conclusion of this webinar, participants should be able to:

- Describe common pitfalls for co-licensing agreements proactively
- Articulate needs to legal what safety departments need to develop co-licensing agreements
- Identify key elements needed for a strong PVA
- Discuss the inter-relatedness of 3rd Party Agreements and how they impact Quality, Safety, and Business in your Company

■ PART 3 WEBINAR #11249 NOVEMBER 2, 2011

Closing the Gap between Safety Signaling and Confirmatory Studies

PRESENTERS

JON MORRIS

Vice President Evidence Development
United BioSource Corporation

KRISTEN VAN DOLE

Epidemiologist
GlaxoSmithKline

Signal detection methods and the computational tools to identify signals continue to expand (based on additional data sources, data mining tools, regulatory requirements), while performing definitive confirmatory studies is labor intensive, time consuming, and not fully automated. As such, more potential “signals” are presenting for evaluation with less capacity for adjudication and definitive study.

This webinar will explore the range of components of evidence available to the safety scientist, epidemiologist, and risk management team (including drug information, disease information, and comparator information), and biopharmaceutical sponsors so they can effectively:

- Triage safety signals
- Leverage observational data to provide additional evidence in the signal strengthening process
- Optimize the use of scarce resources for the subsequent performance of definitive studies

LEARNING OBJECTIVES


At the conclusion of this webinar, participants should be able to:

- Discuss how to leverage multiple data sources for a comprehensive review
- Describe how to reduce the time and resources needed to evaluate observational data for signal strengthening
- Recognize how to triage signals more confidently, in less time
- Identify signals requiring further study
- Identify possible channel bias

3-Part Webinar Series: Pharmacovigilance

PART 1	WEBINAR #11248	OCTOBER 19, 2011	11:00 AM-12:30 PM EDT
PART 2	WEBINAR #11250	OCTOBER 26, 2011	11:00 AM-12:30 PM EDT
PART 3	WEBINAR #11249	NOVEMBER 2, 2011	11:00 AM-12:30 PM EDT

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Continuing Education Credit Allocation

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Webinar 3: Closing the Gap between Safety Signaling and Confirmatory Studies .2 IACET CEUs

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Operating Systems	2000, XP, 2003, 32-bit Vista, 64-bit Vista (not including Remote Access and Productivity Tools), 32-bit Windows 7, 64-bit Windows 7 (not including Remote Access and Productivity Tools)	10.4, 10.5, 10.6	"Ubuntu 9.04, Red Hat 5, Open SuSE 11.1, Fedora 11"
Minimum System Requirements			
Processor	Intel or AMD	PowerPC or Intel	Intel or AMD
JavaScript	JavaScript and cookies enabled	JavaScript and cookies enabled	JavaScript and cookies enabled
Other	Active X enabled (unblocked for IE is recommended)	Apple Java 5 or above	"Sun Java 5 or above, libstdc++ 6.0, GNOME/KDE windowing system"
Browsers (Recommended browsers are shown in bold)			
Internet Explorer	6, 7, 8		
Mozilla			1.7
Firefox	2/3/3.5	2/3/3.5	2/3/3.5
Safari		4-Mar	
Chrome	3		

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3-Part Webinar Series: Pharmacovigilance

- PART 1 WEBINAR #11248 OCTOBER 19, 2011 11:00 AM-12:30 PM EDT
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 - PART 3 WEBINAR #11249 NOVEMBER 2, 2011 11:00 AM-12:30 PM EDT
- You **MUST** indicate which Webinar(s) you will be attending.

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