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Managing Drug Safety

*Strategic Adverse Event Management and
Pharmacovigilance Strategies to Minimize Risk*

MARCH 10-11, 2008, RADISSON-PLAZA WARWICK, PHILADELPHIA, PA

Featuring Case Studies and Lessons Learned from Industry Experts!

- Detail the Differences Between the US and EU Requirements and Prepare for Worldwide Safety Inspections
- Understand the 3 FDA Guidances Concerning Risk Management Programs
- Determine the Opportunities and Challenges of Patient Registries for Efficient Risk Management
- Management and Reporting of Adverse Events: Best Practices and Tools
- How Adaptive Trial Design Can be Used to Maximize Drug Safety Information
- Advanced Quantitative Post-Marketing Safety Signal Analysis

In-Depth Pre-Conference Workshop:

Strategic Risk Management Plan Development: Utilizing Current Tools to Ensure Safety and Expedite Approvals

Led by: David I. Goldsmith, MD, FISPE,
President, Goldsmith Pharmacovigilance and Systems

Yola Moride, PhD, FISPE, Associate Professor, Faculty of Pharmacy,
Université de Montréal, President, International Society for
Pharmacoepidemiology (ISPE)

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PharmaED
RESOURCES, Inc.

Monday, March 10, 2008

8:45 *Chairperson's Welcome and Opening Remarks*

IN-DEPTH PRE-CONFERENCE WORKSHOP

9:00 **Strategic Risk Management Plan Development: Utilizing Current Tools to Ensure Safety and Expedite Approvals**

With regulators looking at pharmaceutical companies to take the lead on evaluating safety data and to predict and proactively look for signals of new or potential safety issues, it is necessary to be familiar with the toolbox that is currently available. The key is to successfully design an appropriate risk management plan in order to avoid delays in marketing. This workshop will review the 3 guidelines published by the FDA, the CHMP Guideline on Risk Management Systems for Medicinal Products for Human Use, as well as Annex C: Template for EU Risk Management Plan (EU – RMP). We will present ideas for conducting effective peri- and post-approval studies through patient registries and automated databases for optimal risk planning and discuss the advantages and disadvantages of these tools. The Workshop will then provide an opportunity for the attendees to work together to define a risk management plan with risk minimization procedures as well as to plan an evaluation procedure for the RMP and RiskMap.

- Discuss and describe the 3 FDA Guidances concerning Risk Management Programs
- Detail the differences between the US and EU requirements
- Recite the major sections that are described in the EU template for RMPs.
- Explain the distinctions between a RMP and a RiskMAP
- Gain an in-depth understanding of risk management programs in order to define goals and objectives for optimal risk planning
- Comprehend how to use epidemiologic data in the preparation of the safety specification
- Determine the opportunities and challenges of patient registries for efficient risk management
- Understand the role of claims databases as a tool for Phase IV risk management programs
- Discuss the possibilities for evaluating the effectiveness of the risk management plan

About your workshop leader:

David I. Goldsmith, MD, FISPE retired in 2001 from his position as Vice President, Safety Surveillance at Sanofi-

Synthelabo, Inc., and currently is President and Senior Consultant of Goldsmith Pharmacovigilance and Systems. He received his MD degree from New York Medical College, and is board certified in Pediatrics and Nephrology. Dr. Goldsmith has been an active participant in Pharmacoepidemiology, and served as a board member and Vice President for ISPE. He played an active role in PhRMA, where he was Chair of the Clinical Safety Surveillance Committee. He has also a participant in the International Conference on Harmonisation, and served on the US and International E2 Expert Working Groups.

12:00 *Luncheon*

PREPARING FOR GLOBAL REGULATORY INSPECTIONS

1:30 **Preparation for Worldwide Regulatory Agency Safety Inspections**

Colin D'Cunha M.B.B.S., M.H.Sc., F.R.C.P.C. , Director, Global Pharmacovigilance, Apotex

Regulatory Agency Inspections are a fact of life in pharmacovigilance. Agencies worldwide are increasing the requirements and enforcement activity. This talk will examine the requirements for regulatory agency inspection preparation and discuss the experience of being inspected by regulatory agencies in North America, Europe and Asia for pharmacovigilance. Suggestions will be offered to prepare a global department for successful pharmacovigilance inspections by worldwide regulatory agencies.

- Preparing for global regulatory agency inspections- some experiences/ insights from FDA/ Health Canada, EMEA/ MHRA and Asian inspections
- What does an FDA/ Health Canada inspector examine in a Pharmacovigilance inspection?
- How to maximize chances for a successful inspection by EMEA/ MHRA
- What can be done to prepare for a regulatory inspection

2:15 **Interpreting the Guidelines on Risk Management Plans**

Robert Sharrar, MD, M.Sc., Executive Director, Clinical Risk Management & Safety Surveillance, Merck & Company, Inc.

A Risk Management Plan (RMP) is now required for all submission to the EMEA for a new product, new

indication, or new formulation. The EMEA Guidelines describe what should be incorporated into these plans and the structure of a RMP. The FDA has also published guidelines describing risk management activities throughout product development and use. PDUFA IV discusses a Risk Evaluation and Mitigation Plan, but the format has not been described. How do these RMPs differ from the annual safety reports for drugs in clinical development or from the Periodic Safety Update Reports, which are already required?

Attendees will learn:

- An approach to combining the recommendations contained in these guidance documents to develop a single RMP
- Points to consider when determining important identified and potential risks and important missing populations
- How annual safety reports from clinical trials and the post-marketing environment can be used with a RMP to monitor product safety throughout product development and use.

3:00 *Refreshment Break*

REQUIREMENTS FOR MANAGING AND REPORTING ADVERSE EVENTS

3:15 *Management and Reporting of Adverse Events: Best Practices and Tools*

Mindy Sickle, Program Manager, Drug Safety Practice, Intrasphere

Increasing case volumes have significantly increased the pressure on drug safety and pharmacovigilance departments to process mandatory expedited and aggregate reports. At the same time regulatory demands, adverse event scrutiny and an effort to maximize efficiency have become irresistible drivers that have led to the development and adoption of new tools. In addition to the core transactional system, leading companies have deployed add-on solutions to more effectively capture, report and analyze AE data.

This session will explore a number of the best practices

associated with the evolution and extension of drug safety systems covering aspects including:

- AE Data Capture
- ICSR Distribution Rule Management and Maintaining Compliance
- SAE Reconciliation
- Aggregate Reporting and Analysis
- Signal Detection
- Portals and Online Reference Tools

4:00 *Organization of Clinical Safety In Response to CIOMS VI*

Jacinta Aniagolu, Ph.D., Ms.C., Patni Life Sciences

This talk will describe how to implement the recommendations contained in the CIOMS VI and VII reports. Global pharmaceutical companies are beginning to realize the importance of these reports and recommendation.

We will review the recommendations from CIOMS VI and CIOMS VII, followed by specific recommendations on what type of organization is required to implement the recommendations. For example, many companies are still handling safety information from clinical trial and post marketing safety using different departments. Both the structure of the organization, and also its philosophy and way of thinking in regards to clinical safety are very important. This presentation will explain the steps that need to be taken in order to address these issues. Attendees will learn the following best practices for the organization of Clinical Safety:

- Scope of Pharmacovigilance
- Roles and Responsibilities
- Process Maps
- Integrated Approach to Product Safety, incorporating an interdisciplinary Corporate Product Safety Committee
- Integrated Approach to Risk Management
- Signal Detection
- Safety Plans
- Corporate Policy on Product Safety
- Processes, SOPs and Working Practices
- They will also learn how to implement these best practices in their organization.

4:45 *Close of Day One*

Tuesday, March 11, 2008

8:30 *Chairperson's Welcome and Opening Remarks*

8:45 ***Strategic Safety Management Throughout the Product Lifecycle***

Gary Slakto, President, ParagonRx

Public and regulatory expectations of drug safety are escalating as evidenced by CNN broadcasts of drug safety hearings, new legislation, and regulatory actions that have affected both product viability and corporate valuations. Drug safety must evolve as a discipline to address the heightened sensitivity, minimize medication risks, and contribute to the overall value of the company's products. Equally important, the executive governance of companies must recognize and support this expanded role. This presentation will propose a framework for the discipline of drug safety, based on the foundation of three sciences: epidemiology, risk management, and pharmacovigilance. We will focus on how to build those disciplines in a way that adds demonstrable value to products in every stage of the lifecycle. Special emphasis will be placed on how to strategically plan and communicate this effort across the corporation.

Participants in this session will be able to:

- Describe concrete examples of increased public and regulatory scrutiny of drug safety performance
- Illustrate a framework for advancing the discipline of drug safety
- Itemize specific ways that drug safety contributes value to products, manufacturers, and the public at each stage of product lifecycle
- Cite the rationale for a drug safety strategic plan
- Outline a plan to communicate drug safety strategy and value to the organization

SAFETY CONSIDERATIONS FOR ADAPTIVE TRIALS

9:30 ***Safety Considerations for Adaptive Trials***

Ajay Singh, Medical Pharmacovigilance, Global Safety, Wyeth

Adaptive clinical trials are being increasingly utilized during the drug developmental process. As such pharmacovigilance and safety surveillance groups need to have a better understanding of these studies.

The following will be covered throughout the course of this presentation:

- Common designs of adaptive clinical trials will be reviewed
- Potential implications of these trials on pharmacovigilance and safety surveillance will be discussed
- Implications for oversight committees such as Data and Safety Monitoring Committees will be discussed.

10:15 *Refreshment Break*

10:30 ***How Adaptive Trial Design Can be Used to Maximize Drug Safety Information***

Eva R. Miller, Ph. D., Head of Biostatistics, ALMAC Clinical Technologies

Adaptive designs cover a broad range of study types such as sample-size re-estimation, stopping rules, allocation rules and decision rules (for example: dosing rules or seamless designs). Emphasis will be placed on two particular design types: allocation rules and seamless phase IIb/III studies and their impact on safety assessment. The allocation rule is a research tool useful for maintaining balance among treatment groups overall and among small subgroups efficiently and effectively throughout the trial. These randomization approaches maximize the individual contribution to safety and efficacy information made by each subject which is certainly an ethical advantage especially if the trial is stopped early for any reason; the balance is maximized even if the study is underpowered. Seamless phase IIb/III study designs are efficient and cost effective designs, but require a great deal of pre-planning and are especially challenging to study teams because they pose interesting logistical considerations in how to proceed while avoiding operational bias.

- How have various research teams handled the shift in target population, the need for sample size re-estimation, and different study endpoints?
- What are some of the planning and logistical concerns that need to be addressed to implement an adaptive trial design?
- How are adaptive randomization algorithms developed and implemented?
- How can technology improve the implementation of seamless designs?

- How can EDC best serve adaptive trial designs and improve timely access to safety information?

11:15 Refreshment Break

PHASE IV RISK MANAGEMENT PROGRAMS

11:30 *Implementing Phase IV Risk Management Programs: Benefits and Returns*
Annette Stenhagen, Dr.Ph, FISPE, Vice President, Epidemiology and Risk Management, United BioSource Corporation

With the reauthorization of the Prescription Drug User Fee ACT (PDUFA) in September 2007, risk management and the design of risk evaluation and mitigation strategies (REMS) are in the forefront. However, risk management is much discussed yet often remains misunderstood. There are ways to maximize the impact of a REMS in minimizing risk while including features to provide added value to product commercialization. Operational aspects and regulatory views of risk management plans will be discussed. To better appreciate these aspects and international implications, several current examples of risk management plans will be presented.

12:15 Luncheon

VOLUME 9A COVERAGE

1:30 *Risk Management and Volume 9 A*
Anshu Vashishtha, M.D., Ph.D., M.A.C.P., Vice President, Pharmacovigilance and Medical Affairs, Sciformix Corporation

Volume 9A of the Rules governing Medicinal Products in Europe includes new guidance for the design and conduct of risk management activities for medicinal products in Europe. This includes the safety specification, pharmacovigilance plan and risk minimization activities required as part of a marketing application. This session will review the requirements in Volume 9 A as related to risk management plans- when they are needed, what are the components and what guidance is available to implement them in Europe.

- What does Volume 9 A of the rules governing medicinal products in Europe say about Risk Management?
- What topics are to be covered in a safety specification and a pharmacovigilance plan?
- When is a risk management plan required?

2:15 Refreshment Break

VOLUME 9A COVERAGE

2:30 *FDAAA – What will be the Impact?*
Dr. Jeffrey Stoddard, Medical and Scientific Affairs, Covance

The Food and Drug Administration Amendments Act of 2007 is the most comprehensive reform of drug and device regulation in 40 years. This presentation will provide an overview of the major provisions of the new law, and will also review what effects FDAAA might potentially have on drug development and commercialization. Implications for sponsors will be the focus.

Attendees will come to understand FDAAA's provisions regarding:

- pediatric research
- labeling rules
- postmarketing safety surveillance and postmarketing commitments
- conflicts of interest considerations for reviewers
- disclosure rules
- risk evaluation and mitigation strategies

3:15 *Strategies for Running a Global Drug Safety Department Utilizing a Global Delivery Model*
Colin D'Cunha M.B.B.S.,M.H.Sc., F.R.C.P.C. , Director, Global Pharmacovigilance , Apotex; Anshu Vashishtha, M.D., Ph.D.,M.A.C.P., Vice President, Pharmacovigilance and Medical Affairs, Sciformix Corporation

New requirements like risk management and higher numbers of case reports have significantly increased the pressure on pharmacovigilance departments to efficiently process adverse events and submit expedited and periodic reports. At the same time costs of processing and reporting are going up in the Western hemisphere. There is a need to optimize the value from the budget by utilizing global delivery models. This session will examine the approaches that can be taken to maximize return on the PV dollar by using a globally resourced model.

- AE Management globally- basics and considerations for a successful approach
- Expedited and aggregate reports -maintaining compliance
- Transitioning to a global model- what are the imperatives and options?

4:00 Close of Conference



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