

AGENDA

Opportunities for Active Surveillance to Improve the Value of Pharmacovigilance as a Public Health Tool

May 22–23, 2007 • Rockville, Maryland

Objectives:

- 1 Assess the potential for existing and new strategies to increase the speed and predictive value of generating and evaluating safety signals.
- 2 Identify next steps necessary to improve the US system for identifying and evaluating potential safety signals.

Tuesday, May 22, 2007

8:30–8:45 AM

Opening Remarks

Richard Platt and Hugh Tilson

8:45–9:00 AM

Introductions

All

9:00–10:40 AM

Pharmacovigilance Overview

9:00–9:20 AM

Therapeutics Life Cycle: What do we Need of Pharmacovigilance?

Elizabeth Andrews

9:20–9:40 AM

IOM Perspective on Drug Safety

Kathleen Stratton

9:40–10:00 AM

Sentinel Network Approach

Jeffrey Shuren

10:00–10:10 AM

Safety Evaluation of Vaccines

Miles Braun

10:10–10:30 AM

Pharmacovigilance "Needs Assessment"

Brian Strom

10:30–10:40 AM

Questions/Discussion

10:40–11:00 AM

Break

Tuesday, May 22, 2007

11:00–11:50 AM

Data Resources for Active Surveillance: What do we have? What do we need?

11:00–11:15 AM

Use of Integrated Administrative and Clinical Data

Richard Platt

11:15–11:30 AM

Use of Registries

Scott Smith

11:30–11:50 AM

Discussion

- 1 What are the potential strengths, limitations and assumptions associated with the use of these data sources?
- 2 What are the information gaps not addressed by these sources? How can they be addressed?

11:50 AM–12:45 PM

Lunch

12:45–1:30 PM

Identification of Anticipated Events

12:45–1:00 PM

Identification of Early Signals

Bruce Fireman

1:00–1:30 PM

Discussion

- 1 What methods do we have that we can use better?
- 2 What are the gaps? What methods might we adopt to address them?

1:30–2:15 PM

Identification of Unanticipated Events

1:30–1:45 PM

Current and Achievable Methods to Identify Unanticipated Events

Alexander Walker

1:45–2:15 PM

Discussion

- 1 What methods, particularly related to datamining, do we have that we can use better?
- 2 What are the gaps? What methods might we adopt to address them?

Tuesday, May 22, 2007

2:15–3:00 PM

Discussion: Practical Considerations Related to Signal Detection

- Can the degree of certainty or uncertainty in safety signals generated from different methods be captured qualitatively or semi-quantitatively?
- How should uncertainty be described or framed in communications to the public or in establishing priorities for more definitive studies?
- What actions should be taken between the time a signal is identified and the results of an evaluation are available?
- What are implications of finding signals, many of which would not indicate a risk that would influence decision making?
- How can active surveillance approaches supplement passive approaches?
- How do considerations (e.g. population affected, severity of disease/condition, risk/benefit profile) play in decision regarding methodology choice?

3:00–3:20 PM

Break

3:20–4:00 PM

Signal Evaluation

3:20–3:35 PM

Methods to Evaluate Safety Signals

Nancy Santanello

3:35–4:00 PM

Discussion

–Existing Methods

- What are the strengths, limitations and assumptions associated with methodologies to evaluate safety signals (common and rare events)?
- What are the strengths, limitations and assumptions associated with these methods?

4:00–4:30 PM

Putting Drug Safety in a Policy Context

Mark McClellan

4:30–4:50 PM

Signal Evaluation (cont'd)

Discussion

–Gaps and Potential New Strategies

- What are the gaps not addressed by existing methods?
- What characteristics would an ideal approach have that would address these gaps?
- What additional alternatives should be considered, e.g. comparative trials? Under what circumstances?

–General Questions

- Are there methodologies that should routinely be used to address certain questions?
- How do considerations (e.g. population affected, severity of disease/condition, risk/benefit profile) play in decision regarding methodology choice?
- How will we know if the methods succeed in overcoming various biases and confounding factors?

Tuesday, May 22, 2007

5:20–5:30 PM

Closing Comments

5:30 PM

Adjourn to Dinner

Wednesday, May 23, 2007

8:30–8:40 AM

Opening Remarks

Hugh Tilson

8:40–9:00 AM

Review Consensus from Day 1

Richard Platt

9:00–9:30 AM

Review of Ticket to Dinner Responses/Discussion

Hugh Tilson

9:30–11:15 AM

Breakout Groups

Group I – Identification of Anticipated Signals

Moderator: Anne Trontell

Reporter: Judy Staffa

Group II – Identification of Unanticipated Signals

Moderator: Gerald Dal Pan

Reporter: Bob Assenzo

Group III – Evaluation of Signals

Moderator: Elizabeth Andrews

Reporter: Robert Reynolds

Assignment:

- 1) What are the three most important changes to improve the national capacity to identify or evaluate signals within the next five years?
- 2) What are the three most important efforts/initiatives to implement the changes within the next two years?
- 3) What are the most feasible and useful next steps?

11:15 AM–12:15 PM

Group Reports

11:15–11:35 AM

Group I: Report and Discussion

11:35–11:55 AM

Group II: Report and Discussion

11:55 AM–12:15 PM

Group III: Report and Discussion

12:15–12:30 PM

Closing Comments

Hugh Tilson

12:30 PM

Adjourn