

Meeting on the Long-term Safety and Efficacy of Extended-release and Long-acting Opioid Analgesics for Chronic Pain

Hosted by the Clinical Trials Transformation Initiative (CTTI)

August 12&13, 2013

Sheraton Silver Spring Hotel

8777 Georgia Avenue · Silver Spring, MD 20910

The purpose of this meeting, hosted by CTTI, is to facilitate a broad scientific discussion about optimal ways to generate additional evidence to help inform the safe and effective use of extended-release and long-acting opioid analgesics.

A public meeting titled, *Assessment of Analgesic Treatment of Chronic Pain: A Scientific Workshop*, was conducted by the FDA in May 2012. Available data on the efficacy of analgesics in the treatment of chronic non-cancer pain was discussed. The materials from the May 2012 meeting provide useful background and are available at <http://www.fda.gov/Drugs/NewsEvents/ucm283979.htm>.

MEETING OBJECTIVES

- Engage multiple stakeholders in discussions around approaches to develop more evidence on the long-term safety and efficacy of extended-release and long-acting opioid analgesics for the treatment of chronic non-cancer pain
 - Review and discuss a proposed study to evaluate the long-term **efficacy** of opioids for the treatment of chronic non-cancer pain
 - Discuss strategies to assess the long-term **safety** of extended-release and long-acting opioid analgesics for the treatment of chronic non-cancer pain
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DAY 1 – AUGUST 12, 2013

7:30 – 8:30am **Breakfast · Elm I&II**

WELCOMING REMARKS · Cypress Ballroom

8:30 – 8:45am Introduction to CTTI and Opening Comments
Pamela Tenaerts, CTTI
Rachel Sherman, FDA

8:45 – 09:00am Meeting Goals
Robert Califf, Duke University

SESSION I: Evidence for the Efficacy of Opioid Analgesics for Chronic Pain

Session Facilitator: Robert Califf

Session Objectives: Review the available evidence on the long-term efficacy of opioid analgesics for the treatment of chronic non-cancer pain

9:00 – 09:30am Review of the Evidence for the Efficacy and Effectiveness of Opioid Analgesics for Chronic Pain
Jane Ballantyne, University of Washington

9:30 – 10:00am Discussion
All Attendees

10:00 – 10:15am **Break**

SESSION II: Review of Proposed Efficacy Study

Session Facilitator: Robert Califf

Session Objectives: Review a proposed study to evaluate the long-term efficacy of opioids

10:15 – 11:00am Overview of Efficacy Protocol Synopsis
Robert Califf

11:00 – 12:00pm Discussion of Efficacy Protocol Overview and Objective
All Attendees

12:00-1:00pm Lunch (Provided) · Elm I&II

SESSION III: Continued Discussion of Efficacy Study

Session Facilitator: Robert Califf, All attendees to contribute to discussion

Session Objectives:

- *Discuss study population and inclusion and exclusion criteria*
- *Discuss study design, duration, and outcome measures*

1:00 - 1:45pm Discussion of Study Population and Inclusion and Exclusion Criteria

1:45 - 3:15pm Discussion of Study Design, Duration, and Outcome Measures

- 3:15 – 3:30pm **Break**
- 3:30 – 5:15pm What additional studies are needed to evaluate efficacy?
All attendees
- 5:15pm **ADJOURN**
- 6:00 - 8:00pm **Reception • Elm I&II**

DAY 2 – AUGUST 13, 2012

- 7:00 – 8:00am **Breakfast • Elm I&II**
- 8:00 – 8:05am Goals of Safety Discussion
Robert Califf

SESSION IV: Existing Data Sources to Evaluate Opioid Analgesic Safety

Session Facilitator: Robert Califf

Session Objectives:

- *Review examples of data sources used to assess opioid misuse, abuse, addiction, unintentional overdose, and death*
- *Discuss the strengths and weaknesses of existing databases and the gaps in data where additional evidence to assess safety is needed*

- 8:05 – 8:25am Monitoring Opioid Analgesic Abuse and Overdose in the United States
Christopher M. Jones, Centers for Disease Control and Prevention
- 8:25 – 8:40am Postmarketing Surveillance of Prescription Drug Abuse
Richard Dart, Rocky Mountain Poison and Drug Center
- 8:40 – 8:55am Harnessing National Data Sets: National Survey on Drug Use and Health (NSDUH) and VA Data
William Becker, VA Connecticut Healthcare System
- 8:55 – 9:10am Using Integrated Health Plan EMR Data to Evaluate Outcomes Associated with Clinical Services for the Treatment of Non-Malignant Chronic Pain
Lynn DeBar, Kaiser Permanente Center for Health Research
- 9:10 – 9:45am Questions and Discussion
- *Are existing data sources sufficient for use in studying safety outcomes, or is new data collection needed?*
- 9:45 – 10:00am **Break**

SESSION V: Gathering Additional Evidence on Opioid Analgesic Safety

Session Facilitator: Robert Califf

Session Objectives: Discuss strategies to gather evidence to assess the long-term safety of extended-release and long-acting opioid analgesics for the treatment of chronic non-cancer pain

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| 10:00 – 12:00pm | Topic Discussion: How to Conduct Studies to Assess Long-Term Safety <ul style="list-style-type: none">• How is exposure to opioids and other drugs best ascertained?• What comparator groups could/should be used?• What outcomes need to be captured to reflect misuse, abuse, addiction, and overdose?• How do we make sure we have complete ascertainment of death? |
| 12:00 – 1:00pm | Working Lunch and Topic Discussions · Cypress Ballroom |
| 1:00 – 2:00pm | Continue Topic Discussions |
| 2:00 - 2:30pm | Summarize Topic Discussions |
| 2:30pm | ADJOURN |