Simple English Explanation Directive

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Priority Area 8: Help Consumers and Professionals Make Informed Decisions About Regulated Products

- October 13, 2010: Plain Writing Act\(^1\)
  - Requires all executive agencies to use “clear, concise, well-organized” writing in any publication that provides information about compliance with federal requirements, federal benefits and services and how to obtain them, or filing taxes

- Example from “Losing Weight Safely” pamphlet\(^2\):
  
  “The Dietary Guidelines for Americans recommends a half-hour or more of moderate physical activity on most days, preferably every day. The activity can include brisk walking, calisthenics, home care, gardening, moderate sports exercise, and dancing.”
  
  “Do at least 30 minutes of exercise, like brisk walking, most days of the week.”

2. “Plain Language Principles,” 2013, Food and Drug Administration
Priority Area 8: Help Consumers and Professionals Make Informed Decisions About Regulated Products

• FDA follows these guidelines\textsuperscript{2}, those posted on plainlanguage.gov

• 21 CFR 208.20 also outlines content and format for medication guides\textsuperscript{3}
  • “shall be written in English, in nontechnical, understandable language, and shall not be promotional in tone or content”

• Do not apply to reports of clinical trials - not held to legal requirements

241,006 registered studies\textsuperscript{4}

76,000 unique visitors daily\textsuperscript{4}

27.7 million visitors per year

Simple English Explanation Directive
Trial record 7 of 1539 for: multiple sclerosis

Duloxetine for Multiple Sclerosis Pain

This study has been completed.
Sponsor: Eli Lilly and Company
Information provided by (Responsible Party): Eli Lilly and Company

ClinicalTrials.gov Identifier: NCT00755807
First received: September 17, 2008
Last updated: November 4, 2011
Last verified: November 2011

History of Changes

Full Text View Tabular View Study Results

Disclaimer How to Read a Study Record
Simple English Explanation Directive (SEED)

Summary of:
• What is this test for?
• What will this test find out?
• Who is the test for?
• How does the test work?
• Where do I sign up?

Basic English⁵:
• 850-word base vocabulary
• 200 international words
• Prefixes and suffixes

SEED Implementation - NCT00755807

PURPOSE

• “This study is designed to primarily assess the efficacy and safety of duloxetine 60-120 mg once daily (QD) compared with placebo on the reduction of pain severity in participants with central neuropathic pain due to Multiple Sclerosis.”

SEED: WHAT IS THIS TEST FOR?

• “This test will see if taking different amounts of the medicine duloxetine (also known as Cymbalta) once a day helps people with a nerve disease called multiple sclerosis (also known as MS) be in less pain.”

### SEED Implementation - NCT00755807

#### How Does the Test Work?

If you get to take the test, you will be put in a group that gets to take the Cymbalta medicine or in another group that takes a different medicine that does not work. You will not know what group you are in, and the person giving you the medicine will not know what group you are in. These groups will not change for six weeks.

After six weeks, you may keep taking the test in a different group. In this group, all people will get to take the Cymbalta medicine for up to 12 weeks. You may ask to stop taking the medicine after talking to the people giving it to you, and you will take less and less each day to keep you from having any bad reaction from stopping the medicine.

**Arms**

<table>
<thead>
<tr>
<th>Placebo Comparator: Placebo</th>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug: Placebo</td>
<td>Participants received placebo oral (po), once daily (QD) for 6 weeks (acute phase). If the participant completes the 6-week double-blind portion of the trial, the participant will be offered the option to participate in the open-label extension period (given 60, 90, or 120 milligrams [mg] QD for 12 weeks).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Experimental: Duloxetine</th>
<th>Drug: Duloxetine Hydrochloride (HCl)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants received 30 mg duloxetine (po, QD) for 1 week followed by 5 weeks at 60 mg in the acute placebo-controlled period. If the participant completes the double-blind portion of the trial, the participant will be offered the option to participate in the open-label extension period (given 60, 90, or 120 mg QD for 12 weeks).</td>
<td></td>
</tr>
<tr>
<td>Other Names:</td>
<td>LY248666</td>
</tr>
<tr>
<td></td>
<td>Cymbalta</td>
</tr>
</tbody>
</table>

#### Detailed Description:

Study is a multicenter, randomized, double-blind, parallel, placebo-controlled, 20-week trial with 4 study periods. Participants who screen successfully (Study Period I) will be randomized in a 1:1 fashion to duloxetine 60 mg QD or placebo. Starting with Study Period II, participants will be treated in a double-blind manner for 6 weeks. Participants who complete the 6-week, double-blind period will have the opportunity to participate in a 12-week, open-label, flexible-dose portion of the study (Study Period III). Study Period IV is a taper phase designed to reduce the occurrence of discontinuation adverse events. Participants may enter Study Period IV at any time after Visit 3.

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SEED Implementation - NCT00755807

Eligibility

Ages Eligible for Study: 18 Years and older (Adult, Senior)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
- Have central neuropathic pain due to multiple sclerosis (MS) based on the disease diagnostic criteria
- Adult males or females
- Have a score of 4 or greater on the daily 24-hour average pain score
- Females must test negative for pregnancy at study entry
- Complete the daily diaries for at least 70% of the days of the study
- Participants may continue other prescription and nonprescription analgesic pain medications as long as the dose has been stable for 1 month prior to study entry, and they agree to maintain that stable dose throughout the study Disease Diagnostic Criteria.
  - Diagnosis of MS at least 1 year prior to study entry
  - No MS flares or change in disease treatment for the 3 months prior to study entry
  - Daily pain due to MS for a minimum of 3 months prior to study entry

Exclusion Criteria:
- Are currently in a clinical trial of MS disease-modifying therapy
- Have pain that cannot be clearly differentiated from causes other than MS
- Any current or historical diagnosis of mania, bipolar disorder, psychosis, or schizoaffective disorder
- History of substance abuse or dependence
- Are pregnant or breast-feeding

SEED Implementation

• Guidance documents, “spell check,” online dictionary
• Responsibility of trial sponsor to submit with initial registration of trial information
  • Trial purpose
  • Study locations
• Responsibility of trial sponsor to update with new information as trial progresses
  • Adverse events
• Survey under SEED tab to evaluate impact, effectiveness

• Eligible demographics
• Inclusion/exclusion criteria
• Trial results
SEED Benefits

• Help consumers understand a trial’s scope, its design, and its impact

• Help patients find eligible studies focused on their health concerns

• Help medical professionals find studies, treatment options for patients and explain details of trials to patients, caregivers, family members

• Help industry professionals and patient advocacy groups see past, present, future studies at a glance and find potential collaborators, areas to expand research
Planting the SEED for better understanding of clinical trials