Simple English Explanation Directive

BETHANY LENNOX – UNIVERSITY OF ROCHESTER

CENTER FOR MEDICAL TECHNOLOGY AND INNOVATION

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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."

1. "Plain Writing Act of 2010," PL 111-274, US Government Publishing Office
2. "Plain Language Principles," 2013, Food and Drug Administration

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

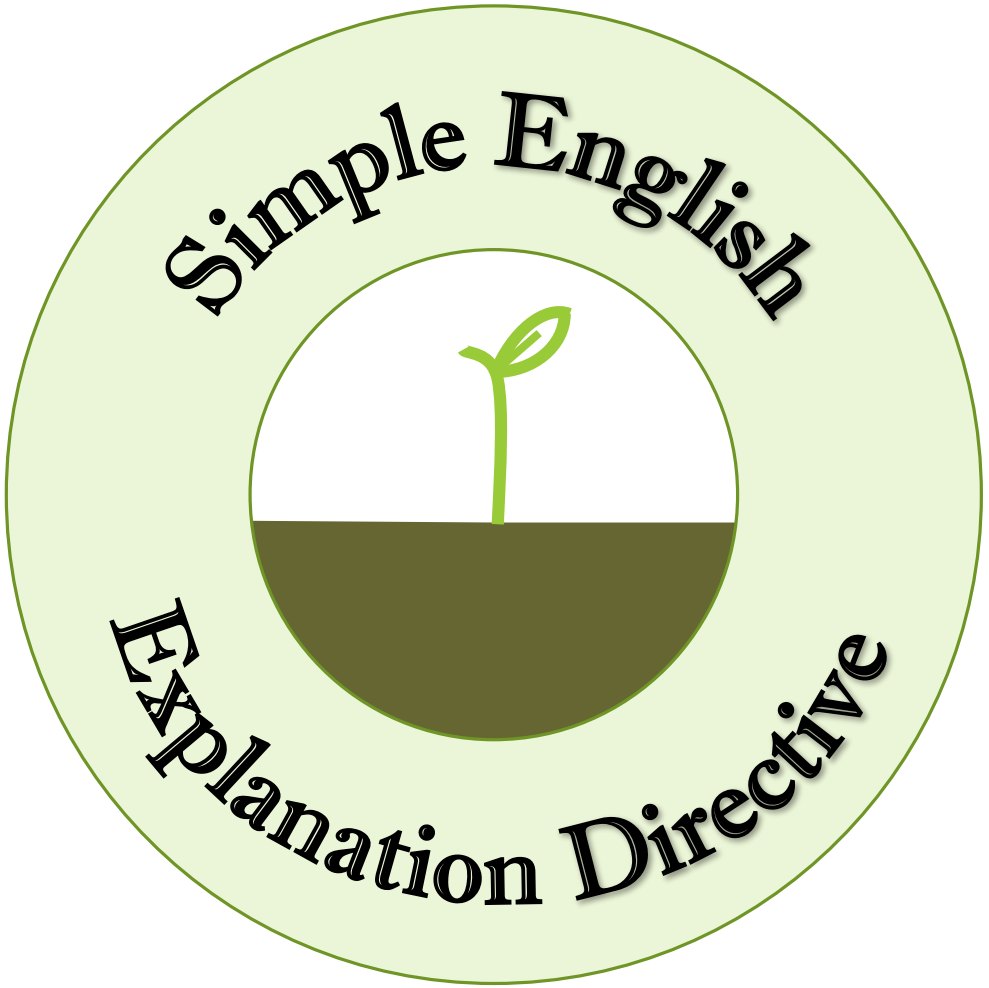
- FDA follows these guidelines[2], those posted on plainlanguage.gov
- 21 CFR 208.20 also outlines content and format for medication guides[3]
  - "shall be written in English, in nontechnical, understandable language, and shall not be promotional in tone or content"
- Do not apply to reports of clinical trials- not held to legal requirements

241,006 registered studies[4]

76,000 unique visitors daily[4]

27.7 million visitors per year

3. "Content and format of a Medication Guide," 21 CFR 208.20 (2016), Food and Drug Administration
4. "Trends, Charts, and Maps," 2017, US National Institutes of Health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ClinicalTrials.gov BETA

Leave beta test site

IMPORTANT: Listing of a study on this site does not reflect endorsement by the National Institutes of Health. Talk with a trusted healthcare

Find Studies ▾ About Studies ▾ Submit Studies ▾ Resources ▾ About Site ▾

Home > Search Results > Study Record Detail

Trial record **7 of 1539** for: multiple sclerosis

◂ Previous Study | Return to List | Next Study ▸

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

Image (edited): US National Institutes of Health

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 English[5]:

- 850-word base vocabulary
- 200 international words
- Prefixes and suffixes

5. "Ogden's Basic English," 2012, Basic English Institute
Image (edited): US National Institutes of Health

SEED Implementation- NCT00755807[6]

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."

6. Eli Lilly and Company, "Duloxetine for Multiple Sclerosis Pain," 2011, US National Institutes of Health

SEED Implementation- NCT00755807[6]

Arms	Assigned Interventions
Placebo Comparator: Placebo	Drug: Placebo 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).
Experimental: Duloxetine	Drug: Duloxetine Hydrochloride (HCl) 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). Other Names: • LY248686 • Cymbalta

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.

6. Eli Lilly and Company, "Duloxetine for Multiple Sclerosis Pain," 2011, US National Institutes of Health
Image (edited): US National Institutes of Health

SEED Implementation- NCT00755807[6]

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

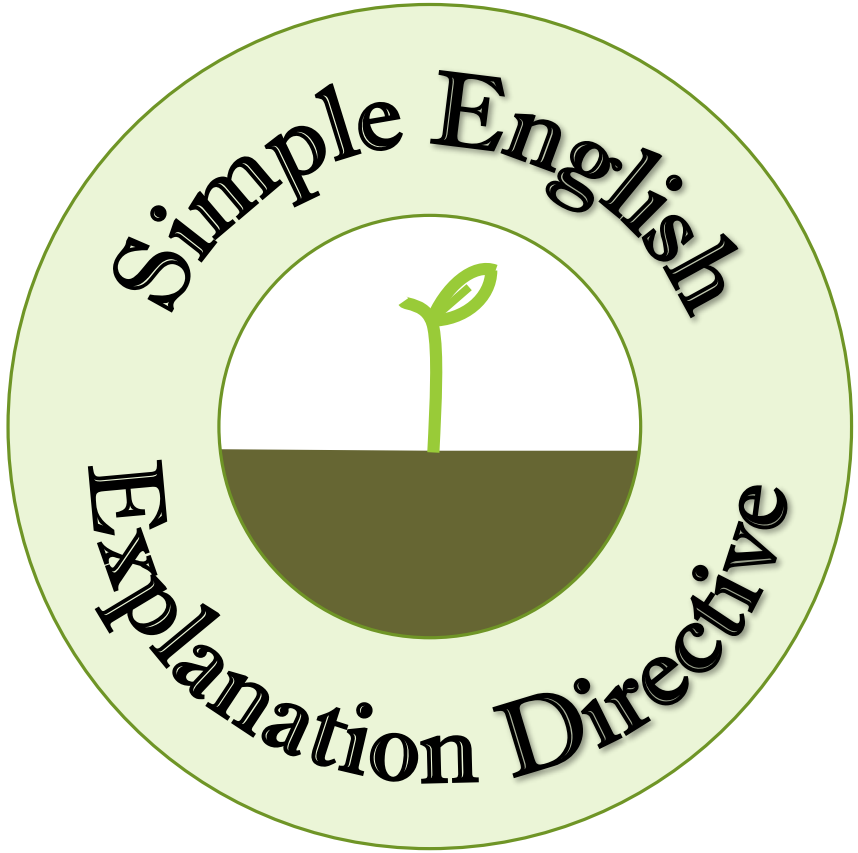
6. Eli Lilly and Company, "Duloxetine for Multiple Sclerosis Pain," 2011, US National Institutes of Health
Image (edited): US National Institutes of Health

SEED Implementation

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

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