Patient-Reported Outcome (PRO) Consortium

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Research Areas

Tool Development
Standard

Data-Sharing Enabler

At a Glance

- Status: **Completed Consortium**
- Year Launched: **2009**
- Initiating Organization: **C-Path**
- Initiator Type: **Nonprofit foundation**
- Location: **North America**

Abstract

The Patient-Reported Outcome (PRO) Consortium aims to develop qualified and publicly available PRO instruments for use in clinical trials in order to support labeling claims. The consortium focuses on developing, evaluating, and qualifying PRO instruments for use as primary or secondary endpoint measures in clinical trials designed to evaluate treatment benefit.

Mission

The Patient-Reported Outcome (PRO) Consortium brings together scientists from C-Path, industry, academia, and regulatory agencies in a pre-competitive environment for the purpose of developing, evaluating, and qualifying PRO instruments for use as primary or secondary endpoint measures in clinical trials designed to evaluate treatment benefit. A patient-reported outcome is any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else. Well-defined and reliable PRO instruments can be used to support a claim in medical product labeling if the claim is consistent with the instrument's documented measurement capability. PRO-based endpoints currently used in clinical trials and incorporated in labeling usually are disease-specific. However, there are multiple PRO tools to measure the same concept (e.g., asthma symptom severity). For some indications, reliable PRO

instruments have not been developed. The lack of standardized, fit-for-purpose PRO tools that are qualified for regulatory use has led to inefficiencies in drug development and review processes. Also, this may result in inconsistencies in the types of outcome information contained in the labeling for drugs approved for the same indication.

The main objectives of the PRO Consortium are to develop, evaluate, and qualify PRO instruments with the U.S. Food and Drug Administration (FDA) for use in clinical trials designed to evaluate the safety and effectiveness of medical products. Specific milestones include:

Consortium History

2008 – The consortium was formed
2009 – The consortium formally launched

Structure & Governance

The PRO Consortium's members are pharmaceutical companies along with C-Path. Representatives from the FDA, EMA, and the U.S. National Institutes of Health provide advice to the PRO Consortium's Coordinating Committee. The PRO Consortium Team is as follows:

Financing

The working groups for the project are mainly funded by industry.

Data Sharing

PRO instruments will be publicly available.

Nine working groups have been established in the following therapeutic areas: asthma, functional dyspepsia, irritable bowel syndrome, major depressive disorder, mild cognitive impairment due to

Alzheimer's disease, multiple sclerosis, myelofibrosis, non-small cell lung cancer, and rheumatoid arthritis.

The following PRO measures have been developed and are undergoing quantitative testing prior to submission to the FDA for qualification for use in exploratory studies:

Asthma Daily Symptoms Diary (ADSD)

Diary of Irritable Bowel Syndrome Symptoms—Constipation (DIBSS-C)

Diary of Irritable Bowel Syndrome Symptoms—Diarrhea (DIBSS-D)

Diary of Irritable Bowel Syndrome Symptoms—Mixed (DIBSS-M)

Functional Dyspepsia Symptom Diary (FDSD)

Non-Small Cell Lung Cancer Symptom Assessment Questionnaire (NSCLC-SAQ)

Symptoms of Major Depressive Disorder Scale (SMDDS)

Homepage	http://c-path.org/programs/pro/
Other website	http://www.fda.gov/AboutFDA/PartnershipsCollaborations/PublicPrivatePartnershipProgram/ucm231129.htm

Points of Contact

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