Open Trials and Open Science

Scientific Data, London, October 2015

Rufus Pollock, Open Knowledge

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OPEN KNOWLEDGE

The Open Definition

The **Open Definition** sets out principles that define "openness" in relation to **data and content**.

It makes **precise** the meaning of "open" in the terms **"open data"** and **"open content"** and thereby ensures **quality** and encourages **compatibility** between different pools of open material.

It can be summed up in the statement that:

> "Open means anyone can freely access, use, modify, and share for any purpose (subject, at most, to requirements that preserve provenance and openness)."

Put most succinctly:

> "Open data and content can be freely used, modified, and shared by anyone for any purpose"

Read the full Open Definition »

THE OPEN DEFINITION IN YOUR LANGUAGE

العربية | Беларуская | Български | Català | Czech | Dansk | Deutsch | Ελληνικά | English | Español | Euskara | Suomi | Français | Galego | עברית | हिन्दी | Croatian | Magyar | Indonesian | Íslenska | Italiano | 日本語 | ಕನ್ನಡ | 한국어 | македонски јазик | Norsk (bokmål) | Polszczyzna | Português Brasileiro | Português | Русский | Shqip | Srpski | Svenska | తెలుగు | Türkçe | Українська | 简化中国 | 中文

Panton Principles (2010)

OPEN KNOWLEDGE

Background
[Clinical Trials]

Date:

OpenTrials
All the Data, on All the Trials, Linked

OpenTrials

All the data, on every trial in medicine

OpenTrials is a linked database for all the available information, on every trial ever conducted, with rankings for transparency and more. It is built and updated with your help.

For Patients
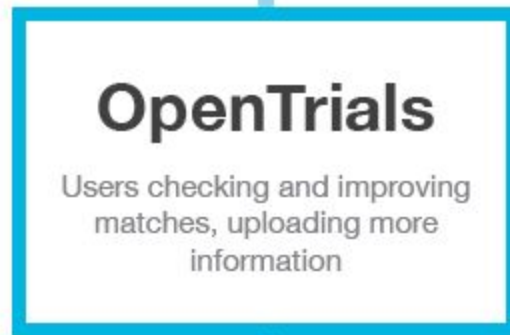Find ongoing trials. Read trial results. Contribute information about trials.

For Researchers
Find trial information. Improve information about trials.

For Transparency
See which companies and drugs are the most and least transparent.

Registries

ClinicalTrials.gov
gsk
World Health Organization
Lilly

Academic publications

PubMed
OPEN ACCESS

Other sources of results

Clinical Study Report
FDA   EPAR
EUROPEAN MEDICINES AGENCY
ClinicalTrials.gov

Structured data on methods and results

SRDR SYSTEMATIC REVIEW DATA REPOSITORY
THE COCHRANE COLLABORATION
Jadad score
XML sources

Trial paperwork

Patient information sheet
Consent forms
Case Report Forms
Protocols
Statistical Analysis Plan

OpenTrials

Users checking and improving matches, uploading more information

Patient View

Trials in progress
Previous trial results
"how much info is missing on this drug?"

Researcher View

All relevant information, linked and indexed
Opportunities to improve the database

Transparency Dashboard

Top 5 best / worst sponsors, principal investigators, drugs, disease areas, countries

OpenTrials

All the Data, on All the Trials, Linked

About | **Patients** | Researchers | Transparency | 🔍

Find a trial

Find trial that you can participate in

Search   Use my registered data

I'm a ⦿ Male ○ Female   Born on [dd ▾] [mm ▾] [yyyy ▾]   Near [POSTCODE]

Treatment [(optional)]   Health condition [(optional)]   **Find a trial**

Browse trials

Lexapro and Pramipexole to Treat Major Depression   👁

Condition: Major Depression.
Teatment: ▬ Pramipexole   ▬ Escitalopram.
Transparency: ★★★☆☆

Evaluation of a Stepped Care Approach to Manage Depression in Diabetes   👁

Condition: Major Depression;   Minor Depression;   Sub-Threshold Depression;   Diabetes Mellitus;   Inflammation
Teatment: Step 1: Diabetes-Specific CBT (5 group sessions)   Step 2: Depression-Specific CBT (6 single sessions)
                 Step 3: Referral to Psychotherapist and/or Psychiatrist   Standard Diabetes Education
Transparency: ★★★☆☆

Depression Management at the Workplace   👁

Condition: Depression
Teatment: Depression Product Detailing   Depression HEDIS detailing
Transparency: ★★★☆☆

Desvenlafaxine vs. Placebo Treatment of Chronic Depression   👁

Condition: Dysthymic Disorder;   Dysthymia;   Depression NOS;   Chronic Depressive Disorder
Teatment: ▬ Desvenlafaxine   ▬ Placebo
Transparency: ★★★☆☆

Outcome of Postnatal Depression Screening Using Edinburgh Postnatal Depression Scale   👁

Condition: Depression, Postpartum
Teatment: Edinburgh Postnatal Depression Scale
Transparency: ★★★☆☆

previous **1** 2 3 4 5 … next

OpenTrials
All the Data, on All the Trials, Linked

Find a trial
Lexapro and Pramipexole to Treat Major Depression

Condition: **Major Depression**	Teatment: **Pramipexole, Escitalopram**	**June 2004 - March 2010**
39 Participants	**Men and women**	Aged **18-65**

This trial has three arms, comparing: **"Lexapro and Pramipexole"; "Lexapro"; and "Pramipexole"**. The main outcome measure was **"the Montgomery Asberg Depression Rating Scale"**.

Results are available for this trial: they may be very technical! You can write (or link to) a **lay summary** of the results for patients and the public.

Patient information

This study compares the effectiveness of the combination of antidepressants: Lexapro and Pramipexole, with the effectiveness of each antidepressant alone.

Purpose: Patients between 18 and 65 years of age with Major Depressive Disorder without psychotic features may be eligible for this 9-week study. Candidates must currently be in a major depressive episode of at least 4 weeks' duration, have failed to respond to treatment with an SSRI (Prozac, Zoloft, Paxil, Luvox, Celexa), and not have failed to respond to more than four antidepressants for the current episode. Candidates are screened with a physical examination, psychiatric evaluation, blood tests, review of vital signs, height and weight measurements, electrocardiogram (ECG), urine test for illegal drugs, and pregnancy test for women.

Participants are tapered off antidepressants or other medications prohibited during the study and remain drug-free for 1 week before starting treatment. They are then randomly assigned to take pramipexole and escitalopram, pramipexole alone, or escitalopram alone for 6 weeks. During the study, participants come to the clinic eight times for health assessments and symptoms assessments, which include a check of vital signs and rating scales for depression and anxiety, adverse events, and sexual functioning. Blood and urine samples are collected periodically to monitor health, detect pregnancy in women, and detect illicit drug use.

At the end of the 6-week treatment period, participants have a physical examination, ECG, blood test, and check of vital signs. Short-term anti-depressant treatment is offered, and plans are made for long-term treatment.

Lay summary document provided by clinicaltrials.gov

Comments

Jane Smith

I participated in this trial and was really impressed by the whole process. I had never done this before but the doctor was really friendly and explained everything patiently. I'm now reading a lot about trials and medicine because it's affecting me personally. I can only recommend getting involved!

Sidebar

Conducted in
USA
★★★☆☆

Principal investigator
Carlos A Zarate
★★★★☆

Sponsor
NIMH
★★★☆☆

See also

Our page for researchers

Lay summary document from clinicaltrials.gov

We are missing

Patient information sheet

The trial consent form

Add Information

OpenTrials
All the Data, on All the Trials, Linked

About   Patients   Researchers   Transparency   🔍

Transparency board
The best and worst performers for withheld results.

OpenTrials › Transparency Board

Five Biggest Sponsors
Ranked by total number of trials sponsored

		Number of trials sponsored	Transparency Score (overall)	Ranking for Transparency
1			★★★★☆	26 / 89
2			★★★★★	26 / 89
3			★★☆☆☆	26 / 89
4			★☆☆☆☆	26 / 89
5			★★★☆☆	26 / 89

See the **biggest 50**   ⓘ How is this calculated?

Five Most Popular Treatments By 2012 Prescriptions

		Transparency Score (overall)	Ranking for Transparency
1		★★★★☆	26 / 89
2		★★★★★	26 / 89
3		★★☆☆☆	26 / 89
4		★☆☆☆☆	26 / 89
5		★★★☆☆	26 / 89

ⓘ How is this calculated?

Five Best Treatments for transparency

		Transparency Score (overall)	Ranking for Transparency
1		★★★★★	1 / 230
2		★★★★★	2 / 230
3		★★★★★	3 / 230
4		★★★★★	4 / 230
5		★★★★★	5 / 230

ⓘ How is this calculated?

Five Worst Treatments for transparency

		Transparency Score (overall)	Ranking for Transparency
1		☆☆☆☆☆	230 / 230
2		☆☆☆☆☆	229 / 230
3		☆☆☆☆☆	228 / 230
4		☆☆☆☆☆	227 / 230
5		☆☆☆☆☆	226 / 230

ⓘ How is this calculated?

Disagree?

Read **here** about how to improve the quality of data for your company, institute, disease, or treatment.

http://opentrials.net

@opentrials

Open forum:

https://discuss.okfn.org/c/projects/open-trials

OPEN KNOWLEDGE

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All the Data, on All the Trials, Linked

About   Patients   Researchers   Transparency

For researchers
Mertrazine and Cobazol to Treat Major Depression

⬇ XML ▼

Overview

Condition: **Major Depression**   Teatment: ⬭ **Mertrazine,** ⬭ **Cobazol**   📅 **June 2004 - March 2010**

218 Participants   **Men and women**   Aged **18-65**

Registries
ClinicalTrials.gov ⚑

BioMet Inc ⚑

⊕ Add another

Regulatory documents
CSR ⊝

EPAR segment ⚑

⊕ Add another

Paperwork
Blank consent form ⚑

Patient information sheet ⊝

Blank case report form ⊝

Protocol ⚑

Statistical analysis plan ⊝

Lay summary ⚑

Ethics/IRB Approval ⚑

⊕ Add another

Papers
Results paper ⊝

Protocol paper ⚑

⊕ Add another

Structured data
ClinicalTrials.gov results ⚑

SRDR from AHRQ ⚑

⊕ Add another

Methodological rigour

The methodological rigour of this trial was scored in a **systematic review** in September 2012, where it was scored as being at "high risk" of bias from "allocation concealment", "unclear" for "method of randomisation", and "unclear" for "blinding". **Read more** about what this means.

Individual Patient Data

We believe individual patient data may be available for this trial on application.

That is because it was: **sponsored by BioMet** and conducted **after 2007**. The trial data sharing policy and data application details for this organisation are **available**. You can read more about **individual patient data sharing**. We are aware of **two successful applications**, and **one unsuccessful application** for this data.

Help us improve this data

- Deduplicate: we think there are 2 more registry entries that might match this one, **review them.**
- Give us results: the last **fuzzy-match search** for results for this trial was 2 days ago. The last **manual search** for results for this trial was 92 days ago by OpenTrials librarians, and 27 days ago by an OpenTrials site visitor. **Search for results.**
- Tell us about **unregistered trials**: **upload** any trial information you have on trials we don't yet know about, whether it's a consent form, or an academic paper.
- Work on the queue: there are **836 documents** currently waiting to be reviewed, that could be attached to an existing trial in the database.

Conducted in ⓘ
Maryland, USA
★★★☆☆

Connecticut, USA
★★★☆☆

Manchester, UK
★★★☆☆

Maastricht, NL
★★★☆☆

Principal investigator ⓘ
Clare M Fitzgerald
★★★★☆

Sponsor ⓘ
BioMet
★★★☆☆

Credits and acknowledgements for data on this page

Protocol matched by **Caroline Smith**, UCSF from her dataset in **this paper**.

EPAR segment uploaded by **Martin Durden**, **Imperial College London.**

Lay Summary imported from **HRA.**