Open Clinical Trials: Are We Nearly There Yet?

Laser imaging of sites in Cambodia has revealed details of ancient cities unknown till now to archaeologists . Will it take as long to reveal clinical trials data?

OpenTrials is described as an "open free database and web service to identify, aggregate, store, match, index and share all available documents and data on all clinical trials." It is a collaboration between Ben Goldacre of the Evidence-Based Medicine Data Lab at the University of Oxford and Open Knowledge. The phase I project has been funded by the Laura and John Arnold Foundation .

Goldacre, with Jonathan Gray, Policy and Research, Open Knowledge, St John's Innovation Centre, University of Amsterdam write in detail about the OpenTrials initiative in *Trials*.

The issues with trials are well-known, and include publication bias, selective outcome reporting and lack of information on methodological flaws. There is much duplication of effort in searching for data. Goldacre and Gray note that "although large collections of structured "open data" on clinical trials would be valuable for research and clinical activity, including linkage to datasets other than those on trials, there is little available and it can be hard to search or access."

See Also: Adaptive Clinical Trials - the Ethical View

In May publishers announced the Linked Reports of Clinical Trials project, which uses the CrossMark system for storing metadata on academic publications as a place where publishers can store a unique identifier (ID) on each trial to create a thread of published academic journal articles.

In their article, Goldacre and Gray outline plans for phase I of a project to create an open database of all structured data and documents on all clinical trials, cross-referenced and indexed by trial.

The project aims to create a freely re-usable index of all such information to:

- increase discoverability
- facilitate audit on accessibility of information
- increase demand for structured data
- facilitate annotation
- facilitate research
- drive up standards around open data in evidence-based medicine
- help address inefficiencies and unnecessary duplication in search, research, and data extraction.

The article describes the plans, the types of documents and data that will be included, the methods for populating the database, and the proposed presentations of the data to different types of users, including patients, researchers, systematic reviewers etc. They note the challenges involved such as ensuring integrity of submitted data, and welcome feedback.

Ben Goldacre has also summed the project up in "OpenTrials: what, why and how?" on the BioMed Central blog.

Get Involved

Goldacre and Gray are keen to receive feedback on OpenTrials. Progress can be viewed at www.OpenTrials.net, where the service will be hosted. The project is also on Twitter.

Image credit: opentrials.net

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