

Ottawa Group dialogue on

Principles of the disclosure of trial results and its implementation

Introduction:

The Ottawa group aims at building principles of registration and disclosure of results on existing experience in the broader domain of open access and knowledge sharing as well as on principles of the [Ottawa Statement Part 1 \(OS 1\)](#) and [Part 2 \(OS 2\)](#).

We are therefore inviting you to consult the [Budapest](#) and [Berlin](#) declarations on open access to research results as well as the [Mexico Summit on knowledge sharing](#) as well as [OS 1](#) and [OS 2](#).

Please contribute to these selected issues that we believe merit broad analysis and discussion.

Also if you have any other issue that you wish to bring forward for a broader discussion, or at the [Dublin meeting](#), please let us know via email to OttawaGroup@ohri.ca.

The following **Working Definitions** are proposed to create a common ground for this discussion. If you disagree with some of them please suggest improvements. You might also wish to propose some more definitions.

There are several suggested definitions for the trial duration, especially on the end of trial. Without clearly defining the end of a trial it is difficult to determine the time point when we expect results to be reported. **The end of trial time** is used to start the clock for when results should be publicly disclosed

Following are some of proposed terms and definitions of the “end”

Please comment via email to OttawaGroup@ohri.ca

Possible definitions of the end of trial:

1. **The end of the trial** is the point in time of the last follow up of the last recruited study participant.
2. **Completion of Data Collection/Final data closeout:** the time of last follow-up of the last recruited study participant as defined in the study protocol.
3. **The endpoint of a trial** is when either the a priori primary endpoint is reached or a decision is made that it cannot be reached.

Publication refers to a publication in a peer review journal, either paper or electronic.

Methods refer to the design and execution of a trial.

Results refer to the quantitative and qualitative data collected on study participants and outcomes, as well as the data analyses.

The scope of results to be disclosed: sufficient information of the trial result to allow a minimum level of critical appraisal of the trial's contribution to the scientific evidence base.

Disclosure of results refers to a process of making results publicly available on Internet, on an unbiased recipient that guarantees a long term archiving and free access.

Internet based repository for results: It might be a register, trial bank. Characteristics are in principle similar to trial registry's: Internet based, free public access (no payment), unbiased.

Please share your opinion regarding the following via email to OttawaGroup@ohri.ca:

Selected issues in the preparation of the Ottawa Statement Part 3

CONTENT: what to report

Beside the publications in the peer review journal(s) and their archiving in freely accessible depositories, the principles of implementation of registration and disclosure of methods and results include:

1. Full open access to results
2. No peer review is necessary for results that are disclosed
3. Full protocol, including the consent form from the primary study site, is made publicly available at the end of a trial.

CONTENT: Options to comment / consider

Option 1: Minimum dataset

- a. Publication
- b. List the publications in an open access online depository Report on all outcomes required for registration in the OS2
- c. Lay summary including all results
- d. For RCT, add the CONSORT based report
- e. Report on all elements of OS2 not included in CONSORT
- f. Other than RCT: following principles similar to consort?
- g. Reference to the systematic review(s) which justified trial
- h. Full protocol
- i. Consent form

Option 2 Optimum: all the above plus

- j. the raw data

REMINDER

OS 2: report on the OS 2 list of protocol items, provide all amendments, the full protocol (please see below), consent form(s), reference to systematic reviews, and contracts and financial arrangements. For details please see [OS 2 section 3.6](#).

Full protocol. Ideally protocol should be presented in a structured format and user friendly. Such a format does not exist as yet, thus for the time being the protocol should include all items proposed by the OS2. The pdf text file might be added.

Berlin declaration:

- Individual patient data
- original scientific results
- raw data
- metadata
- source materials

2. Timing of results reporting and disclosure

2.1. Should results reporting be in two steps: deposit and disclosure? Namely should deposit of results precede the disclosure?

Options to consider (please feel free to propose other options)

Option 1 (all trials, a one step process, no time difference btw deposit in results database and disclosure) Disclosure of methods and results is done in at the time of or immediately after the publication. If a publication has not occurred within 2 (3) years of the end of trial, disclosure will automatically happen. This option provides a possibility to negotiate certain delay.

Option 2 (all trials, a two step process)

Results are deposited upon the end of the analysis, and disclosure is at the latest at 3 (5) yrs after the end of the trial. The rationale behind the option 2 is to make access to results as early as possible.

2.2. Should scope and timing of disclosure be different for RCT vs. non RCT and why?

For example: non RCT (early) trials: results are deposited upon the end of the analysis; disclosure 2 years following the end of a trial, or when the RCT starts whichever is earlier.

References

OS 1 and OS2: <http://ottawagroup.ohri.ca>

Budapest declaration: <http://www.soros.org/openaccess/index.shtml>

Berlin declaration: <http://www.zim.mpg.de/openaccess-berlin/berlindeclaration.html>

WHO:

Trial registration platform: <http://www.who.int/ictrp>

Mexico summit: <http://www.who.int/rpc/summit/en/>

Knowledge for better health WHO, Geneva: www.who.int/rpc/wr2004