Data Sharing Statements and Results Reporting – requirements for clinical trials

Background – importance of reporting of trial results

When a clinical trial is conducted researchers commit to not only conduct the trial, but also share the findings in accordance with basic ethical principles. (https://www.who.int/ictrp/results/en/)

In April 2015 the WHO published a statement on the public disclosure of clinical trial results. In the statement is defined timeframes for reporting as well as a call for the reporting of older unpublished trials. It outlines steps on how linkages between trial registry entries and published results can be improved

To further this process it has now become a WHO requirement for all completed registered trials to include, at a minimum, summary results or a link to summary results within the trial registration record. This should be done within 12 months of the study completion date. Also all trials being registered within a WHO-recognised registry since 1 January 2019 must include an Individual Patient Data (IPD) Sharing Statement outlining how and where results will be stored and how they will be available for the public good.

This leads to the question what is an IPD Sharing Statement and what results needs to be reported.

Section A: Individual patient data Sharing Statement

The Individual patient data Sharing Statement is defined by WHO as a statement about the intended sharing of de-identified individual trial participant data. It should indicate whether or not IPD will be shared as well what elements will be shared. The plan should also include a timeframe for sharing, with who it will be shared and how it will be shared. It should also include an indication for what types of analysis the data will be available.

The following is a link to the recommendations of the International Committee of Medical Journal Editors (ICMJE) regarding clinical trial registration and data sharing:

http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html

Table: Examples of Data Sharing Statements that Fulfil ICMJE Requirements*

	Example 1	Example 2	Example 3	Example 4
Will individual participant data be available (including data dictionaries)?	Yes	Yes	Yes	Yes
What data in particular will be shared?	All of the individual participant data collected during the trial, after deidentification	Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices)	Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices)	Not available

	Example 1	Example 2	Example 3	Example 4
What other documents will be available?	Study Protocol, Statistical Analysis Plan, Informed Consent form, Clinical Study Report, Analytic Code	Study protocol, Statistical Analysis Plan, Analytic Code	Study Protocol	Not available
When will data be available (start and end date)?	Immediately following publication, No end date	Beginning 3 months and ending 5 years following article publication	Beginning 9 months and ending 36 months following article publication	Not applicable
With who?	Anyone who wishes to access the data	Researchers who provide a methodologically sound proposal	Investigators whose proposed use of the data has been approved by an independent review committee ("learned intermediary") identified for this purpose	Not applicable
For what types of analyses?	Any purpose	To achieve aims in the approved proposal	For individual participant meta-analysis	Not applicable
By what mechanism will date be made available	Data are available indefinitely at *(Link to be included)*	Proposal should be directed to xxx@yyy. To gain access, data requestors will need to sign a data access agreement. Data are available for 5 years at a third party website *(Link to be included)*	Proposal may be submitted up to 36 months following article publication. After 36 months the dta will be available in out University's data warehouse but without investigator support other than deposited metadata. Information regarding submitting proposals and accessing date may be found at *(Link to be included)*	Not applicable

*These examples are meant to illustrate a rand of, but not all, data sharing options

The above table lists examples of the information which should be included in an IPD Sharing Statement http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html (accessed 09 April 2019)

Section B: Results Reporting

On 14 April 2015 the World Health Organization (WHO) issued a statement regarding the public disclosure of trial results. In the statement timelines for the reporting of results are outlined. The full statement can be accessed at https://www.who.int/ictrp/results/reporting/en/

The rationale for this decision is outlined in the following paper.

Moorthy VS, Karam G, Vannice KS, Kieny M-P. Rationale for WHO's New Position Calling for Prompt Reporting and Public Disclosure of Interventional Clinical Trial Results. PLOS Medicine; April 14 2015 https://doi.org/10.1371/journal.pmed.1001819

It is a mandatory requirement to report summary results of all registered clinical trials within a year from completion of the trial. The following items of results should be included:

1. Date of posting of results summaries
2. Date of the first journal publication of results

3. URL hyperlink(s) related to results and publications
4. Baseline Characteristics: Data collected at the beginning of a clinical study for all participants and for each arm or comparison group. These data include demographics, such as age and sex, and study-specific measures.
5. Participant flow: Information to document the progress and numbers of research participants through each stage of a study in a flow diagram or tabular format.
6. Adverse events: An unfavourable change in the health of a participant, including abnormal laboratory findings, and all serious adverse events and deaths that happen during a clinical study or within a certain time period after the study has ended. This change may or may not be caused by the intervention being studied.
7. Outcome measures: A table of data for each primary and secondary outcome measure and their respective measurement of precision (e.g. a 95% confidence interval) by arm (that is, initial assignment of participants to arms or groups) or comparison group (that is, analysis groups), including the result(s) of scientifically appropriate statistical analyses that were performed on the outcome measure data, if any.
8. URL link to protocol file(s) with version and date. This will apply when the protocol has wither been published in a journal or on an institutional website.
9. Brief summary