

World Health Organisation (WHO)
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Royal Statistical Society response to WHO Statement on Public Disclosure of Clinical Trial Results

The Royal Statistical Society (RSS) is a learned society for statistics, a professional body for statisticians and a charity which promotes statistics, data and evidence for the public good. Today the Society has more than 6000 members around the world, of whom some 1250 are professionally qualified as Chartered Statistician.

The RSS is committed to transparency in scientific and social research, and supports that it is crucially important that the results of scientific research be made publicly available and disseminated as widely as is practical, in a timely fashion. Decisions to publish should not be based on whether research findings are 'positive' or 'negative'. We are a long-standing supporter (since January 2013) of the AllTrials campaign, which was founded on this basis. We strongly support that your draft policy should adopt the following principles advocated by the AllTrials campaign.

1. The results of all past clinical trials to be reported, as well as all future clinical trials.
2. Requiring results to be reported within in 12 months, rather than permitting delays of 18-30 months. The USA's FDA Amendment Act, the newly adopted EU Clinical Trials Regulation and pharmaceutical companies including GSK and LEO Pharma all agree that 12 months is enough time to report results.
3. Encouraging researchers to put results on publicly accessible registers, in useful, standardised formats.

We would particularly welcome the following amendments, with thanks for your consideration.

Locator (Page & Line No or section heading, footnote number)	Comment	Suggested Amendment
Page 2 line 38	It is important to hold reporting to the primary clinical trial registry to a common standard internationally.	Clinical trial results are to be reported to the primary clinical trial registry within 12 months of the study completion date.



Locator (Page & Line No or section heading, footnote number)	Comment	Suggested Amendment
Page 2 lines 39 to 52	Reporting on the primary clinical trial registry should be preferred as the common standard. Subsequent publication of a journal paper or papers should be encouraged but not required, as this process is less controllable and may lead to delayed reporting of results.	Delete “Reporting is to occur in BOTH of the following two modalities” as well as subsequent assertions that apply new mandatory standards to the peer review process. Add an assertion that publication of results in the clinical trials registry does not prejudice subsequent publication of a peer reviewed paper based on the results and that this should be encouraged.
Page 3, lines 60-66	The Royal Statistical Society supports that the WHO should be actively engaged with multiple initiatives related to data-sharing to maximise the value of health research data. In addition, the important issue of disclosure of the results of past trials on the treatments we use today needs to be addressed.	A section setting a common expectation for the reporting of past trials to be added, stating that getting old results into the public domain is crucial even if these results have not been stored to the same reporting standards as today. Work should begin on the type of standards that can be applied to this.