IAPO Comment Form: WHO Statement on Public Disclosure of Clinical Trial Results

Comment as individual or on behalf of agency or institution: Institution

Commenter's Name in Full, Title, Institution, City, Country, Tel., Email address:

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Locator (Page & Line No or section heading, footnote number)	**Comment**	**Suggested Amendment**	**Internal Use Only [blank]**
P1, section line start line 2 (**Background**), lines 3-28.	IAPO is the only global alliance representing patients of all nationalities across all disease areas and promoting patient-centred healthcare worldwide. Our members are patients' organizations working at the local, national, regional and international levels to represent and support patients, their families and carers. IAPO has almost 250 members which span over 65 countries and disease areas, and through our membership we represent an estimated 365 million patients worldwide. IAPO supports the development and enforcement of appropriate regulations on all aspects of clinical trials and research. Utilising the expertise and experience of our members we have responded to several initiatives and consultations on clinical trials and research, which inform this submission. These include:		

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	• Responding to a World Medical Association (WMA) consultation on the Declaration of Helsinki in 2013 • Following approval at its May 2013 Governing Board Meeting, IAPO endorsed the AllTrials campaign as an important step towards greater transparency and patient information The IAPO policy statements on patient information and health literacy, and patient involvement in health policy decision-making also underpin our response, alongside our core Declaration on Patient-Centred Healthcare. The key issues regarding clinical trials and the public disclosure of results from the patients' perspective are: • Protection of the rights and welfare of patients • Ensuring that patients have access to quality information regarding clinical trials • Meaningful informed consent, with specific strategies regarding vulnerable patient groups • Meaningful patient involvement across all aspects of clinical trials and throughout the process • Transparency about all outcomes and results of trials, whether successful or not.		
P1, lines 5-9	IAPO strongly supports the WHO International Clinical Trials Registry Platform and the current WHO position that all interventional trials should be registered.		

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P1, lines 14-17	IAPO commends the efforts of the WHO to analyse the extent to which trials are not only registered, but also reported, whether the results are negative or positive.		
P1, lines 23-28	The publication of all clinical trial results is vital in improving the quality of healthcare to patients.	IAPO suggests that the WHO consider the added value to clinical trials reporting and subsequent decision-making that could be gained by including a recommendation that results of past clinical trials are publically reported, as well as current and future trials.	
P2, Section line start 37 (**Reporting timeframes for clinical trials**), lines 37-47	Patient information is a core principle of patient-centred healthcare. To IAPO, accurate, relevant and comprehensive information is essential to enable patients and carers to make informed decisions about their healthcare. A key component of good quality patient information is that it is presented in an appropriate format. Therefore, it is essential that clinical trial results are published in a way that can be understood by patients and the general public.	IAPO suggests including in this section a strong recommendation that clinical trial results are published in clear and unambiguous language that will be understood by patients and the general public.	
P2, lines 38-43 and 50-52	Without full access to the results of all clinical trials, healthcare professionals and regulators cannot make informed recommendations on treatment options and patients are unable to make informed decisions on their healthcare. The timely publication of clinical trial results is critical to ensuring that patients have accurate information on treatments, their efficacy and their relative benefits versus	IAPO suggests that the WHO strengthen its statement by requiring all results to be reported publically within 12 months.	

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	risk. IAPO supports the WHO highlighting that the timeframes recommended are the 'longest possible acceptable' however we are concerned that still using a 30 month timeframe for full reporting disclosure could cause undue delays and a shorter, more timely deadline could prevent potential harm to patients.		
P2, section start 53 (**Inclusion of Trial ID in clinical trial publication**), lines 54-58	IAPO supports the WHO message that consistent trial identification information should always be provided and should enable effective database searches.	An unambiguous statement could be added to this section, for example: All results should be reported on publically accessible registers in useful and standardized format.	
P2, section start line 60 (**Note on Data Sharing Initiatives**), lines 61-66	IAPO welcomes the inclusion of a comment in the statement on increasing access to data, as this is aligned with measures to increase transparency on clinical trials results. However, this must not come at the expense of patient privacy. The patient perspective must be solicited to make sure that patient needs are met in relation to the protection of personal information and the presentation of clinical trials results. Where there are trials that are undertaken on small sample sizes, particularly in the development of orphan drugs, it is critical that patient privacy is protected and that all potentially identifiable information is removed prior to publication.	IAPO suggests the inclusion in this section of a strong call for those sharing and accessing data to ensure they consider and meet the needs of patients. This means that patient privacy and confidentiality needs are protected. Patients should be fully involved in policy and decision-making processes at all levels of national health systems, clinical trials and reporting, and treatment.	

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