

## Briefing on some proposed amendments to resolution *Improving the transparency of markets for medicines, vaccines and other health-related technologies* at 72<sup>nd</sup> World Health Assembly

From Sile Lane on behalf of the AllTrials campaign for clinical trial transparency  
16<sup>th</sup> May 2019

### SYNOPSIS:

Please support the resolution “Improving the transparency of markets for medicines, vaccines and other health-related technologies” put forward by Italy and 10 other countries to the 72<sup>nd</sup> World Health Assembly. Discussion on agenda item 11.7 Access to medicines and vaccines is due to be taken up on Wednesday 22<sup>nd</sup> May.

However, the AllTrials campaign is concerned about some of the apparent proposed amendments to point 7 of the resolution. AllTrials is the global campaign for clinical trial transparency, calling for all clinical trials to be registered and results from them reported. Amendments suggested here also risk rolling back collaborative progress made by academic researchers, governmental and charitable research funders and pharmaceutical companies in recent years. Some of the amendments suggested to point 7 would put the WHO in direct opposition to the World Medical Association’s Declaration of Helsinki - the internationally agreed statement of ethical principles for medical research involving human subjects – which says that every researcher has a duty to share results from research involving human subjects.

### ALLTRIALS CAMPAIGN:

AllTrials is the global campaign for clinical trial transparency, calling for all clinical trials to be registered and results from them reported. The campaign has been joined by 95,000 people and 750 organisations worldwide including groups that between them represent the voices of 600 million patients. [www.AllTrials.net](http://www.AllTrials.net)

For more information please contact Sile Lane [slane@senseaboutscience.org](mailto:slane@senseaboutscience.org)

### EXTRACT FROM THE WORLD MEDICAL ASSOCIATION’S DECLARATION OF HELSINKI:

#### [Research Registration and Publication and Dissemination of Results](#)

35. Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.

36. Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

## Commentary on proposed amendments to resolution

Original text	Text from 10 <sup>th</sup> May meeting	Comment on amendments
<p>7. Noting with concern that despite the latest Declaration of Helsinki outlining the ethical imperative to make publicly available the results of all clinical trials, including negative and inconclusive as well as positive results, the public access to complete and comprehensive data on clinical trials is still limited, and that this in fact reduces access to knowledge that is critical for advances in science, which has direct and negative consequences on the knowledge about the safety and efficacy of medicines that are prescribed to patients;</p>	<p>Noting [with concern that despite (DEL USA)] the latest Declaration of Helsinki [ ,which promotes making (USA)][outlining the ethical imperative to make (DEL USA)]</p>	<p>The WMA’s Declaration of Helsinki is the internationally agreed statement of ethical imperatives for medical researcher involving human subjects. It states that making results from research involving human subjects is an ethical obligation for researchers. Deleting ‘outlining the ethical imperative to make’ and changing to ‘promotes’ misrepresents the status of the declaration and the weight it carries.</p>
	<p>publicly available the results of [all (DEL Germany, Switzerland)]/[some (Germany, Switzerland)]</p>	<p>The WMA’s Declaration of Helsinki specifies that the results of all research involving human subjects should be made publicly available (paragraph 36 of the Declaration). The World Health Organisation’s statement on public disclosure of clinical trial results states: “There is an ethical imperative to report the results of all clinical trials, including those of unreported trials conducted in the past.” Accepting the amendment from ‘all’ to ‘some’ would gravely misrepresent the WMA’s declaration and the WHO’s statement.</p>
	<p>clinical trials, including [negative and inconclusive (DEL Switzerland)] as well as positive results,</p>	<p>The WMA’s Declaration of Helsinki specifies that the results of all clinical trials should be made publicly available, specifically</p>

		mentioning at paragraph 36 “Negative and inconclusive as well as positive results must be published or otherwise made publicly available.”
	[the (DEL USA)]/[and noting that (USA)] public access to [complete and comprehensive (DEL Switzerland)] data on clinical trials is [still limited (DEL USA)]/[important for promoting (USA)] [, and that this [in fact reduces (DEL Denmark, Germany)]/[can reduce (Denmark, Germany)] (DEL USA)] access to knowledge that is critical for [the advancement (USA)]/[advances (DEL USA)] in science	It would be disingenuous to say that when data from clinical trials is not publicly available ‘can’ reduce access to knowledge. It does. When results from research are not publicly shared access to this knowledge it by definition reduced.
	[and successful treatment of patients (USA)]	This is a core and crucial amendment. Movements towards transparency in clinical trial research We recommend accepting this amendment.
	[, which [has direct and negative (DEL Denmark, Germany)]/[can have (Denmark, Germany)] consequences on the knowledge about the safety and efficacy of medicines that are prescribed to patients; (DEL USA)]	There’s no can have negative consequences, it does. Accepting the amendment to ‘can’ here would put this resolution in opposition to WHO itself who, in its Rationale for WHO’s new Position Calling for Prompt Reporting and Public Disclosure of Interventional Clinical Trial Results the WHO said that when the body of knowledge from clinical trials is incomplete: <ul style="list-style-type: none"> <li>• “It affects understanding of the scientific state of the art.</li> </ul>

		<ul style="list-style-type: none"> <li>• It leads to inefficiencies in resource allocation for both research and development and financing of health interventions.</li> <li>• It creates indirect costs for public and private entities, including patients themselves, who pay for suboptimal or harmful treatments.</li> <li>• It potentially distorts regulatory and public health decision making.”</li> </ul>
	<p>[7bis: Also noting the need for protection of confidential clinical trial data including personal patient information (USA)]</p>	<p>The Declaration of Helsinki applies to the results of clinical trials. Generally accepted that ‘results’ refers to the level of information asked for in the results sections of WHO ICTRP partner clinical trial registers and/or in academic journal articles. This is not data at the patient level.</p>