

Checklist - WHO best practices in clinical trial transparency

The checklist below, originally compiled by the team at EBM Data Lab, summarizes WHO best practices based on the WHO Joint Statement on public disclosure of results from clinical trials, which has so far been signed by six of the twenty largest medical research funders worldwide.

Research funders and clinical trial sponsors, including universities, can use this checklist to identify and address gaps in their current policies.

DO YOUR POLICIES	CONTAIN THE FOLLOWING ELEMENTS?	YES	NO
Registration	Have a policy on registration		
	Require that trials are registered		
	Mention that they are registered before commencement		
	Mention registry must be updated as necessary to include final enrolment and completion date		
	Mention registry must be updated if trial terminated, including disclosure of n recruited		
Reporting Results	Have a policy on reporting results		
	Give a timeline / deadline		
	Report results within 12 months of completion		
	Mentions registry disclosure ("As timelines for publication in a journal are not fully within the control of the sponsor or investigator, this joint statement focuses on use of registries – such as clinicaltrials.gov and EU-CTR - to meet this results disclosure expectation").		
	Mention journal publication "with an indicative timeframe of 24 months"		
Reporting results - extra elements	Mention that protocols should be published by time of results disclosure ("we also encouragement development of requirements")		
	Mention that protocol should include amendments		
	Trial ID should be in all results publications, and propagated to PubMed		
	Plan for disclosure should be included at time of grant submission		
	Reasonable funds to ensure compliance is a cost eligible item		
Monitoring and incentivising	Mention that applicants previous track record of publishing results is considered when assessing new grant applications		
disclosure of past trials	Mention that PI asked to provide a list of previous trials as PI, and explanation for any unreported trials		
Monitoring compliance	Mention of monitoring compliance ("We each agree to monitor registration and endorse the development of systems to monitor results reporting on an ongoing basis.")		
	Mention that outputs of monitoring process are publicly available ("We agree that transparency is important and therefore the outputs from the monitoring process will be publicly available")		
	Current compliance audit available now		

Note that the WHO Joint Statement does not contain concrete provisions related to IPD sharing and Open Access.