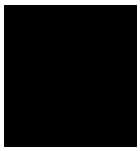
Trial registration v1.0

Document

Pharmacology Module

WorldWide Antimalarial Resistance Network (WWARN)



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Version History

Version number	Revision(s) & reason for amendment	Release Date
1.0	Creation of procedure	[DD/MM/YYY]

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WorldWide Antimalarial Resistance Network (WWARN)
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What do the regulations and other role-players say?

Trial registration is an important contribution to transparency of research findings. The Declaration of Helsinki , which is the basis of other guidelines and even regulations, states that "*Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject. 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".*

There has been a ground-swell of calls for all trials to be registered, whether past or present, so that they contribute to evidence about a drug, whether positive or negative (http://www.alltrials.net/find-out-more/all-trials/). As such, trial registers provide policy-makers, prescribers and the public with updated information on the trial's purpose, who may participate(d), where it is/was located, and contact details for key trial personnel. Some regulatory authorities then hold investigatrors to account after the trial and expect a summary of the reslts to be also posted publicly

Another important consideration is that researchers must register specific minimum criteria before trial start should they wish to subsequently publish their results in journals belonging to the International Committee of Medical Journal Editors (ICMJE). There are, however, various registers; some may be a requirement depending on where the trial is conducted or who the funder is (e.g. trials in South Africa need to be registered with the South African National Clinical Trials Registry, SANCTR). The ICMJE recognises all primary registries that feed into the World Health Organization international registry http://apps.who.int/trialsearch/ (including the US register www.clinicaltrials.gov, and the Pan African Clinical Trial Registry (PACTR), www.pactr.org). However, as SANCTR, for instance, does not comply fully with the WHO registry requirements, trials in South Africa that will be published in an ICMJE journal should register with both SANCTR and another WHO-regcognised registry (or the WHO register directly).

Which trials need to be registered?

The ICMJE defines trials that need to be registered as: "*Any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause and effect relationship between a medical intervention and a health outcome*." Health-related interventions are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioural treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes. Health outcomes are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. The ICMJE does not define the timing of first participant enrollment, but best practice dictates registration by the time of first participant consent. Other registries may have their own definitions and requirements for which trials need registering.

Useful links

Visit https://globalhealthtrials.tghn.org for further information and discussion on this topic.