CCMO statement on publication policy[1]

Human subjects often take part in clinical trials for altruistic reasons. Their participation makes an important contribution to the development of new drugs and improving health care. The CCMO is of the opinion that human subjects must be able to assume that the trial in which they participate will be conducted in a skilled and objective manner and that its results will be disclosed.
Publication in peer-reviewed scientific journals is an important way for the disclosure of results. However, negative results are sometimes not published at all or published only after a long delay [1,2]. The CCMO finds this unacceptable.
Over the past few years, increasing attention has been paid to the independence of investigators. In 2001 some leading scientific journals established rules so that the independence of investigators from the pharmaceutical industry can be (more) guaranteed [3].

The CCMO considers that medical ethics committees also have a role in the disclosure of research results. They should take account of the agreements between the sponsor and the investigators on disclosure / publication of the results of the trial when assessing the protocol.
This statement contains the basic principles of the CCMO's position on the disclosure / publication of trial results obtained from studies involving human subjects.

Basic principles

1. the results of scientific research involving human subjects must be disclosed unreservedly. All parties concerned must justify their actions in this regard. Patients and subjects are entitled to public disclosure of the results of the trial on the basis of their participation in it (and the arguments that play a role therein);
2. agreements on disclosure / publication between the sponsor and the investigators must be transparent and laid down in advance in the trial protocol. These agreements must be approved by the medical ethics committee. In some cases it may be desirable for the agreements to be set out in a contract to be signed by both parties. The investigator may want to involve his employer in this. Of course, the agreements as laid down in the trial protocol and in the signed contract must be identical. The patient information should contain a general statement to describe that the results of the trial will be disclosed;
3. both positive and negative trial results must be disclosed. In general, the results of research will be submitted for publication to peer-reviewed scientific journals. These journals often do not consider negative results for publication. However, there are other ways of disclosing research results, such as trial registers, websites (for instance www.biomedcentral.com), databases and so on;
4. agreements must also involve the participation in publication, if possible before the start of the trial. These agreements are particularly important in the case of multicentre trials. The basic principles in this regard are the rules of the Vancouver convention [4] and the editors' statements of a number of authoritative biomedical scientific journals [3];

[1] This statement relates to all research undertaken under the *Medical Research Involving Human Subjects Act* (WMO).

5. the sponsor is entitled to examine the manuscript prior to publication and to make comments on it. This applies in particular to research organized or funded by industry. The sponsor may delay publication for up to three months after analysing the research results if it is applying for a patent or for other important reasons [5];
6. disputes on the interpretation of the results may not lead to an unnecessary delay in publication. Disputes can be dealt with by continuing the debate in the form of letters sent to the scientific journal;
7. none of the parties concerned has a right of veto. The parties concerned must attempt to resolve disputes by negotiation. Should one of the parties feel that it has been disadvantaged, or should any other problem relating to publication arise, the parties can contact the CCMO or the medical ethics committee for mediation.

Bibliography

1. Yamey G, Scientists who do not publish trial results are "unethical". *BMJ* **319**:939, 1999
2. Montaner JSG, et al., Industry-sponsored clinical research: a double-edged sword, *The Lancet* **358**:1893-1895, 2001
3. Davidoff F et al., Sponsorship, authorship and accountability, *NEJM* **345**:825-826, 2001
4. Uniform requirements for manuscripts submitted to biomedical journals. *JAMA* **277**:927-934,1997
5. ICH Harmonised tripartite guideline for Good Clinical Practice. CPMP/ICH/135/95. www.ifpma.org/ich5e.html#GCP

As of **15 March 2002** the CCMO will be following the aforementioned basic principles in respect of new research protocols submitted to it for assessment.
The statement also serves as a set of non-binding basic principles for the accredited medical ethics committees.

Reactions?

The CCMO would be pleased to receive your reaction.
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You can also find the text of the *CCMO statement on publication policy* at the CCMO's website (www.ccmo.nl).