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Copper-bearing intrauterine contraceptive devices — Guidance on the design, execution, analysis and interpretation of clinical studies

Dispositif intra-utérin au cuivre à but contraceptif — Recommandations relatives à la méthodologie, la réalisation, l'analyse et l'interprétation des résultats des études cliniques

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics*.

Introduction

This clinical study guidance is intended to help in the design, execution, analysis, and interpretation of clinical studies conducted in accordance with the requirements of ISO 7439.

Intrauterine devices (IUD) are highly effective at preventing pregnancy. A new device aims at maintaining or improving the efficacy of intrauterine contraception and/or reducing the side effects associated with IUDs, such as excessive menstrual bleeding. Trials evaluating new or modified IUDs should be conducted to the highest standards and this guidance will help those preparing for an IUD trial.

This guidance is based on the structure and content of a clinical investigation plan (CIP) as described in ISO 14155 to assist in the writing of a CIP and includes sections of the CIP that are of special relevance to IUD trials.

This guidance also draws on the experience gained in preparing the Cochrane systematic review of trials of copper-containing IUDs, which has been used to inform the updating of the WHO/UNFPA Specification for TCu380A IUD.

It is important that persons designing, running, and analysing clinical studies of new IUDs are familiar with all relevant standards for research designed to protect the rights, safety and well-being of human subjects.

This guidance should be read in conjunction with ISO 14155.

Clinical studies are also subject to local regulations and, in most countries, require prior approval from the local regulatory body.

Copper-bearing intrauterine contraceptive devices — Guidance on the design, execution, analysis and interpretation of clinical studies

1 Scope

This document provides guidance on the design and conduct of clinical studies to determine the performance characteristics of new intrauterine devices. It also provides advice on the analysis of data when the study is completed, as well as interpretation of these results by manufacturers, researchers and regulatory bodies.

It is intended to ensure the scientific conduct of the clinical investigation and the credibility of the clinical investigation results, and to assist sponsors, monitors, investigators, ethics committees, regulatory authorities and other bodies involved in the conformity assessment of medical devices.

Certain clinical trial concerns are not addressed in this document, including subject compensation, confidentiality of subjects and their records, use of local ethics committees, etc. These and many other clinical trial design issues are covered in great detail in ISO 14155.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

3.1
adverse device effect
ADE
adverse event (3.2) related to the use of a *medical device* (3.27)

Note 1 to entry: This includes any adverse event resulting from insufficiencies or inadequacies in the instructions for use, the deployment, the implantation, the installation, the operation, or any *malfunction* (3.26) of the medical device.

Note 2 to entry: This includes any event that is a result of a use error or intentional misuse.

3.2
adverse event
AE
any untoward medical occurrence, unintended disease or injury or any untoward clinical signs (including an abnormal laboratory finding) in *subjects* (3.35), users or other persons whether or not related to the *investigational device* (3.25)

Note 1 to entry: This includes events related to the investigational device or the *comparator* (3.10).

Note 2 to entry: This includes events related to the procedures involved.