
**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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Foreword

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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.

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