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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 42168.1-2022

Condoms - Guidance on clinical studies - Part 1: Male condoms, clinical function studies based on self reports

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foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part 1.Structure and Drafting Rules for Standardization Documents"

drafting.

This document is part 1 of GB/T 42168 "Guidelines for Clinical Research of Condoms". GB/T 42168 has issued the following parts.

--- Part 1.Male condom based on self-reported clinical function research.

This document is identical to ISO 29943-1.2017 "Guidelines for clinical research on condoms Part 1.Male condoms based on self-report

Clinical Functional Research".

Please note that some contents of this document may refer to patents. The issuing agency of this document assumes no responsibility for identifying patents.

Introduction

GB/T 42168 "Guidelines for Clinical Research of Condoms" aims to guide the clinical research of condoms, and is proposed to be composed of two parts.

--- Part 1.Male condom based on self-reported clinical function research.

--- Part 2.Clinical functional studies of female condoms based on self-report.

Male condoms made of natural latex rubber (NRL) have a long history of safety and effectiveness, and their

Performance has been proven. However, male condoms made from new materials need clinical validation to ensure their performance in real-world use

Not inferior to NRL condoms. Such clinical validation studies, called clinical functional studies, are designed to compare acute failure events (i.e., clinical slippage and

incidence of clinical damage). Statistical analyzes based on non-inferiority comparisons ensured that differences were modest.

All clinical failure events as defined in this document represent a risk of vaginal exposure to semen and other penile secretions. Non-clinical

There is no risk of exposure in the event of a failure.

This document is intended to aid in the design, implementation, analysis and interpretation of clinical functions performed in accordance with the requirements of ISO 23409 Synthetic Male Condoms.

able to study. However, it can also be used with appropriate modifications to evaluate other male condoms, with additional criteria for improved efficacy or safety.

Statement (please refer to Chapter 8 of GB/T 7544-2019). In addition to information on clinical validation studies, this guidance provides

Proposals for curative research and statistical analysis plans. Attachments include previously used case report forms and protocols that may be modified or adapted.

Note. According to the normative clinical requirements of the relevant standards, these studies were designed to select patients who agreed to use the test and control condoms for vaginal intercourse.

couple. Incidentally, these studies also collected data on condom use during anal sex; of course, this was not the primary goal. In order to meet the research

To meet the force requirements, it is crucial to collect adequate reports of condom use during vaginal intercourse. Study sponsors usually take precautions,

Examples include initial screening and obtaining informed consent from research subjects and obtaining consent to condom use in this manner.

These clinical functional studies are generally not aimed at directly evaluating the protection of condoms against pregnancy or sexually transmitted infections (STIs).

Finally, it is important to realize that clinical functional studies of condoms are human studies. Therefore, the design, implementation and analysis of new condom clinical

All persons involved in clinical research should be familiar with all relevant research standards involving subject populations, including ethical issues. For additional information, see

ISO 14155.

Condom Clinical Research Guidelines Part 1.

Male condoms based on self-reported

clinical function research

1 Scope

This document is provided to aid in the design, execution, analysis and interpretation of clinical functional studies according to the requirements of ISO 23409.

This document is applicable to compare the performance of the new male condom and the marketed male condom during vaginal intercourse (non-anal intercourse). research

The primary objective of the study was to assess acute failure events (i.e., clinical slippage and clinical breakage) during use.

This document also provides an analysis of the data at the completion of the study, as well as an interpretation of the results by the manufacturer and regulatory agencies, etc.

Certain clinical trial elements, including compensation, confidentiality of personal information and records, participation of local ethics committees, etc., are not specified in this document, which are

These and other clinical trial design issues are discussed in detail in ISO 14155.

2 Normative references

This document has no normative references.

3 Terms and Definitions

The following terms and definitions apply to this document.

The address of the terminology database for standardization maintained by ISO and IEC is as follows.

Note. All clinical failure events described below refer to possible vaginal exposure to semen and other penile secretions. There is no risk of exposure for nonclinical failure events.

3.1

Clinical breakage clinicalbreakage

A condom breaks or tears during intercourse or when the penis is withdrawn from the vagina.

Note 1.This may not be discovered until the condom is checked at the end of intercourse.

Note 2.All breakages that do not meet the definition of clinical breakage are considered "non-clinical breakage" (e.g. tearing a condom when opening the package).

3.2

clinical breakage rate

The number of condoms broken or torn during intercourse or penile withdrawal divided by the total number of condoms used during intercourse.

Note. Usually the clinical damage rate is expressed as a percentage.

3.3

clinical slippage clinicalslippage

Complete slippage of the condom during intercourse or withdrawal of the penis from the vagina.

Note 1.Occasionally, slippage occurs because the user does not secure the condom at the base of the penis during withdrawal, and/or the user delays withdrawal after intercourse. this

These events were considered user-related failures and recorded as "non-clinical slippage". These events were not counted when calculating the number of clinical slip events.

Note 2.If the condom slips mainly due to breakage, it will not be recorded as a slip event.