

ISO 29943-2:2017-07 (E)

Condoms - Guidance on clinical studies - Part 2: Female condoms, clinical function studies based on self-reports

| Contents | | Page |
|--------------------|---|-------------|
| Foreword | | v |
| Introduction | | vi |
| 1 | Scope | 1 |
| 2 | Normative references | 1 |
| 3 | Terms and definitions | 1 |
| 4 | Risk assessment | 3 |
| 5 | Pilot clinical studies | 3 |
| 6 | Clinical validation investigation | 4 |
| 6.1 | Objectives of clinical validation investigation | 4 |
| 6.2 | Outcome measures | 4 |
| 6.3 | Study subjects | 4 |
| 6.3.1 | General | 4 |
| 6.3.2 | Enrolment of study subjects | 5 |
| 6.4 | Informed consent | 6 |
| 6.5 | Test and control condoms | 6 |
| 6.5.1 | General | 6 |
| 6.5.2 | Test condom | 7 |
| 6.5.3 | Control condom | 7 |
| 6.5.4 | Trial duration exceeds one year | 7 |
| 6.5.5 | Sampling of control condoms for bench testing | 8 |
| 6.6 | Randomization | 8 |
| 6.7 | Allocation concealment and study masking | 8 |
| 6.8 | Use of additional lubricant | 8 |
| 6.9 | Instructions and interactions with study couples | 8 |
| 6.10 | Interviews and data collection | 9 |
| 6.10.1 | Schedule for interviews and condom distribution | 9 |
| 6.10.2 | Enrolment interview | 9 |
| 6.10.3 | Individual condom use CRF | 10 |
| 6.10.4 | Mid-study CRF, crossover trial | 10 |
| 6.10.5 | Compiling data from CRFs | 11 |
| 6.11 | Data integrity | 11 |
| 6.11.1 | General | 11 |
| 6.11.2 | Interactive voice response systems (IVRS) | 11 |
| 6.11.3 | Mail-in and web-based data reporting | 11 |
| 6.11.4 | Web-based data collection systems, additional suggestions | 12 |
| 6.12 | Control of distribution chain | 13 |
| 6.13 | Analysis of returned condoms | 13 |
| 6.14 | Other methodological details | 13 |
| 6.15 | Statistical analysis plan | 14 |
| 6.15.1 | General | 14 |
| 6.15.2 | Primary study hypothesis | 14 |
| 6.15.3 | Secondary study hypotheses | 15 |
| 6.15.4 | Study design | 15 |
| 6.15.5 | Statistical analysis | 15 |

| | | |
|--|--|----|
| 6.15.6 | Additional statistical comments and concerns | 16 |
| 6.16 | Clinical study results: Review and interpretation | 16 |
| 6.16.1 | General | 16 |
| 6.16.2 | Total clinical failure rates for control condom | 16 |
| 6.16.3 | Non-inferiority | 16 |
| 6.16.4 | Superiority | 17 |
| 6.16.5 | Safety (adverse events) | 17 |
| 6.16.6 | What happens if one is unable to conclude non-inferiority? | 17 |
| Annex A (informative) Formula for power calculation | | 18 |
| Annex B (informative) Pilot clinical investigation (sample outline) | | 19 |
| Annex C (informative) Time and events schedule for individual study subject (sample) | | 21 |
| Annex D (informative) CRF -- Study entry (sample) | | 22 |
| Annex E (informative) CRF -- Mid-study (sample) | | 25 |
| Annex F (informative) CRF -- Single use of female condom (sample) | | 27 |
| Annex G (informative) CRF -- Adverse event (sample) | | 31 |
| Annex H (informative) Protocol for evaluation of returned used condoms | | 33 |
| Bibliography | | 39 |