致力法規科學，守護生命健康
Regulatory Science,Service for Life

醫療器材試驗計畫書撰寫原則

醫療器材組
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醫療器材優良臨床試驗基準

- 十、試驗計畫書：記載臨床試驗之目的、設計、方法、統計考量、編制等事項之文件。其得載明試驗之相關背景與理論。
- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) of GCP guidelines
- ISO 14155:2011 -- Clinical investigation of medical devices for human subjects -- Good clinical practice

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INTERNATIONAL STANDARD

ISO 14155

Second edition
2011-02-01

Clinical investigation of medical devices for human subjects — Good clinical practice

Investigation clinique des dispositifs médicaux pour sujets humains — Bonnes pratiques cliniques

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Clinical Investigational Plan (CIP)

Document that state(s) the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the clinical investigation

NOTE The term "protocol" is synonymous with "CIP". However, protocol has many different meanings, some not related to clinical investigation, and these can differ from country to country. Therefore, the term CIP is used in this International Standard.

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Clinical Investigational Plan (CIP)

- A.1 General
- A.2 Identification and description of the investigational device
- A.3 Justification for the design of the clinical investigation
- A.4 Risks and benefits of the investigational device and clinical investigation

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Clinical Investigational Plan (CIP)

- A.5 Objectives and hypotheses of the clinical investigation
- A.6 Design of the clinical investigation
- A.7 Statistical considerations
- A.8 Data management

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Clinical Investigational Plan (CIP)

- A.9 Amendments to the CIP
- A.10 Deviations from clinical investigation plan
- A.11 Device accountability
- A.12 Statements of compliance
- A.13 Informed consent process

Clinical Investigational Plan (CIP)

- A.14 Adverse events, adverse device effects and device deficiencies
- A.15 Vulnerable population
- A.16 Suspension or premature termination of the clinical investigation
- A.17 Publication policy
- A.18 Bibliography


敬請指教
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