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강연제목: 미충족의료수요 기반 의료제품 설계서

Clinical unmet needs based intended use establishment (CLUE) process & template

Abstract(영문):

This tool aims to facilitate the formulation of the intended use and indications for use of medical devices by systematic and step-by-step review and analysis of unmet needs in the healthcare field, and consulting and reflecting the knowledge and experiences of the experts. This CLUE (Clinical unmet needs based intended use establishment) process can generate the information that can be used to determine medical device class and as background for planning clinical evaluation and clinical investigations as the medical device development stages progress.

- During the process of medical device development
 - Determining the adoption of clinical unmet needs
 - Extracting benefits and concerns expected from the healthcare field, providing feedback for product development.
 - Establishing strategy for usability evaluation, medical device clinical investigations, and clinical evaluation
 - Evidence for the intended use and indications for use to be presented for medical device approval
- Clinical investigations and clinical evaluation of the medical device
 - Establishing evidence for designing clinical investigation plan
 - Establishing evidence for designing clinical evaluation plan
 - Establishing evidence for planning of medical device's safety and effectiveness

Brief Biosketch (간단한 이력, 연구/대외활동 소개, 국문/영문)

학력: 1995 년 2 월 순천향대학교 의과대학 의학과 졸업, 동대학 석사(1995), 박사(2003)

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