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강연 제목: 유럽의 신의료기기법(MDR)에 따른 의료기기의 임상평가
Clinical evaluation for medical devices under MDR

Abstract:
The CLINICAL EVALUATION is a systematic and planned process to continuously generate, collect, analyze and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer. It should be conducted throughout the life cycle of a medical device. This means that clinical evaluations should be repeated periodically, depending on the risk classification of the device and the identification of new safety and/or performance information. Verification of clinical benefits has significant implications. The SOTA(state of the art), the natural course of the disease, and alternative available treatment options need to be addressed in the clinical evaluation. In cases of high-risk devices, they are subject to high clinical scrutiny by the expert panel under the MDCG(Medical Device Coordinator Group).
For the clinical investigation in (EU) member states, the sponsor shall submit a clinical investigation application including a protocol, safety and performance verification results, technical documents, and a clinical evaluation plan. This means that the purpose of the clinical investigation is to confirm the conformance of the GSPRs(General Safety and Performance Requirements) of the device in question. If the clinical data is not adequate and sufficient evidence in proportion to the manufacturer's claim, it may be problematic in the subsequent clinical evaluation/assessment.

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

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미)FDA, (유럽) CE 마킹, 일본의 규제 승인 등 의료기기의 해외 인증/등록을 위한 컨설팅 서비스
Medical Device Overseas Certification/Registration Consulting services for US FDA, (EU) CE marking, Japanese regulatory approval, and etc.