

MFDS-Asan Joint Symposium on Proof of Concept Studies

식품의약품안전처-서울아산병원 임상시험글로벌선도센터
공동 주관 심포지엄

MFDS-Asan
Collaboration to Accelerate
Proof of Concept Studies:
Strategic, Scientific
and Operational Excellence

AGENDA

| Time | Title | Speaker |
|--|--|------------------------------------|
| 13:00 - 13:10 ('10) | Welcome | |
| Session 1 Investigational New Drugs (IND) : Investigators, Sponsors and Regulatory Bodies | | |
| 13:10 - 13:40 ('30) | Reviewing IND/Protocol Application : Principles and Practice | US FDA Geoffrey Kim, M.D. |
| 13:40 - 14:00 ('20) | IND Application : Korea vs Outside Korea | 한미약품 정진아 이사 |
| 14:00 - 14:20 ('20) | A Translational Investigator's Checklist for IND Application | 서울아산병원 김규표 교수 |
| 14:20 - 14:40 ('20) | Panel Discussion | |
| 14:40 - 14:50 ('10) | Break | |
| Session 2 Proof of Concept (PoC) Trials : Emerging Issues | | |
| 14:50 - 15:10 ('20) | Clinical Trial Endpoints for Patient Phase 1 : Maximum Tolerated Dose vs Pharmacodynamic Endpoint (Safety vs Efficacy) | 식품의약품안전처 남경탁 연구관 |
| 15:10 - 15:40 ('30) | Strategies for Early Clinical Development and Meetings FDA Offers | US FDA Tamy Kim, Pharm. D. |
| 15:40 - 16:00 ('20) | New Challenges in Site Selection & Project Management | 노바티스 김은경 상무 |
| 16:00 - 16:20 ('20) | Practical Problems and Reasonable Solutions in Performing Patient Phase 1 Trial | 퀀타일즈 Wendy Bilham, Sr. Director |
| 16:20 - 16:40 ('20) | Panel Discussion | |
| 16:40 - 16:50 ('10) | Break | |
| Session 3 Issues after Investigational New Drugs (IND) Approval | | |
| 16:50 - 17:05 ('15) | Setting-up Internal Audit within an Academic Medical Center | 서울아산병원 김성윤 교수 |
| 17:05 - 17:20 ('15) | Investigational Drug Services : What Non-Pharmacists Should Know | 서울아산병원 송경아 약사 |
| 17:20 - 17:35 ('15) | Drug Supply for Investigational Drugs from Outside of Korea | Fisher Clinical Services 김주미 이사 |
| 17:35 - 17:45 ('10) | Closing Remark | |



일시·장소

2015년 7월 9일 (목) 13:00 - 17:45
서울아산병원 동관 6층 대강당



사전등록

임상시험센터 홈페이지 온라인 접수
<http://ctc.amc.seoul.kr>

6월 12일, 금요일까지
선착순 : 300명
(선착순 등록으로 조기 마감 될 수 있습니다.)
* 동시통역으로 진행



문의처

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