AIRIS 2025
Regulation for AI, Together for Tomorrow
AI Regulatory & International Symposium

AIRIS 2025

Regulation for AI, Together for Tomorrow

INSPIRE RESORT INCHEON
Sep. 10(Wed) **~ 12**(Fri)**, 2025**

Ministry of Food and Drug Safety

World Health Organization

INTRO

PROGRAM

SPEAKERS

MODERATOR

WELCOME MESSAGE

Today, artificial intelligence (AI) is not just an innovative technology—it is transforming our daily lives more than we ever expected. This transformation is also taking place in the field of medical products. Recognizing this growing significance of AI technology, the Ministry of Food and Drug Safety (MFDS) of the Republic of Korea and the World Health Organization (WHO) will co-host the AIRIS 2025. MFDS and WHO expect the AIRIS 2025 to serve as a platform for regulators and industry to exchange insights and ideas on how to effectively utilize AI in medical product development and regulation.

Since the AIRIS 2024, there have been innovative developments in AI at an incredibly fast pace bringing fundamental changes to the development and approval of medical products. For example, we have seen the implementation of digital twins for refractory disease treatments and the advancement of Large Language Models (LLMs) for analysis of massive safety data and prediction of adverse events.

Against this backdrop, the AIRIS 2025 will continue in-depth discussions on innovation, advancement, safety and reliability of AI-enabled medical products. As the only international symposium in the field of AI-enabled medical products, the symposium will serve as a platform for practical global cooperation among regulatory authorities, businesses, and research and academic institutions. I would like to kindly invite you to the AIRIS 2025

Yu-Kyoung OH
Minister of Food and Drug Safety

초대의 글

이제 우리 주변에서 인공지능의 역할은 혁신을 넘어 일상이 되고 있습니다. 이는 의료제품 분야에서도 마찬가지일 것입니다.
대한민국 식품의약품안전처(MFDS)와 세계보건기구(WHO)는 의료제품 개발과 규제에서 업계와 규제기관이 AI 기술을 효과적으로 활용할 수 있도록 돕기 위해 AIRIS 2025를 개최합니다.

2024년 2월, AIRIS 2024에서 우리는 AI를 활용한 의료제품의 관리체계와 고려해야할 사항, 향후 과제 등에 대해 논의하였으며, 이를 기반으로 글로벌 규제협력 증진과 지속에 관한 'AIRIS 2024 서울 성명문'을 발표한 바 있습니다. 이후 AI 기술은 혁신적으로 발전하여 난치질환 치료를 위한 디지털 트윈 모델 구현, LLM (Large Language Model) 활용 대규모 안전성정보 분석 및 부작용 예측 기술 등이 빠르게 발전하고 있으며, 의료제품의 개발과 허가에 근본적인 변화를 가져오고 있습니다.

이에 따라, AIRIS 2025에서는 AI 의료제품의 혁신과 성장, 안전과 신뢰에 대해 심도있는 논의를 계속 이어나갈 예정이며, AI 의료제품 분야의 유일한 국제 심포지엄으로, 규제기관, 기업, 연구·학술기관에게 모두 실질적인 글로벌 협력의 장이 될 수 있도록 여러분의 많은 관심과 성원을 바랍니다.

감사합니다.

오유경
식품의약품안전처장

WELCOME MESSAGE

Artificial intelligence is rapidly reshaping our world, including the development and regulation of medical products. As AI technologies become more sophisticated and their applications in health expand, so must our collective efforts to ensure that they are safe, effective, ethical, and equitable.

It is in this spirit that the World Health Organization is pleased to co-host AIRIS 2025, alongside the Ministry of Food and Drug Safety of the Republic of Korea. Taking place from September 10 – 12, 2025 in Incheon, Republic of Korea, AIRIS 2025 brings together global regulators, researchers, industry, and innovators to share perspectives and shape coherent pathways for the regulation of AI in medical products.

AIRIS 2025 offers an important forum for regulators to convene and engage in collective dialogue on the safe and effective use of AI in medical product development. Together, we must ensure that AI technologies serve public health goals - safely, equitably, and for the benefit of all.

Building on the success of AIRIS 2024 and WHO's guidance on Regulatory Considerations for AI in Health, this year's symposium will explore critical developments such as the use of digital twins, large language models, and real-world implementation challenges and opportunities. By fostering global collaboration, AIRIS 2025 seeks to advance robust regulatory frameworks that protect public health while enabling responsible innovation.

We look forward to welcoming you to this important event and to working together so that safe, scientific, and equitable AI serves the health and well-being of all people, everywhere.

Dr, Tedros Adhanom Ghebreyesus
Director-General World Health Organization

초대의 글

인공지능(AI)은 세상을 빠르게 변화시키고 있으며 의료제품 개발과 규제 분야도 예외는 아닙니다. AI 기술이 더욱 정교해지고 보건 분야에서도 그 활용 범위가 확대됨에 따라 AI 기술을 안전하고 효과적이며, 윤리적이고 공정하게 사용하기 위한 공동의 노력이 그 어느 때보다 중요해지고 있습니다.

이런 점에서 세계보건기구는 대한민국 식품의약품안전처와 AIRIS 2025를 공동 주최하게 되어 매우 기쁘게 생각합니다.

2025년 9월 10일부터 12일까지 대한민국 인천에서 열리는 AIRIS 2025는 전 세계 규제기관, 학계, 산업계, 혁신가들이 한 자리에 모여 AI 의료제품규제에 대한 의견을 나누고 향후 나아갈 방향을 논의하는 자리입니다.

AIRIS 2025는 규제기관들이 의료제품 개발에 AI 기술을 안전하고 효과적으로 활용할 수 있는 방안을 모색할 수 있도록 집단적 논의의 장을 제공합니다. 우리는 AI 기술이 안전하고 공정하게, 그리고 모두에게 도움이 되는 방식으로 공중 보건 목표 달성에 기여하도록 협력해야 합니다.

AIRIS 2024의 성과를 바탕으로, 올해 심포지엄은 디지털 트윈과 대규모언어모델의 활용, AI 실제 적용의 어려움 및 기회 등 주요 현안을 다룰 예정입니다. AIRIS 2025는 글로벌 협력을 촉진함으로써 공중보건을 보호하는 동시에 책임 있는 혁신을 가능하게 하는 견고한 규제 체계를 발전시키고자 합니다.

이렇듯 중요하고 의미 있는 행사에 여러분을 모시고 안전하고 과학적이며 공정한 AI 활용이 인류의 건강과 복지에 기여할 수 있도록 공동의 노력을 기울일 수 있기를 바랍니다.

테드로스 아드하놈 거브러여수스 박사
세계보건기구 사무총장

OBJECTIVE

To explore collaborative initiatives for developing regulatory frameworks for the use of AI in public health ecosystems, including medical product development, and to examine case studies for promoting AI utilization within regulatory environments.

CO-HOSTS

Ministry of Food and Drug Safety

World Health Organization

OVERVIEW

Title	AIRIS 2025 (AI Regulatory & International Symposium)
Theme	Regulation for AI, Together for Tomorrow
Date	Sep.10(Wed.) - 12(Fri), 2025
Venue	INSPIRE RESORT INCHEON
Participants	All stakeholders interested in the topic of the symposium such as global regulatory authorities, international organizations, industry, and academia
Co-organized by	MFDS and WHO

개최목적

의료제품 개발을 포함한 공중 보건 생태계에서 AI 활용 규제 프레임워크 개발을 위한 협력적 이니셔티브 탐구 및 규제 환경에서의 AI 활용 촉진 사례 연구 검토

공동주최

식품의약품안전처

World Health Organization

행사개요

행사명	AIRIS 2025 (AI Regulatory & International Symposium)
주제	글로벌 AI규제 조화, 함께 여는 미래
기간	2025년 9월 10일(수)-9월 12일(금)
장소	인스파이어 엔터테인먼트 리조트
참가자	글로벌 규제기관, 국제 기구, 산업계, 학계 등 심포지엄 주제에 관심 있는 모든 분
주최	식품의약품안전처, 세계보건기구(WHO)

PROGRAM

Sep.10(Wed.)	Sep.11(Thu.)	Sep.12(Fri.)
Opening Ceremony 10:00 - 10:40 Inspire Ballroom A	**Session 3 :** AI Regulatory Frameworks 09:00 - 11:50 Inspire Ballroom A	**Session 5 :** C Regulatory Round Table **Closing Ceremony** 09:00 - 12:00 Mountain
Keynote Address Design of New Protein Functions Using Deep Learning 10:40 - 11:25 Inspire Ballroom A	**Lunch** C 11:50 - 13:00 Inspire Ballroom B	**Lunch** C 12:00 - 13:20 Mountain
Session 1 : Global Ecosystem for AI in Healthcare 11:30 - 12:20 Inspire Ballroom A	**Session 4 :** AI Technologies and Regulatory Status 13:00 - 16:40 Inspire Ballroom A	
Lunch C 12:20 - 13:40 Inspire Ballroom B	**Dinner** C 18:00 - 19:30 Inspire Ballroom B	
Session 2 : Latest Trends in AI-enabled Medical Products 13:40 - 16:40 Inspire Ballroom A		
Welcome Dinner C 18:00 - 20:00 Inspire Ballroom A		

C **Closed Event**

Above programs and venues are subject to change.

프로그램

9월10일(수)	9월11일(목)	9월12일(금)
개회식 10:00 - 10:40 Inspire Ballroom A	**세션 3 :** AI규제 프레임워크 09:00 - 11:50 Inspire Ballroom A	**세션 5 :** C 규제기관 라운드 테이블 **폐회식** 09:00 - 12:00 Mountain
기조연설 Design of New Protein Functions Using Deep Learning 10:40 - 11:25 Inspire Ballroom A	**오찬** C 11:50 - 13:00 Inspire Ballroom B	**오찬** C 12:00 - 13:20 Mountain
세션 1 : 의료분야 AI활용을 위한 글로벌 환경 11:30 - 12:20 Inspire Ballroom A	**세션 4 :** AI 기술 및 규제 현황 13:00 - 16:40 Inspire Ballroom A	
오찬 C 12:20 - 13:40 Inspire Ballroom B	**만찬** C 18:00 - 19:30 Inspire Ballroom B	
세션 2 : AI활용 의료제품 최신동향 13:40 - 16:40 Inspire Ballroom A		
환영만찬 C 18:00 - 20:00 Inspire Ballroom A		

C **비공개 행사**

주최측의 사정에 따라 일정 및 장소는 변경될 수 있습니다.

DETAILED PROGRAM

SEP. 10(WED.)
OPENING • SESSION 1

Time	Program	Topic	Speaker / Panelist
[Day 1] Setting the Stage for AI Regulation in Health			
10:00 - 10:20	Opening Remarks	Setting the stage for AI regulation in health	**Yu-Kyoung OH,** MFDS Minister **Tedros Adhanom Ghebreyesus,** Director General of WHO (video)
10:20 - 10:40	Congratulatory Remarks		**Min-Seok KIM,** Prime Minister (video) **Ali Mohamed Ghamrawy,** Minister & Chairman of EDA **Mojisola Christianah Adeyeye,** Director General of NAFDAC **Nils Falk Bjerregaard,** Director General of DKMA (video)
[Keynote Address]			
10:40 - 11:10	Keynote Address	Design of New Protein Functions Using Deep Learning	**David Baker,** Professor, Director University of Washington, Institute for Protein Design (video)
11:10 - 11:25	**Q&A** (Live Q&A with on-site audience)		
11:25 - 11:30	**Break**		
[Session 1] Global Ecosystem for AI in Healthcare Moderator: **Kidong Park (Director, WHO), Jong Chul Ye (Professor, KAIST)**			
11:30 - 12:20	Panel Discussion	1. Overview of regulatory approaches 2. Reflections on AIRIS 2024 Seoul Outcome Statement 3. Global Landscape Mapping on AI regulations for health	Panelists: **Tala Fakhouri (Parexel)** **Bruce Church (Aitia)** **Hwayoung Lee (LG AI Research)** **Pat Baird (Philips)** **Simao Campos (ITU)**
12:20 - 13:40	**Lunch**		

*** Above programs are subject to change**

세부 프로그램

9월 10(수) 개막 • 세션 1

시간	프로그램	주제	연사/패널
[Day 1] 보건분야 AI 인공지능 규제의 기반 마련			
10:00 - 10:20	개회사	보건분야 AI 인공지능 규제의 기반 마련	**오유경,** 대한민국 식약처장 **Tedros Adhanom Ghebreyesus,** WHO 사무총장 (영상)
10:20 - 10:40	축사		**김민석,** 대한민국 총리(영상) **Ali Mohamed Ghamrawy,** 이집트 EDA 청장 **Mojisola Christianah Adeyeye,** 나이지리아 NAFDAC 청장 **Nils Falk Bjerregaard,** 덴마크 DKMA 청장(영상)
기조강연			
10:40 - 11:10	기조강연	딥러닝을 이용한 새로운 단백질 기능 설계	**David Baker,** 워싱턴대학교 교수 (영상)
11:10 - 11:25	**질의 응답** (실시간 영상 연결)		
11:25 - 11:30	**Break**		
[세션 1] 의료분야 AI활용을 위한 글로벌 환경 좌장: **박기동 (국장, WHO), 예종철 (교수, KAIST)**			
11:30 - 12:20	패널 토의	1. 규제 접근법 개요 2. AIRIS 2024 서울 성과 선언문 회고 3. 보건 분야 AI 규제에 대한 글로벌 동향 지도(글로벌 맵핑)	Panelists: **Tala Fakhouri (Parexel)** **Bruce Church (Aitia)** **이화영 (LG AI Research)** **Pat Baird (Philips)** **Simao Campos (ITU)**
12:20 - 13:40	**오찬**		

* 위 일정은 상황에 따라 변동 가능

DETAILED PROGRAM

SEP. 10(WED.)
AFTERNOON • SESSION 2

Time	Program	Topic	Speaker / Panelist
[Session 2] Latest Trends in AI-enabled Medical Products Moderator: **Jong Chul Ye (Professor, KAIST), Mengji Chen (Medical Officer, WHO)**			
13:40 – 14:00	Presentation 1	Latest AI Technologies and Regulatory Trends in Pharmaceutical Field	**Tala Fakhouri,** VP, AI & Digital Policy, Real-World Research Parexel International
14:00 – 14:20	Presentation 2	Opportunities and Challenges of AI-Driven Protein Structure Prediction in Drug Development	**Minkyung Baek,** Assistant Professor Seoul National University
14:20 – 14:40	Presentation 3	The Way to Leverage LG EXAONE to Make Clinical Trials Effective and Efficient	**Hwayoung Lee,** Vice President, Lead of AI Business Transformation Unit LG AI Research
14:40 – 15:00	Presentation 4	Gemini Digital Twins for Drug Discovery and Development	**Bruce Church,** Chief Mathematics Officer and EVP, Research and Early Development Aitia
15:00 – 15:20	**Coffee Break**		
15:20 – 15:40	Presentation 5	Latest Trends in AI-Enabled Medical Products – Product Examples and Standards Projects	**Pat Baird,** Senior Regulatory Specialist Philips
15:40 – 16:00	Presentation 6	TBD	**Camille Vidal,** Vice President of Regulatory Affairs, GE HealthCare
16:00 – 16:20	Presentation 7	Generative AI in Medicine: Trends, Evidence, and the SaMD Boundary	**Woong Bae,** CEO Soombit.ai
16:20 – 16:40	**Q&A**		

*** Above programs are subject to change**

세부 프로그램

9월 10(수) 오후 • 세션 2

시간	프로그램	주제	연사/패널
[세션 2] AI활용 의료제품 최신동향 좌장: **예종철 (교수, KAIST), Mengji Chen (담당관, WHO)**			
13:40 – 14:00	Presentation 1	제약 분야의 최신 AI 기술 및 규제 동향	**Tala Fakhouri,** Parexel International 부사장
14:00 – 14:20	Presentation 2	신약 개발에서 AI 기반 단백질 구조 예측의 기회와 과제	**백민경,** 서울대학교 교수
14:20 – 14:40	Presentation 3	LG EXAONE을 활용한 임상 시험 유효성 및 효율성 제고 방안	**이화영,** LG AI사업개발부문장
14:40 – 15:00	Presentation 4	신약 후보물질 탐색 및 개발을 위한 Gemini 디지털 트윈	**Bruce Church,** Aitia 수학 전략 책임자 겸 연구 및 초기 개발 부문 부사장
15:00 – 15:20	**Coffee Break**		
15:20 – 15:40	Presentation 5	AI 기반 의료제품 최신 동향: 제품 사례 및 표준 연구 과제	**Pat Baird,** Philips 수석 규제 담당자
15:40 – 16:00	Presentation 6	TBD	**Camille Vidal,** GE 헬스케어 디지털헬스 및 AI 규제 인허가 담당 부사장
16:00 – 16:20	Presentation 7	의학 분야의 생성형 AI: 동향, 근거, 소프트웨어 의료기기의 범주	**배웅,** 숨빗AI 대표
16:20 – 16:40	**질의 응답**		

* 위 일정은 상황에 따라 변동 가능

DETAILED PROGRAM

SEP. 11(THU.)
MORNING • SESSION 3

Time	Program	Topic	Speaker / Panelist
[Day 2] Strengthening AI Regulation through Global Collaboration			
[Session 3] AI Regulatory Frameworks **Moderator: HyeWon Roh (Director, MFDS), Sameer Pujari (Lead AI, WHO)**			
09:00 - 09:15	Presentation 1	TBD	**Ib Alstrup,** GxP IT Medicines Inspector Danish Medicines Agency, Denmark
09:15 - 09:30	Presentation 2	Regulatory Approaches to AI-based Medical Devices in Australia	**Tracey Duffy,** Head, Medical Devices and Product Quality Division Therapeutic Goods Administration, Australia
09:30 - 09:45	Presentation 3	Singapore's Regulatory Landscape for AI in Medical Devices	**Woei Jiuang Wong,** Assistant Group Director Health Sciences Authority, Singapore
09:45 - 10:00	Presentation 4	AI Regulatory Frameworks WHO	**Sameer Pujari,** Lead AI, WHO
10:00 - 10:15	**Q&A**		
10:15 - 10:35	**Coffee Break**		
10:35 - 10:50	Presentation 5	Regulatory Perspectives on AI/ML-based Medical Devices in Korea	**ByungGwan KIM,** Deputy Director, Ministry of Food and Drug Safety, Korea
10:50 - 11:05	Presentation 6	Regulation and Review Points of AI-enabled Medical Devices in Japan	**Mitsuru Yuba,** Reviewer, Pharmaceuticals and Medical Devices Agency, Japan
11:05 - 11:20	Presentation 7	Implications of the EU AI Act for Medical Devices	**Rolf Oberlin Hansen,** Senior Advisor Danish Medicines Agency, Denmark
11:20 - 11:35	Presentation 8	The EU AI Act and Interplay with EU MDR/IVDR	**Nada Alkhayat,** Policy Officer DG Sante, European Commission(EC)
11:35 - 11:50	**Q&A**		
11:50 - 13:00	**Lunch**		

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세부 프로그램

9월 11일(목) 오전 • 세션 3

시간	프로그램	주제	연사/패널
[Day 2] 글로벌 협력을 통한 AI 규제 개발			
[세션 3] AI 규제 프레임워크 좌장: **노혜원 (의료기기심사부장, MFDS), Sameer Pujari (AI총괄, WHO)**			
09:00 - 09:15	Presentation 1	TBD	**Ib Alstrup,** 덴마크 의약품청(DKMA) GxP IT 의약품 검사관
09:15 - 09:30	Presentation 2	호주의 AI 기반 의료기기 규제 접근법	**Tracey Duffy,** 호주 식품의약청(TGA) 의료기기 및 제품품질국장
09:30 - 09:45	Presentation 3	싱가포르의 의료기기 분야 AI 규제 현황	**Woei Jiuang Wong,** 싱가포르 보건과학청(HSA) 의료기기그룹 부국장
09:45 - 10:00	Presentation 4	AI Regulatory Frameworks WHO	**Sameer Pujari,** 세계보건기구(WHO) AI 총괄
10:00 - 10:15	**질의 응답**		
10:15 - 10:35	**Coffee Break**		
10:35 - 10:50	Presentation 5	한국의 AI/ML 기반 디지털의료기기 규제체계	**김병관,** 식품의약품안전처(MFDS) 사무관
10:50 - 11:05	Presentation 6	일본의 AI 적용 의료기기에 대한 규제와 심사 관점	**Mitsuru Yuba,** 일본의약품의료기기청(PMDA) 심사관
11:05 - 11:20	Presentation 7	의료기기 분야에서 EU 인공지능법(AI Act)의 의미	**Rolf Oberlin Hansen,** 덴마크 의약품청(DKMA) 자문관
11:20 - 11:35	Presentation 8	EU 인공지능법(AI Act)과 EU MDR/IVDR의 상호작용	**Nada Alkhayat,** 유럽연합 집행위원회 내 정책 담당관
11:35 - 11:50	**질의 응답**		
11:50 - 13:00	**오찬**		

* 위 일정은 상황에 따라 변동 가능

DETAILED PROGRAM

SEP. 11(THU.)
AFTERNOON • SESSION 4

Time	Program	Topic	Speaker / Panelist
[Session 4] AI Technologies and Regulatory Status Moderator: **Junhee Pyo (Vice Chief, CAIID), Jinho Shin (Medical Officer, WHO)**			
13:00 – 13:20	Presentation 1	Rewriting Molecular Discovery: How Generative AI is Transforming Large Molecule Therapeutics	**Alan Russell,** Vice President, Research & Head, R&D Technology & Innovation Amgen
13:20 – 13:40	Presentation 2	AI's Role in Novel Target Discovery – High Unmet Needs Areas Through Multi-Omics Interaction	**Namshik HAN,** Professor University of Cambridge, Yonsei University CTO & Co-founder CardiaTec Bio Ltd
13:40 – 14:00	**Q&A**		
14:00 – 14:10	Special Remarks		**Jung-Woo HA,** Senior Presidential Secretary
14:10 – 14:30	Presentation 3	AI Applications in Pharmaceutical Manufacturing	**Ehab Taqieddin,** Senior Regulatory Group Director, Roche
14:30 – 14:50	Presentation 4	Digital Longevity Medicine	**Dean Ho,** Provost's Chair Professor, Institute Director, National University of Singapore
14:50 – 15:10	Presentation 5	Developing AI Knowledge and Training Tools for Regulators	**Sam Halabi,** Professor Georgetown University
15:10 – 15:40	**Coffee Break**		
15:40 – 16:00	Presentation 6	From Static Law to Adaptive Governance: Regulating Medical AI at the Speed of Innovation to Ensure Legal Certainty, Risk Control and Fundamental Rights	**Claudia Seitz,** Professor Faculty of Law, Private University in the Principality of Liechtenstein (UFL)
16:00 – 16:20	Presentation 7	Cybersecurity for AI-based Digital Medical Devices	**Jiho BANG,** Managing Director, Intelligence & Information Business Division Korea Testing Certification Institute
16:20 – 16:40	**Q&A**		

*** Above programs are subject to change**

세부 프로그램

9월 11일(목) 오후 • 세션 4

시간	프로그램	주제	연사/패널
[세션 4] AI 기술 및 규제 현황 좌장: **표준희 (부원장, CAIID), Jinho Shin (담당관, WHO)**			
13:00 – 13:20	Presentation 1	물질 발견의 재정의: 생성형 AI가 고분자 치료제를 혁신하는 방식	**Alan Russell,** Amgen 연구소 부사장 겸 R&D 기술 및 혁신부서 책임자
13:20 – 13:40	Presentation 2	신규 타겟 발굴에 있어서 AI의 역할 – 다중 오믹스 통합을 통한 높은 미충족 수요 분야	**한남식,** 케임브리지 대학교 및 연세대학교 교수, CardiaTec Bio Ltd CTO 겸 공동창립자
13:40 – 14:00	**질의 응답**		
14:00 – 14:10	특별 기념사		**하정우,** 대통령비서실 AI미래기획수석
14:10 – 14:30	Presentation 3	의약품 제조에서 AI 적용	**Ehab Taqieddin,** 로슈(Roche) 규제그룹 선임 이사
14:30 – 14:50	Presentation 4	디지털 장수 의학	**Dean Ho,** 싱가포르국립대학교 생의학공학과 교수
14:50 – 15:10	Presentation 5	규제기관 담당자를 위한 AI 지식 및 교육 도구 개발	**Sam Halabi,** 조지타운대학교 교수
15:10 – 15:40	**Coffee Break**		
15:40 – 16:00	Presentation 6	정적 법률에서 적응형 거버넌스로: 혁신 속도에 맞춘 의료 AI 규제와 법적 확실성·위험관리·기본권 보호	**Claudia Seitz,** 리히텐슈타인 공국 사립대학교 교수
16:00 – 16:20	Presentation 7	AI 기반 디지털 의료기기 사이버보안	**방지호,** 한국기계전기전자시험연구원(KTC) 지능정보사업본부장
16:20 – 16:40	**질의 응답**		

* 위 일정은 상황에 따라 변동 가능

SPEAKER

KEYNOTE ADDRESS

THE ROLE OF AI IN MEDICAL PRODUCTS

KEYNOTE SPEECH

David Baker
Professor, Biochemistry Director, Institute for Protein Design

BIOGRAPHY

David Baker is a Nobel laureate, professor of biochemistry, HHMI investigator, and director of the Institute for Protein Design at the University of Washington. His lab develops software for protein design and uses it to create molecules that address challenges in medicine, technology, and sustainability. Recent work includes the development of machine learning methods for generating functional proteins.
David is also an adjunct professor of genome sciences, bioengineering, chemical engineering, computer science, and physics at the University of Washington. He has published more than 650 scientific papers, been awarded over 100 patents, and co-founded 21 biotechnology companies. More than 100 of his trainees have gone on to independent faculty positions.
He is the recipient of numerous awards, including the 2024 Nobel Prize in Chemistry “for computational protein design.” He is an elected member of the National Academy of Sciences and was included on TIME’s list of the 100 Most Influential People in health.
David received his PhD in biochemistry with Randy Schekman at the University of California, Berkeley, and conducted postdoctoral research in biophysics with David Agard at UCSF.

TOPIC

Design of New Protein Functions Using Deep Learning

PRESENTATION SUMMARY

Proteins mediate the critical processes of life and beautifully solve the challenges faced during the evolution of modern organisms. Our goal is to design a new generation of proteins that address current-day problems not faced during evolution. In contrast to traditional protein engineering efforts, which have focused on modifying naturally occurring proteins, we design new proteins from scratch to optimally solve the problem at hand. Increasingly, we develop and use deep learning methods to design amino acid sequences that are predicted to fold to desired structures and functions. We produce synthetic genes encoding these sequences and characterize them experimentally. In this talk, I will describe several recent advances in protein design.

SPEAKER

SESSION 2

LATEST TRENDS IN AI-ENABLED MEDICAL PRODUCTS

PRESENTATION 1

Tala Fakhouri
VP, AI & Digital Policy, Real-World Research, Parexel International

BIOGRAPHY

Dr. Tala H. Fakhouri is the Vice President Consulting, AI & Digital Policy, Real-World Research at Parexel. Previously, she was Associate Director for Data Science and AI at the FDA’s CDER, leading AI policy efforts in drug development. In her most recent FDA role, she led the development of the first draft CDER AI Guidance, established the CDER AI Council, and contributed to real-world evidence and digital health technologies policies. Dr. Fakhouri also served as Senior Health Scientist and Chief Statistician for CDC’s NHANES, focusing on epidemiologic and statistical issues. Her career includes roles as CDC Epidemic Intelligence Service Officer and deputy lead for health surveys at ICF International. She has authored numerous government reports and peer-reviewed publications. Dr. Fakhouri holds a PhD in Oncological Sciences from the University of Utah, an MPH from Johns Hopkins, and completed a postdoctoral fellowship at Harvard University. She earned her BSc in Medical Technology from Jordan University of Science and Technology.

TOPIC

Latest AI Technologies and Regulatory Trends in Pharmaceutical Field

PRESENTATION SUMMARY

The presentation will address recent trends in AI-enabled technology use across the drug product lifecycle and will provide updates on regulatory trends related to AI use, with a focus on FDA and EMA.

SPEAKER

SESSION 2

LATEST TRENDS IN AI-ENABLED MEDICAL PRODUCTS

PRESENTATION 2

Minkyung Baek
Assistant Professor, Seoul National University

BIOGRAPHY

Minkyung Baek is an Assistant Professor at the Department of Biological Sciences at Seoul National University. Her research focuses on developing artificial intelligence methods for predicting the structure and interactions of biomolecules, such as proteins and nucleic acids. She is a main developer of RoseTTAFold and has contributed to advancing AI-driven approaches for protein folding, design, and drug discovery. Her lab integrates structural biology, computational modeling, and deep learning to understand life at the molecular level.

TOPIC

Opportunities and Challenges of AI-Driven Protein Structure Prediction in Drug Development

PRESENTATION SUMMARY

Artificial intelligence (AI) has dramatically advanced the field of protein structure prediction, achieving near-experimental accuracy for many soluble proteins and expanding our ability to characterize previously inaccessible targets. These advances have begun to reshape drug development, particularly in the context of biologics discovery and protein engineering, where accurate structural models enable rational design and optimization of therapeutic candidates. AI-driven methods have also opened the door to protein design, allowing the creation of novel binders, enzymes, and vaccine antigens with unprecedented precision.

However, significant challenges remain before these technologies can be fully integrated into drug development pipelines. Current models struggle to account for protein dynamics, conformational heterogeneity, and protein–ligand interactions with sufficient accuracy, particularly in the context of small-molecule drug discovery. Moreover, the reliable modeling of multi-protein assemblies, membrane-bound targets, and nucleic acid–binding proteins remains a major hurdle. In this talk, I will discuss where AI-based protein structure prediction has already made a measurable impact on drug development and protein therapeutics design, and where key limitations still persist. I will also highlight ongoing efforts to bridge these gaps, including multi-state modeling, AI-driven docking, and large-scale in silico screening approaches that could accelerate the development of next-generation therapeutics.

SPEAKER

SESSION 2

LATEST TRENDS IN AI-ENABLED MEDICAL PRODUCTS

PRESENTATION 3

Hwayoung Lee
Vice President, Lead of AI Business Transformation Unit, LG AI Research

BIOGRAPHY

Work Experience
2025 – Lead of AI Business Transformation Unit, LG AI Research
2022 – 2024 Lead of AI Business Development Unit, LG AI Research
2020 – 2021 Lead of AI Business Development Division, LG AI Research
2019 – 2020 Lead of AI Strategy Division, LG Sciencepark
2012 – 2019 Director of Business & Technology Strategy, LG Corporation
2007 – 2012 Product Manager, Mobile Communication Company, LG Electronics
2004 – 2007 Software Engineer, Central Technology Organization, LG Electronics

Role & Responsibility
Lead how to leverage AI to accelerate the transformation of entire businesses in LG affiliates
Look for business opportunities in terms of LG group business portfolio especially focusing on AI, Bio, and Clean Tech as new growth engines.

TOPIC

The Way to Leverage LG EXAONE to Make Clinical Trials Effective and Efficient

PRESENTATION SUMMARY

A growing number of drug candidates could be emerged in the near future by leveraging protein structure prediction or protein-protein interaction AI models. However, it is quite unfortunate that there seldom are impressive tools in clinical trials. LG AI Research has been developing a multi-modal AI model, which could understand pathology images and genes to stratify patients during clinical trials with Vanderbilt hospital and University of Pittsburgh Medical Center. LG would like to share the practical status of AI technology itself, what would be anticipated in the future, and what is required for better drug development.

SPEAKER

SESSION 2

LATEST TRENDS IN AI-ENABLED MEDICAL PRODUCTS

PRESENTATION 4

Bruce Church
Chief Mathematics Officer and EVP, Research and Early Development, Aitia

BIOGRAPHY

Bruce Church is responsible for AI algorithm development, developing innovative applications for Causal AI, and management of Aitia's technology stack. Bruce is a member of the founding team of Aitia and GNS Healthcare.
An expert in Causal AI, Statistical Physics, Machine Learning, Parallel Computing, and Causal Inference, Bruce is the principal inventor of the REFS platform. Bruce's original graduate training was in Theoretical and Computation Plasma Physics for applications to Fusion Energy. Post doctoral work focused on the Grand Challenge Protein Folding borrowing ideas from renormalization theory to better predict protein structure from sequence, developing global optimization methods for computational protein folding, the results of which have been published in several peer-reviewed journals. Bruce has served as the principal investigator on several major grants, including a $2.5 million award from the Department of Energy.
Balancing work in AI technology with sport, Bruce is an accomplished level-3 rugby coach and senior sports leader for over 30 years. Bruce coached Cornell Women's Rugby to 7 consecutive championships, was the founding head coach for the Northeast U23 team, head coached Boston Women's Rugby from 2003-2009, served as President of the Northeast Rugby Union and served on the Board of Directors for USA Rugby's national governing body from 2001-2006. He is currently the founding head coach of Mystic River Girls U19.

TOPIC

Gemini Digital Twins for Drug Discovery and Development

PRESENTATION SUMMARY

The amount of clinically curated multi-omic data is growing exponentially and its resolution is increasing by orders of magnitude. While traditional statistics can solve important classes of correlative questions such as risk stratification, the development of Causal AI provides the mathematical foundations for algorithms that learn deep and detailed biological mechanism directly from observational data. The computational complexity of these causal frameworks scales super exponentially with the number of observed variables so the exponential growth in cloud computing power is necessary but not sufficient for high resolution multi-omic Causal AI. Combining Bayesian causal network framework with Metropolis Monte Carlo sampling algorithms from statistical physics allows us to do Causal AI with sufficient resolution and scale to reverse engineer digital twin-mechanistic models of human diseases. These digital twins recover both known biology and as yet undiscovered interactions that can identify novel therapeutic targets and predictors of response. Digital twins have been developed with this approach for neurological disease including Alzheimer's, Parkinson's and Huntington's diseases and in oncology for blood and solid tumors. Here we will describe a findings from a digital twin for metastatic, castrate resistant prostate cancer.

SPEAKER

SESSION 2

LATEST TRENDS IN AI-ENABLED MEDICAL PRODUCTS

PRESENTATION 5

Pat Baird
Senior Regulatory Specialist, Philips

BIOGRAPHY

Pat Baird works at Philips as a Software Standards Specialist, with a focus on the use of AI in healthcare. Pat likes to think of his job as "Policy Engineering" – understanding the unmet needs (and frustrations) of regulators and developers, and developing standards, whitepapers, and training to meet those needs. Past roles have included software developer, engineering manager, project manager, lead engineer, and Director of Risk Management before getting involved in regulatory & standards. He co-chairs multiple committees related to artificial intelligence at AAMI, ISO, CTA, and AdvaMed, and is involved with other software committees regarding topics such as cloud services for a regulated environment, risk management, cybersecurity, and is a member of the IMDRF AI for Medical Devices committee; Pat also was one of the authors of the RAPS Software as a Medical Device book.

TOPIC

Latest Trends in AI-Enabled Medical Products – Product Examples and Standards Projects

PRESENTATION SUMMARY

AI/ML is a quickly evolving topic for many industries – including healthcare. This session will discuss some example applications of AI in healthcare and will discuss some of the standards that are being developed.

SPEAKER

SESSION 2

LATEST TRENDS IN AI-ENABLED MEDICAL PRODUCTS

PRESENTATION 6

Camille Vidal
Vice President of Regulatory Affairs, Digital, GE HealthCare

BIOGRAPHY

Dr. Camille Vidal is Vice President of Regulatory Affairs for Digital Products at GE HealthCare. Dr. Vidal brings deep technical and regulatory expertise to the evolving landscape of AI regulation for medical devices. In her day-to-day responsibility she collaborates with product managers, data scientists and global regulators to define regulatory pathways for AI-enabled medical devices. She is also involved in several regulatory policy initiatives. She leads the AdvaMed Imaging AI Committee and serves as a medical device industry member in several International Medical Device Regulator Forum working groups focused on Software and Artificial Intelligence.

SPEAKER

SESSION 2

LATEST TRENDS IN AI-ENABLED MEDICAL PRODUCTS

PRESENTATION 7

Woong Bae
CEO, Soombit.ai

BIOGRAPHY

Woong Bae, CEO of Soombit AI, advances radiology workflows with generative AI. Former Chief Healthcare Officer at KakaoBrain and R&D Head at VUNO, leading medical imaging and bio-signal AI.

TOPIC

Generative AI in Medicine: Trends, Evidence, and the SaMD Boundary

PRESENTATION SUMMARY

Overview of generative-AI medical products—from medical searching to image-analyzing SaMD—with evidence on efficacy and clinical errors; and raise the question of what defines the category of generative-AI–based SaMD.

SPEAKER

SESSION 3

AI REGULATORY FRAMEWORKS

PRESENTATION 1

Ib Alstrup

GxP IT Medicines Inspector, Danish Medicines Agency, Denmark

BIOGRAPHY

- Is a Medicines Inspector, GxP IT, with the Danish Medicines Agency since 2017.
  Leads the agency's inspection of pharmaceutical industry's use of IT systems across all GxP areas, and is a frequent speaker at conferences.
- Works across all GxP areas, focusing on the integrity of systems and data including the validation and safe operation of systems; and lately, the use of AI/ML in critical applications, for which he has proposed a set of questions in 2021.
- Has been a member of and contributor to a number of drafting groups writing guidelines for industry, including but not limited to the PIC/S Data Integrity Guideline, the OECD GLP guidelines on Data Integrity, Cloud Computing, and Security, the EMA Guideline on Computerised Systems in GCP, and currently, the EU and PIC/S GMP Chapter 4.
- Since 2019, he has chaired the drafting group and been the EMA rapporteur for the revision of the EU and PIC/S GMP Annex 11 on Computerised Systems and the new GMP Annex 22 on Artificial Intelligence.
- Is an electronic engineer (software) with over 30 years of experience in software design, test, quality assurance, auditing and inspection from within and outside the pharmaceutical industry.

SPEAKER

SESSION 3

AI REGULATORY FRAMEWORKS

PRESENTATION 2

Tracey Duffy

Head, Medical Devices and Product Quality Division, Therapeutic Goods Administration, Australia

BIOGRAPHY

Tracey Duffy is the First Assistant Secretary of the Medical Devices and Product Quality Division at the Therapeutic Goods Administration (TGA) in Australia. The TGA is Australia's national safety regulator for medicines, biologicals and medical devices. Her team is responsible for assessing, approving and monitoring medical devices. Tracey is a Management Committee (MC) member on the International Medical Devices Regulators Forum (IMDRF), she was the Chair of the IMDRF MC in 2022, Chair of the IMDRF Personalised Medical Devices Working Group and is the current Chair of the Medical Devices Single Audit Program (MDSAP). She has also held a number of senior positions in the Department of Health in Australia including for health technology assessment.

TOPIC

Regulatory Approaches to AI-based Medical Devices in Australia

PRESENTATION SUMMARY

This presentation will provide an overview of how medical devices that are AI or have AI incorporated are regulated in Australia. AI is regulated as part of the Software as a Medical Device Framework. The presentation will also share a recent review of regulation to assess whether the current regulatory framework is sufficient for emerging AI technologies.

SPEAKER

SESSION 3

AI REGULATORY FRAMEWORKS

PRESENTATION 3

Woei Jiuang Wong
Assistant Group Director, Health Sciences Authority

BIOGRAPHY

Ms Wong Woei Jiuang currently holds the position of Assistant Group Director at Singapore's Health Sciences Authority (HSA), where she heads the Medical Devices Cluster. Her portfolio encompasses the oversight of several critical branches, including Therapeutic Devices, Diagnostic Devices, Digital Health, and Quality System, Adverse Events and Compliance.
In her capacity as Assistant Group Director, Ms Wong spearheads the implementation of a comprehensive life-cycle approach to medical device regulation, encompassing both pre-market assessment and post-market surveillance. This systematic methodology ensures the maintenance of stringent standards for safety, quality and performance of medical devices within Singapore's healthcare ecosystem.
At the international level, Ms Wong serves as Singapore's representative to the International Medical Device Regulators Forum (IMDRF), where she contributes significantly to global harmonisation initiatives in medical device regulations. Her participation facilitates the alignment of Singapore's regulatory framework with international standards whilst ensuring responsiveness to local healthcare requirements.
In the ASEAN context, Ms Wong maintains a prominent position within the ASEAN Medical Device Committee (AMDC), where she advances regional regulatory convergence and enhances collaborative efforts among ASEAN member states in medical device regulation. This international cooperation is fundamental to facilitating trade whilst upholding rigorous standards for medical device safety and efficacy across Southeast Asia.
Her expertise has been particularly instrumental in developing and implementing regulatory frameworks for emerging technologies, with specific emphasis on the rapidly evolving domains of digital health and medical software.
Since 2023, Ms Wong has served as a member of the Strategic and Technical Advisory Group on Medical Devices (STAG MEDEV) for World Health Organization (WHO). She has made substantial contributions to global regulatory frameworks, notably through her involvement in the development of the World Health Organization's Global Regulatory Framework for Medical Devices and in vitro diagnostics. Furthermore, her expertise has been crucial in the formulation of the WHO Global Benchmarking Tool for medical devices, thereby strengthening international regulatory standards.

TOPIC

Singapore's Regulatory Landscape for AI in Medical Devices

PRESENTATION SUMMARY

Singapore's regulatory framework for AI-based medical devices is primarily overseen by the Health Sciences Authority (HSA). The framework adopts a risk-based approach, categorising AI medical devices into four classes (A to D) based on their potential risk level, with Class D representing the highest risk.
Key aspects include:
- Pre-market evaluation requirements vary by risk classification
- Post-market surveillance and vigilance reporting obligations
- Mandatory registration for Class B and above devices
- Special focus on software validation and clinical evidence requirements
- Requirements for continuous monitoring and performance updates

Singapore has also introduced the AI Verify toolkit, a voluntary framework to help companies assess their AI systems' performance and risks. HSA actively participates in international harmonisation efforts through the International Medical Device Regulators Forum (IMDRF) and maintains alignment with global standards while adapting them to local context.

SPEAKER

SESSION 3

AI REGULATORY FRAMEWORKS

PRESENTATION 4

Sameer Pujari
Lead AI, WHO HQ Geneva

BIOGRAPHY

Mr. Sameer Pujari led the development and negotiations with 194 countries on the WHO Global Strategy on Digital health and is currently leading all initiatives on AI for health at the Data, Digital Health, Analytics, and AI department of WHO. He is also the Vice chair – WHO and ITU Focus group on AI4 Health.
Sameer joined WHO headquarters in Geneva in Feb 2008. With WHO, he has worked extensively on Digital Health including mHealth, Big Data and AI and set up several digital global initiatives. He has provided in country support in over 75+ countries across all WHO regions of WHO & has provided oversight for work with several partners. He has contributed close to 100 publications, guidance and reports on digital health and AI and is a core digital enthusiast and has been coveted with the WHO DGs reward for excellence in 2016 and the Greenpeace Innovations Award in 2018 for his work.

TOPIC

AI Regulatory Frameworks WHO

PRESENTATION SUMMARY

I will present the Global Initiative on AI for health, the WHO guidance on Regulatory considerations for AI in health and the ongoing work of the WHO Expert group on regulatory frameworks.

SPEAKER

SESSION 3

AI REGULATORY FRAMEWORKS

PRESENTATION 5

ByungGwan Kim
Deputy Director, Medical Device Safety Bureau, Ministry of Food and Drug Safety

BIOGRAPHY

ByungGwan Kim is the deputy director of the Medical Device Safety Bureau of Ministry of Food and Drug Safety (MFDS), which is health authority of South Korea.
ByungGwan joined MFDS in 2011 and worked in the Medical Device Policy division for 8 years, and he then moved to the Regulatory Reform and Legal office for 4 years. Based on his extensive experiences, he returned to the Medical Device Policy division and has continued to contribute to the advancement of medical device regulation & policy in Korea.
Recently, he has been in charge of the Digital Medical Product Act in Korea, which will provide regulatory governance for digital medical products such as digital medical devices (SaMD, AI/ML-enabled medical devices), digital convergence pharmaceuticals, digital medical/health supporting products.

TOPIC

Regulatory Perspectives on AI/ML-based Medical Devices in Korea

PRESENTATION SUMMARY

This presentation introduces Korea's regulatory perspectives on AI/ML-based medical devices, highlighting current frameworks, approval cases, and future regulatory directions.

SPEAKER

SESSION 3

AI REGULATORY FRAMEWORKS

PRESENTATION 6

Mitsuru Yuba
Reviewer, Office of Software as a Medical Device, Pharmaceuticals and Medical Devices Agency, Japan

BIOGRAPHY

I'm working as a reviewer of Software as a Medical Device (SaMD) in Pharmaceuticals and Medical Device Agency (PMDA). I'm in charge of computer-aided diagnosis (CAD) that utilize AI technology and products that analyze the results of genetic testing and contributes to the prediction of drug efficacy and the determination of the optimal treatment strategy. I also have experience in reviewing medical devices used in the field of gastroenterology and urology, including robotic surgical devices and colon stents. In addition, I represent Japan as a member of the AI Working Group of the International Medical Device Regulatory Forum (IMDRF).
Previously, I was a research associate at Waseda University, where I studied AI-based medical device regulation and earned Ph.D. I continue to lecture to graduate students as a part-time lecturer at Waseda University and as a visiting associate professor at Hiroshima University.

TOPIC

Regulation and Review Points of AI-enabled Medical Devices in Japan

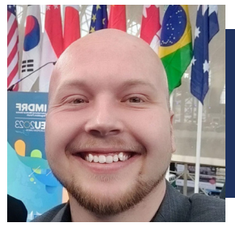
PRESENTATION SUMMARY

AI-enabled medical devices can address medical needs that could not be met in the past are now emerging. In such products, existing standards and evaluation methods may not be applicable, and the appropriateness of evaluation methods and achievement criteria must be examined on a product-by-product basis. During the approval review process, the effectiveness and safety of the product in clinical practice are discussed. However, there is actually little difference between traditional medical devices and those developed using AI in this regard. Rather, the differences in the characteristics of each product as a medical device have a greater impact on the evaluation system. In this presentation, I will outline regulation and the review points under the Pharmaceutical and Medical Device Act for AI-enabled medical devices.

SPEAKER

SESSION 3

AI REGULATORY FRAMEWORKS



PRESENTATION 7

Rolf Oberlin Hansen
Senior Advisor, Danish Medicines Agency

BIOGRAPHY

Rolf Oberlin Hansen is a Senior Advisor at The Danish Medicines Agency at the Unit for Medical Devices. He works for national implementation of software and AI related legislation and guidance, as he has been following the AI Act since its inception and provided sectorial input throughout the trilogue negotiations of it.
He is also heavily involved in these areas at both EU level, where he co-chairs the working group for developing AI Act guidance for the medical devices sector, and at International level as an active member of IMDRF working groups related to these topics, representing the EU.

TOPIC

Implications of the EU AI Act for Medical Devices

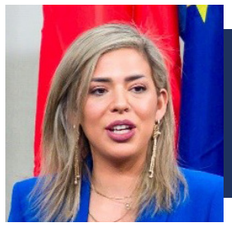
PRESENTATION SUMMARY

The EU has introduced new horizontal legislation, which impacts the already thoroughly regulated area of medical devices. Hear about how it impacts the sector, both from a manufacturer, governance and health institution perspective.

SPEAKER

SESSION 3

AI REGULATORY FRAMEWORKS



PRESENTATION 8

Nada Alkhayat
Policy Officer and International Lead, European Commission

BIOGRAPHY

Nada Alkhayat is a Policy Officer at the European Commission's unit for Medical Devices in the Directorate General for Health and Food Safety (DG SANTE).
In her team, Nada holds a horizontal role in the implementation of the medical devices regulations and chairs the Medical Device Coordination Groups on New Technologies, International Matters and Nomenclature. Her special interest areas include medical device software, Artificial intelligence and *in vitro* diagnostic medical devices.
Nada is a Management Committee member of the International Medical Device Regulators Forum and the EU representative to the Medical Device Single Audit Program.

TOPIC

The EU AI Act and Interplay with EU MDR/IVDR

SPEAKER

SESSION 4

AI TECHNOLOGIES AND REGULATORY STATUS

PRESENTATION 1

Alan Russell
Vice President, Research & Head, R&D Technology and Innovation, Amgen

BIOGRAPHY

Dr. Alan Russell (Ph.D., Imperial College) is Vice President of Research (Large Molecule Discovery & Data Science) and Head of R&D Technology & Innovation at Amgen Inc. He leads global teams focused on large molecule therapeutics and the application of data science across R&D. He champions talent development, safety, and innovation.
Previously, Alan was the Highmark Distinguished Career Professor at Carnegie Mellon University and Director of the Disruptive Health Technology Institute. From 2012 to 2016, he also served as Executive Vice President and Chief Innovation Officer at Allegheny Health Network. He founded Agentase LLC (acquired by FLIR/Teledyne), led BioHybrid Solutions as CEO, and chaired YouScript and Rheogene, both acquired. He was the founding director of the McGowan Institute for Regenerative Medicine at the University of Pittsburgh (2001–2011).
Alan's passion at the interface of regulation and science led to him serving on the FDA Science Board for a decade, chairing its major review of the Center for Devices and Radiologic Health. His research spans chemical and polymer synthesis, tissue engineering, and homeland defense, earning a US Army "Greatest Invention" award. He has founded four companies, delivered over 500 invited lectures, authored 250+ peer-reviewed papers (20,000+ citations), and holds numerous patents worldwide.

TOPIC

Rewriting Molecular Discovery: How Generative AI is Transforming Large Molecule Therapeutics

PRESENTATION SUMMARY

Artificial intelligence is not only accelerating drug discovery but also redefining it. In the era of biologics, where complexity and specificity are critical, traditional discovery approaches are struggling to keep pace with therapeutic demand. We will explore how generative biology, powered by deep learning and molecular design algorithms, is enabling the rapid, scalable, and precise creation of novel large molecule therapeutics. As drug discovery evolves to fully embrace multi specific targeting, AI is uniquely positioned to deliver molecules that are targeted to specific cells and tissues.
We will share how platforms like AMPLIFY are integrating AI across every phase of discovery, from target understanding and sequence generation to optimization and prediction, dramatically impacting timelines. Drawing on real-world applications, we will illustrate how AI-centric innovation is not just enhancing R&D productivity but also reshaping the fundamental science of drug development. This transformation aligns with global trends in AI and life sciences, offering insights into how public and private sectors can strategically invest in the AI-biotech intersection. Exquisitely targeted biologic therapeutics also create new opportunities for streamlined clinical trials and regulatory approvals.

SPEAKER

SESSION 4

AI TECHNOLOGIES AND REGULATORY STATUS

PRESENTATION 2

Namshik Han
Professor, University of Cambridge, Yonsei University
CTO & Co-founder, CardiaTec Bio Ltd

BIOGRAPHY

Highly qualified computational drug discovery scientist with core expertise in the areas of quantum information, artificial intelligence, computational biology, and multi-omics. The position of Head of AI Research at Milner Therapeutics of University of Cambridge would come with a remit to lead frontier AI and quantum technology applications for the analysis of complex multimodal biomedical datasets. This will be instrumental in the discovery of new disease pathways and mechanisms. In parallel to these roles at Milner, I also hold an appointment as a Faculty at the Cambridge Centre for AI in Medicine and an Affiliated Principal Investigator at the Cambridge Stem Cell Institute. In my academic contributions, I also serve as a Professor at the Department of Quantum Information, Yonsei University.
Further to this field of academic sciences, I am also engaged in linking the gap of academic research and its use in industrial use, more in-depth in the field of therapeutics and patient care. I eagerly look forward to the possibilities AI brings to revolutionize disease identification, discovery of drug targets, and indeed very wide scope in patient care, just to ensure our industrial collaborators are well-placed in these advances. It will allow me to develop creative computational strategies common to us both in our grand goal of new therapeutic solutions via the analysis of big data. In addition to these positions, I have also served the scientific function of founding Storm Therapeutics. I am also a co-founder of two high innovative AI drug discovery start-ups: Kure.ai Therapeutics in the field of developing immunotherapies with NK cells and CardiaTec Biosciences to bring forward therapeutics for revolutionary cardiological patients.

TOPIC

AI's Role in Novel Target Discovery - High Unmet Needs Areas Through Multi-Omics Interaction

PRESENTATION SUMMARY

Artificial intelligence and data-driven methodologies are reshaping drug discovery by enabling deeper understanding of disease mechanisms and more efficient identification of therapeutic targets. This talk will provide an accessible overview of how AI and multi-omics integration support target discovery and pathway analysis. I will share examples from our lab's research using machine learning and mathematical modeling to analyze complex datasets and uncover novel targets. The presentation will also highlight how these academic insights translate into real-world applications through my experience co-founding AI-driven biotech startups, Kure.ai and CardiaTec Bio. These examples will demonstrate the relevance of computational approaches in developing innovative therapies, particularly for cardiovascular diseases. The session will conclude with a Q&A and invite discussion on how AI technologies can drive precision and efficiency in the future of therapeutics across academic and industrial settings.

SPEAKER

SESSION 4

AI TECHNOLOGIES AND REGULATORY STATUS

PRESENTATION 3

Ehab Taqieddin

Senior Regulatory Group Director, International Regulatory Affairs APAC.
F. Hoffmann-La Roche

BIOGRAPHY

Ehab is a Senior Regulatory Group Director at F. Hoffmann-La Roche in Singapore, working with the International Regulatory Group. He has over 20 years of experience in various roles at companies including Biogen, Sanofi, and Shire HGT (now Takeda). A pharmacist by training with an M.Sc. in Drug Delivery and Biomedical Sciences, he currently focuses on setting regulatory strategies for international markets, including areas for acceleration and the use of innovation in the pharmaceutical field.

TOPIC

AI Applications in Pharmaceutical Manufacturing

PRESENTATION SUMMARY

This presentation will share current trends and opportunities for the use of AI in the pharmaceutical manufacturing field. It will cover examples and discuss some regulatory aspects for consideration.

SPEAKER

SESSION 4

AI TECHNOLOGIES AND REGULATORY STATUS

PRESENTATION 4

Dean Ho

Provost's Chair Professor, Institute Director, and Head of Department of Biomedical Engineering, National University of Singapore

BIOGRAPHY

Professor Dean Ho is Provost's Chair Professor, Director of The N.1 Institute for Health, Director of The Institute for Digital Medicine (WisDM) and Head of the Department of Biomedical Engineering at the National University of Singapore.
Prof Ho and collaborators successfully developed and validated CURATE.AI, which develops digital twins to personalise treatment. He co-led the first CURATE.AI clinical trials, which have resulted in life-saving outcomes.
In October of 2024, Prof. Ho and team launched DELTA, a first-in-kind human trial - with Prof. Ho as the test subject. This N-of-1 protocol harnesses a combination of AI, fasting, fitness, and food to optimise metabolic health, monitored using an array of digital health platforms. This unprecedented study will culminate in a digital twin of Prof Ho to hyper-personalise his cardiometabolic health protocol. Learnings from DELTA will be used to design population-scale healthspan trials.
Prof Ho is an elected member of the US National Academy of Inventors, American Association for the Advancement of Science, American Institute for Medical and Biological Engineering, and Royal Society of Chemistry. He has appeared on the National Geographic Channel Program "Known Universe," and his discoveries have been featured on CNN, The Economist, Forbes, Washington Post, NPR and other international news outlets. Prof Ho is Co-Chair of the World Health Organization AI for Health Working Group for Regulatory Considerations.

TOPIC

Digital Longevity Medicine

PRESENTATION SUMMARY

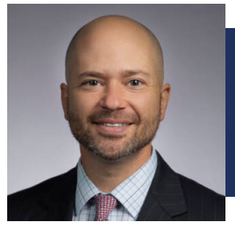
In 2024, Prof. Dean Ho and team launched DELTA, a first-in-kind human trial - with Prof. Dean Ho as the test subject. This N-of-1 protocol harnesses a combination of AI, digital medicine, fasting, fitness, and food to optimise metabolic health, monitored using an array of digital health platforms. Built from an unprecedented dataset, this study will culminate in a digital twin of Dean to hyper-personalise his cardiometabolic health protocol. Outcomes from this trial will create data collection frameworks to power population-scale healthspan optimisation and design regimens that do *not* require sustained digital monitoring to impact even larger communities.
Prof. Ho will share his trial experiences, actionable learnings, and broadly-applicable opportunities to re-imagine population health.

SPEAKER

SESSION 4

AI TECHNOLOGIES AND REGULATORY STATUS

PRESENTATION 5



Sam Halabi
Professor, Georgetown University

BIOGRAPHY

Sam Halabi, JD, MPhil is the Bette Jacobs Endowed Chair of Health Management and Policy at Georgetown University Medical Center and the Director of the Center for Transformational Health Law at the O'Neill Institute for National and Global Health Law. He served as the 2018 Fulbright Canada Research Chair in Health Law, Policy, and Ethics, and he is a member of the World Health Organization's Working Group on Regulatory Approaches to AI and Health where he leads its training workstream. His work is published in JAMA, the Lancet, the New York Times, and the New England Journal of Medicine, and his research on the law of companies and corporations has been cited by both state and federal courts in the U.S. Before earning his J.D. from Harvard Law School, Professor Halabi was awarded a British Marshall scholarship to study in the United Kingdom where he earned an M.Phil in International Relations from the University of Oxford (St. Antony's College). During the 2003-04 academic year, he served as a Rotary International Ambassadorial Scholar at the American University of Beirut.

TOPIC

Developing AI Knowledge and Training Tools for Regulators

PRESENTATION SUMMARY

For the past year, a working group convened by the World Health Organization has developed legal mapping, model laws, training tools, and implementation guidance to address the numerous regulatory complexities arising from the burgeoning use of AI applications at the clinical and public health interfaces. This presentation focuses on the approach and findings of the WHO's training workstream of its broader working group on Regulatory Considerations for AI and Health.

SPEAKER

SESSION 4

AI TECHNOLOGIES AND REGULATORY STATUS

PRESENTATION 6

Claudia Seitz
Professor, Faculty of Law, Private University in the Principality of Liechtenstein (UFL)

BIOGRAPHY

Prof. Dr. Claudia Seitz is a Professor of Public Law, European Law, International Law, and Life Sciences Law, with a particular focus on the legal regulation of life sciences and emerging technologies. She studied law in Freiburg, Basel, and Strasbourg, and trained at the European Court of Justice in Luxembourg following her First State Examination.
With over 25 years of experience in legal practice, she has worked as an attorney in private practice, in-house counsel for an international life sciences company, and as legal expert for European, UN and other international organizations. She earned her doctorate (Dr. iur.) from the University of Basel in 2001 and an M.A. from King's College London in 2009. From 2014 to 2019, she served as Assistant Professor at the University of Basel and co-founded the Center for Life Sciences Law.
Her habilitation thesis [Health and the State] was completed in 2022. In 2023, she obtained a second master's degree in Law and AI from BSC Brussels. The same year, she was appointed Full Professor at the UFL. She is also Visiting Professor at the University of Gent and BINUS University (Jakarta, 2023), and Lecturer in Basel and Bonn. She is a frequent speaker at international conferences and has authored several books and over 100 legal publications.

TOPIC

From Static Law to Adaptive Governance – Regulating Medical AI at the Speed of Innovation to Ensure Legal Certainty, Risk Control and Fundamental Rights

PRESENTATION SUMMARY

The rapid development and integration of AI systems in medicine presents fundamental and new challenges for traditional legal systems and regulatory frameworks. Static legal instruments often lag behind technological innovation, resulting in regulatory uncertainty, insufficient risk governance, and inadequate protection of fundamental rights. As innovation accelerates, legal frameworks must evolve to ensure legal certainty, effective risk control, and democratic legitimacy. This presentation explores adaptive governance approaches in public law that address the evolving nature of medical AI technologies while safeguarding core legal principles. It discusses how dynamic, forward-looking, proportionate, and transparent regulation can enable innovation, while maintaining public trust and rights protection. In light of the structural mismatch between innovation cycles and legal responsiveness, the presentation outlines key strategies for building resilient and future-oriented regulatory frameworks. Drawing on legal theory and comparative practice, the presentation identifies foundational legal principles for the trustworthy and responsible use of AI in medicine.

SPEAKER

SESSION 4

AI TECHNOLOGIES AND REGULATORY STATUS

PRESENTATION 7

Jiho Bang
Managing Director, Intelligence & Information Business Division, Korea Testing Certification Institute

BIOGRAPHY

July 2001 – August 2014: Senior Researcher, Korea Internet & Security Agency (KISA)
September 2014 – Present (July 2025): Head of Intelligence & Information Business Division, Korea Testing Certification Institute (KTC)

TOPIC

Cybersecurity for AI-based Digital Medical Devices

PRESENTATION SUMMARY

This presentation will review recent trends in the cybersecurity of digital medical devices both globally and within Korea. It will also introduce the regulatory frameworks and ongoing research activities related to the cybersecurity of AI-based digital medical devices in Korea. In particular, the research activities currently being conducted in Korea will be highlighted, focusing on the development of SBOM authoring tools, an integrated risk management system based on SBOM, and an AI Red Team testing framework.

MODERATOR

SESSION 1

Kidong Park
Medical Officer, Division of Health Systems & Services,
World Health Organization (WHO)

BIOGRAPHY

Dr Kidong Park is the Director of the Division Data, Strategy and Innovation in the WHO Regional Office for the Western Pacific. Dr Park has more than 30 years of extensive experience in the broad are global public health. His international career in public health spans from technical work on communicable disease control, strategic planning and evaluation to a high-level leadership role at three level of WHO. Before joining WHO in 2006, Dr Park served his home country for more than 12 years at various position in the Ministry of Health and Welfare and the Korea Centers for Disease Control & Prevention. Before joining the Government, Dr Park participated in a WHO-funded District Health System demonstration project in Yonchon County, Republic of Korea from 1988 to 1991.
Dr Park is a medical doctor and earned master's and Ph D degree in medicine specialized in health policy and medicine from Seoul National University College of Medicine. He is married with two daughters.

SESSION 1&2

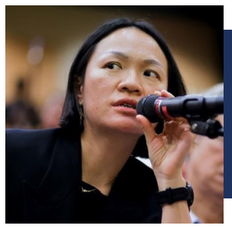
Jong Chul Ye
Professor, Graduate School of Artificial Intelligence (AI), KAIST

BIOGRAPHY

Jong Chul Ye is a Professor at the Graduate School of AI of Korea Advanced Institute of Science and Technology (KAIST), Korea. He received his B.Sc. and M.Sc. degrees from Seoul National University, Korea, and his PhD from Purdue University. Before joining KAIST, he worked at Philips Research and GE Global Research in New York. He has served as an associate editor of IEEE Trans. on Image Processing, IEEE Computational Imaging, IEEE Trans. on Medical Imaging and a Senior Editor of IEEE Signal Processing and an editorial board member for Magnetic Resonance in Medicine. He is an IEEE Fellow, was the Chair of IEEE SPS Computational Imaging TC, and IEEE EMBS Distinguished Lecturer. He is the Fellow of the Korean Academy of Science and Technology, and National Academy of Medicine in Korea, and was the President of the Korean Society for Artificial Intelligence in Medicine. He received various awards including Merck Fellow Award, and Choi Suk-Jung Award- one of the most prestigious awards for mathematicians in Korea. His research interest is in generative AI for healthcare and computer vision.

MODERATOR

SESSION 2



Mengji Chen
Medical Officer, Division of Health Systems & Services,
World Health Organization (WHO)

BIOGRAPHY

Ms. Mengji Chen is the technical lead for Research, Ethics and Innovation in the WHO Regional office for Western Pacific. Her current work is focused on providing support to Member States in implementing the Regional Health Innovation Strategy and strengthening Member States' capacity in research for health.
Over the past 11 years, Mengji has worked extensively on health innovation, data analytics, community engagement in diverse settings in the United States and India. Before joining WHO, Ms. Chen co-founded a predictive data analytics startup and held leadership positions in digital health startups in China.
Ms. Chen has a master's degree in health science from Brandeis University and bachelor's degree in Journalism and Communications from Tsinghua University.

SESSION 3

Hye-won Roh
Director General, Medical Device Evaluation Department,
Ministry of Food and Drug Safety, South Korea

BIOGRAPHY

The primary task of the department focuses on the in-depth review of medical devices to ensure their safety and effectiveness, and to ultimately provide the public with access to qualified medical devices.
She started her career at the MFDS in 1997 and has served in a number of positions, and has gained medical, scientific, and national health policy experience through involvement in various areas, including scientific review, research, medical device evaluation, QMS inspection, standards development, IVD regulations, GCP inspection, and innovative medical device policy and regulations. She has also contributed to global harmonization efforts at the IMDRF as an MFDS representative, as well as a Management Committee (MC) member since 2024.

MODERATOR

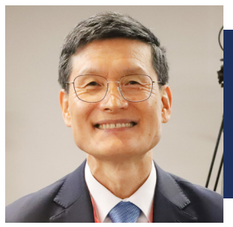
SESSION 4

Junhee Pyo
Ph.D Vice Chief, Convergence AI Institute for Drug Discovery,
Korea Pharmaceutical and Bio-pharmaceutical Manufacturers Association

BIOGRAPHY

Junhee Pyo, Ph.D Vice Chief, Convergence AI Institute for Drug Discovery, Korea Pharmaceutical and Bio-pharmaceutical Manufacturers Association; Adjunct Professor, Graduate School of Convergence Science and Technology, Seoul National University. Formerly at D5 Tx, Roche, IQVIA, and Tufts Medical Center, Dr. Pyo leads Data Science & AI drug discovery initiatives and holds patents in biomarker prediction.

SESSION 4



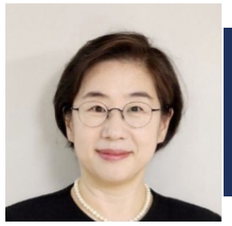
Jinho Shin
Medical Officer, Division of Health Systems & Services, World Health Organization (WHO)

BIOGRAPHY

Dr Jinho Shin is a Medical Officer for Regulatory Systems Strengthening within the Essential Medicines and Health Technologies unit at the WHO Regional Office for the Western Pacific in Manila.
Since joining WHO in 2003, Dr Shin has focused on developing global standards for vaccines and biologicals, strengthening national regulatory systems, and improving health equity and public health protection by supporting Member States.
Prior to WHO, he served as a Senior Scientific Officer at Korea's Ministry of Food and Drug Safety, starting in 2000 a year after earning his PhD from the University of Minnesota.

MODERATOR

SESSION 5



Jeewon Joung
Director, Pharmaceutical and Medical Device Research Department,
National Institute of Food and Drug Safety, Ministry of Food and Drug Safety

BIOGRAPHY

Dr. Jeewon Joung began her carrier as a quality reviewer from 1993 in the Biotechnology division in KFDA (Former MFDS), Republic of Korea. Since then, she had more than 30 years of experience of review and approval of biological products. She received her PhD in biotechnology from the Ewha Women's University in 2002.
After becoming review management director in 2015, she was responsible for assessment of quality, safety and efficacy of biotech products including biosimilar, recombinant products and cell/gene therapy products during IND and NDA process. She also has many experiences in establishment of biological and biosimilar guidelines in Korea. In 2007 and 2008, she worked at WHO Immunization, Vaccine Biologicals department as a Scientist. At there, she was responsible officer for development of WHO Biosimilar Guidelines and still she is a drafting group member of that guideline. Based on those experiences, she has been playing key roles in many international activities such as International Pharmaceutical Regulators Program (IPRP) Biosimilar Working Group (BWG), WHO Biological Standardization Program, and APEC Harmonization Center (AHC) to build up regulatory harmonization among global countries. From 2024, she has taken the office of Pharmaceutical and Medical device Research department Director NIFDS/MFDS Republic of Korea. Based on 32 years of review and international collaborative experiences, she exerts herself in growing and advancing the regulatory science of cutting-edge area in the medicinal products.

SIDE EVENT

International Forum on Medical Device Regulations 2025 : EU MDR & MDSAP Compliance and Market Access Strategies

Date : Sept. 11(Thu.) / Venue : INSPIRE RESORT Mountain Hall

Host NIDS 한국의료기기안전정보원 National Institute of Medical Device Safety Information · KMDIA 사단법인 한국의료기기산업협회 Korea Medical Devices Industry Association **Sponser** 식품의약품안전처 Ministry of Food and Drug Safety

Time	Program	Speakers
09:25 - 09:30	Welcome and Opening Remarks	**Namhee Lee,** Director General, Medical Device Safety Bureau of MFDS
Session 1: MDR Forum		
09:30 - 10:00	Regulatory Updates on EU MDR/IVDR	**Nada Alkhayat,** Policy Officer Medical Devices Directorate-General for Health and Food Safety European Commission
10:00 - 10:30	Navigating the EU Medical Device Market under MDR: Key Opportunities and Challenge	**Diana Kanecka,** Director of International Affairs, MedTech Europe and Co-chair of GMTA
10:30 - 11:00	MDR Compliance Strategies from AI-based SaMD Manufacturer's Perspective	**Sung-gyun Park,** Chief Product Officer and Co-founder of Lunit
11:10 -12:00	MDR Certification of AI-based Medical Devices: A Notified Body Perspective on Conformity, Risk, and Clinical Assurance - From Algorithmic Design to Clinical Acceptability and Cybersecurity Assurance	**Alireza Sheikhi Nasrabadi,** Lead Auditor and Decision Maker at SZUTEST GmbH
Session 2: MDSAP Forum		
14:00 - 14:30	Regulatory Updates on MDSAP	**Tracey Duffy,** First Assistant Secretary Medical Devices and Product Quality Division Therapeutic Goods Administration, Chair of MDSAP
14:30 - 15:00	Benefits of MDSAP Certification, Strategies for Accelerated Regulatory Approval, and Distribution Channels & Partnership Strategies in the Australian Medical Device Market	**Jasjit Baveja,** Director of Regulatory and Industry Policy at MTAA
15:00 - 15:30	Benefits of MDSAP Certification, Strategies for Accelerated Regulatory Approval, and Timeline & Risk Management for Entering the Canadian Medical Device Market	**Mia Spiegelman,** Vice President of Regulatory and Quality and Environmental Affairs at MedTech Canada
15:40 - 16:10	MDSAP Certification Journey of a Robotic Surgical System Manufacturer: Challenges, Learnings, and Market Expansion Outcomes	**Jung-eun Park,** Director of Regulatory Affairs at CUREXO
16:10 - 16:15	Closing Remarks	**Jeong-Rim Lee,** President of NIDS

부대행사

2025 국제 의료기기 규제 포럼 : EU MDR 및 MDSAP 규제 준수와 시장 진입 전략

일시 : 9월 11일(목) 장소 : 인스파이어리조트 마운틴홀

주최 NIDS 한국의료기기안전정보원 National Institute of Medical Device Safety Information · KMDIA 사단법인 한국의료기기산업협회 Korea Medical Devices Industry Association **후원** 식품의약품안전처 Ministry of Food and Drug Safety

시간	프로그램	연사
09:25 - 09:30	환영사 및 개회사	**이남희,** 식품의약품안전처 의료기기안전국장
Session 1: MDR Forum		
09:30 - 10:00	EU MDR/IVDR 규제 최신 동향	**Nada Alkhayat,** 유럽연합 집행위원회 보건식품안전총국(DG SANTE) 의료기기 부서 정책 담당자
10:00 - 10:30	EU MDR 체계에서의 의료기기 시장 진출 전략: 주요 기회와 도전 과제	**Diana Kanecka,** 유럽 의료기기산업협회 (MedTech-Europe) 이사, 글로벌 의료기기 기술연합(GMTA) 공동 의장
10:30 - 11:00	AI 기반 의료소프트웨어(SaMD) 제조업체의 관점에서 본 MDR 대응 전략	**박승균,** 루닛 (Lunit) 공동 창업자, 최고 제품 책임자
11:10 -12:00	AI 기반 의료기기의 MDR 인증: 알고리즘 설계에서 임상 적용 및 사이버보안까지 — 적합성, 위험 관리, 임상적 유효성에 대한 인증기관의 관점	**Alireza Sheikhi Nasrabadi,** SZUTEST GmbH 선임심사원 및 인증 결정권자
Session 2: MDSAP Forum		
14:00 - 14:30	MDSAP 규제 최신 동향	**Tracey Duffy,** 호주의약품청(TGA) 의료기기 품질국 수석 차관보, MDSAP 의장
14:30 - 15:00	MDSAP 인증의 이점 및 신속한 규제 승인 전략, 그리고 호주 의료기기 시장의 유통 채널 및 파트너십 전략	**Jasjit Baveja,** 호주의료기기산업협회(MTAA) 규제 및 산업정책 이사
15:00 - 15:30	MDSAP 인증의 이점 및 신속한 규제 승인 전략, 그리고 캐나다 의료기기 시장 진출을 위한 일정 관리 및 리스크 관리	**Mia Spiegelman,** 캐나다의료기기산업협회(MedTech -Canada) 규제 및 품질담당 부사장
15:40 - 16:10	로봇수술시스템 의료기기 제조업체의 MDSAP 인증 여정: 도전과제, 배운점 그리고 시장 확장 결과	**박정은,** ㈜큐렉소 이사
16:10 - 16:15	맺는 말씀	**이정림,** 한국의료기기안전정보원장

MEMO

MEMO

인천광역시 Incheon Metropolitan City
인천관광공사 Incheon Tourism Organization

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