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Application of AI in Clinical Trials

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Meet the Speaker

Minseok Kim

Title: CBO(Chief Business Officer)

Organization: JNPMEDI Inc.

Education

M.S. in Graduate School of Information, Yonsei University (2004)

B.S. in Dept of Chemical Engineering, Yonsei University (2002)

Work experience

~ 2020 Director, Chong Kun Dang Holdings

~ 2018 Director, PwC Consulting

~ 2006 Senior Consultant, Samsung SDS Co., Ltd.



Agenda

1. AI in Clinical Trials
2. Use cases of AI Application
3. Challenges and Considerations




Intro

Application of AI in Clinical Trials

- Opening a New Horizon in Medical Innovation

 **You**

Please create 10 subtitles that match the title "Application of AI in Clinical Trials"

 **ChatGPT**

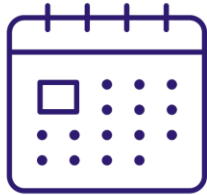
1. "AI Integration: Revolutionizing the Landscape of Clinical Trials"
2. "Enhancing Efficiency: The Strategic Application of AI in Clinical Trials"
3. "Innovative Insights: How AI Transforms Clinical Trial Dynamics"
4. "Optimizing Outcomes: The Role of AI in Precision Medicine Trials"
5. "Unveiling the Future: **Opening a New Horizon in Medical Innovation**"
6. "Data-Driven Trials: Unveiling the Power of AI in Research"
7. "Next-Gen Trial Management: AI's Impact on Clinical Research"
8. "Elevating Precision: Applications of AI in Clinical Trial Strategies"
9. "Strategic Innovations: AI's Influence on Healthcare Research"
10. "Navigating the Future: AI's Transformative Role in Clinical Trials"



1. AI in Clinical Trials

Digital Tech in Clinical Trials

- Developing new drugs takes a huge amount of time and money...



Bringing a drug to market typically takes

10 to 12 years

with several years apiece for R&D efforts and clinical trials.

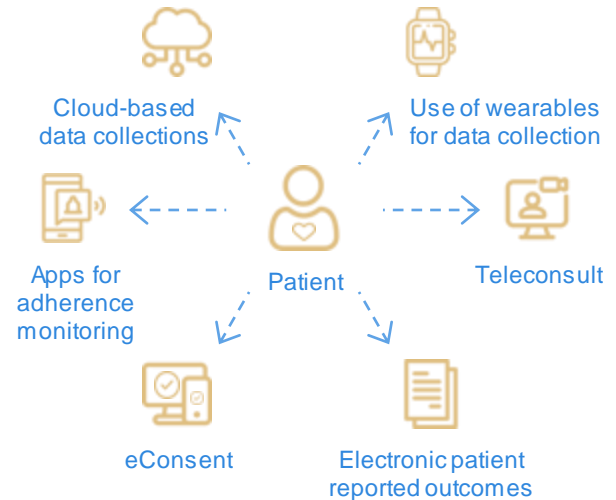
The mean estimated cost to bring a drug to market is

\$1.6 billion

Reference: Stamind



- The latest digital technologies are being introduced to **increase the efficiency of clinical trials**, which account for the largest portion



ChatGPT by OpenAI

- The most rapidly growing digital technology : **AI(Artificial Intelligence)**
- **ChatGPT**, a generative AI developed by OpenAI, stands out



- **Generative AI** refers to artificial intelligence that creates results according to the request when a person requests to create something through a specific input(prompt)

You
What is Generative AI?

ChatGPT
Generative AI refers to a class of artificial intelligence algorithms and models that are designed to generate new content, often in the form of images, text, or other types of data. These models are capable of learning patterns and structures from existing data and using that knowledge to create new, similar content.

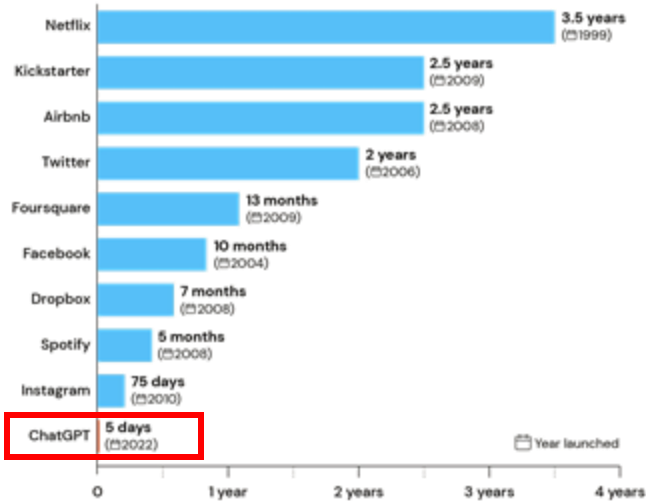
One prominent type of generative AI is Generative Adversarial Networks (GANs). GANs consist of two neural networks, a generator, and a discriminator, which are trained simultaneously through adversarial training. The generator creates new data instances, while the discriminator evaluates them for authenticity. This process continues until the generator produces content that is indistinguishable from real data.

ChatGPT by OpenAI

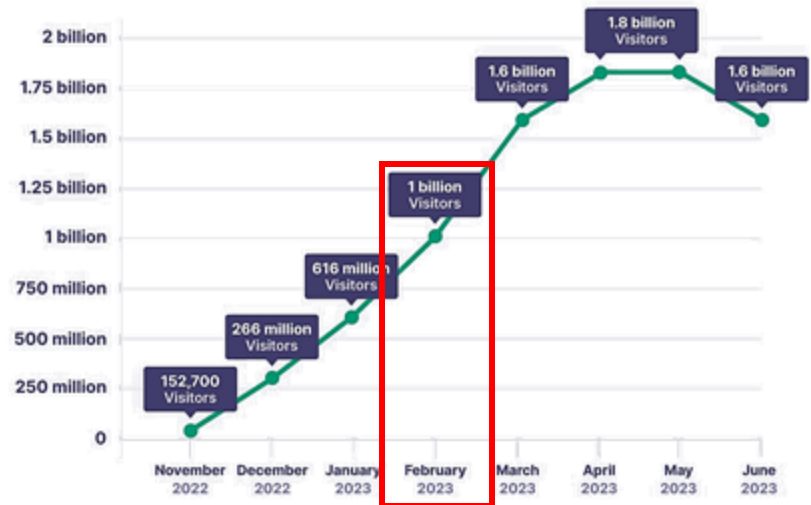
- The number of subscribers reached 1 million within 5 days of launch, and the number of monthly active users (MAU) exceeded 100 million within 2 months

CHATGPT STATISTICS

Time to reach 1 million users



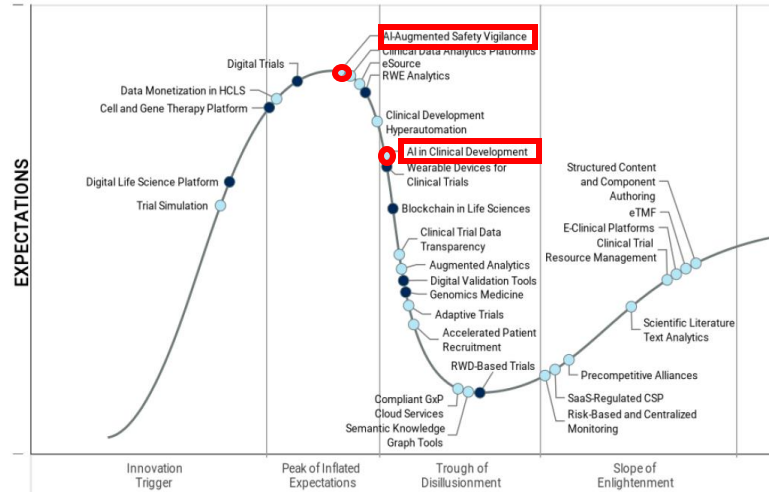
Change in ChatGPT website visits since launch



Hype Cycle for Life Science

- The sudden emergence of Peak of Inflated Expectations in the field of life sciences as well

Hype Cycle for Life Science Clinical Development, 2022



Hype Cycle for Life Science Clinical Development, 2023



Plateau will be reached: ○ <2 yrs. ● 2-5 yrs. ● 5-10 yrs. ▲ >10 yrs. ✖ Obsolete before plateau

Opportunities for AI in Clinical Trials

- Based on the strengths of AI, it is expected that it can be used throughout the clinical trial process area, including subject recruitment and consent, data capture, and safety confirmation

Area	Opportunities
Engagement & Recruitment	Multifaced engagement with potential participants likely to contribute informative data
Consent	Bidirectional, ongoing, informed consent process tailored to the participant in terms of delivery, language, cultural context, and understanding
Participant Management	Customized study procedures, ongoing engagement with complete follow-up
Data Capture and Curation	Comprehensive data set describing all health domains of interest for every participant
Outcomes and Safety Ascertainment	Completely captured clinical and patient-reported outcome trajectories
Data Analysis and Reporting	Automated reporting integrated with interpretation based on all information available globally



2. Use cases of AI Application

Application Overview

- Engagement & Recruitment - [Deep 6 AI](#)
- Consent - [GPTrial](#)
- Participant Management - [Nuance DAX](#)
- Data Capture and Curation - [Unlearn.AI](#)
- Outcomes and Safety Ascertainment - [illuminate IQ](#)
- Data Analysis and Reporting - [Owkin Connect](#)



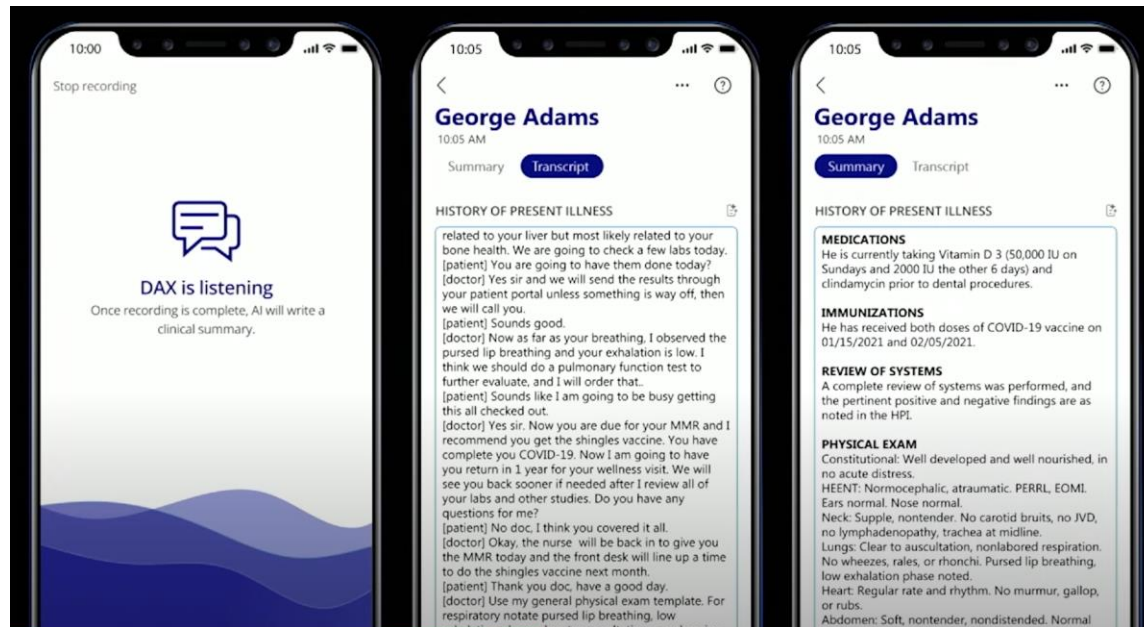
GPTrial

- Perform inquiry-based clinical trial information search using **GPT Companion technology on clinical trial open-source data(ClinicalTrials.gov)**
- Provides information by understanding user query sentences **based on LLM (Large Language Model)**

The screenshot displays the GPTrial web application interface. On the left is a sidebar with search filters: ClinicalTrials (Study Detail, Study Match, Study Match all), Specify what trials you are looking for (Condition or Disease: weight loss, Treatment/Intervention: ozempic, Location City: Example: Houston, Other terms: Example: Pfizer, Status: RECRUITING, Model: GPT), and a Find and Chat button. The main chat area shows two AI-generated responses. The first response lists four studies: 1. Study 1: Semaglutide, 1.34 mg/mL, Placebo; 2. Study 2: Semaglutide Injectable Product, Standard of care; 3. Study 3: Semaglutide Pen Injector [Ozempic], Very-low Calorie Diet; 4. Study 4: Semaglutide Pen Injector. The second response, triggered by the query "what is the inclusion criteria for study id NCT04854083", lists four criteria: 1. Age ≥ 18 years and < 65 years; 2. BMI: ≥ 27 kg/m2; 3. Type 2 Diabetes Mellitus (T2DM) with HbA1c ≥ 6.0% if on anti-diabetic medication or HbA1c ≥ 6.5% if non-medicated; 4. Participant is willing and able to give informed consent for participation in the study. A note below the criteria states: "Please note that these criteria are specific to this study. Other studies may have different inclusion criteria." At the bottom of the chat area is a text input field with a "Send" button and a "Clear Conversation" button.

Nuance DAX

- A clinical document creation automation app developed by Nuance, a Microsoft subsidiary, based on OpenAI's GPT-4 model
- Based on the conversation with the patient (Speech to Text), a **draft clinical record is automatically created** within seconds by organizing unnecessary content



1. Record
conversation



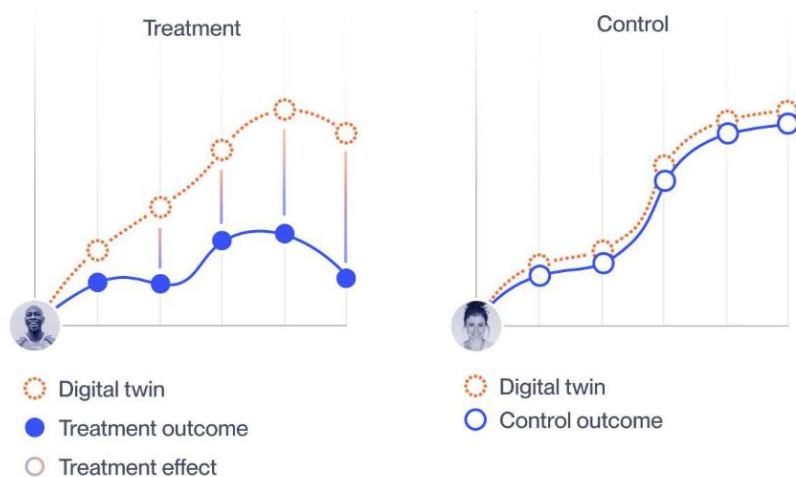
2. Write
Clinical Notes



3. Create a
Draft Clinical Record

Unlearn.AI

- **Design RCTs using AI models learned from large-scale data** (data on specific diseases, how the disease progresses through treatment, etc.)
- At the first visit, a **digital twin** that replicates the unique characteristics of each clinical trial subject is created through an AI model and health status is predicted over time
- Subjects are randomly assigned to a treatment group or control group, and the treatment effect is estimated by comparing the previously derived digital twin information with the clinical trial period



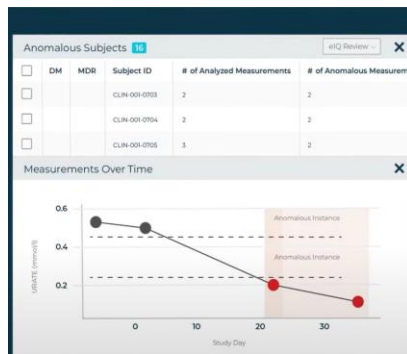
eIlluminate IQ

- Utilize AI to **detect abnormal data and automate the data review process** (AI-Enabled data review to ensure data integrity)
- Quickly analyze massive amounts of clinical trial data to detect errors, allowing researchers to focus on important data

Lab and Vitals Tests Containing Anomalies

Domain	Test Category	Test Type	Units	# of Analyzed Subjects
VS	VS	WEIGHT	kg	96
LB	HEMATOLOGY	MCH	pg	86
LB	CHEMISTRY	URATE	umol/L	86
LB	CHEMISTRY	GGT	U/L	86
VS	VS	RESP	breaths/min	117
LB	CHEMISTRY	ALT	U/L	86
LB	HEMATOLOGY	RBC	10 ¹² /L	86
LB	HEMATOLOGY	ALP	U/L	86
LB	HEMATOLOGY	NEUT	10 ⁹ /L	86
LB	HEMATOLOGY	PLAT	10 ⁹ /L	86
LB	HEMATOLOGY	WBC	10 ⁹ /L	86

Central Statistical Monitoring

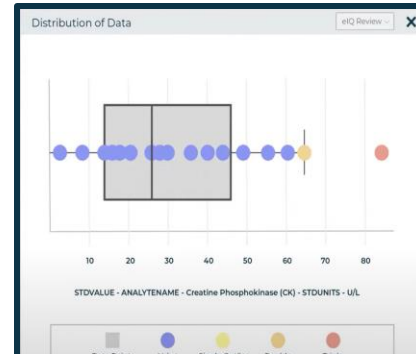


Anomalous Shift in Labs

AEs Containing Anomalies

AEDECOD	# of Subjects	# of Adverse Events	# of Anomalous AEs
Aphasia	1	1	1
Diarrhea	3	4	1
Hematuria	1	1	1
Hypertension	1	2	1
Hypotension	2	2	2
Influenza	0	0	0
Pyrexia	10	8	2
Syncope	1	1	1
Thrombocytopenia	8	10	4
Urinary Tract Infection	3	1	1
Wheezing	4	6	1

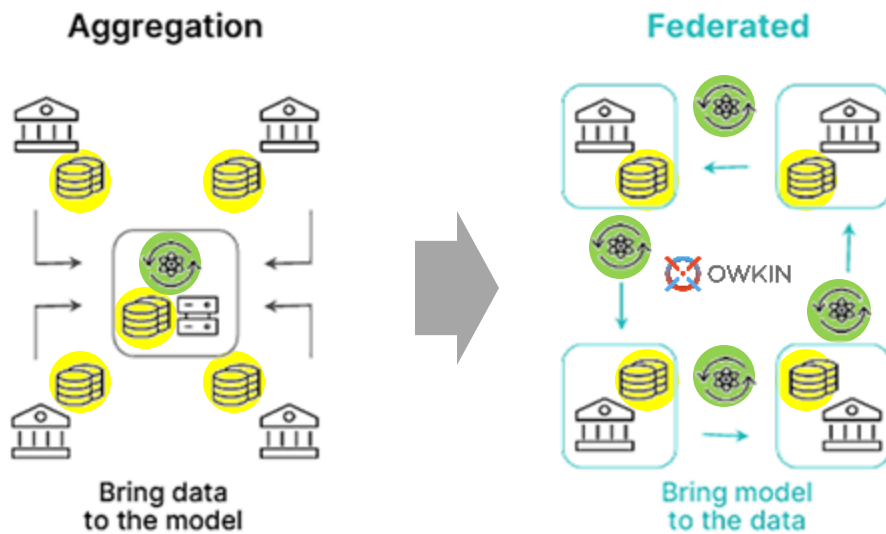
Anomalous Adverse Event Duration



Univariate Outlier Detection

Owkin Connect

- **Federated Learning software** that allows AI to be learned by multiple research institutes
- Machine learning technology that allows you to train models on multiple distributed servers **without the need to share sensitive data**
- Instead of sharing patient data from partner institutions, only AI algorithms learned with large amounts of data are used





3. Challenges and Considerations

Challenges to Overcome

- In May 2023, the World Health Organization(WHO) expressed its position that LLM(Large Language Model) in the medical field has various positive functions but requires strict verification and supervision.
- The reasons why WHO requires strict caution when using LLM in the medical field include **△ the possibility of bias and error in the learning data, △ the possibility of creating and disseminating false information and misuse, and △ the possibility of leakage of sensitive health-related information**
- In February 2023, Nature also mentioned the risks of generative AI content in the medical field, pointing out that problems arise due to the lack of accuracy of the generative model

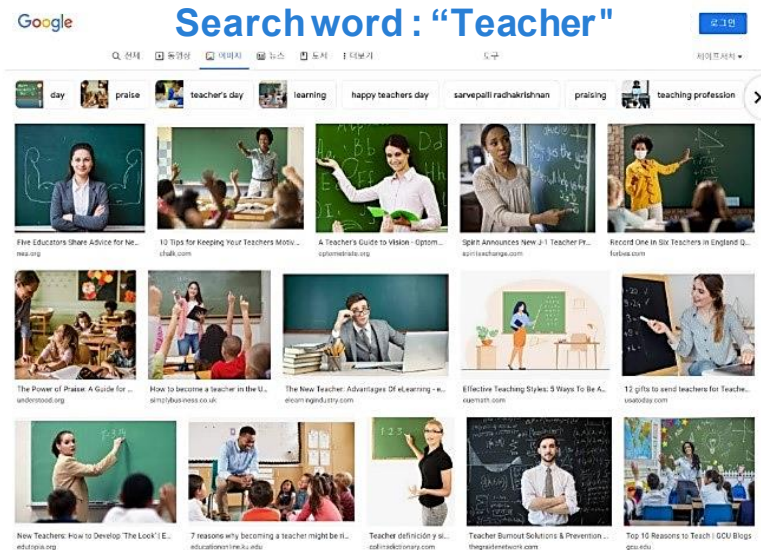
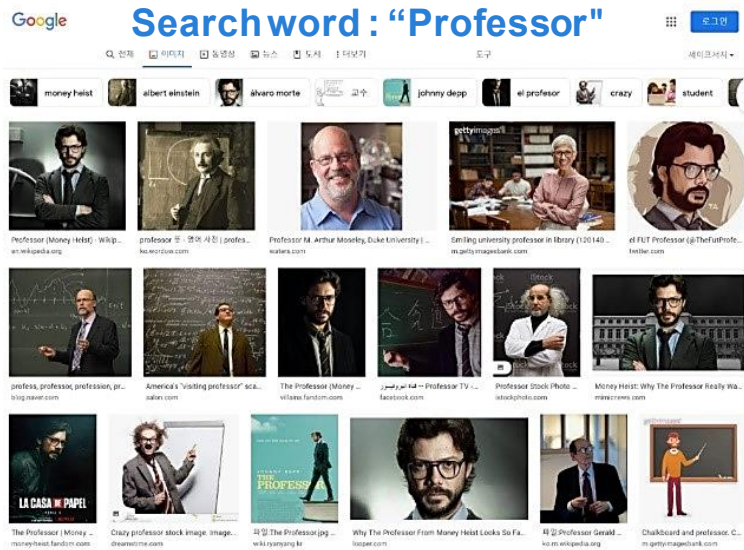


**World Health
Organization**

**nature
medicine**

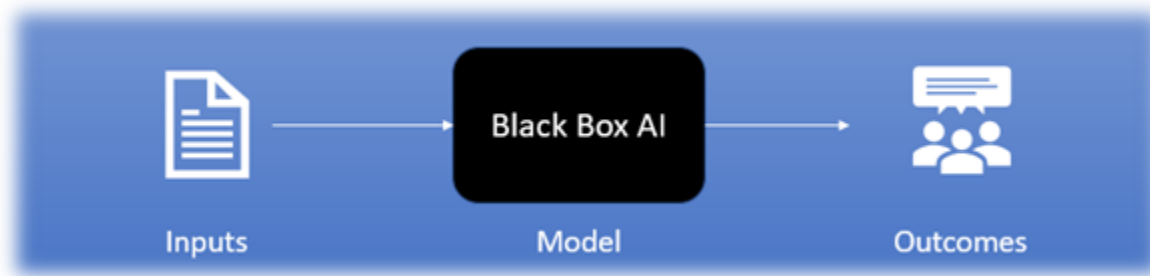
Challenge #1_Data Bias

- AI learned with biased data ultimately **reduces the reliability and safety of the model**
- Diagnose and correct problems in AI models with algorithms that measure AI bias, such as MS 'Fairlearn' and Google 'What-if Tool'



Challenge #2_Blackbox Model

- AI learns and finds patterns in vast amounts of data that cannot be compared to humans, but **there is no way to know what process led to such results**
- The process created by AI through hundreds of millions of parameters and artificial neural network (ANN) exceeds the scope of human understanding
- Before introducing and utilizing artificial intelligence in sensitive and important fields such as medicine, efforts are needed to utilize **at least some explainable AI(Explainable AI) models.**



Challenge #3_Privacy

- The data used for AI model training **includes confidential clinical trial information such as personal data and drug information**, and carries the risk of legal issues if information is leaked
- In March 23, Italy temporarily banned ChatGPT for using personal information in training data
- In July 23, the Personal Information Protection Commission imposed a fine on OpenAI for violating reporting obligations for leaking personal information of ChatGPT users but failing to report it to the country.



Regulatory Agency Response



“Goal of promoting equity when using AI/ML technologies by preventing and correcting discrimination”

- In May 23, a draft report on drug development using AI/ML was released
- Expressing concerns about favoring certain categories of people or using opaque algorithms
- To prevent risks such as bias and inaccuracy in AI algorithm training data, we **emphasize approaches to monitor and evaluate them.**



“Human-centered approach should lead the development and deployment of AI/ML technology”

- In July 23, draft opinion paper on AI utilization **emphasizing a human-centered approach was announced**
- Mentioned that related risks should be considered and systematically managed from the beginning of development to disposal.



Closing Remarks

- ✓ **The integration of AI technology** that goes beyond human limitations is expected to **open a new horizon in medical research and development**
- ✓ As the clinical stage is the process that takes the longest time and costs the most, **the development of AI solutions for efficient clinical trials** needs to be promoted and is expected to be used in a variety of areas
- ✓ Although there are concerns about the introduction of AI, it is becoming more important to **prepare countermeasures such as improving data quality, reducing bias, and related regulations and guidelines**
- ✓ **Collaboration between researchers, clinicians, and regulators** is essential to leverage the full potential of AI in the clinical trial space.



Thank You!

