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AI ethics and law in Healthcare

- Domestic and Foreign Regulation and Policy Trends in Healthcare Sector Using AI

2021 AI Ethics and Law

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I. The Concept and Status of Healthcare AI

▪ A trend of AI utilization in healthcare industry

• Definition, merits, and types of healthcare AI technologies

– **Definition:** Technology developed to use human-level intelligence to diagnose, predict, and treat diseases with personalized treatments

– **Merits:** (1) Rapid, accurate diagnosis and treatment, (2) Consistent individualized prediction and prevention of customized diseases, (3) Measurements without time and space constraints, medical treatment, etc.

– **Types**: See table on the right
[Source: GBSA(2018)]

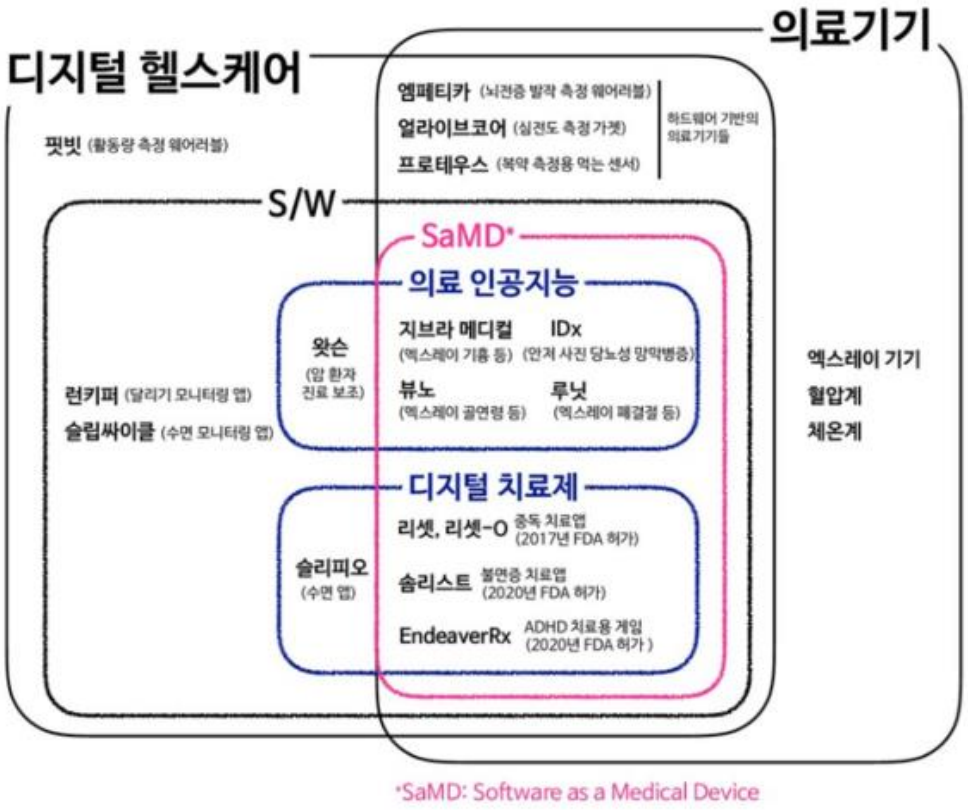
구 분	적 용 형 태	적 용 분 야
딥러닝	스스로 학습하는 능력을 이용해 대량의 의료 영상기록을 처리함으로써 의료진의 치료 결정에서의 불확실성 감소	진단영상, 헬스케어 IT
영상처리	대규모 의료영상을 빠르게 처리해 질환 형태, 음성양성 판단 등에 적용	
자연어 처리	진료 기록과 같은 긴 서술형 문자 묶음들을 해석할 수 있도록 변환	의료기기, 헬스케어 IT
음성인식	환자의 음성과 언어를 포착해 중요한 정보를 전자 기록함에 기록	
통계분석	대용량 환자의 의료데이터를 빠르게 조사하고, 분석하여 환자의 치료 결과를 예측 가능	의약품, 헬스케어 IT
빅데이터 분석	헬스케어 기관들이 보유한 방대한 환자 의료데이터를 처리하고 환자와 치료제공자들에게 맞춤형 치료를 제공	
예측 모델링	위험 질환 예측 등과 같은 진료 결과를 예측하는데 수학 모델 적용	
로보틱스	수술 과정의 정밀함과 정확도를 높여 질 높은 치료를 제공	의료기기, 헬스케어 IT
디지털 개인비서	환자의 상태를 알 수 있는 지표들을 지속적으로 모니터링하고 필요 상황에 간호사에게 알림을 줌으로써 골든타임 확보	
머신러닝	치료결과에 영향을 미치는 데이터를 기반으로 패턴 예측 및 분석	헬스케어 IT

자료 : 한국보건산업진흥원(2018).

Ⅰ. The Concept and Status of Healthcare AI

▪ A trend of AI utilization in healthcare industry

- Healthcare AI is classified as medical device (SaMD) artificial intelligence and non-medical device artificial intelligence
- The medical artificial intelligence in the right graph (Source: Yoonsupchoi.com)



I. The Concept and Status of Healthcare AI

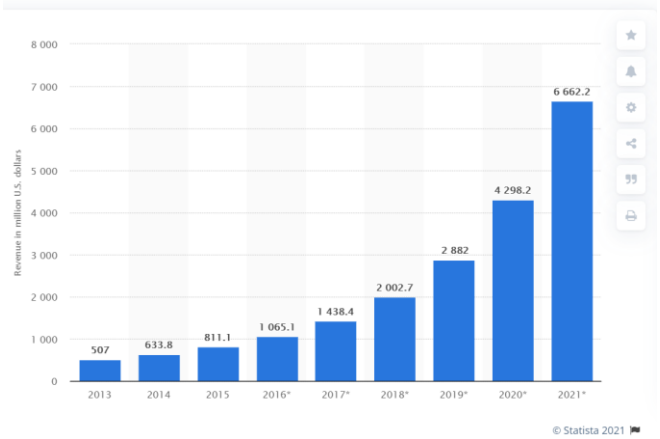
▪ A trend of AI utilization in healthcare industry

• Growth of AI Market in Healthcare Industry

– The global AI healthcare market is expected to grow from about **$ 500 million** in 2013 to about **$ 6.7 billion** in 2021(Source: Statista)

– In Korea, it is expected to grow from **$ 94 million** in 2017 to **$ 2 billion** in 2025.

(Source: Markets and market)



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I. The Concept and Status of Healthcare AI

▪ A trend of AI utilization in healthcare industry

• Healthcare data is key to AI use in the healthcare industry

– **Data Type 1:** (1) Genetic information, (2) Health information, (3) Electronic medical records (medical information), (4) National Health Information (Source: SAMJONG KPMG (2018)]

– **Data Type 2**: Big data, paper data, etc. created by processing primary data

헬스케어 데이터의 종류 및 동향

구분	관리자	설명	동향
개인유전 정보	유전체 분석 서비스 업체	▪ 1인당 약 30억 개의 유전자 염기서열 정보 존재 ▪ 개체 간 약 0.1%의 차이 존재	▪ 유전체 분석비용 2000년대 초 9,000만 달러였으나, 2017년 100 달러로 하락 ▪ 2016년 기준 79,110건의 유전체 정보 분석 프로젝트 완료
개인건강 정보	개인	▪ 스마트폰 앱 또는 IoT 디바이스로 수집되는 Life-log* (예: 수면패턴 등)	▪ 다양한 디바이스와 서비스 증가
전자의무 기록	의료기관	▪ 환자의 모든 진료정보를 전산화하여 입력, 저장, 관리하는 형태(예: 진단정보, 처방자료, 처장결과 등)	▪ 전세계적으로 디지털화 가속
국민건강 정보	공공기관	▪ 자격 및 보험료, 진료내역, 건강검진결과, 의료급여 등	▪ 한국의 경우 단일 건강보험체계를 갖고 있다는 특수성으로 인해 국민의 건강관련 빅데이터가 공공기관에 집중

Source:과학기술정책연구원, KDB 산업기술리서치센터 자료, 삼정KPMG 경제연구원 재구성
Note: Life-log는 개인의 일상생활 활동에 관한 모든 데이터를 의미함

I. 개관

▪ A Case Study on AI in Healthcare Industry

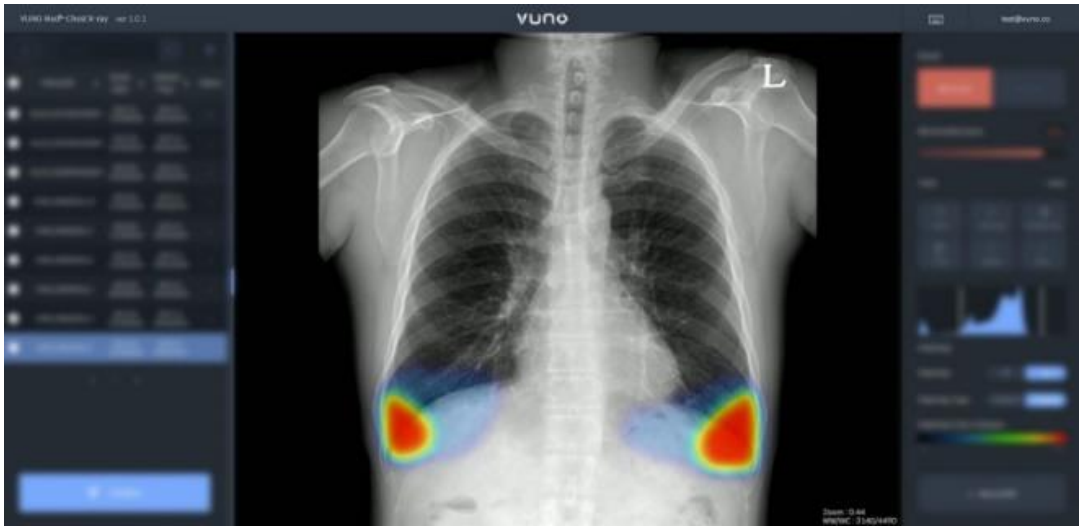
- **The application of healthcare AI technology depends on the utilization field of data**
  - Hospital Solutions / Personal Health Care / Insurance / New Drug Development [Soruce: Lee et al.(2020)]
  - Prevention / Diagnosis / Treatment / Management [Source: Park(2019)]

		Data Collection (Protection of personal data)	Data Utilization (License of medical devices)		Data management (Liability for Illegal activities)
		Prevention	Diagnosis	Treatment	Management
Type 1	Genetic Information		Hospital Solution (Ex.VUNO)		
	Health Information				Personal Health Management (Ex.PRIVY)
	EMR				
	National Health Information	Insurance (Ex. BARO)			
Type 2				Development of New Drug (Ex. Cyntekabio)	

I. 개관

▪ A Case Study on AI in Healthcare Industry

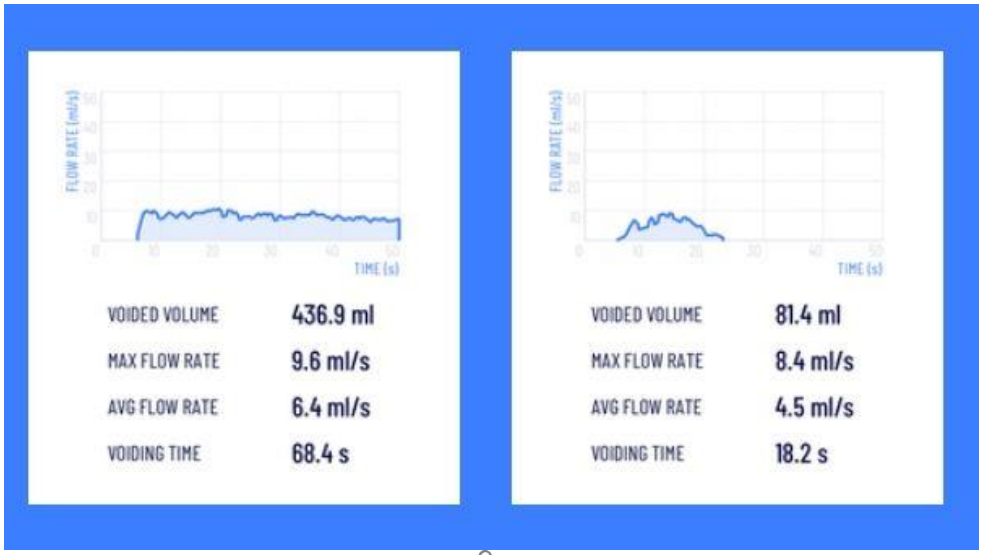
- **(Case 1) VUNO**
  - AI to help early screening for lung cancer by analyzing chest CT
  - Solutions that let patients know eight hours before cardiac arrest



I. 개관

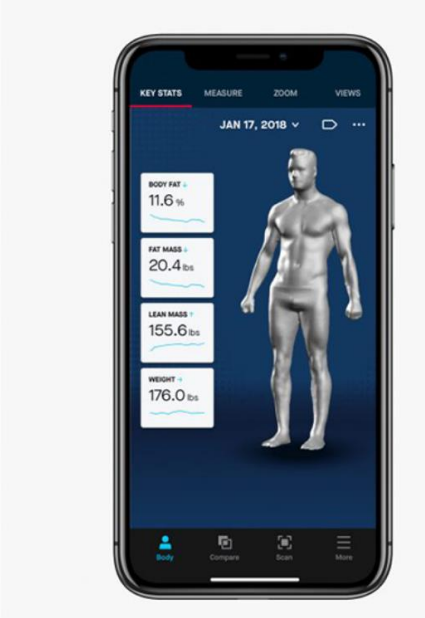
▪ A Case Study on AI in Healthcare Industry

- **(Case 2) PRIVY**
  - Smartphone AI automatically records and analyzes sound data that occurs when a patient's urine touches water
  - Apps that graph the amount, maximum rapidity, and time of urination to manage chronic diseases such as prostate hyperplasia as well as help doctors diagnose and treat urological diseases



▪ A Case Study on AI in Healthcare Industry

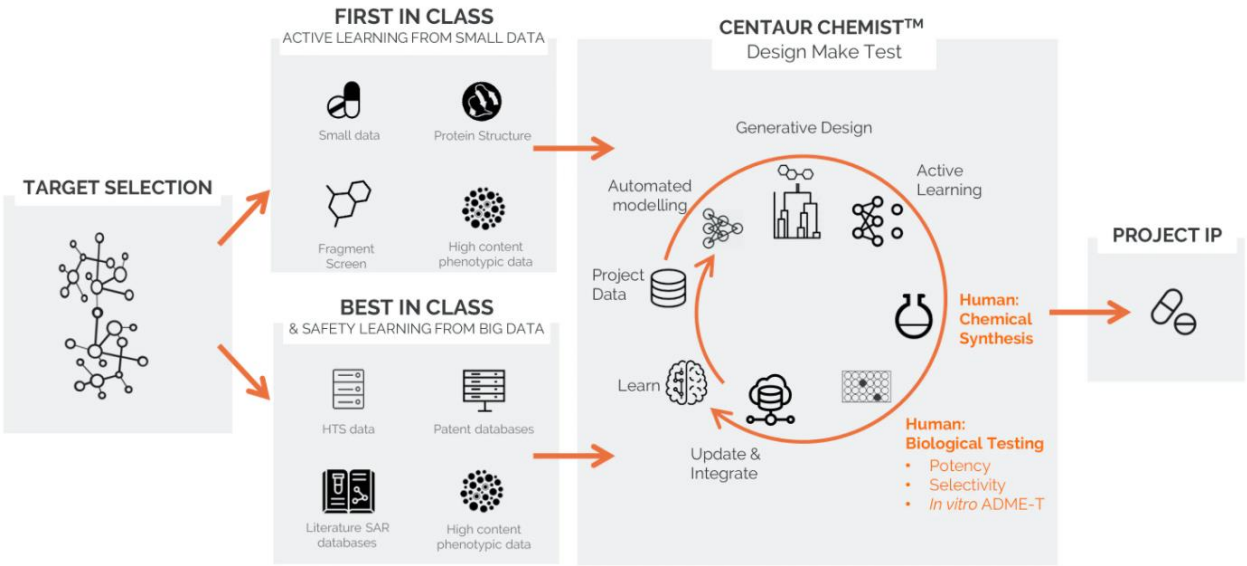
- **(Case 3) Naked 3D Fitness Tracker**
  - AI measuring weight, visceral fat and muscle mass for 25 seconds through products made of large mirrors and turntable sets
  - Applications that help users set goals and change their body shape



▪ A Case Study on AI in Healthcare Industry

- **(Case 4) Exscientia**

  – After setting the target, the long time it takes to enter the clinical trial is shortened to a short period of time by utilizing AI modeling



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II. Domestic and Foreign Healthcare AI Regulation and Policy Trends

▪ 1. Healthcare data utilization

- **Domestic status**

  – (2020. 2.) The Personal Information Protection Act provides a special provision for the processing of pseudonym information.

  – (2020. 9.) As a follow-up measure, the Guidelines for Utilizing Health and Medical Data are prepared.

  – The 'health information' which is a pseudonym can be used for statistical writing and research purposes without the consent of the individual

II. Domestic and Foreign Healthcare AI Regulation and Policy Trends

▪ 1. Healthcare data utilization

- **Domestic status**
  - However, there are limitations in developing personalized healthcare and healthcare services
  - Processing of Pseudonymous Data is greatly burdened, and there is a restriction on real-time updates of personal health information

II. Domestic and Foreign Healthcare AI Regulation and Policy Trends

▪ 1. Healthcare data utilization

- **Domestic status**
  - Furthermore, personal information is currently regulated separately under the Medical Law
  - In the case of medical information, it is difficult to use it because the third party transmission request is not allowed.
  - An amendment is proposed to establish a right to transmit the records of patients treated at medical devices to other institutions.

II. Domestic and Foreign Healthcare AI Regulation and Policy Trends

▪ 1. Healthcare data utilization

- **Domestic status**

  – When conducting 'human object research' under the THE BIOETHICS AND SAFETY ACT, written consent and research plan should be prepared to the information subject

  – -It must be deliberated by the Institutional Board (IRB; Institutional Review Board)

  – (2020. 9.) The Ministry of Health and Welfare has a clear interpretation that the 'pseudonym information' in the Personal Information Protection Act is included in the 'anonymization' of the THE BIOETHICS AND SAFETY ACT.

II. Domestic and Foreign Healthcare AI Regulation and Policy Trends

▪ 1. Healthcare data utilization

• Foreign status

– US

- Information that is not identified according to the non-identification guidelines(HIPAA(Health Insurance Portability and Accountability Act) can be freely used without personal consent.
- Common Rule was revised in 2017 to simplify the creation of personal consent forms.
- Multi-agency research allows one IRB deliberation to pass.

– EU

- (2020. 5.) The rights of the subjects of information are strengthened, and even in the case of health information, the same pre-consent system is required as standard, and the right to request direct transmission is recognized. In GDPR
- The Right to data portability of the EU GDPR Art20

II. Domestic and Foreign Healthcare AI Regulation and Policy Trends

▪ 1. Healthcare data utilization

• Foreign status

– **Finland**

- (2013) By introducing a comprehensive consent system through the implementation of the Biobank Act, No additional consent need when using the collected genetic information for research purposes.
- (2019. 3.) the law about the medical care and social security data secondary utilization is passed. 'the Fin data' which is data permit institution is set up
- The regulation was improved so that data linkage, collection and provision would not cause redundant and excessive administrative burden, and the obligation to provide information was imposed.

– **Australia and Japan**

- Utilize the Opt-out System by Act revision etc.

II. Domestic and Foreign Healthcare AI Regulation and Policy Trends

▪ 2. The License Process of AI Medical Devices Using Healthcare Data

- **Domestic status**

  – Medical device AI takes hundreds of days to get on the market

    ▪ Ministry of Food and Drug Safety -> National Evidence-based healthcare Collaborating Agency, NECA -> Health Insurance Review & Assessment Service

  – The government enacts the Medical Device Industry Act, utilizes integrated examination, and creates guidelines.

    ▪ However, there are many situations where the National Health Insurance is not applied and it is practically difficult.

II. Domestic and Foreign Healthcare AI Regulation and Policy Trends

▪ 2. The License Process of AI Medical Devices Using Healthcare Data

- **Foreign status**

  – **US**

    ▪ If included in the Medicare Convergence of Innovative Technology (MCIT), the automatic insurance payment system will apply.

  – **Germany**

    ▪ The Digital Healthcare Act, which was enacted in 2019, That is, if the developed digital medical app empirically lacks evidence related to medical effects, a test period is provided for 12 months.

II. Domestic and Foreign Healthcare AI Regulation and Policy Trends

▪ 3. Responsibility of AI Healthcare using healthcare data

- **Domestic status**

  – The Government will review the amendment of the Civil Act by 2023 to allow the right to remedy damages and crimes incurred by AI.

    ▪ This is because it is difficult to recognize the right of AI in the current civil law and it is difficult to include criminal acts in the existing criminal law system.

    ▪ But there is criticism of AI, which is just an object of rights.

  – There is a view that policy decisions should be made based on the socialization of AI surgery risk.

II. Domestic and Foreign Healthcare AI Regulation and Policy Trends

▪ 3. Responsibility of AI Healthcare using healthcare data

• Foreign Status

– (2020. 10.) EU advised that AI should be applied to the AI law if it causes damage to life, health, etc, or if it is directly linked to a 'verifiable economic loss'.

Civil liability regime for artificial intelligence European Parliament resolution of 20 October 2020 with recommendations to the Commission on a civil liability regime for artificial intelligence (2020/2014(INL))

Different liability rules for different risks

(16) **This Regulation should cover harm or damage to life, health, physical integrity, property and significant immaterial harm that results in a verifiable economic loss above a threshold**, harmonised in Union liability law, that balances the access to justice of affected persons with the interests of other involved persons. The Commission should re-evaluate and align the thresholds for damages in Union law.

...

This Regulation should set out a significantly lower ceiling for compensation than that provided for in the Product Liability Directive, as this Regulation only refers to the harm or damage of a single person resulting from a single operation of an AI-system, while the former refers to a number of products or even a product line with the same defect.

II. Domestic and Foreign Healthcare AI Regulation and Policy Trends

▪ 3. Responsibility of AI Use Using Healthcare Data

• Foreign Status

– The aim is to ensure that makes regime of liability for strict damages by AI healthcare

Civil liability regime for artificial intelligence European Parliament resolution of 20 October 2020 with recommendations to the Commission on a civil liability regime for artificial intelligence (2020/2014(INL))

Different liability rules for different risks

14. Recognises that **the type of AI-system the operator is exercising control over is a determining factor regarding liability**; notes that an AI-system that entails an inherent high risk and acts autonomously potentially endangers the general public to a much higher degree; considers that, based on the legal challenges that AI-systems pose to the existing civil liability regimes**, it seems reasonable to set up a common strict liability regime for those high-risk autonomous AI-systems**; underlines that such a risk-based approach, that might encompass several levels of risk, **should be based on clear criteria and an appropriate definition of high risk and provide for legal certainty;**

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III. Implication

1 The Need for Integrated Healthcare Data Management

- **Integration of healthcare data management centered on institutions like Finland**

Need	• Pseudonymous Data system has limitation in the practical use of healthcare services by causing financial and time problems of developing service. • Medical information is not allowed to request third party transmission(Right to data portability).
Solution	• A centralized institution like Finland should be created to integrate anonymous or pseudonymized healthcare data, for increasing the possibility of practicality enhanced and that of the danger lowered.

III. Implication

2 Extension of licenses for medical devices using healthcare data

- **The Requirement for Discussion on the 'Preliminary' Insurance List by Referring to Overseas Cases in Germany and others**

Need	• Many AI medical devices are difficult to be included in the national health insurance system.
Solution	• Even if there is not enough evidence related to the empirical medical effect, it is necessary to discuss the issue of being included in the National Health Insurance support like Germany and having a test period of several months.

III. Implication

3 Responsibility of AI using Healthcare Data for Illegal Actions

- **Reference to EU Cases to the Need of Guideline Discussions from Medical Device AI**

Need	• In the situation where healthcare AI can affect the health and medical system of consumers, there is no guideline for illegal act liability, and it is necessary to rely on court decision.
Solution	• It is necessary to increase the predictability in the healthcare AI industry and the medical field by establishing guidelines related to the most dangerous AI, such as the EU guidelines.

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Thank you!

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