

디지털헬스케어를 통한 생활 속 혈당관리: 환자, 의사, 제약바이오

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K-제약바이오 포럼



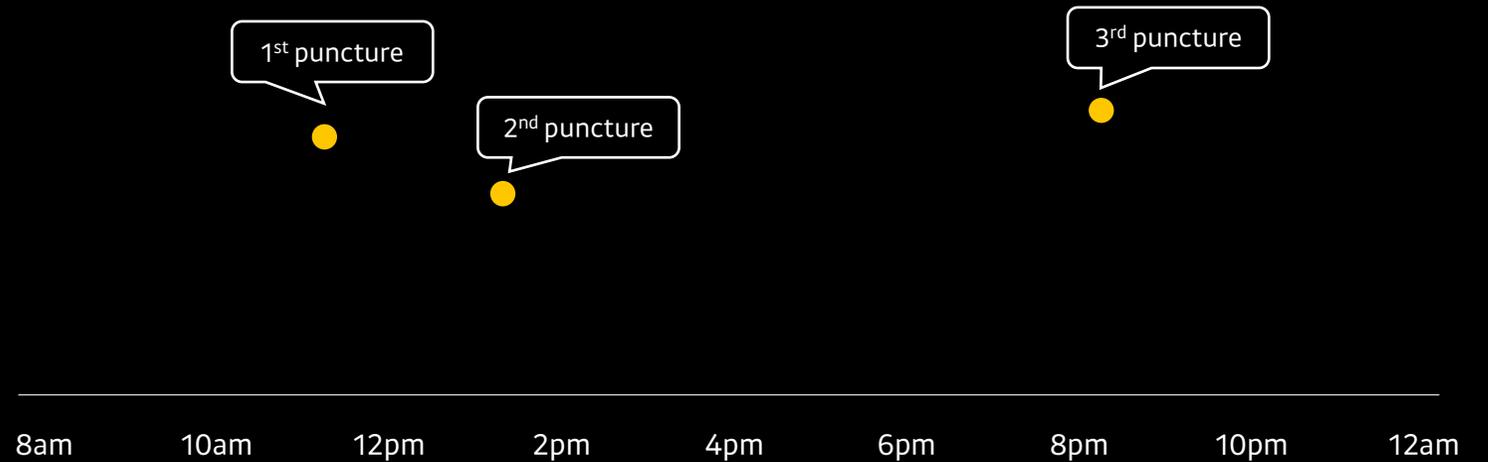
Conventional Blood Glucose Monitoring(BGM)

BGM



Inconvenient and painful
measuring method

“Not enough information to visualize the blood glucose level trend with a **snap-shot view**”



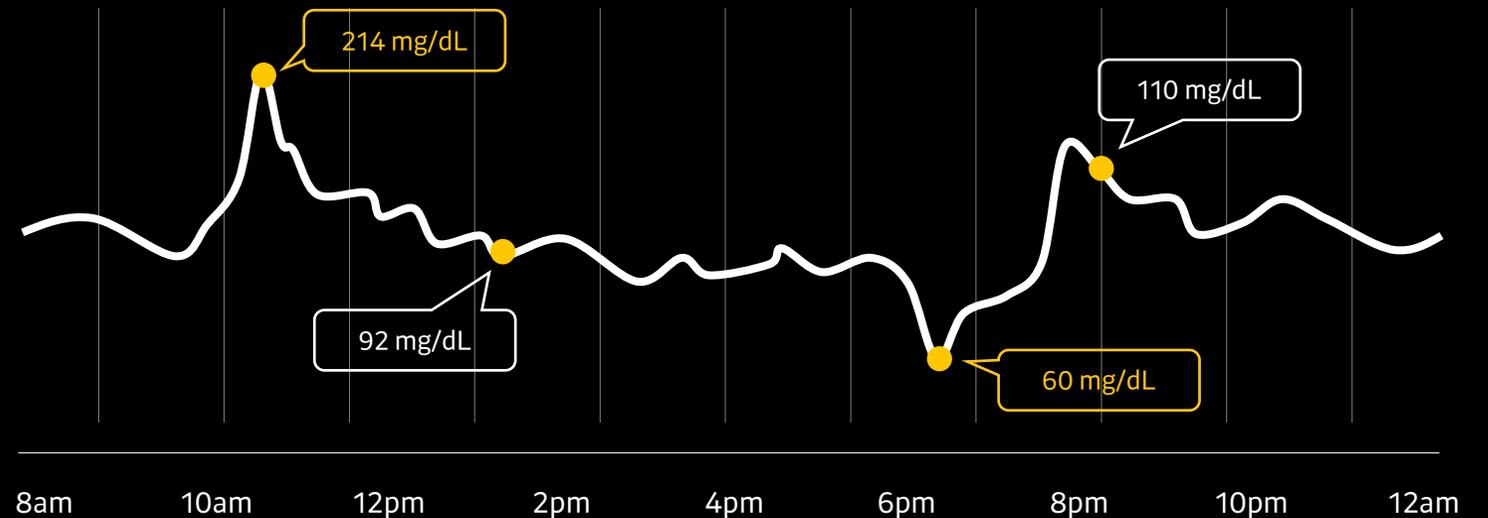
Introduction of continuous glucose monitoring(CGM)

CGM



A single sensor can monitor in real time up to 15 days

“Continuously monitors changes in blood glucose level in real time throughout the day”



CGM recommendation guideline by countries

Republic of Korea



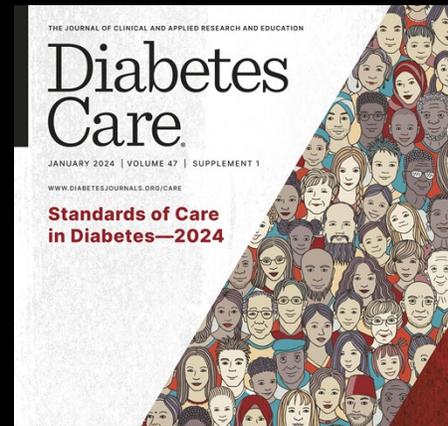
Blood sugar monitoring and evaluation: With the widespread recommendation of **CGM** as a method for blood sugar control monitoring, indicators of **CGM** devices are included as additional metrics for blood sugar control goals.

Pregnant women with T1DM: Recommend to use **CGM** to **reduce the hypoglycemia, and to enhance the pregnant outcome**

Hypoglycemia management: Recommend to use **CGM** to **monitor frequent hypoglycemic events**. Also, to evaluate hypoglycemia unawareness for patients who are unaware of such event.

Glycemic control for inpatients and severe illness: Glycated hemoglobin level of less than 8% is recommended for patients scheduled for surgery. The timing and frequency of blood glucose monitoring should be individualized based on dietary methods and insulin administration. **CGM devices may be applied to prevent hypoglycemia during hospitalization.**

USA



Guideline recommendation on CGM devices

- CGM should be offered for diabetes management in adults with diabetes on **multiple daily injection (MDI) or continuous subcutaneous insulin infusion (CSII)**
- CGM should be offered for diabetes management in adults with **diabetes on basal insulin**
- CGM should be offered for diabetes management in youth with **type 1 diabetes**
- CGM should be offered for diabetes management in youth with **type 2 diabetes**

The language was added to **“Continuous Glucose Monitoring in Pregnancy” to encourage individualization for CGM use in pregnant individuals with type 2 diabetes or gestational diabetes mellitus (GDM)**. Language was also added to clarify the international consensus on time in range for pregnant individuals with type 2 diabetes or GDM

Japan



Short-term or intermittent use

- Patients are changing their treatment (adding or changing drugs, increasing or decreasing drug doses, etc.),
- Patients **need educational guidance for lifestyle improvement** by helping them understand how diet, exercise, etc. affect blood glucose fluctuation

Patients who may be considered for continued use

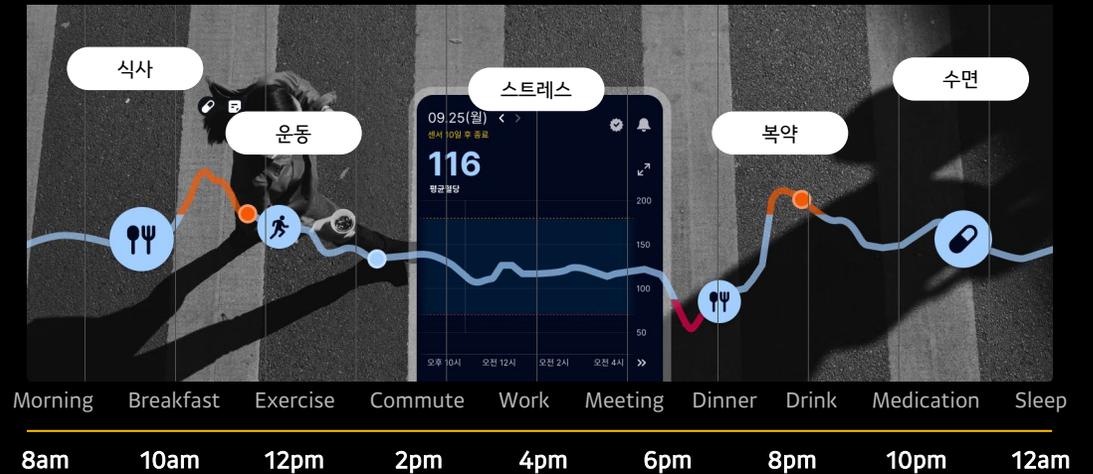
- Patients with large blood glucose fluctuation ranges even with insulin therapy
- Patients with unstable blood glucose due to irregular lifestyle
- Patients whose blood glucose levels are easily fluctuate due to high activity levels such as sports and physical work

pasta

“Invisible to visible”

Through easy-to-comprehend visualization of real-time glucose levels, users are able to self-recognize the impact of everyday routine (meals, exercise, sleep cycle, stress, and more).

We assist further by combining insights and suggesting what users themselves can implement into one's lifestyle modification, ultimately supporting the maintenance of optimal glucose levels.



Partnership

dexcom

Global Leading CGM Device Company

SDK-based real-time data integration and CGM distribution agreements



Global Top Pharma Company

Link insulin pens to manage doses and inject insulin based on blood glucose

i.sens

Korea's Sole CGM Device Company

SDK-based real-time data integration and CGM distribution agreements



Korea Top Food and Bio Company

Personalized diets designs based on personal blood glucose data



글로벌 헬스케어 규제기관 RWE 도입현황

의료분야의 RWE
규제확산

아시아

대한민국



2019. 의료기기 RWE 적용 가이드라인 발간
2020. 의약품 안전관리 계획: RWE 도입 발표
2023. 데이터베이스 연구 설계시 고려사항 다수 발표



중국



2019. RWE Guidance(s) 발간
2020. "Hainan Boao Lecheng International Medical Tourism Pilot Zone" 생성
2020. Use of real-world data to support clinical evaluation for medical devices draft guideline 발행

일본



2014. RWE 약물역학연구 가이드라인 발표
2018. 의약품 시판 후 조사 MID-NET 시행
2021. RWE 실사용데이터 규제 활용 촉진 지침
2021. Basic Principles on Registry Utilization for Applications

북미 / 유럽

미국



2016. 21st Century Cures ACT: RWE 활용 시작
2019. RWE 기반 인허가 가이드라인 발표
2020. RCT-DUPLICATE 시행
2023. RWE 연구 및 데이터 사용 지침 다수 발표



캐나다



2018. RWE Research Project 시행
2019. RWE 기반 규제 및 활용 권고안 발표

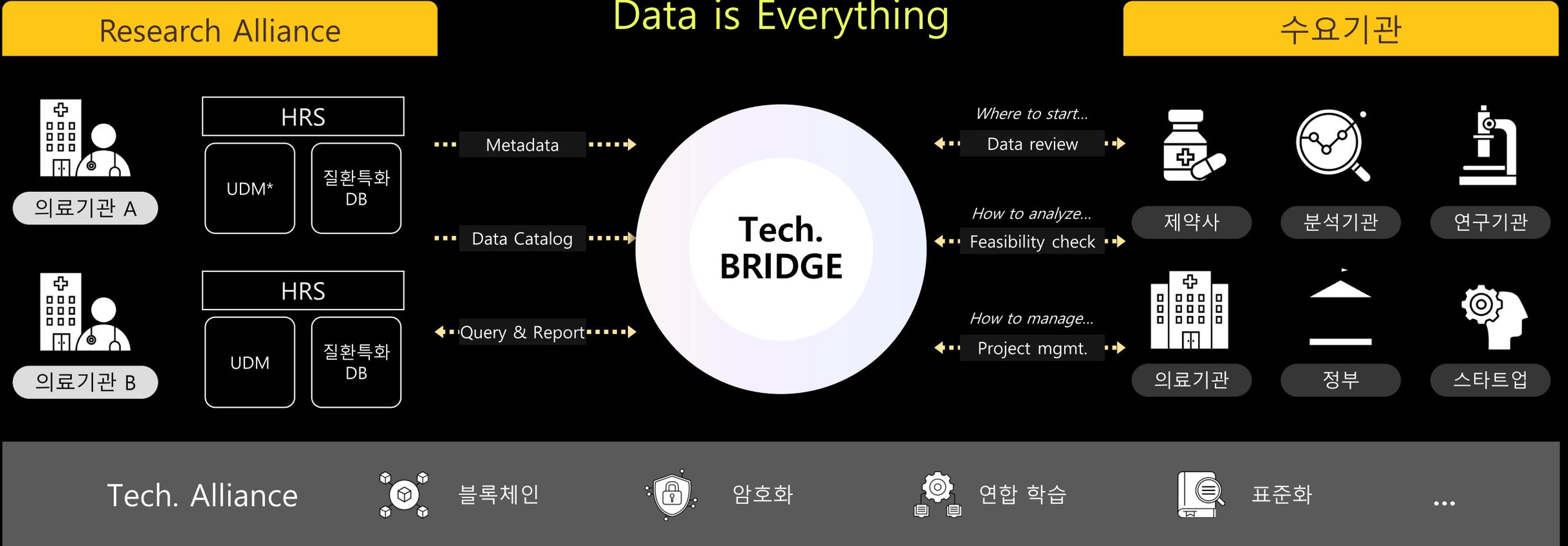
유럽연합



2014. RWE 신약허가 파일럿 프로그램 시행
2016. RWE 기반 인허가 가이드라인 발표
2021. 레지스트리 기반 연구 가이드라인 발표
2023. 의약품 규제 RWE 센터 설립

Source
[1] <https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence> [2] <https://www.ema.europa.eu/> [3] 미국, 유럽, 일본의 실사용데이터 연구사업 추진현황과 시사점, 약학회지, 2020

데이터 플랫폼을 넘어 기술로 연결



* UDM: Universal Data Model

kakaohealthcare