

A Proposed Foundational Architecture for AI-Powered Digital Health Platforms

Abhimanyu Kumbara, MS, MBA, Mansur E. Shomali, MD, CM,
Anand K. Iyer, PhD, MBA

WellDoc, Inc., Columbia, MD, USA

**Conference on Health IT and Analytics
2025**

April 26, 2025 – April 27, 2025

AT&T Hotel & Conference Center
1900 University Avenue
Austin, TX 78705



Agenda

1. Introduction
2. AI Goal: Intelligently Transform the Care Continuum
3. Four Pillars of AI-Powered Digital Health
4. Real World Examples of AI-Powered Digital Health Platform
5. Responsible AI Adoption: Monitoring, Quality, and Governance
6. Regulatory and Policy Efforts

Introduction

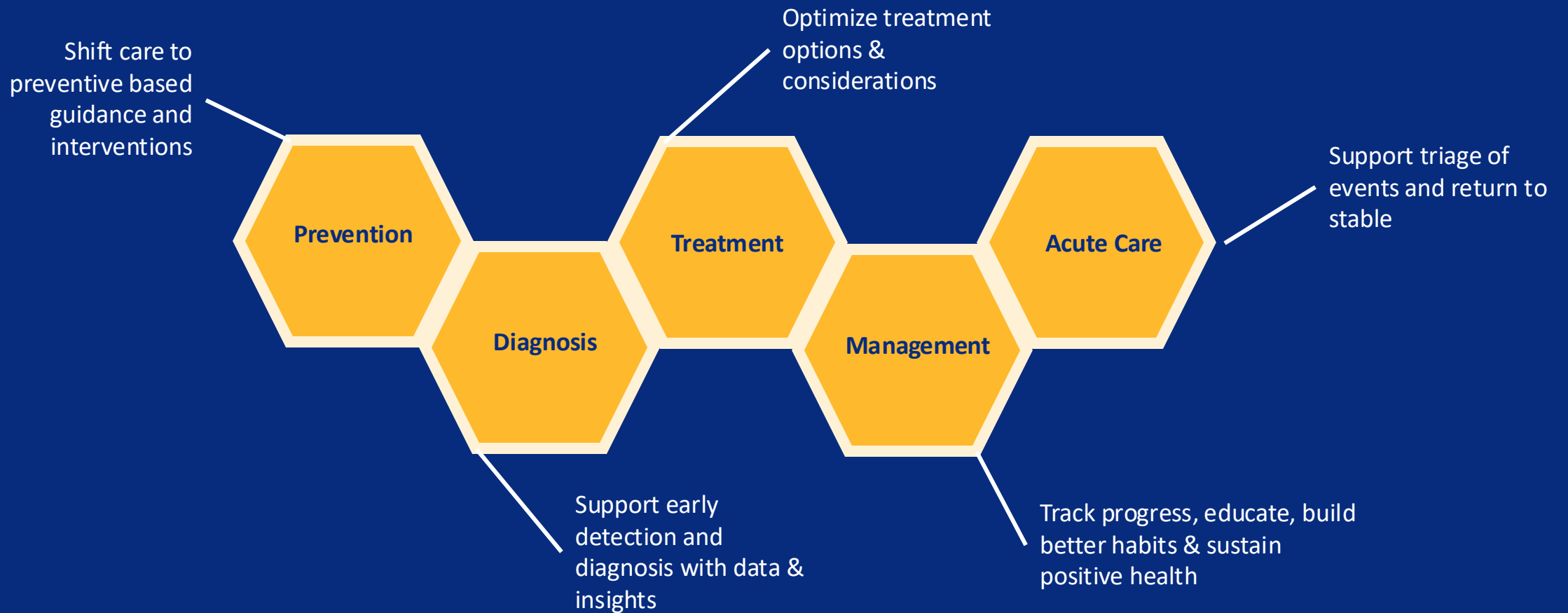
- AI is transforming clinical practice and healthcare delivery
- AI enables:
 - Improved clinical workflows
 - Enhanced decision-making
 - Personalized patient care
- Benefiting from AI in healthcare requires clear goals, solid data foundation, and alignment with governance and regulatory best practices

AI Goal: Intelligently Transform the Care Continuum

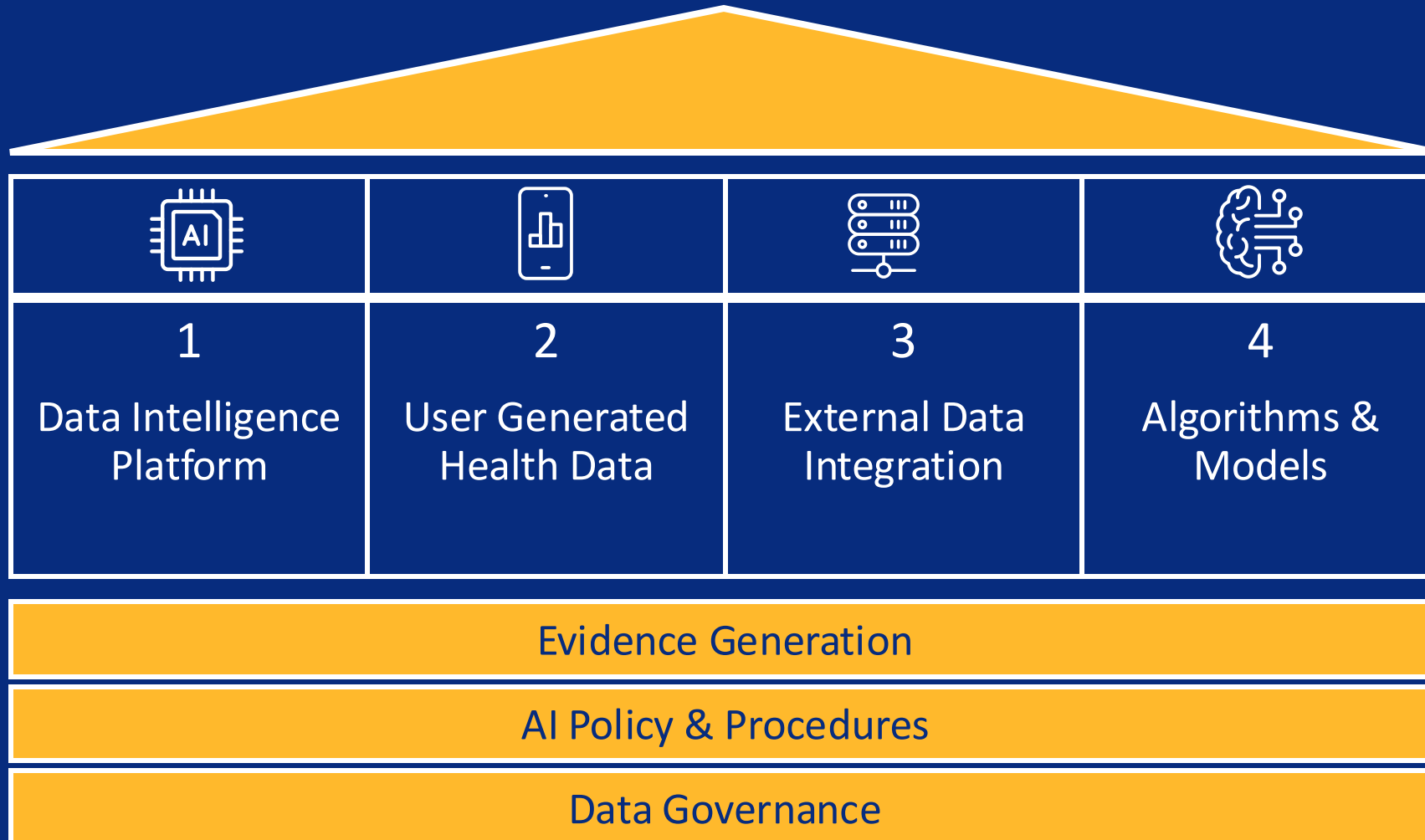


Creating value through:

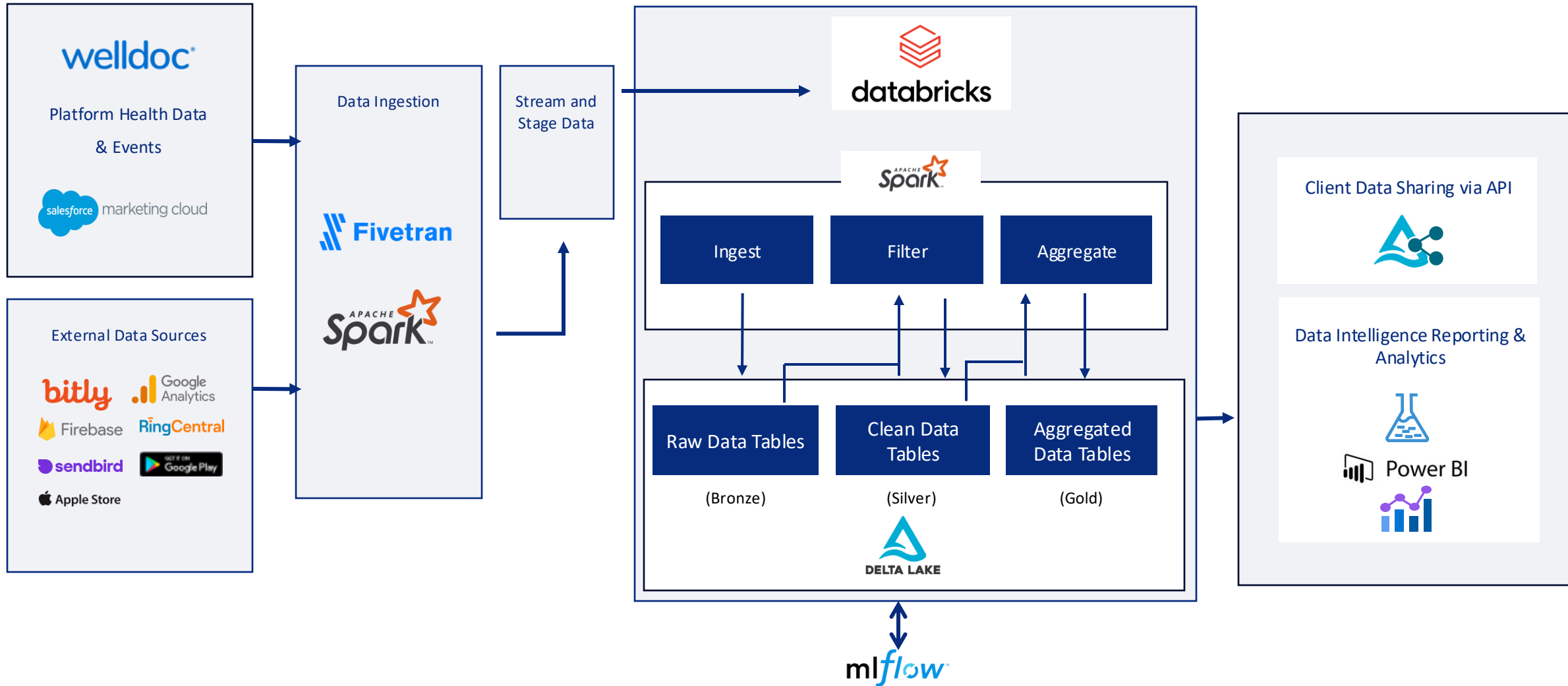
- Operational efficiency
- Innovation
- Increased effectiveness



Four Pillars of AI-Powered Digital Health



Data Intelligence Platform Sample Architecture

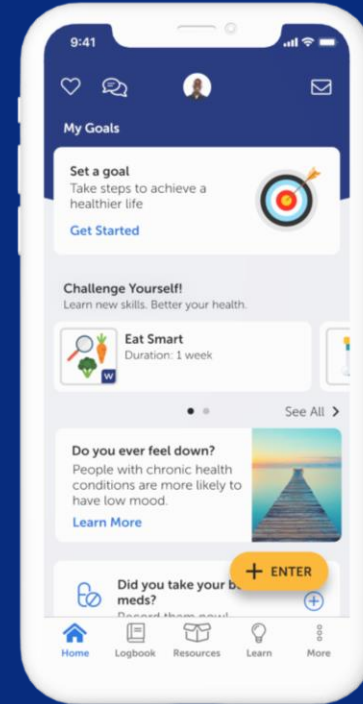


Data Governance

User Generated Health Data



User Generated Health Data



 Nutrition

 Labs

 Activity

 Symptoms

 Psycho-social

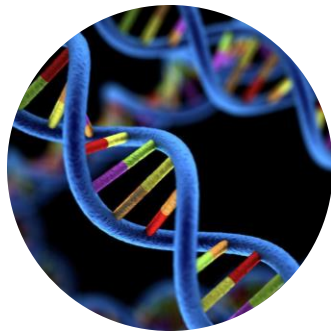
 Meds

 Engagement

External Data Source Examples



Electronic Health Records



Genomics



Survey & feedback



Eligibility, Claims & Utilization

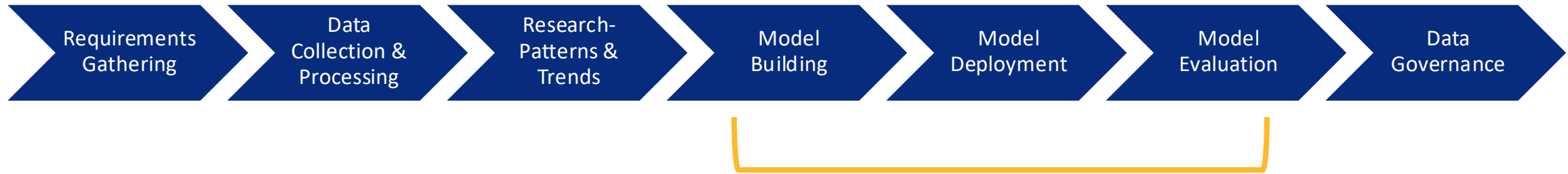


Social Determinants of Health



Geospatial

Algorithms & Models



Types of Algorithms

Unsupervised Learning

- Learns from data without human supervision

Supervised Learning

- Uses human-labeled datasets to train algorithms to predict outcomes and recognize patterns

Semi-Supervised Learning

- Combines supervised and unsupervised learning by using both labeled and unlabeled data to train AI models for classification and regression tasks

Reinforcement Learning

- Trains software to make decisions to achieve the most optimal results.
- Mimics the trial-and-error learning process that humans use to achieve their goals

Real-World Examples: AI/ML driven CGM coaching capabilities

Based on three-hour delayed CGM data

Feedback & coaching based on CGM data

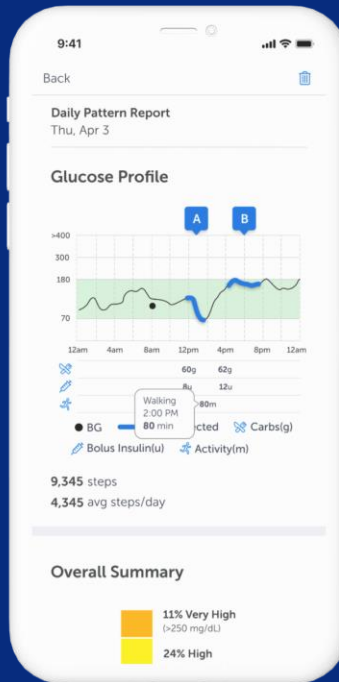
A Event Detected

You dropped too low after lunch. It might have been related to your exercise activity. Next time, eat more carbs or ask your provider how to adjust your insulin for exercise.

B Event Detected

You stayed high for 4 hours. No one is perfect. Ask your provider about taking correctional insulin 2 hours after a meal so that when you go high, you can safely get back to range sooner.

Daily reporting



Provider reporting



Responsible AI Adoption: Monitoring, Quality, and Governance

Diligence in operationalizing extensive and diverse data sets, clinical evidence, data governance, interoperability and data intelligence platform

Ensure privacy, inclusivity and scalable application in real-world settings

Fairness and bias testing allows for inclusive models to be built and operationalized

Distributed and scalable application development in real-world settings

Regulatory and Policy Efforts: FDA Guidance on AI-Enabled Medical Devices

Overview:

- The FDA promotes a **Total Product Lifecycle (TPLC) approach** for overseeing AI-powered medical devices
- It emphasizes **risk assessment, data management, model development, validation, cybersecurity, and ongoing performance monitoring**

Key Considerations for AI-Enabled Medical Devices:

- 1.Regulatory Documentation:** AI-based devices must include clear device descriptions, risk assessments, and validation protocols in FDA submissions
- 2.Transparency & Bias Control:** Manufacturers should evaluate data diversity to minimize AI bias and ensure equitable healthcare outcomes
- 3.Clinical Validation:** AI models should undergo robust testing to assess performance across different patient populations and use environments
- 4.Cybersecurity Risks:** AI-enabled devices require protection from adversarial attacks, data poisoning, and cybersecurity threats
- 5.Lifecycle Management:** Continuous monitoring and improvement of AI models are necessary post-market to ensure sustained effectiveness

Impact on Medical AI Development:

- Encourages **responsible AI adoption** with **data-driven insights** for healthcare applications
- Supports the development of **clinically validated AI models** that integrate with **real-world medical workflows**
- Strengthens **FDA oversight** to **ensure patient safety and regulatory compliance**