




In Vitro Diagnostic Solutions

**Pioneering a New Era in Metabolic
Disorder Care (e.g. PKU)**



Inherited Metabolic Disorders

DISEASE OVERVIEW

 **Inherited Metabolic Disorders (IMDs)**
Drastically impair health outcomes and quality of life. Genetic issues that chronically disrupt metabolism leading to the accumulation of toxic substances affecting **~170K US patients**



Impact

- Mortality | **>21x** higher mortality likelihood
- Organ dysfunction | **>50%** of patients
- Developmental disabilities | **>40%** of patients



Management

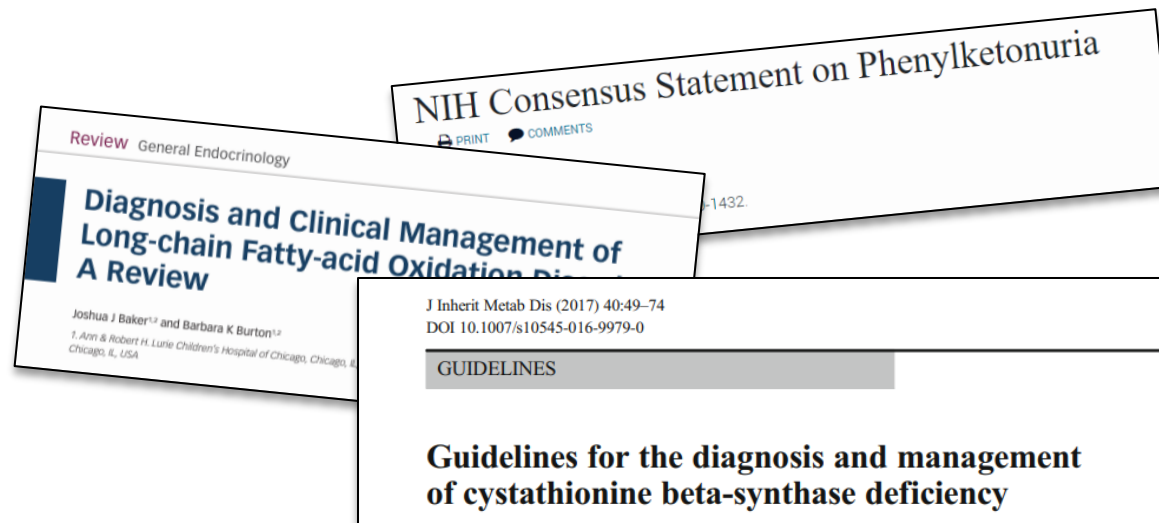
Dietary changes, medication and **monitoring**



Sources: Epidemiology- [Journal of Global Health 2018](#), Disabilities- [Frontiers in Neurology 2023](#), Mortality- [Journal of Pediatrics 2023](#)

Monitoring IMDs

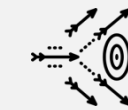
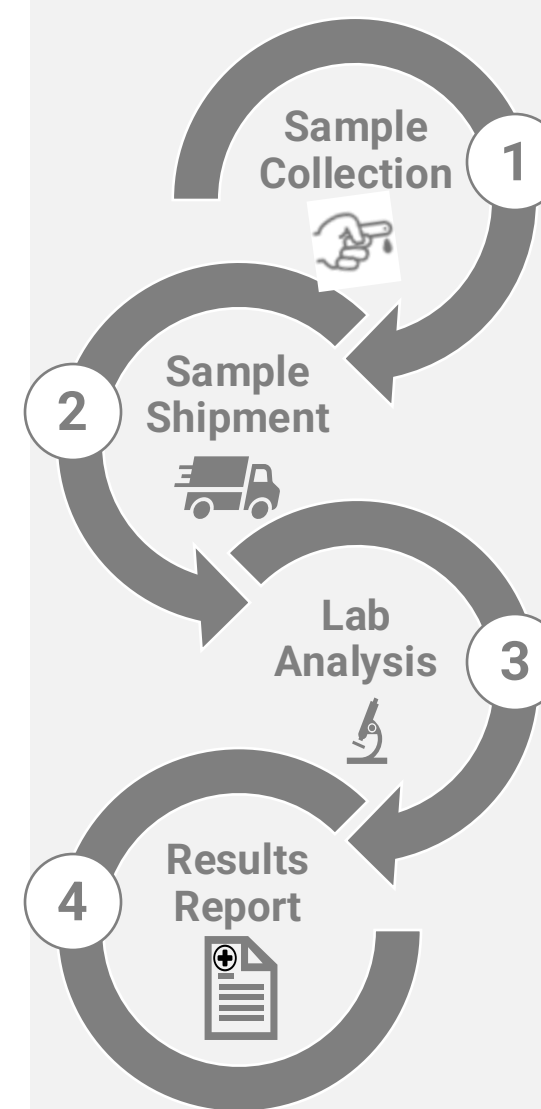
IMD MEDICAL GUIDELINES



Frequent monitoring is essential to manage diet, medication, activity but challenging leading to poor outcomes

Sources: [PKU Guidelines](#), [FAOD Guidelines](#), [HCU Guidelines](#)

Current Testing Process



Inaccurate

"I would love if they were reliable and accurate. We can't trust them at all"

-FAOD Patient



Inactionable

"It takes two weeks to get results back, which makes it irrelevant"

- PKU Patient



Time Consuming

"Two weeks is long; a faster timeline can help with diet & med changes"

-CYS Patient



Inconvenient

"It's difficult to fit into my family's busy schedule."

- PKU Caregiver



Poor Outcomes

"We simply can't comply with the guidelines"

-PKU HCP

PKU Now

PKU Now is the first handheld Phe-monitor providing accurate results instantly and easily, enabling better health outcomes



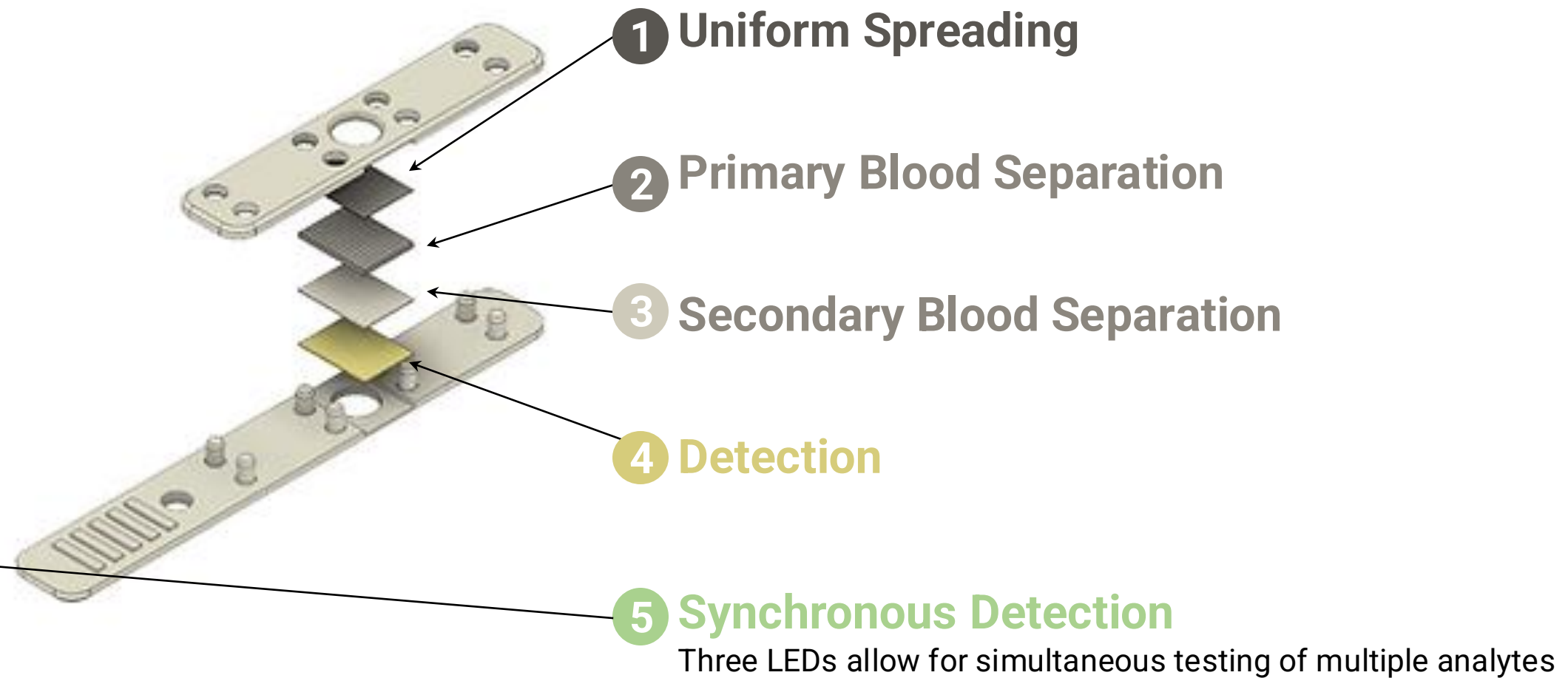
Test Strip Configuration

Proprietary blood separation enables simultaneous analysis of multiple analytes

IVDS OnSight Meter



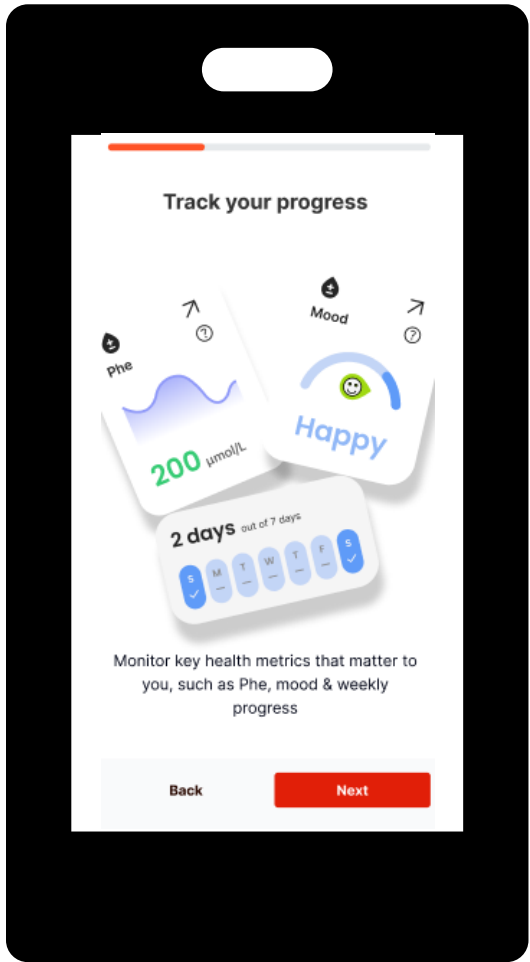
OnSight Strip



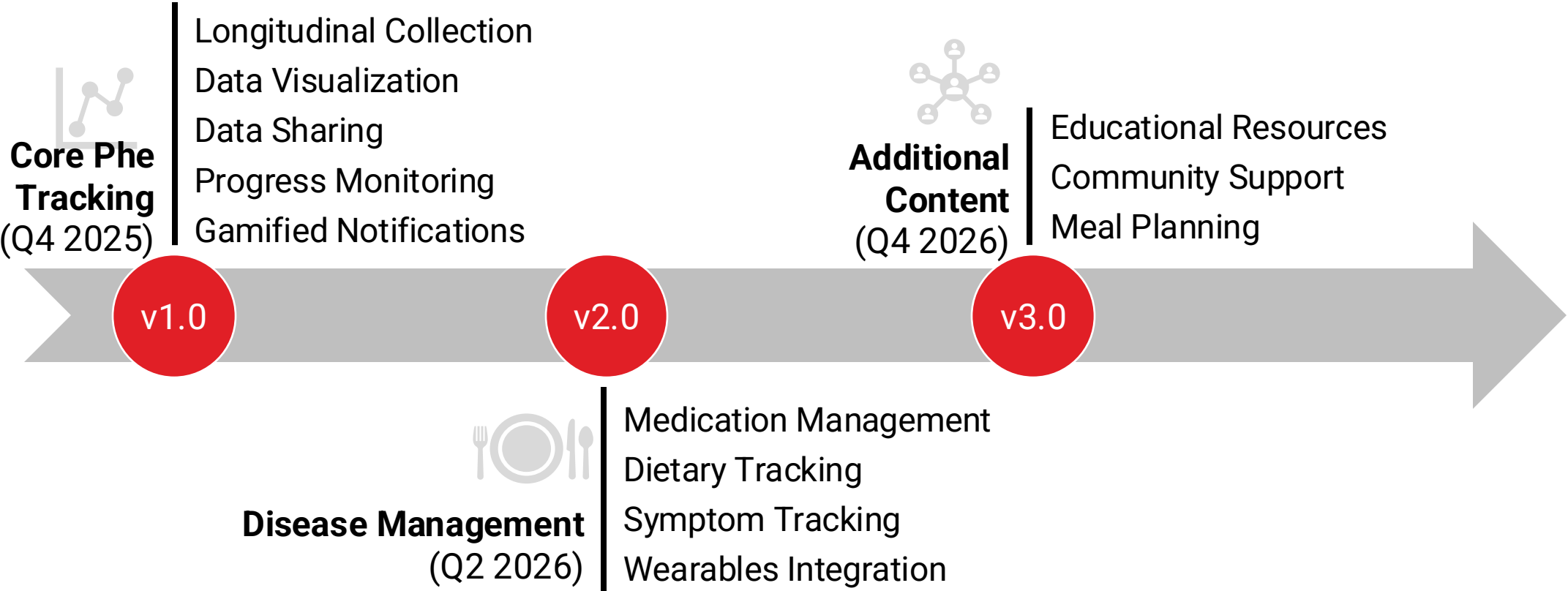
PKU Now Instructions for use (Video)

PKU Now Connect

Provide insights for patients to optimize health



PKU Connect Mobile Application Feature Roadmap



PKU Now Timeline

Major Milestones

Historical Accomplishments

- ✓ \$10M non-dilutive funding
- ✓ Talented team
- ✓ Strong patent portfolio
- ✓ Validated technology
- ✓ Custom R&D / Mfg. facility
- ✓ Expert advisors
- ✓ Strong patient advocates

2025

Preclinical
Trial

Pivotal Trial

2026

FDA
Review

EU MDR
Review

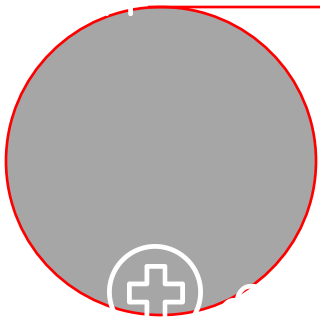
Key Takeaways

IMD MANAGEMENT

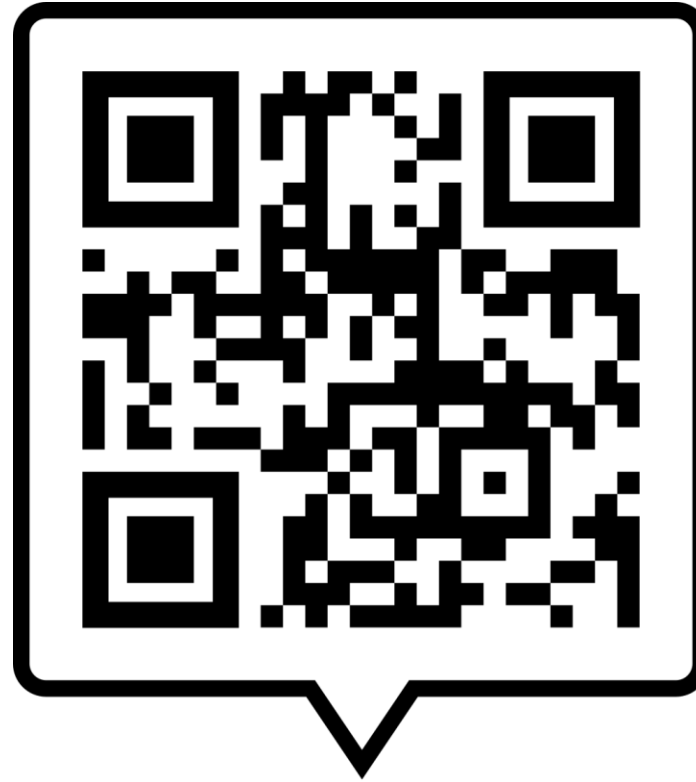


Despite progress in IMD management, studies show **dietary compliance and monitoring remain a significant challenge**

FEEDBACK



Majority of interviewed **patients, caregivers and clinicians** believe that the 'PKU Now' will be **broadly adopted**, and **increase compliance and monitoring** leading to **better health outcomes**



SCAN ME

**Sign up (scan code) and
Join Us in Transforming
Metabolic Disorder Care**