LOWELL · WORCESTER
M2D2
UMASS
Advancing Med Device & Biotech Innovations
CAPCaT
Center for Advancing Point of Care Technologies

GPX
General Prognostics

CardioID
Bloodless Blood Tests for remote monitoring of heart failure

Motivation

Blood tests are the gold standard for predicting disease progression in heart failure (HF).

They are also:
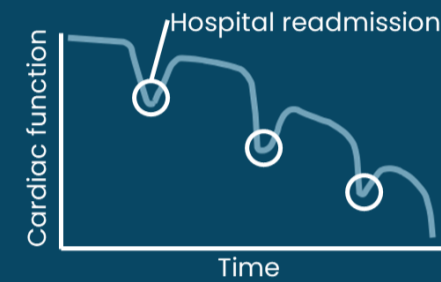- **time consuming**
- **expensive**
- **painful**

What if your smartwatch could tell you when important blood biomarkers change?

The unmet need & opportunity

Without monitoring, patients are under-medicated

<1% of HF patients are on optimal medication levels
(Greene 2018)

Without optimal medication patients cycle downward

Hospital readmission
Cardiac function
Time

25% Of HF patients are readmitted within 1 month

Most HF patients lack access to high quality monitoring

cardiomems   ENDOTRONIX

Limited access due to implant, regulatory, & reimbursement

| NYHA I 20% | NYHA II 60% | NYHA III / IV 20% |

Opportunity

>80% of HF patients lack clinically-validated remote monitoring
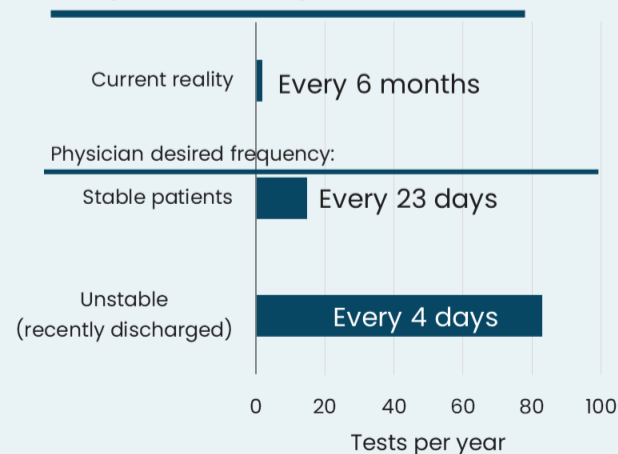
5M US patients

$10B TAM

Market research

NT-proBNP is the single most important measure of HF patient condition and has received a Class 1 recommendation in HF guidelines.

Our survey of 154 heart failure physicians revealed that despite reviewing patient NT-proBNP levels every 6 months, they preferred much more frequent access to NT-proBNP levels to assess patient condition more effectively.
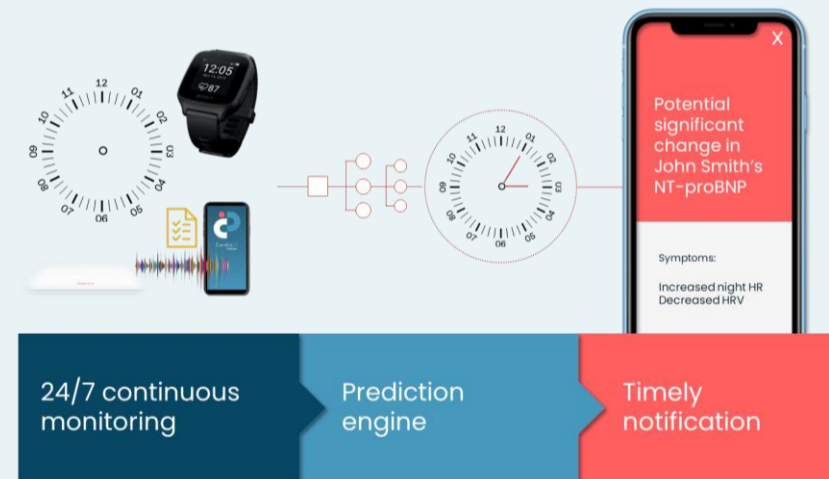
Current & desired frequency of NT-proBNP for HF patients

Current reality — Every 6 months
Physician desired frequency:
Stable patients — Every 23 days
Unstable (recently discharged) — Every 4 days

Tests per year

Proposed solution

NT-proBNP tests are expensive and burdensome, requiring a clinic visit.

CardioID delivers valuable continuous NT-proBNP information to clinicians by combining the collection of non-invasive biomarkers and Bloodless Blood Test algorithms.

Potential significant change in John Smith's NT-proBNP
Symptoms:
Increased night HR
Decreased HRV

24/7 continuous monitoring → Prediction engine → Timely notification

How CardioID works

HF patients simply wear the **CardioID** smartwatch and periodically interact with the app. The collected digital biomarker data is scanned by Bloodless Blood Test algorithms to identify spikes in NT-proBNP. When a spike is predicted, this is an early sign of a worsening condition, and the clinician is notified to intervene to potentially avoid a hospitalization.

Digital biomarkers: Heart rhythm, Voice biomarker, Activity, Weight
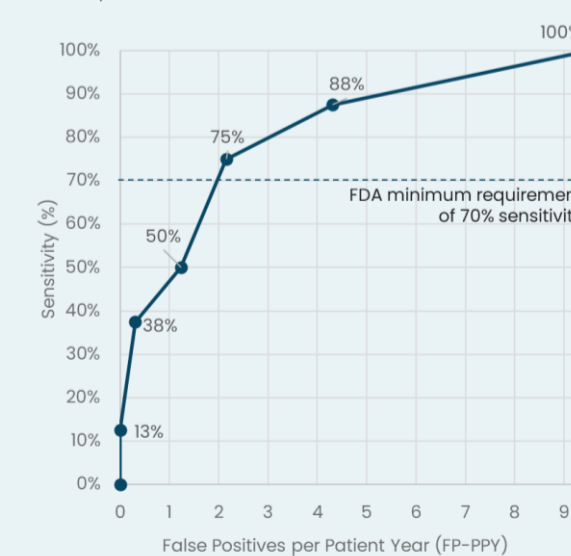Blood biomarkers: NT-proBNP, Creatinine

Bloodless Blood Test algorithms were trained on GPx's proprietary database of paired digital and blood biomarkers from HF patients spanning over 15 patient-years.

Clinical research

GPx is currently running clinical studies to further refine and validate the Bloodless Blood Test algorithms. The TRIBE-HF 2 study is live and recruiting up to 150 heart failure patients to monitor for 6 months.

Done — TRIBE-HF 1
Usability validation
N = 10

LIVE — TRIBE-HF 2
Algorithm training & validation
N = 150

ROC performance curve
>50% NT-proBNP events

Sensitivity (%): 100%, 90%, 80%, 70%, 60%, 50%, 40%, 30%, 20%, 10%, 0%
Values: 13%, 38%, 50%, 75%, 88%, 100%
FDA minimum requirement of 70% sensitivity
False Positives per Patient Year (FP-PPY)

Early versions of the Bloodless Blood Test algorithms have shown encouraging performance in predicting >50% spikes in NT-proBNP in NYHA Class 3 HF patients. With an AUC of 0.81, and 2 false positives per patient-yr at a sensitivity of 75%, the performance exceeds FDA requirements and approaches the performance of implanted devices.

Project team

Javier Echenique — Principal Investigator
Sean Matsuoka — Co-investigator
Dr. Andrew Sauer — Clinical Advisor

Partners

KU MEDICAL CENTER The University of Kansas   CentraCare   Jewish Hospital UL Health   Saint Luke's Health System   Narayana Health   IDEO   SONY