# LINK-HF
## Continuous Wearable Monitoring Analytics to Detect Heart Failure Exacerbation

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# Disclosure Statement of Financial Interest

I DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

Faculty disclosure information can be found on the app

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# Disclosure Statement of Financial Interest

Within the past 24 months, I have had a financial interest/arrangement or affiliation with the organizations listed below.

| Affiliation/Financial Relationship | Company |
|---|---|
| Grant/Research Support | Natera, Merck |
| Consulting Fees/Honoraria | TransMedics, Natera, Alnylam |

**All Relevant Financial Relationships have been mitigated**.
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# LINK-HF Pilot, LINK-HF, LINK-HF2

- Noninvasive remote monitoring with predictive analytics for timely detection of HF exacerbation

- Work done in collaboration with PhysIQ LLC, Chicago, IL

# LINK-HF Pilot

- Title: Telehealth Predictive Analysis Pilot. 2011-2013
  Veterans Affairs Industry Innovations Competition (VA118-11-P-0031)
  Source: Dept of Veterans Affairs Office of Information & Technology

- Safety and feasibility pilot study (N=18)
- Wearable wireless multi-sensor monitoring device
- Acquisition of continuous (6+ hrs/day) bio-signals in ambulatory setting
- Use machine learning to detect physiological changes potentially indicative of HF exacerbation

# LINK-HF Pilot

- 2-electrode ECG baseline
- Bioimpedance
- 3-axis accelerometer
- Continuous pulse oximetry
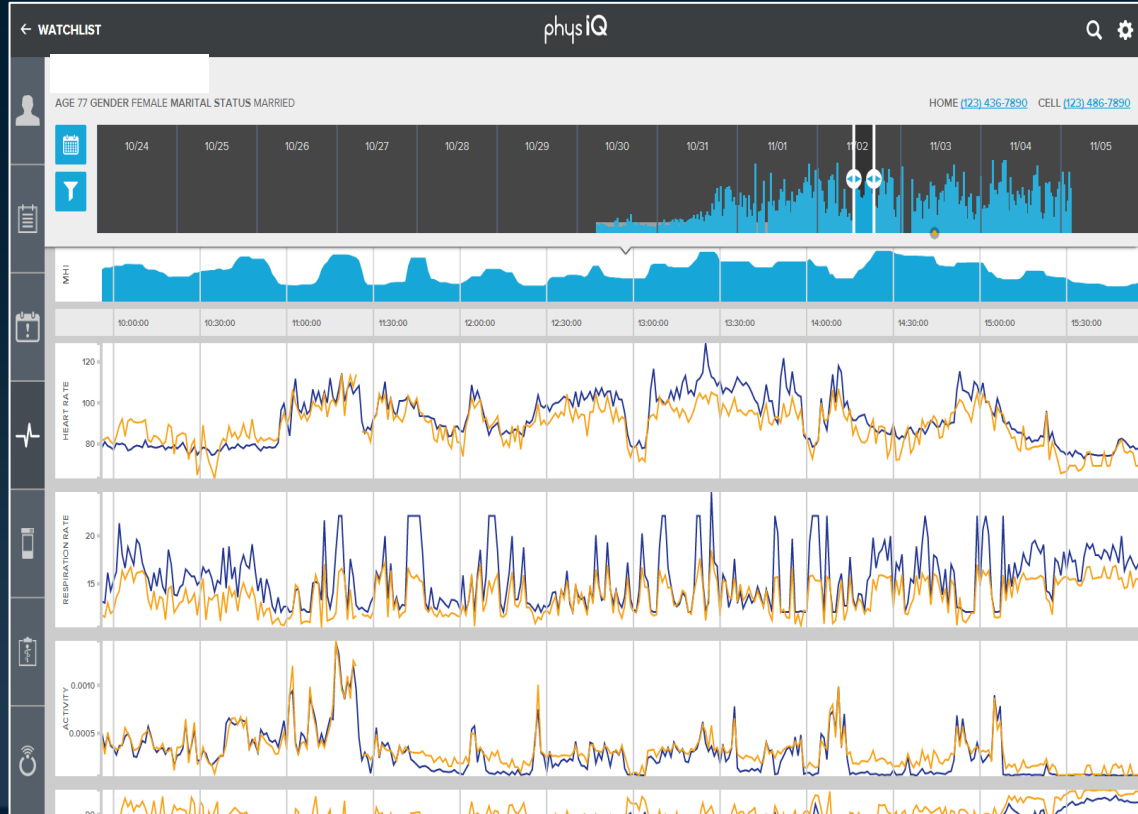- Skin and ambient temperature
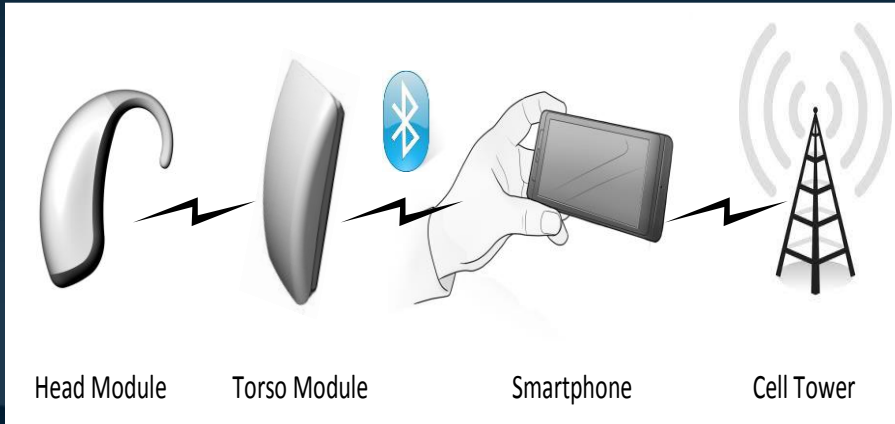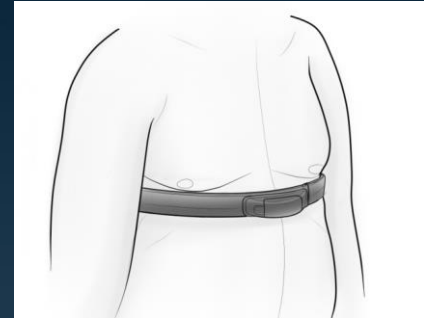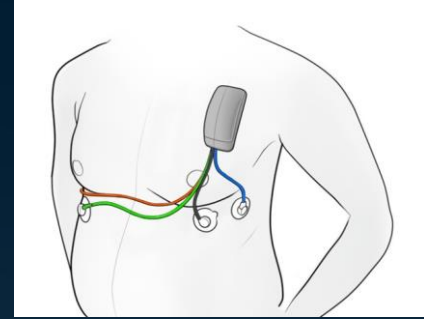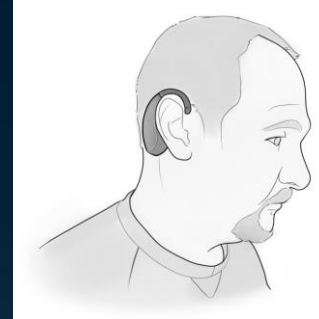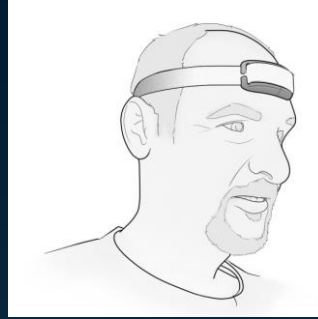


Head Module    Torso Module    Smartphone    Cell Tower

# AI Analytics Platform

- Establish physiological data baseline

- Monitor expected vs observed parameter behavior

# AI Analytics Platform

- Establish physiological data baseline

- Monitor expected vs observed parameter behavior

- Expected vs observed parameter deviation exceeding a threshold results in alert

# LINK-HF Multicenter Observational Study

- Title: Multi-sensor Non-invasive Telemonitoring System for Prediction of Heart Failure Exacerbation (LINK-HF)
  Source: Veterans Affairs Center for Innovation. 2015-2017

**Primary objective:**

- Determine the accuracy of AI analytics of a remote patient monitoring system in predicting HF readmission

**Secondary objectives:**

- Subject compliance
- Reliability of data capture

| Site | PI |
|------|-----|
| Coordinating center: VAMC Salt Lake City, UT | Josef Stehlik, MD |
| Enrolling sites: | |
| VAMC Salt Lake City, UT | Jose Nativi Nicolau, MD |
| VAMC Palo Alto, CA | Michael Pham, MD |
| VAMC Houston, TX | Biykem Bozkurt, MD |
| VAMC Gainesville, FL | Carsten Schmalfuss, MD |

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# LINK-HF Multicenter Observational Study

- Disposable adhesive patch & battery
- Reusable electronics module
- Sensors
    - EKG
    - 3-axis accelerometer
    - Thermistor

| Signal type |
| --- |
| EKG |
| Heart rate |
| Heart rate variability |
| Respiratory rate |
| Posture |
| Activity |
|   - x/y/z accelerometer |
|   - steps |
| Sensor impedance |
| Skin temperature |

Wearable patch (up to 90 days)

Tablet

Cloud analytics

Battery Life 35%   Status

PATCH-LITE

EKG

63   33
HEART RATE   RESP. RATE

65
DAYS

MENU
Tap or Pull Up

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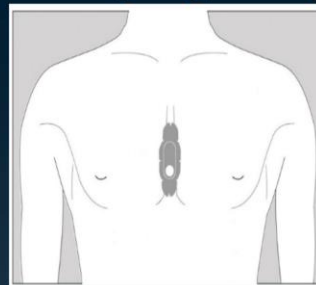
# LINK-HF Results

| Characteristic | N=100 |
|---|---|
| Heart failure type | |
| HFrEF | 75 (75%) |
| HFpEF | 25 (25%) |
| Age (median; IQR) | 67.6 (61.9; 75.0) yrs |
| Male gender [N (%)] | 98 (98%) |
| Race [N (%)] | |
| White | 79 (79%) |
| Black | 15 (15%) |
| Asian | 4 (4%) |
| Other | 2 (2%) |
| BMI (median; IQR) | 29.9 (25.6; 37.3) |
| Comorbidities [N (%)] | |
| Hypertension | 90 (90%) |
| Diabetes mellitus | 57 (57%) |
| Renal dysfunction | 51 (51%) |
| Anemia | 31 (31%) |
| Atrial fibrillation | 51 (51%) |
| COPD | 28 (28%) |



Worsening HF Hospitalization
Event-Specific Positive Window

Analytics AUC: 0.893
Random AUC: 0.592



HF hospitalization

Entire population
Alert-free population
Population with an alert

p=0.001*
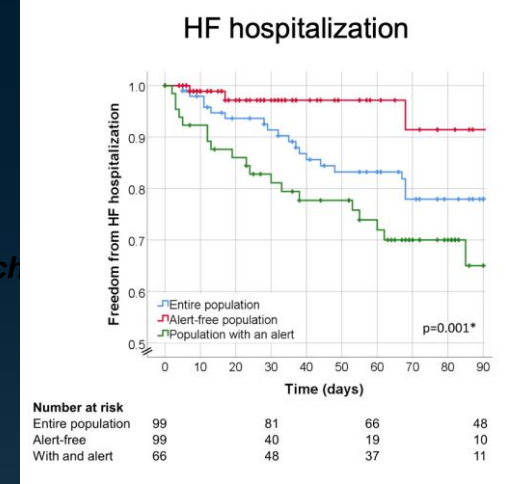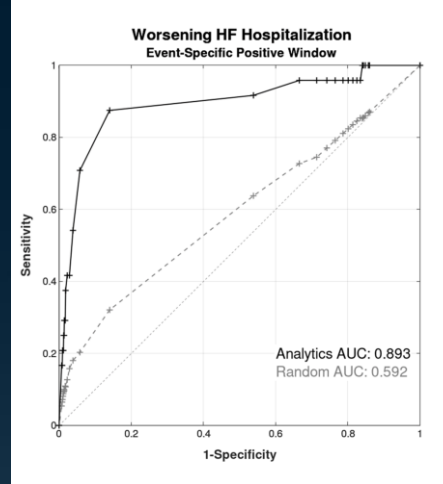
Number at risk
| | | | | |
|---|---|---|---|---|
| Entire population | 99 | 81 | 66 | 48 |
| Alert-free | 99 | 40 | 19 | 10 |
| With and alert | 66 | 48 | 37 | 11 |

| Event-specific window | Sensitivity | Specificity |
|---|---|---|
| HF hospitalization | 87.5% | 86.0% |

*Alert-to-hospitalization time (lead time)*

| Event-specific window | Mean SD, d | Median (IQR), d |
|---|---|---|
| HF hospitalization | 10.4±8.7 | 6.5 (4.2/13.7) |

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# LINK-HF2 – Multicenter Interventional Study

- Add intervention
- Implementation
- Clinical outcomes
- Cost assessment

- Title: Continuous Wearable Monitoring Analytics Predict Heart Failure Decompensation. LINK-HF2 randomized multicenter implementation study
  Source: VHA HSR&D, VHA Innovation Ecosystem
  Operational Partner: PhysIQ.
  2020+ (recruiting)



SLC: Josef Stehlik, MD, Tom Hanff, MD
Gainesville: Carsten Schmalfuss, MD
Richmond: Neil Lewis, MD
Houston: Biykem Bozkurt, MD
Palo Alto: Karim Sallam, MD

Charlene Wier, PhD
Susan Zickmund, PhD
Richard Nelson, PhD
Matthew Samore, MD
Tom Greene, PhD

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| A. STRUCTURAL COMPONENTS OF IMPLEMENTATION | | | | |
|---|---|---|---|---|
| **Determinants** | Interventions | Intervention Mapping | Pilot Vanguard Sites | Full Implementation |
| **Resources** | HSR&D Grant funding<br>VHA:IE matching funding<br>PhysIQ in-kind support | HSR&D Grant funding<br>VHA:IE matching funding<br>PhysIQ in-kind support | Site visits<br>Training material finalized | Training material distributed<br>Orientation/training of all sites |
| **VA staff** | Stakeholders at each of 5 sites - assessment | Research team and facilitator | Stakeholders at 2 vanguard sites | Stakeholders at each of 5 sites |
| **PhysIQ** | Clinician and coordinator training | Device and analytical platform<br>Clinician web-interface | Device and analytical platform<br>Clinician web-interface | Device and analytical platform<br>Clinician web-interface |
| B. TIMELINE OF THE INTERVENTION/MEASSUREMENT PROCESSES | | | | |
| **Determinants** | Pilot measures | Formative assessment | Continuous assessment | Final outcomes |
| **Equipment and algorithm rules** | 3-month testing at 2 vanguard sites<br>Validation of performance metrics | Reliable functioning Adverse events | Reliable functioning Adverse events | Acceptable performance |
| **Facilitator dentification and training**<br><br>**Clinician skills, knowledge, and attitudes** | Test initial feedback, training and communication facilitation strategies.<br><br>Cognitive task analysis results | Interview of vanguard participants<br><br>Self-efficacy ratings<br>Response time to alerts<br>Appropriateness of decisions | Use and response to feedback<br><br>Response time to alerts<br>Log book of issues | Implementation fidelity and acceptable adoption<br><br>Hospitalization rate<br>Clinician focus groups |
| **Patient attitudes, knowledge and compliance** | Patient education test created, tested, and instituted at enrollment stage. | Phone interviews of vanguard participants | Days of use<br>Log book of issues | Patient interviews Assessment of decision appropriateness<br>Days of use |
| **Cost** | n/a | n/a | Classification of costs in intervention and control arms<br>Health-related quality of life | Classification of costs in intervention and control arms<br>Health-related quality of life |

# LINK-HF 2 – Vanguard Phase

**Key results of implementation phase:**

- Refinement of algorithmic response
- Aggregating repeated MCI alerts within 72 hours into a single event
- Expansion of clinician education
- Improved education of subjects on the notification meaning



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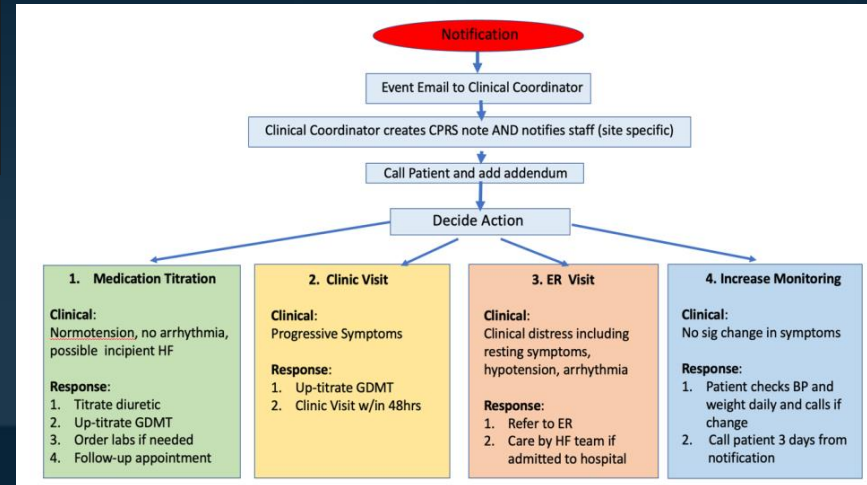
# LINK-HF 2 – Randomized Phase

- 59 patients enrolled
- Recruitment ongoing