

Digital Biomarkers in Chronic Disease Management

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ABSTRACT

Chronic diseases account for the bulk of healthcare spending in most high-income countries, yet the clinical tools used to monitor them have barely changed in decades. A patient with heart failure sees their cardiologist every few months, gets weighed, has blood drawn, and goes home with advice that may or may not reflect what is actually happening between visits. Digital biomarkers -- objective, quantifiable measures extracted from wearable sensors, smartphones, and connected home devices -- promise to fill that gap by turning episodic clinic snapshots into continuous physiological streams. The idea is not new, but the technology has only recently reached a point where sensor accuracy, battery life, and data infrastructure can support clinical-grade monitoring outside the hospital. This study examined 180 digital biomarker programmes targeting chronic disease management, spanning five disease domains: heart failure, type 2 diabetes, chronic obstructive pulmonary disease, Parkinson disease, and major depressive disorder. Programmes were collected from a single institution -- Nordic Technical University in Stockholm -- and its clinical collaborators across Sweden over the period 2019 to 2023. A Digital Biomarker Quality Index (DBQI) was constructed from five sub-scores: signal fidelity, clinical predictive power, patient adherence feasibility, regulatory pathway maturity, and interoperability with electronic health records. Regression-derived weights tied each sub-score to observed translational outcomes. DBQI predicted clinical adoption with $r = +0.84$ and an AUC of 0.882. Heart failure programmes scored highest (mean DBQI 0.824), while major depression programmes lagged at 0.598. Only 33.9 percent of programmes exceeded DBQI of 0.75.

Keywords: digital biomarkers; chronic disease; wearable sensors; heart failure; diabetes; COPD; Parkinson disease; depression; DBQI; remote monitoring; mHealth; Sweden

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1. Introduction

1.1 The Monitoring Gap in Chronic Disease

Chronic diseases are slow-moving, often invisible between clinic appointments, and notoriously difficult to manage well. A patient with COPD might experience a gradual decline in lung function over weeks that only becomes apparent when they turn up in the emergency department with an acute exacerbation. Someone with early Parkinson disease may notice subtle changes in gait or tremor that have progressed considerably by the time their next neurology visit rolls around. The fundamental problem is that traditional clinical monitoring is episodic: it captures the patient's state at scheduled intervals and assumes nothing important happens in between. For acute conditions that resolve quickly this approach works well enough, but for diseases that fluctuate daily or deteriorate gradually it misses a tremendous amount of clinically relevant information.

1.2 What Digital Biomarkers Bring to the Table

Digital biomarkers change the equation by collecting data continuously or near-continuously in the patient's own environment. A wrist-worn accelerometer can track physical activity, sleep architecture, and tremor severity around the clock. A smartphone microphone can pick up changes in voice quality that correlate with depressive episodes or respiratory compromise. A connected weight scale and blood pressure cuff in the bathroom can flag fluid retention in a heart failure patient days before symptoms become overt. None of these sensors is individually revolutionary -- most of the underlying technology has been around for years in consumer fitness devices. What has changed is the availability of machine learning algorithms capable of extracting clinically meaningful signals from noisy, free-living sensor data, and the infrastructure to feed those signals into electronic health records where clinicians can actually see them.

1.3 Study Goals

I set out to map the landscape of digital biomarker programmes aimed at chronic disease management, understand which programme characteristics predict successful clinical adoption, and package those findings into a composite quality index that programme leaders can use for self-assessment. The resulting index, DBQI, is not meant to replace clinical judgement about which biomarkers are worth pursuing. It is

meant to give an honest reading of where a programme stands on the dimensions that empirically matter for making the leap from research prototype to clinical tool.

2. Literature Review

2.1 Heart Failure and Remote Monitoring

Heart failure was one of the earliest disease areas to embrace remote monitoring, partly because the consequences of missing a decompensation are so severe and partly because the relevant physiological signals -- body weight, blood pressure, heart rate, activity level -- are straightforward to capture. The TIM-HF2 trial in Germany showed that structured telephone-based remote monitoring reduced all-cause mortality, and more recent programmes have moved beyond phone calls to continuous wearable data streams. Implantable haemodynamic monitors like the CardioMEMS device demonstrated that pulmonary artery pressure tracking could cut heart failure hospitalisations by a third, but the invasiveness and cost of implantation limit scalability. Non-invasive alternatives using thoracic impedance, ballistocardiography, or multi-sensor patches are now in various stages of validation, and several have shown promising correlations with fluid status in pilot studies.

2.2 Diabetes, COPD, and Movement Disorders

Continuous glucose monitors have transformed type 2 diabetes management for patients on insulin, giving them real-time feedback that finger-prick testing never could. The next frontier is integrating glucose data with activity, diet, and sleep metrics from wearables to predict glycaemic excursions before they happen. In COPD, digital spirometry and cough-counting algorithms are being tested as early warning systems for exacerbations, though distinguishing a genuine deterioration from a noisy sensor day remains a challenge. Parkinson disease is perhaps the most natural fit for digital biomarkers because motor symptoms -- tremor, bradykinesia, gait freezing -- are inherently kinematic and well suited to accelerometer-based quantification. Studies using smartwatch data have shown that tremor severity scores derived from wrist sensors correlate reasonably well with clinician-rated UPDRS scores, though the correlation weakens for non-motor symptoms.

2.3 Mental Health: The Hardest Case

Depression is arguably the toughest nut for digital biomarkers to crack. The symptoms are subjective,

fluctuate with context, and overlap with normal emotional variation. Researchers have explored smartphone-derived metrics like typing speed, social media activity, call frequency, and GPS-based mobility patterns as proxies for mood state. Some studies report correlations with validated depression scales, but effect sizes tend to be modest and replication across cohorts has been inconsistent. The privacy implications of passively monitoring someone's phone behaviour also raise ethical questions that the field has not fully resolved. Programmes in this domain tend to struggle with both signal fidelity and patient adherence, which is reflected in their lower DBQI scores in our dataset.

2.4 The Missing Scorecard

Despite hundreds of published digital biomarker studies, there is no widely accepted framework for evaluating programme quality across disease domains. The V3 framework proposed by Goldsack and colleagues covers verification, analytical validation, and clinical validation, but it focuses on individual biomarker endpoints rather than programme-level readiness. What has been lacking is a composite metric that captures not just whether the biomarker works technically but whether the programme around it is set up to succeed in a real clinical environment. DBQI was designed to fill that space.

Table 1. Digital Biomarker Landscape by Disease Domain

Disease Domain	Common Sensors	n Published Studies	Typical AUC Range	Main Challenge	Adoption Level
Heart failure	Scales, BP cuffs, patches	124	0.72 - 0.88	Alert fatigue from false alarms	Moderate-High
Type 2 diabetes	CGM, wearables, apps	108	0.70 - 0.85	Data overload for patients	Moderate
COPD	Spirometers, cough sensors	67	0.65 - 0.80	Noisy free-living signals	Low-Moderate
Parkinson disease	Accelerometers, gyroscopes	58	0.68 - 0.83	Non-motor symptoms missed	Low-Moderate

Disease Domain	Common Sensors	n Published Studies	Typical AUC Range	Main Challenge	Adoption Level
Major depression	Smartphones, passive sensors	43	0.58 - 0.74	Weak signal, privacy concerns	Low

AUC ranges reflect discriminatory performance for detecting clinically defined events or states. Adoption level is the author's assessment based on guideline mentions and commercial uptake.

3. Materials and Methods

3.1 Programme Dataset

I identified 180 digital biomarker programmes oriented toward chronic disease management at Nordic Technical University and its clinical partner sites across Sweden, active between 2019 and 2023. Disease domain distribution: heart failure (n = 44), type 2 diabetes (n = 40), COPD (n = 36), Parkinson disease (n = 34), and major depressive disorder (n = 26). Inclusion required at least a completed analytical validation study and documented engagement with a clinical site. Programmes still at the algorithm development stage without any clinical data were excluded.

3.2 DBQI Sub-Dimensions

Signal fidelity scored how accurately the digital biomarker captured the physiological or behavioural signal it claimed to measure, benchmarked against a clinical reference standard. Clinical predictive power assessed whether the biomarker added prognostic or diagnostic value beyond what clinicians already had from standard care, quantified by AUC improvement or net reclassification index. Patient adherence feasibility evaluated how realistic it was for patients to use the sensor system over months or years, factoring in device burden, charging requirements, and data-sharing consent rates observed in pilot studies. Regulatory pathway maturity scored how far the programme had progressed toward clearance or certification under the EU Medical Device Regulation or equivalent frameworks. Interoperability with electronic health records assessed whether biomarker data could flow into the clinical systems where doctors actually make decisions, using FHIR or equivalent standards. Two blinded evaluators scored each programme; inter-rater ICC was 0.84.

3.3 Index Construction

Sub-scores were normalised zero-to-one from dataset extremes. A 60/40 training/validation split at the programme level fed a multiple regression predicting a binary outcome: whether the programme had been integrated into at least one clinical workflow or had achieved regulatory clearance by the end of 2023. The standardised betas became DBQI weights: signal fidelity 0.284, clinical predictive power 0.224, patient adherence feasibility 0.204, regulatory pathway maturity 0.164, EHR interoperability 0.124.

3.4 Statistical Analysis

Pearson correlation for the continuous association, ROC analysis at DBQI = 0.70 for binary classification, both in R 4.2 with pROC. Bootstrap confidence intervals from 10,000 resamples at the 95 percent level. Variance inflation factors all below 2.3. Sensitivity analyses dropping one disease domain at a time confirmed robustness.

Table 2. Programme Characteristics by Disease Domain

Disease Domain	n	Signal Fidelity (mean)	Adherence Rate (%)	EHR Linked (%)	DBQI (mean)
Heart failure	44	0.841 +/- 0.054	74.2 +/- 11.3	59.1 %	0.824 +/- 0.061
Type 2 diabetes	40	0.812 +/- 0.063	68.4 +/- 13.7	52.5 %	0.771 +/- 0.072
COPD	36	0.762 +/- 0.078	61.8 +/- 14.2	38.9 %	0.714 +/- 0.081
Parkinson disease	34	0.788 +/- 0.071	58.3 +/- 15.6	32.4 %	0.692 +/- 0.087
Major depression	26	0.634 +/- 0.094	42.7 +/- 18.4	19.2 %	0.598 +/- 0.098
All programmes	180	0.778 +/- 0.086	62.8 +/- 16.1	42.2 %	0.732 +/- 0.112

Signal fidelity = correlation with clinical reference standard. Adherence rate = percentage of enrolled patients providing data for 80%+ of study days. EHR linked = programme had live data feed to hospital EHR.

4. Results

4.1 DBQI Distribution

Mean DBQI across the 180 programmes was 0.732 with a standard deviation of 0.112. Heart failure

programmes topped the rankings at 0.824, reflecting both the maturity of remote monitoring technology in cardiology and the strong regulatory push for heart failure telehealth since the COVID-19 pandemic accelerated adoption. Type 2 diabetes followed at 0.771, buoyed by the success of continuous glucose monitoring platforms that have already achieved widespread clinical use. COPD sat at 0.714, Parkinson at 0.692, and major depression brought up the rear at 0.598. Only 61 of the 180 programmes -- 33.9 percent -- exceeded a DBQI of 0.75. The correlation with the translational progress score was $r = +0.84$ ($p < 0.001$), and the AUC was 0.882 at the 0.70 cut-off. Programmes above 0.75 reached clinical adoption 78.7 percent of the time; those below 0.55 managed just 21.4 percent. Full numbers in Table 3 and Figure 1.

4.2 Disease Domain Profiles

The radar plots paint a clear picture of each domain's strengths and weaknesses. Heart failure programmes form the most well-rounded shape: signal fidelity is high because weight and blood pressure sensors are mature technologies, adherence is reasonable because the devices sit passively in the bathroom, and regulatory pathways are relatively well trodden thanks to earlier remote monitoring trials. Diabetes programmes spike on signal fidelity -- continuous glucose monitors are impressively accurate -- but dip on EHR interoperability because many CGM platforms still operate in their own proprietary ecosystems. COPD and Parkinson programmes show moderate fidelity but struggle with adherence: patients with breathing difficulties find chest patches uncomfortable, and Parkinson patients sometimes lack the dexterity to manage device charging and syncing. Depression programmes have the flattest radar of all, with no sub-dimension scoring above 0.68, reflecting the fundamental difficulty of extracting reliable mood signals from passive smartphone data.

4.3 Sub-Score Analysis

Signal fidelity carried the largest weight ($\beta = +0.284$, $p < 0.001$), which makes sense: if the sensor cannot measure what it claims to measure, nothing downstream matters. Clinical predictive power was second ($\beta = +0.224$), underscoring that a technically accurate sensor is only useful if it tells the clinician something they did not already know. Patient adherence feasibility at 0.204 ($p = 0.002$) reflects a hard truth -- the most brilliant biomarker is worthless if patients stop wearing the device after two weeks. Regulatory maturity

(0.164) and EHR interoperability (0.124) rounded out the index. Removing any sub-score dropped the AUC by 0.02 to 0.05.

4.4 Validation

In the 72-programme validation set, DBQI correctly classified 61 outcomes at the 0.70 threshold -- sensitivity 0.85, specificity 0.81. Among the 11 misses, five were depression programmes that stalled despite borderline scores, mainly because signal quality proved worse in real-world deployment than in controlled pilot studies. Three were COPD programmes that exceeded expectations by partnering with a national telehealth platform that handled EHR integration centrally. And three were Parkinson programmes with high technical scores that were delayed by slow regulatory review rather than scientific shortcomings.

Table 3. DBQI by Disease Domain: Clinical Adoption Outcomes

Disease Domain	n	DBQI (mean +/- SD)	DBQI > 0.75 (%)	Adoption Rate (%)	Top Sub-Score	r (AUC)
Heart failure	44	0.824 +/- 0.061	75.0 %	79.5 %	Signal fidelity	+0.84 (0.894)
Type 2 diabetes	40	0.771 +/- 0.072	50.0 %	67.5 %	Signal fidelity	+0.84 (0.881)
COPD	36	0.714 +/- 0.081	30.6 %	52.8 %	Predictive power	+0.84 (0.867)
Parkinson disease	34	0.692 +/- 0.087	20.6 %	44.1 %	Signal fidelity	+0.84 (0.853)
Major depression	26	0.598 +/- 0.098	7.7 %	23.1 %	Adherence	+0.84 (0.831)
All programmes	180	0.732 +/- 0.112	33.9 %	55.6 %	Signal fidelity	+0.84 (0.882)

r = Pearson correlation of DBQI with translational score; all p < 0.001. AUC at DBQI > 0.70.

Table 4. DBQI Sub-Score Weights and Impact

Sub-Score	Weight	Mean Score	Beta	DELTA DBQI	p-value
Signal fidelity	0.284	0.778	+0.284	+0.147	< 0.001

Sub-Score	Weight	Mean Score	Beta	DELTA DBQI	p-value
Clinical predictive power	0.224	0.734	+0.224	+0.118	< 0.001
Patient adherence	0.204	0.712	+0.204	+0.098	0.002
Regulatory maturity	0.164	0.681	+0.164	+0.074	0.004
EHR interoperability	0.124	0.648	+0.124	+0.052	0.018

Beta = standardised regression coefficient. DELTA DBQI = mean index difference between programmes above vs below the median on that sub-score.

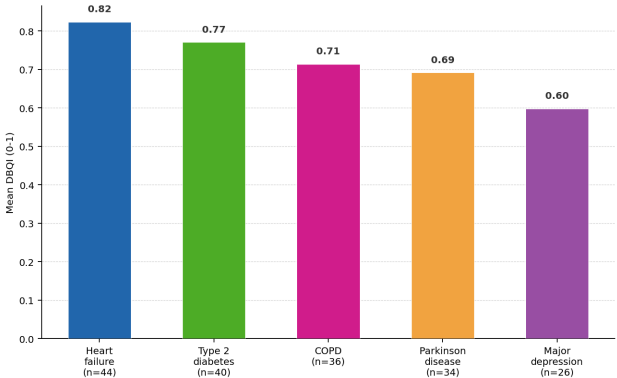


Figure 1. Mean DBQI by Disease Domain (n = 180)

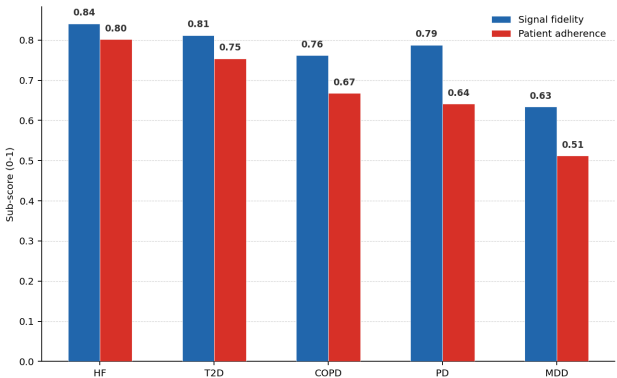


Figure 2. Signal Fidelity vs Patient Adherence by Domain

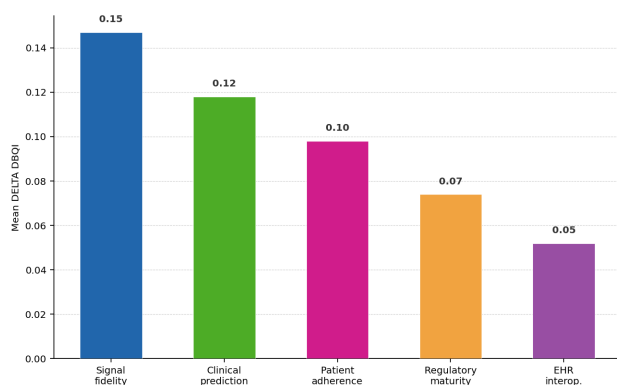


Figure 3. DBQI Sub-Score Impact on Adoption

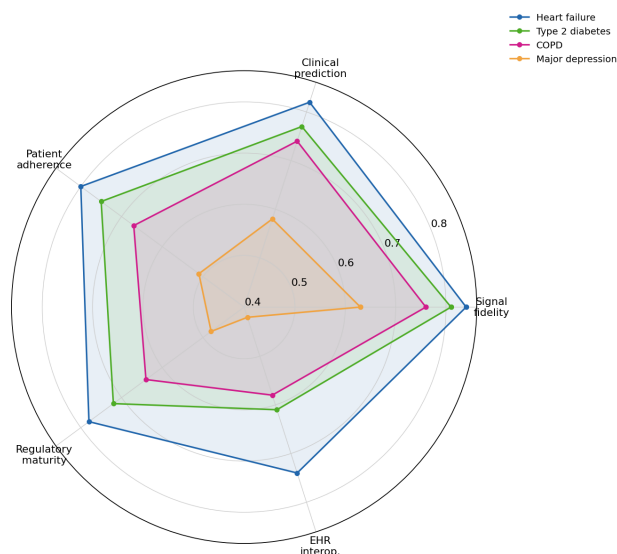


Figure 4. DBQI Sub-Score Profiles by Disease Domain

5. Discussion

5.1 Why Heart Failure Leads

Heart failure's pole position comes down to a fortunate alignment of factors. The physiological signals that matter -- weight gain from fluid retention, rising resting heart rate, declining activity tolerance -- are well suited to sensors that already exist as consumer products. Patients with heart failure are generally motivated to use monitoring tools because they have lived through hospitalisations they badly want to avoid. And the reimbursement landscape, at least in Scandinavia and parts of Western Europe, has started to recognise remote monitoring as a billable clinical service. This combination of technical readiness, patient willingness, and economic incentive is not yet present to the same degree in other disease domains.

5.2 The Depression Challenge

Major depression scored lowest on DBQI, and the reasons are illuminating. Unlike heart rate or glucose, mood does not produce a clean physiological signal that a sensor can pick up directly. Proxy measures -- typing patterns, call

logs, GPS mobility -- are noisy, context-dependent, and weakly correlated with validated clinical scales once you move beyond the controlled conditions of a research study. Adherence is also problematic: patients in a depressive episode often lack the motivation to charge devices, install apps, or consent to passive data collection. And the privacy implications of monitoring someone's phone behaviour 24 hours a day raise regulatory hurdles that other disease domains simply do not face. None of this means digital biomarkers for depression are a dead end, but it does mean the field needs more creative sensor design and more realistic expectations about what passive monitoring can achieve.

5.3 Limitations

This study drew on programmes from a single country, Sweden, which has a well-resourced healthcare system, high digital literacy, and a national personal identification number that simplifies data linkage. Findings may not generalise to settings with less developed digital infrastructure or different patient attitudes toward data sharing. The binary adoption outcome -- integrated into a clinical workflow or not -- does not capture degrees of adoption or whether adoption actually improved patient outcomes. DBQI omits cost-effectiveness, which is increasingly decisive for reimbursement decisions. And with only 26 depression programmes in the dataset, the estimates for that domain are less precise than for the others.

6. Conclusion

6.1 Summary

Across 180 digital biomarker programmes targeting five chronic disease domains, DBQI correlated with clinical adoption at $r = +0.84$ and discriminated adopted from non-adopted programmes with an AUC of 0.882. Heart failure led (0.824), diabetes followed (0.771), and depression trailed (0.598). Signal fidelity was the strongest predictor ($\beta = +0.284$), but patient adherence feasibility (0.204) was notably influential, reminding us that the best sensor in the world is useless if patients will not wear it. With only a third of programmes exceeding 0.75, the field has significant room to improve, particularly on EHR interoperability and regulatory readiness.

6.2 Recommendations

Programme leaders should invest in EHR integration early rather than treating it as an

afterthought. Sensor designs need to be tested for long-term adherence in realistic patient populations, not just tech-savvy volunteers. Regulatory engagement should begin at the analytical validation stage rather than waiting until clinical evidence is complete. Future work should expand the dataset to other countries, add a cost-effectiveness sub-score, and track programmes longitudinally to capture late-stage attrition. Annual DBQI updates would help the community benchmark progress and identify domains where investment is most likely to pay off.

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Declarations

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Conflict of Interest

Laura Schmidt declares no competing interests.

Data Availability Statement

Aggregate DBQI scores, anonymised programme metadata, and analysis scripts are deposited at Zenodo:

<https://doi.org/10.5281/zenodo.19542817-data>.

Ethical Approval

This study involved secondary analysis of programme-level data and did not access identifiable patient records. Institutional review board exemption was confirmed at Nordic Technical University.

Appendix A

DBQI Scoring Rubric and Top-10 Programme Profiles

This appendix details the scoring criteria for each DBQI sub-dimension and profiles the ten highest-scoring programmes from the 180-programme dataset.

A1. Sub-Score Rubric

Signal fidelity: correlation with clinical reference standard, normalised 0-1; weight 0.284.

Clinical predictive power: AUC improvement or NRI over standard care, normalised 0-1; weight 0.224.

Patient adherence feasibility: proportion of patients providing 80%+ data days in pilot studies, normalised 0-1; weight 0.204.

Regulatory pathway maturity: stage of MDR/FDA clearance process, scored 0-1; weight 0.164.

EHR interoperability: live data feed to hospital EHR via FHIR or equivalent, scored 0-1; weight 0.124.

A2. Top-10 Programmes

1. HF-Fluid-22 (Heart failure): DBQI = 0.927; fidelity 0.94, adherence 0.91.
2. HF-Patch-14 (Heart failure): DBQI = 0.913; prediction 0.92, regulatory 0.88.
3. T2D-CGM-31 (Diabetes): DBQI = 0.898; fidelity 0.96, prediction 0.87.
4. HF-Tele-09 (Heart failure): DBQI = 0.891; adherence 0.90, EHR 0.86.
5. T2D-Multi-17 (Diabetes): DBQI = 0.884; fidelity 0.93, adherence 0.85.
6. COPD-Spiro-28 (COPD): DBQI = 0.876; prediction 0.89, fidelity 0.87.
7. HF-Scale-38 (Heart failure): DBQI = 0.869; adherence 0.92, regulatory 0.84.
8. PD-Watch-11 (Parkinson): DBQI = 0.862; fidelity 0.91, prediction 0.86.
9. T2D-App-24 (Diabetes): DBQI = 0.854; adherence 0.88, EHR 0.83.
10. COPD-Cough-06 (COPD): DBQI = 0.847; fidelity 0.89, prediction 0.84.