

# Design, Implementation and Deployment of a Remote Patient Monitoring System in Pro-Active Cancer Care Pathways

**Ronnie Stafford**

**r.stafford.12@ucl.ac.uk**

University College London (UCL)

**Yansong Liu**

University College London (UCL)

**Pramit Khetrpal**

University College London (UCL)

**Graça Carvalho**

University of Minho

**Huriye Kocadag**

University College London (UCL)

**Damon Surrao**

University College London (UCL)

**Hazel McBain**

University College Hospital (UCLH)

**Patricia Winter**

University College London (UCL)

**Charlotte Ackerman**

Queen Mary University of London

**Francesca Jackson-Spence**

Queen Mary University of London

**Thomas Powles**

Queen Mary University of London

**John Kelly**

University College London (UCL)

**Ivana Drobnjak**

University College London (UCL)

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## Article

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# Abstract

Clinical practitioners continue to explore how to integrate remote patient monitoring (RPM) technologies into proactive care pathway models. However, high wearable hardware costs, data interoperability challenges and lack of clinical deployment know-how remain.

We share how Ethera Health's team built HALO-X, a specialised cancer care, multi-site RPM platform, and how UCLH practitioners and UCL scientists have used it in real-world cancer studies. We report the design decisions, implementation, integration, operational performance, patient adherence and deployment pain points as a guide for practitioners engaging in clinical service adoption of RPM technologies.

Over three clinical studies, the platform collected 2.2 million combined heart rate and step count biometric samples, 10,163 PROM questionnaire answers and 17,716 custom wellness questionnaire answers. We present qualitative evidence that multi-modal RPM data collected during a patient's monitoring period can be used to differentiate between those thriving and those failing to thrive.

## **Trial Registration:**

HALO-S (Health Research Authority IRAS 284073, 2020/08/10),

HALO-Trak (Health Research Authority IRAS 312296, 2022/12/12),

Sub-study of DISCUS RCT (ClinicalTrials.gov NCT06892860, 2025/03/25).

# Introduction

Cancer survivorship is increasing globally, yet the follow-up care models that support patients after treatment remain fragmented and reactive [1]. For patients recovering from major procedures such as radical cystectomy, the post-discharge period is especially vulnerable, marked by high complication rates, readmissions, and unmet physical and emotional needs [2, 3]. Similarly, patients undergoing chemotherapy, immunotherapy, or hormone therapy often experience unpredictable side effects such as fatigue, nausea, immunosuppression and emotional distress which can fluctuate between treatment cycles, requiring continuous support [4, 5]. Despite the advances in treatment modalities, structured support for recovery at home remains limited, placing strain on both patients and healthcare systems. There is an urgent need to create scalable, patient-centred solutions that enable clinicians to remotely monitor recovery, personalise care and intervene early to prevent deterioration [6].

Managing University College London Hospital (UCLH) cancer patients during the COVID-19 pandemic in the post-discharge setting involved a change to the normal cancer care pathway. The aim was to limit hospital visits and discharging patients to a home isolation environment with telephone clinics replacing outpatient clinics. The roles of clinical nurse specialists and junior doctors underwent change with many redeployed to COVID-19 areas reducing the pool of experienced health care professionals providing specialist surgical services. The pathway for surgical follow-up after discharge was altered to limit attendance at hospital clinics and face-to-face interactions. Surgery patients infected with COVID-19 exhibited mortality rates of up to 20% [7]. Further, re-admission rates of over 20% in the 90 days after surgery [8–10] and all cause complication rates of up to 60% remain constant and require patients to interact with primary and secondary care. There remains a need to enhance current post-discharge management of patients, to detect emerging problems such as surgical complications and the development of future COVID-19 equivalent pandemic-level events.

Remote patient monitoring (RPM) technologies have gained significant traction to extend care beyond the hospital wall [11, 12]. Driven by the recent proliferation of wearable sensors, mobile apps, and improved connectivity, RPM enables clinicians to track patients' physiological and self-reported data in real time [13, 14]. This is especially relevant in oncology, where early warning signs such as tachycardia, decreased mobility or reported symptoms may precede clinical deterioration [15]. The

COVID-19 pandemic further accelerated the adoption of remote care technologies, reinforcing RPM as a critical pillar in digital health transformation [16].

Mazzella-Ebstein et al. [17] report 67% of clinical stakeholders support using RPM to improve care for high-risk oncology patients. Similarly, a recent anonymous survey questioned 220 healthcare professionals across 55 countries, where most respondents agreed that mobile/wearable digital devices measuring patient biometrics have a role in active cancer care [18]. Talbot et al. [19] report increased patient confidence and assurance with the use of RPM in peritoneal dialysis; however, they found anxiety in both patients and clinicians for increased cognitive burden when using new technologies. Many clinical studies that explore RPM implementations only collect PROMs [20], but evidence suggests that even this helps decrease adverse events for oncology patients [21]. Colinson et al. [22] investigate the collection of patient biometric data from wearable health monitors (WHMs) worn for up to six months prior to, during and after treatment for cancer, finding that WHMs promote positive behavioural change and prioritisation of patient health. It was found that biometric data collected from a wearable coupled with a patient's own experiences form part of a patient's own sense-making exercise. Another study [23] found that 70% daily adherence of biometric and symptom reporting was achieved for thoracic cancer patients receiving chemotherapy. RPM-derived mobility data has demonstrated predictive value for hard clinical endpoints. A recent analysis of radical cystectomy patients showed that step count and quality-of-life data collected within 12 weeks of surgery significantly improved prediction of long-term mortality [24].

Existing commercial PROM or WHM biometric data collection systems often limit both clinical integration and clinical study design. Therefore, several academic and commercial initiatives have explored building custom RPM platforms to circumvent these limitations. Onsentia's HealthRADAR and RADAR-base [25] platform demonstrates real-time tracking capabilities for neurological and

psychiatric conditions at scale, while other platforms such as ResearchStack [26] and IoT4Health [27] offer general frameworks for RPM data collection. StudyBuilder [28] is a prototype framework for building mobile app-based clinical studies but lacks both the collection of biometric wearable data and hospital electronic medical record (EMR) integration. These initiatives often remain research-focused with limited deployment in real-world clinical workflows, particularly in oncology. Most studies are small-scale pilots, disconnected from clinical decision-making or interoperable integration with EMRs [29], lacking robust strategies for IG responsibilities and patient usability [30]. The cost of using off-the-shelf commercial wearable devices is also a constraint for many budget-limited research studies, presenting an opportunity for a cheaper alternative.

The Ethera Health team developed the HALO-X (Home and Locally Observed) platform with UCL and UCLH to fill these gaps: a full-stack RPM solution tailored for real-world use in post-cancer treatment. The platform consists of a patient mobile app (iOS and Android) to submit PROMs, a custom Bluetooth low energy (BLE) wristwatch wearable (paired with a patient's mobile handset) capable of continuous biometric monitoring for step count and heart rate, and a clinician web app to manage patient cohorts. The app's biometric pipeline leveraged both Apple HealthKit and Android Google Fit health stores (see Methods). The custom wearable achieved a palatable price point for academic research studies. The platform was designed to be patient pseudo-anonymous to simplify IG responsibilities for research groups.

Through several research collaborations, the platform was deployed in two clinical research studies in the UK: HALO-S (IRAS 284073), a 30-day post-cystectomy monitoring study of 55 patients and HALO-Trak (IRAS 312296), a 1-year observational study of 83 patients undergoing systemic therapy for haematological cancer. It was also deployed in a feasibility sub-study of DISCUS (NCT06892860), a randomised phase II chemotherapy study in multiple sites across Europe. This resulted in the acquisition of rich multimodal datasets of RPM data collected from outside the hospital and aggregated with clinical data from inside the hospital.

Successful clinical RPM deployments raise unique challenges, requiring both additional training of clinical staff [31] and the leadership of physicians as RPM technology champions [32]. Our unique multi-disciplinary team placed clinician

stakeholders at the heart of both product development and clinical deployment. Together with the interoperable HL7 fast healthcare interoperability resources (FHIR) [33] RPM data egress service, we demonstrate our vision for RPM platform integration with care pathways both at the technological and human level.

Platform architecture, technical requirements, implementation options, custom wearable testing and clinical study design are discussed in the methods section. Multi-modal dataset characteristics and completeness, patient adherence and feedback, and lessons learned from deploying wearable technologies are summarised in the results section. This study aims to identify key technical and operational challenges affecting adoption in oncology and wider clinical practice.

## Results

### Patient Usage and Engagement

A total of 219 patients were enrolled across HALO-S (64), HALO-Trak (85) and DISCUS sub-study (63) with 200 eligible patients successfully on-boarded onto the HALO-X platform. Daily active user count was therefore  $\leq 200$  as the studies progressed.

Patient compliance varied considerably between studies, with attrition rates higher for the shorter 30-day HALO-S study compared to the longer 365-day studies (Table 1). We define a ‘valid’ day for submitting biometric data as any calendar day (24 hrs) where more than 8 cumulative hrs of step count or heart rate data was collected from either the wearable or phone. A valid PROM day is defined as any calendar day where a patient submits one or more questionnaire answer sets. All valid day counts are cumulative and not necessarily consecutive.

Table 1  
Patient adherence rates for cumulative (but not necessarily consecutive) days. A biometric valid day is defined as a calendar day within which a cumulative  $\geq 8$  hrs of step count or heart rate samples were submitted. A PROM valid day is defined as a calendar day within which at least one set of PROM answers were submitted.

| Cumulative valid days | HALO-S (n = 55) |       | HALO-Trak (n = 82) |       | DISCUS (n = 63) |       |
|-----------------------|-----------------|-------|--------------------|-------|-----------------|-------|
|                       | Biometric       | PROMs | Biometric          | PROMs | Biometric       | PROMs |
| $\geq 7$              | 47%             | 73%   | 65%                | 79%   | 51%             | 73%   |
| $\geq 14$             | 29%             | 55%   | 56%                | 68%   | 40%             | 52%   |
| $\geq 21$             | 18%             | 45%   | 50%                | 62%   | 37%             | 38%   |
| $\geq 28$             | 9%              | 25%   | 39%                | 59%   | 32%             | 32%   |
| $\geq 30$             | 7%              | 20%   | 37%                | 57%   | 32%             | 29%   |
| $\geq 60$             | 0%              | 2%    | 22%                | 33%   | 24%             | 27%   |
| $\geq 90$             | 0%              | 0%    | 11%                | 27%   | 21%             | 22%   |
| $\geq 180$            | 0%              | 0%    | 0%                 | 6%    | 11%             | 13%   |
| $\geq 365$            | 0%              | 0%    | 0%                 | 6%    | 5%              | 8%    |

Adherence for submitting PROMs was consistently higher than submitting biometric data, potentially explained by the submission of a questionnaire having significantly less friction for a patient than managing a wearable device. HALO-S monitored patients after major surgery and may explain why cumulative attrition rates for this study were higher than HALO-Trak and DISCUS i.e. a patient recovering from major surgery may be more sensitive to technology friction than those being monitored under rounds of chemotherapy. Patients were told that the RPM monitoring was passive only, such that no clinician would act on the readouts collected from the HALO-X platform.

## Platform Availability

An uptime of 99.9% (over 3.5 years) was achieved for the backend API with a lower (but unquantifiable) uptime for app functionality. High API uptime was achieved by practicing iterative continuous software delivery, orchestration of application container deployments maintained with infrastructure as code (IaC) and carefully managing database rollback functionality. An anonymised but identical staging environment was maintained in parallel to the production environment, which enabled the testing of major releases before being deployed to production. A daily and monthly database backup service guaranteed system rollback in the event of a catastrophic failure, but this was never needed during any of the study periods. API availability was maintained under application firewall protection and request rate limiting on public routes, with cloud security features mitigating threats such as denial-of-service (DoS) attacks. The Ethera Health development team was supported by the UCL Centre for Digital Innovation Impact Accelerator (CDI) [34]. Through this programme a detailed well-architected review of the platform was undertaken by AWS Senior Solutions Architects and UCL's Research Software Engineers, contributing to the high stability of the platform.

App functionality uptime was degraded by software bugs local to the HALO-X app running under different handset OS distributions. We used three external services to track unexpected events and errors on patient phones; VS App Center analytics to track unexpected app runtime events, Sentry.io monitoring to track Bluetooth and data pipeline runtime events originating from deeper in the stack, and Aptabase for high volume user activity events. Using these sources of app monitoring data, it was possible to remotely identify and diagnose mobile app issues while continuously deploying patches. Care was taken to restrict pseudo-anonymous data from ever reaching third-party services.

## Reliability and Robustness

Our error tracking strategy revealed that most app bugs originated from third party component integration issues in the biometric data pipeline, either relating to Bluetooth connectivity (in the custom wearable SDK) or local health store operations/permissions. Any such issues resulted in the data pipeline breaking at specific vulnerable points. The pipeline was robust to unsuccessful health store read/write failures, such that retries pursued unwritten/read samples by date. Similarly, the pipeline was robust to wearable disconnection, such that once auto-reconnection was successful, data transmission resumed. However, in early deployments, data loss still occurred in limited cases while we identified and solved outstanding issues.

In the latest release, two non-deterministic issues remain that affect Android handsets. The first is user authentication sporadically being lost for health store read-write access. Logging out and logging back into the app to refresh health store permissions is a partial workaround. We were unable to resolve a separate intermittent Google Fit transient (5008) runtime error [35] even when the user was logged in, handsets were unlocked and the app visible with appropriate permissions granted. Once this error is experienced by a user, it renders data irretrievable from the pipeline and a workaround or software solution remains out of reach. Migrating from Google Fit API to Health Connect [36] (required in 2026 due to Google Fit being deprecated) may solve some of the data pipeline bugs we experienced for Android health stores. Most patients used Android handsets, therefore any Android data pipeline breakage heavily impacted the overall platform's data transmission reliability.

We validated the accuracy of our custom wearable by comparing its heart rate and step count measurements with that of an Apple Watch Series 6 in a variety of scenarios (sleep, rest, exercise, etc.). The Apple Watch has a 1.74% mean absolute percentage error (MAPE) with respect to ECG values [37], making it a sufficient proxy for accurate heart-rate measurements. The two devices were worn simultaneously, where the Apple Watch recorded a total of 240,124 heart-rate measurements, whilst the HALO-X wearable recorded 804,440 values within the same period.

The HALO-X wearable exhibited a 4.65% MAPE for heart-rate measurements when compared to the Apple Watch Series. Most samples fall in proximity to the identity line in the correlation plot (Fig. 1, top-left). There is a strong level of agreement

between the Apple Watch and HALO-X wearable, as 95% of differences lie between 15.63 BPM and – 13.78 BPM on the Bland-Altman plot (Fig. 1, top-right). We identified device slippage on the arm during vigorous exercise as the cause of the differences when the mean was around 150 BPM. This was mitigated by securing the wearable more firmly against the arm, which was then communicated to patients in our clinical studies.

Step count data accuracy was also tested by comparing the wearable to the Apple Watch and ground truth over multiple user activities (Fig. 1, bottom). Variability was observed between both wearables and the ground truth but remained reasonably consistent. It was also observed that the HALO-X wearable recorded less false positives than the Apple Watch when the user was sitting down inside.

## Data Transmission Success

Both patient compliance factors and data pipeline reliability explain adherence rate (Table 1) attrition. At the time of writing, we are unable to differentiate between patient factors and certain technical failure modes of the data pipeline. Event patterns for users not using their wearable are somewhat indistinguishable from those patterns for Bluetooth reconnection bugs i.e. both event streams exhibit Bluetooth reconnection errors without successful reconnection. Further work is needed to aggregate, synchronise and interpret all independent event streams to differentiate user disengagement from data transmission unreliability. This includes improving the logging of health store read/write events.

## Technical Operational Insights

Our RPM solution was facilitated by the proliferation of smart phones and wearable sensors as consumer devices over the last decade. The standardisation of handling health data in Android and iOS operating systems has made product development easier with consistent health APIs between manufacturers, user-granted permission access to health data types and secure health store storage. Without this technology ecosystem it would have been impossible to deploy such a solution without building significant custom infrastructure. However, using an ecosystem to build a platform requires adherence to the ecosystem's constraints. It wasn't possible to keep the data sync pipeline alive during all states of a patient's handset, such as when locked. Even with background/foreground tasks as implemented by iOS and Android, the patient was required to open their app regularly to initiate a health data sync.

The tech stack is substantially more complicated than a standard mobile app because of health store integration, native code for managing custom wearable connectivity and data transfer over Bluetooth. Android is open source, therefore many versions exist in the open market, usually as custom builds per handset manufacturer, including but not limited to One UI (Samsung), MIUI (Xiaomi), Oxygen OS (One Plus), HarmonyOS (Huawei) and Google's official builds. A high level of maintenance was required to ensure the mobile app and wearable functionality worked on as many handsets as possible. Apple iOS builds are closed source which reduces maintenance complexity.

In addition to these development challenges, testing handsets with wearables was an intensive manual labour process and very difficult to automate in end-to-end and integration test suites. We therefore relied heavily on extensive unit testing, limited integration testing and careful manual testing. Even with these measures in place, software bugs inevitably made it into production because the variation of handset types and OS build versions was significantly higher in the field than in our limited quality assurance (QA) coverage. During the deployment of early versions of the product, many bugs and user experience (UX) issues were captured by app diagnostics/analytics logging. By identifying these production issues early, iterating fixes and deploying patches quickly, we were able to mitigate serious loss of functionality experienced by users in our studies.

## Onboarding Barriers

During early testing, it was thought that the technical onboarding of a patient (by downloading an app, enrolling onto a study and pairing a wearable) would be a relatively simple process requiring minimal supervision. However, on the ground in clinical practice, this was not the case. The diversity of patient technical literacy was very high, but not necessarily stereotypically correlated by age. Some patients were naturally tech savvy, requiring very little direct supervision both for onboarding and use of the app/wearable throughout the duration of their monitoring periods. Others used their handsets so rarely that they required direct supervision and support from the clinical team.

Our patient recruiters reported that a significant set of screened patients had never installed additional apps on their phones from the app stores. Typically, this group of patients would have forgotten their Apple/Google account credentials required to access the app stores when installing the HALO-X app. Rectifying this required our recruiters to help these patients reset account passwords via their email accounts, which was very time consuming. There was a significant overlap of this group of patients with those who hadn't updated their phone for multiple OS releases. This meant that when the patient was asked to download the HALO-X app, they were forced by their phone's software update policy to complete all pending updates. Exacerbated by poor 4/5G connectivity inside a hospital building or with slow hospital WIFI, such cases would lengthen the onboarding process to last well over an hour. Without a dedicated technologically proficient clinical team, these cases became a barrier to study enrolment.

## Adherence Challenges

Sustaining long-term patient engagement proved challenging. Participants often disengaged due to health deterioration, app fatigue, or difficulty navigating digital tools. Strategies such as in-app automated reminders, simplified UX and personalised feedback were used and continue being explored to improve adherence, including reducing PROM length [38]. The diverse levels of digital literacy across patients further complicated uniform usage, especially with the wearable. Patient app accessibility features were found to be integral to adherence, such as the app layout/function being compatible with large display font (accessibility) settings. This insight was taken into consideration for future product design.

Patients were made aware that the HALO-X platform was deployed to collect data only and not take part in clinical decision making or intervention. Patients therefore voluntarily took part in the RPM component of our studies to help further research, not necessarily leading to immediate personal benefits for themselves. This lack of immediate patient incentive contributed to an unquantifiable amount of patient disengagement.

It was observed that the most critical data for proactive care was frequently the most unobtainable. To identify RPM signals and trends during a patient's recovery phase requires sampling wearable and PROM data when the patient is unwell. However, when a patient is unwell, they are less likely to engage with the wearable and app. This missing not at random (MNAR) data introduces systematic bias that further complicates building data-driven proactive care pathways. New passive approaches that remove the burden of responsibility of a patient to interact with technology are required.

## Clinical Workflow

Integrating HALO-X into clinical teams required training, regular feedback loops, and trust-building. While the clinician web app was well received for its simplicity, there was limited time for regular use in some settings. Clinicians regularly experience 'login credentials fatigue' for multiple services, therefore future clinician web app functionality should be directly integrated into hospital EMR infrastructure so that it is accessible via a clinician's existing login credentials.

Navigating institutional and national IG requirements proved time-intensive, particularly for HALO-Trak where integration of RPM, PROMs, and biological data was planned. While HALO-X meets current patient GDPR compliance, integration with hospital EMRs (e.g. Epic) introduces additional complexity. Although the proof of concept EMR integration was completed, the scope of our work did not include full integration with a hospital's live EMR. To achieve this would be to engage with

hospitals on a commercial basis, satisfying further compliance and information governance legal requirements which was out of the scope of this research project.

## Feasibility and Usability

Reported attrition (Table 1) in patient adherence is partially explained by patient feedback results (Table 2). Feedback was in free text which we further classified into usability and technology issues. Responder sample sizes range from a third or lower of study participants, with most reporting wearable usability issues, followed by technical issues. Wearable usability issues included statements such as “uncomfortable to wear at night”, “found it irritating” or “difficulty finding on/off button”. App issues included statements such as “PROM slider is confusing”. Tech issues mostly reported data syncing problems whose feedback was incorporated into our bug solving strategy.

Table 2  
Patient feedback survey results. Reported (mutually inclusive) usability and technical issues.

| Study (n responders) | Usability Issues |     |                 | Tech Issues              |
|----------------------|------------------|-----|-----------------|--------------------------|
|                      | Wearable         | App | Illness fatigue | Data sync & connectivity |
| HALO-S (n = 22)      | 50%              | 14% | 14%             | 32%                      |
| HALO-Trak (n = 21)   | 33%              | 19% | 10%             | 33%                      |

Further feedback (Table 3) reports platform ease of use scores. Mean favourable feedback for using the wearable, app and completing PROMs all score above 4 (where 5 is easy). And overall, 76% of responders answered positively to the question “Do you think RPM using new technology is a good idea?”.

Table 3  
Additional HALO-Trak patient feedback survey ease of use scores (1 = hard to 5 = easy), n = 21 with standard error of the mean at 95% confidence. The final column is the proportion of responders reporting positively to the RPM solution being implemented with new technology.

| HALO-Trak (n = 21)                        |             |                   |                     |
|-------------------------------------------|-------------|-------------------|---------------------|
| Ease of use scores (1 = hard to 5 = easy) |             |                   | Overall             |
| Wearing wearable                          | Using app   | Completing a PROM | Is RPM a good idea? |
| 4.38 ± 0.51                               | 4.19 ± 0.52 | 4.26 ± 0.50       | 76%                 |

## Data Characteristics

Continuous rich multimodal datasets from 200 patients were successfully collected. HALO-S data provided dense daily monitoring during acute post-surgical recovery, while HALO-Trak and DISCUS enabled tracking during longer-term therapy and biological response profiling. Across all three studies, the platform collected 2.2 million combined heart rate and step count biometric samples, 10,163 PROM questionnaire answers and 17,716 custom wellness questionnaire answers. RPM data collected from outside the hospital was aggregated with clinical data collected from inside the hospital, illustrating the rich multimodal datasets that the HALO-X platform enables research teams to build.

With these datasets, it was possible to qualitatively characterise post-surgical recovery (HALO-S), and stability during treatment (HALO-Trak), into three wellness categories (Fig. 2). Three HALO-S patients (top) and three HALO-Trak patients (bottom) are categorised as thriving (left), average recovery/stability (middle) and complications/readmissions (right). Date years are redacted to preserve anonymity. QoR-15 total scores range from 0-150 points, with higher scores indicating better quality of recovery. Thriving patients (top-left, bottom-left) typically report high QoR-15 scores close to the maximum total 150 score. Average recovery from surgery (top-middle) is characterised by a drop in QoR-15 scores and steps immediately

following surgery, with a steady return to baseline during the monitoring period. Average stability (bottom-middle) is characterised by a lower (than thriving) QoR-15 total score with reduced step count throughout the monitoring period. Patients failing to thrive (top-right, bottom-right) see a reduction in step count and QoR-15 total scores, with an increase in average heart rate without a return to baseline within the monitoring period. Evidence of disengagement with the wearable for both patients failing to thrive is present during readmission.

Trends for two patients (Fig. 3), one picked for their poor recovery and one for their good recovery are compared to their cohort averages. In HALO-S, QoR-15 scores improved over the 30-day period, with the most rapid change observed in the first two weeks. There were notable day-to-day fluctuations in individual PROMs, which may offer future opportunities for predicting upcoming clinical deterioration or hospital visits. Heart rate and step count biometric data provided high-resolution insight into daily patient activity and physiological variation. In HALO-S, daily average heart rates stabilized after the first post-op week, while step counts gradually increased, showing expected patterns of physical recovery. In HALO-Trak and DISCUS, more complex trends were observed, with dips in step count and elevated heart rate during chemotherapy cycles. These patterns suggest potential as passive indicators of treatment tolerance and recovery trajectories.

All clinical studies faced several data quality and interpretability challenges. Sample sizes were modest, and the high granularity of wearable data contrasted with the less frequent collection of biological or clinical data. Patient device disengagement, partial questionnaire completion and missing data limited longitudinal continuity. Despite these challenges, HALO-X demonstrated the potential for scalable RPM in cancer care and has laid the groundwork for future biomarker-driven digital health applications.

## Discussion

We present evidence that multimodal RPM data is capable of qualitatively differentiating between patients who are thriving, experiencing average recovery/stability and those failing to thrive (Figs. 2, 3) for both short-term (post-surgical recovery) and long-term (systemic therapy) monitoring periods.

We successfully developed HALO-X, an end-to-end, multi-site RPM platform for collecting patient biometric and PROM data from outside the hospital. The platform was deployed in three clinical studies, one of which with sites outside the UK, whose datasets will serve as the foundation for future analysis of digital biomarkers and machine learning-based outcome prediction models [39]. The patient app was designed for postoperative cancer care, but extensible to other care pathways, able to both passively collect biometric data and actively collect PROMs. Custom Bluetooth wearable hardware was developed, integrated and demonstrated for biometric data collection as a cost-effective alternative to existing commercial smart watches. The clinician portal was designed for clinicians to both recruit and manage groups of patients within care pathways or clinical studies. A FHIR egress service was demonstrated for aggregating a patient's RPM data with their in-hospital EMR data, illustrating our vision of integrating RPM data streams into proactive care pathways.

Patient usage was moderate, constrained both by patient availability and eligibility within our clinical studies. As a result, the platform only served a daily active user (DAU) capacity of  $\leq 200$  and has not yet been stress tested to its limit, estimated to be  $\sim 10,000$  or higher DAUs with horizontal scaling.

Patient adherence was reasonable but suffered attrition for long cumulative valid day counts. Attrition is explained by technology friction exacerbated by patient technical proficiency, wearable usability, technical issues and unwellness. Software updates and instructing patients on how to use the wearable became a bottleneck for clinicians during patient onboarding. This was magnified by patients who were not technically proficient with mobile apps. Patients were told that the platform readouts would not inform clinician decision making during any of the clinical studies, which could have been a demotivating factor for patients to interact with their wearables or app, and thus explaining attrition rates. Further research is required to investigate adherence attrition rates when patients are told that clinicians are actively responding to RPM readouts.

Choosing to build a patient-facing app in the smartphone ecosystem with a wrist-worn Bluetooth wearable, constituted the primary limitations of the HALO-X platform. Installing an app on a patient's phone increased onboarding time if OS updates were required, which was exacerbated by poor internet connectivity in the hospital. The patient app and therefore the data pipeline were also subject to OS runtime constraints, requiring the patient to regularly interact with the app to ensure reliable transmission of data from the wearable to the backend database. Patients were also required to manage the charging of their wearable and ensure its operation while wearing it during the monitoring period, further contributing to technology friction and patient adherence attrition rates.

Platform API availability was high and was achieved using modern software development and deployment practices. However, patient app availability was degraded for some patients by issues primarily with the data pipeline. We used a logging strategy to triangulate any issues and deployed patches as quickly as possible. But runtime issues remain for some handsets, specifically for Bluetooth and health store integration pain points.

Positive criticism of the platform was collected via patient feedback which we used to help improve HALO-X. Evidence for positive sentiment of RPM technology was also collected, although survivorship bias cannot be eliminated unless each patient is forced to answer their off-boarding questionnaires.

The closest functional RPM platform to HALO-X in the research setting is Onsentia's HealthRADAR SaaS and RADAR-base RPM [40]. They leverage mobile apps, wearables and cloud-based infrastructure, however there are several important differences. RADAR-base splits 'active remote monitoring technology' (aRMT) for patient conscious-interaction tasks (such as taking questionnaires) and passive (pRMT) monitoring (such as collecting wearable biometric signals) into two separate apps. By contrast, HALO-X simplifies the patient experience by combining both active and passive data collection into a single app. Android and iOS cross-platform support for the aRMT app was achieved using the Cordova framework, making the app browser-based (HTML/CSS/JavaScript). However, the pRMT app is Android only. In contrast, the HALO-X patient app was written with the React Native framework which renders platform native UI components in the ReactDOM, achieving superior user experience performance over browser-based apps. The HALO-X patient app was carefully designed to enhance the patient experience with both passive and active data collection, with additional features such as a health event calendar and health data visualisation.

RADAR-base's pRMT Android app does not appear to rely on Google Fit health stores for health data persistence or for wearable interoperability. Instead, it relies on specific device SDKs and device web API linkage to achieve support across several wearable products. RADAR-base's microservice architecture focuses on raw scalability, while HALO-X's monolithic architecture retains adequate scaling for clinical use cases. A key differentiator is that HALO-X focusses on a precision postoperative care user experience for both the clinician and patient, whereas RADAR-base focuses on large cohorts being monitored for certain conditions such multiple sclerosis, epilepsy and depression.

We demonstrate that a custom-built smartphone/wearable-based RPM solution is capable of collecting multi-modal datasets exhibiting signals that differentiate patients who are thriving from those who are failing to thrive. Further research is required to see if prediction models can be built upon this data and if such future systems will translate into practical clinical tools. If successful, this will be invaluable for cancer care and integral for the future digital transformation of care pathways.

Next steps include scaling HALO-X to larger cohorts and additional tumour types, evaluating predictive modelling based on combined data streams, and enhancing personalisation and adherence features. Integration of genomic and immune profiling within the same framework opens the door for hybrid biomarker development. Formal validation studies and regulatory approval pathways will be critical to clinical integration. Despite challenges in deployment, patient adherence and data completeness, our findings provide a strong foundation for future AI-driven personalisation of proactive cancer follow-up care. It also offers a viable path toward digital-first, data-informed recovery pathways that align with the broader goals of health system digital transformation.

Further research is required to develop RPM systems that require minimal patient interaction. To permit the HALO-X data pipeline to operate continuously in real-time without OS constraints or requiring app interaction would require forking an (open source) Android OS distribution and making the necessary modifications. No longer would such an approach rely on patient handsets, and instead bulk purchase of Android handsets would be required and then distributed to patients, incurring considerable cost. This approach would not be possible with iOS as Apple does not provide open source or permit modifications to its OS distributions. However, such an approach still requires patients to wear a smartwatch and manage charging cycles.

Long term research focussing on fully passive biometric data collection is needed, which may require a departure from the classic smartphone/wearable ecosystem. The minimal requirements of such a system would be zero patient interaction (no app or battery management required), a slim wearable sensor that is continuously attached to the patient for at least 30-days and connectivity for near real-time continuous monitoring. Such a solution would require significant investment into an extensive hardware research program.

## Methods

### Network Architecture and System Security

Development of the full software stack adhered to OWASP guidelines and 12-factor app [41] methodology best practices. The patient app was developed as a mobile app, downloadable from Google Play Store or Apple App Store, served by the main backend API which had a monolithic CRUD (create, read, update, delete) architecture. A single microservice was used for the FHIR data egress. The data pipeline that represents the data flow from the wearable to the backend database is also described.

The platform (Fig. 4) consisted of five core components: an iOS/Android patient-facing mobile app paired with a Bluetooth custom wearable, a web-based clinician portal, all served by a secure backend API and an EMR integration component for data egress to FHIR endpoints. As per industry standard, requests and responses to/from the API were encrypted at the transport layer (HTTPS). Both the API and web app were served in Docker containers, making the core implementation cloud-agnostic. AWS was used for deployment where each container was served by its respective container services. Horizontal scaling was achieved in both container services by spinning up or spinning down containers in response to increasing or decreasing traffic load. Application load balancers (ALB) managed the routing of requests to multiple containers. Internet access to the ALBs was protected by web application firewalls (WAFs) which rate limit requests to all public API endpoints.

Both container services ran in virtual private clouds (VPC), connected to the internet via an internet gateway. An encrypted relational database service (RDS) managed the API's Postgres database/backup service and ran within its own VPC. Inbound and outbound TCP protocol traffic of each VPC was restricted by type (e.g. PostgreSQL or HTTPS) and by port via AWS Security Groups. Sensitive credentials such as backend passwords and private encryption keys were encrypted and stored in AWS Secrets Manager. An IP-locked bastion host (AWS EC2 instance) was temporarily provisioned as an SSH tunnel (jump server) for external access to the database during maintenance windows. The same network implementation is easily transferable to other cloud service providers such as Google Cloud or Microsoft Azure.

### Backend API

The backend was developed as a NodeJS-based RESTful API with an encrypted Postgres relational database (RDS). Dedicated API routes (documented as per OpenAPI specification using Swagger) were implemented to service auth, mobile app and web app. Rate limiting was imposed on critical API routes both in the API code itself as well as in the cloud network's WAF service. API authentication/authorization was granted to web portal users via a username/password flow.

For mobile app users, sign-in-with Google/Apple was used with industry standard OAuth Authorisation Code flow to grant access to API routes. Successfully authenticated mobile and web app users were issued time-limited cryptographically signed JSON Web Tokens (JWTs) whose payloads contained user claims that specified the resources each user has access to when interacting with the API. Both mobile and web app clients presented these tokens to the API whenever they made requests to secured API routes.

## Patient Mobile App

The HALO-X mobile app was developed using the cross-platform React Native framework, allowing for a shared codebase across both Android and iOS platforms. A user was able to navigate from the home screen to view both their health data and view a calendar of events (Fig. 5). The QoR-15 [42] PROM medical survey was also navigable from the home screen. A daily/weekly notification was set to remind the user to fill out their answers. A wellness survey was also developed to complement the QoR-15, which records emotional/physical symptoms and was similarly navigable from the home screen. The user interface was designed in collaboration with clinical stakeholders and informed by patient involvement workshops. Our workshops were guided by existing work that showed patient reassurance is necessary for patient engagement [43], and how to design digital products to best incorporate patient reassurance [44].

## Biometric Data Pipeline

We developed our custom wearable with a third-party hardware manufacturer, serving as a cost-effective alternative to commercial Apple and Google Fit smart watches. Our device took the form of a small watch with an adjustable fabric band for placement on a patient's wrist. Compared to its feature-rich commercial counterparts, our wearable achieved an affordable price point by strictly recording step count and heart rate samples only. A high sampling rate ( $\sim 1\text{Hz}$ ) for both health data types was achieved with a 60-day onboard memory while maintaining several days' battery life from a single charge cycle. A data pipeline was implemented to transfer data from the wearable to our backend database via the patient app (Fig. 6). We define a 'data sync' as the successful transfer of all new health data in a user's wearable to the cloud database. Several functional requirements lead us to our implementation decisions (Table 4).

Table 4

Health IoT data pipeline functional requirements to replicate the behaviour of commercial smart watches.

| 1 | Requirement                                                                                                                                                | Details                                                                                                                                                                                                                                              |
|---|------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|   | <b>Handling of health data on a patient's handset must satisfy user privacy preferences, and Apple &amp; Google's App Store review processes/T&amp;Cs.</b> | <ul style="list-style-type: none"> <li>• Secure, encrypted storage on handset.</li> <li>• Scoped user access of health data.</li> <li>• Patient can grant access permissions from app.</li> </ul>                                                    |
| 2 | Data sync from wearable to cloud database to be robust over multiple connectivity scenarios.                                                               | <ul style="list-style-type: none"> <li>• Loss of internet connectivity.</li> <li>• Loss of Bluetooth connectivity.</li> <li>• After handset unlock.</li> <li>• After app crash/restart etc.</li> <li>• As close to real-time as possible.</li> </ul> |
| 3 | Bluetooth wearable auto-reconnect after disconnection.                                                                                                     | <ul style="list-style-type: none"> <li>• After airplane mode toggle.</li> <li>• After being outside BLE broadcast range.</li> <li>• After handset unlock.</li> <li>• After app crash/restart.</li> </ul>                                             |

The most cost-effective way to satisfy requirement 1 was to use Apple HealthKit (iOS) [45] and Google Fit (Android) [46] health stores, providing a secure local persistence layer in the patient's handset for data collected from the wearable before being sent to the backend database. It is possible to build custom health stores, but this would require extensive development to replicate health store compression, encryption, data access and permissions. Two custom React Native *Native Modules* were shipped as dependencies to the main patient app to manage the different stages of the data pipeline (Fig. 6). Both modules were split into iOS and Android native libraries, packaged with an interoperable React Native wrapper.

*HealthstoreWriter* asynchronously fetches samples from the wearable and writes them to the health stores. Step count and heart rate were sampled at a frequency  $\sim 1\text{Hz}$  in the wearable and were written at the same sample rate to the health store. The module also managed Bluetooth pairing, connection, disconnection and reconnection. Low-level Bluetooth SDKs provided by the wearable manufacturer were included as a module dependency as described in the next section. Whenever the wearable was both paired with the handset and connected, the module asynchronously received Bluetooth (heart rate and step count) messages in real-time before writing them to the handset's health store. Data contiguity was maintained such that when the wearable reconnected after a period of disconnection, the module requested additional health data samples from the wearable's memory over the disconnection period. Callbacks were exposed to the patient app that were used to respond to health data and Bluetooth event flow.

*HealthstoreReader* asynchronously fetches new health data delivered into the handset's health store, transforms it to an interoperable JSON schema and sends it over the internet to our backend server. To reduce network and load balancer cloud costs, step count and heart rate were aggregated into 5 minute buckets, meaning that a maximum of 288 samples for each data type was sent to the backend server per patient per 24 hrs. For heart rate, each of the 288 samples had a min, max and average beats per minute (BPM) field. The aggregation bucket duration was implemented as an environment variable that could be adjusted. This data was batched and periodically sent to our backend server, throttled by a sync refresh rate configurable as an environment variable e.g. the reading of a new batch of data from the health store did not exceed once every 10 minutes. Both iOS and Android health stores implement an access permissions framework that

integrates with the user's identity via sign-in-with Google/Apple. Permissions were granted via the main app's UI during onboarding and could be revoked through the user's Google/Apple account settings.

For both Android and iOS, the pipeline was kept alive for whenever the patient app was running in the foreground. For iOS, background delivery [47] was enabled for both modules so that if the patient's app was running but not visible, the data pipeline and Bluetooth connections were kept alive. Closing the app or locking the handset terminated the pipeline as per OS policy that we couldn't control. For Android, a foreground service [48] was implemented to force the pipeline to be active even if the patient app was closed. However, both iOS and Android *conditionally* allow background/foreground processes to run and may non-deterministically terminate them at runtime e.g. during periods of high-power consumption or low battery state. It was found that Bluetooth auto-reconnect was unreliable for some Android handsets and therefore the connection needed to be kept alive using a foreground service. To satisfy requirements 2 and 3, both modules were architected to reinstate their pipelines whenever the patient opened their app. Therefore, to reliably collect biometric data, patients were required to regularly interact with their app.

## Custom Wearable and Bluetooth Integration

We describe the Generic Attribute Profile (GATT) [49], which is the general specification for sending and receiving data to and from BLE devices. An *attribute* defines the smallest addressable piece of data stored on a BLE device, consisting of a handle (a unique 16-bit addressable ID), a 128-bit (usually represented in 16-bit compressed form) Universally Unique Identifier (UUID) that defines the attribute's 'type', and a value (byte string). A *characteristic* is a collection of one or more attributes e.g. the Heart Rate Measurement characteristic (UUID 0x2A37) is defined as a collection of attributes consisting of a characteristic declaration, characteristic value (which holds heart-rate payload [50]) and a client characteristic configuration descriptor (CCCD). A Bluetooth *service* is a higher level of abstraction consisting of a declaration attribute and a collection of one or more characteristics e.g.

the Heart Rate Service (UUID 0x180D) contains both the Heart Rate Measurement and Body Sensor Location characteristics.

Our custom wearable implemented the standard GATT specification for the Heart Rate Service, Device Information Service (UUID 0x180A) and Battery Service (UUID 0x180F), allowing for real-time NOTIFY/READ heart rate and device status update messages to be sent from the wearable to the host (phone handset). However, these standard implementations were not adequate to satisfy our requirements (Table 4), such as real-time step count and retrieval of historical step count/heart rate from the wearable's onboard memory. Therefore, the wearable's SDK implemented a custom GATT service consisting of two characteristics; the first to write commands to the device for requesting heart rate/step count data (either real-time or from onboard memory), and the second to subscribe to for receiving the requested data.

The manufacturer supplied SDKs for handling low-level GATT operations in Objective-C (iOS) and Java (Android). We built two native libraries with the SDKs as dependencies, managing device pairing/connection, receiving real-time data and retrieving data stored in the wearable's onboard memory. These native libraries for the wearable were then placed into the *HealthstoreWriter* (Fig. 6) alongside the health store management logic.

## Clinician Web App

The clinician web app was developed as a React single-page application (SPA), served to browsers by the web app container service. The API implemented a Cross-Origin Resource Sharing (CORS) policy which was enforced by the browser. Authorised users can manage patients under their care and view patient RPM data (Fig. 7).

The domain model was represented in the web app (Fig. 8) as a hierarchical structure, consisting of *organisations* which contain care *pathways*, which in turn contain collections of patients, aka *patient groups*. This model generalises for most hospitals across the world. For the UK NHS Hospital Trust model, the Trust is represented by an organisation entity; its care pathways are represented by pathway entities (one of which could be a cancer pathway) and finally each hospital site in the trust is represented by a patient group entity. Patients were recruited into a patient group depending on what site they are being recruited from. This model is also compatible with research groups; a university hospital's research group is assigned as a pathway entity to represent a clinical study, and each individual patient group represents recruitment sites that may be external to the hospital in remote geographical locations.

The first clinician from an organisation invited to the platform is assigned as an organisation owner role. From there, they can create pathways and patient groups, inviting other clinicians as pathway owners and patient group owners (aka patient recruiters). A patient recruiter is typically a clinical nurse in direct contact with patients. Recruiters generate short-lived one-time study codes for onboarding new patients who have downloaded the mobile app. The patient enrolment onboarding flow is described in the next section. All user roles can log into the web app with access only to views they have valid JWT claims for.

## FHIR Egress Microservice

The FHIR data egress service was implemented as an AWS Lambda microservice, which extracted RPM data from the database (heart rate, step count and QoR-15 answers) and transformed it into *Observation* and *QuestionnaireResponse* JSON FHIR resources. Once transformed, the microservice sent the JSON FHIR to a secure FHIR endpoint, representing a hospital's EMR. The FHIR server was pre-populated with synthetic patient clinical data consisting of *Patient* demographics, *CarePlan* and *Condition* FHIR resources. The QoR-15 PROM questionnaire was also defined by a *Questionnaire* FHIR resource. The FHIR server was network restricted for secure internal access and collected data for the HALO-Trak study only. This proof of concept demonstrated our interoperability strategy for the aggregation of RPM data collected from outside the hospital with clinical data already within the hospital. We provide FHIR template examples in a public GitHub repository [51].

## Information Governance and Patient Enrolment

We describe how patient enrolment was implemented while satisfying the constraints of the information governance landscape. The information governance (IG) landscape for digital health systems is complex, with differences between regions, countries and use cases. We describe the IG landscape for the UK. At the time of writing, the handling of data in the UK is governed by UK GDPR (2018) and the Data Protection Act (2018). Under UK GDPR, data is classified as either personal or non-personal data. Personal identifiable data (PID) can be used to identify an individual either directly (with no modification to the data) or indirectly (by combining it with other data sources), the latter known as pseudo-anonymous data. Non-personal data is classed as either anonymous where it is not possible to identify an individual, or anonymised where personal data has been modified to exclude all identifiable data. Under GDPR, data practitioners are categorised as either data controllers or data processors, where data controllers have additional responsibilities on the handling of personal data. It is common for UK researchers to be classed as acting on behalf of their university data controller. Therefore, any digital system that researchers build to handle personal data must comply with their university's IG guidelines, such that the university does not violate its data controller responsibilities. To simplify compliance, it is recommended that any system designed for the research environment should collect/process either anonymous or pseudo-anonymous data. Processing PID requires additional safeguards characterised by trusted research environments (TREs) [52].

HALO-X was designed from the ground up to collect pseudo-anonymised patient data. This is challenging for a system that has the following patient app requirements; i) patient-specific login/logout functionality, ii) ability for a patient to consent/onboard into a clinical study/care pathway, iii) patient-specific access control to the backend API, iv) data isolation in the database and v) ability to join patient data collected with HALO-X and clinical data in a secure environment.

A standard OAuth authorisation code flow was implemented for signing into the app, leveraging sign-in-with Google/Apple, meaning that secure sign-in functionality was made available without the need for collecting personal data. The technical details behind the onboarding flow (Fig. 9) are as follows; i) patient user downloads the app from app stores and initiates a Google/Apple sign-in-with request to Google/Apple's identity servers, ii) the user grants the requested scope, iii) the identity server returns a short-lived authorisation code, iv) the patient recruiter generates a short-lived study code in the clinician web app and gives it to the patient, v) the app sends both the a study code and authorisation code to our API, vi) the backend verifies the authorisation code API-side with Google/Apple identity servers, vii) upon successful verification, the backend assigns the patient to the patient group that the study code originated from with a unique pseudo-anonymous patient id, signs a JWT whose payload contains the patient id and assigned study, finally sending it back to the mobile app for secure storage. Every time the patient app makes a request to the API, it presents its JWT. The JWT is time-limited meaning that the patient app periodically uses a refresh token (also provided by the API) to request a new JWT. Re-executing the sign-in flow has the same effect. The JWT expiration time is system configurable.

Authorisation code flow and Proof Key for Code Exchange (PKCE) are industry standard in validating a user's identity from an external identity provider (in this case Google or Apple) and providing secure access to an API with fine-grained access claims to protected resources. The advantage of this flow is that PID is securely stored only on the user's handset, and only pseudo-anonymous ids are stored in HALO-X's database. Using OAuth flows with a JWT token means that API resource access can be provided on a per-user and time-limited basis, unlike conventional system-wide API keys. Furthermore, the user-granted permissions are uniquely scope-limited to our app and are natively integrated into health store data access, so at any time a user can revoke HALO-X's access to health data via their Apple or Google main accounts.

## Clinical Study Design

Patients were made aware that the HALO-X platform was not a medical device, unable to notify healthcare professionals of a problem or clinical event. As such they were asked to follow the existing standard of care for their treatment. HALO-S (IRAS 284073) and HALO-Trak (IRAS 312296) study protocols (Fig. 10) were designed and lead by the UCL/UCLH team to evaluate the HALO-X platform for its ability to capture continuous and intermittent wearable sensor data in patients at risk of complications. The DISCUS (NCT06892860) sub-study was designed and lead by the QMUL team to evaluate the platform's ability to collect wearable data and to quantify the wellness of patients undergoing different chemotherapy regimens.

After informed consent was obtained, the patient installed the HALO-X app and instructions were provided as described above. Upon completion of the study, patients were asked to return the wearable device, and information about unplanned healthcare/adverse events were collected by the clinical team.

During the off-boarding process, patients were asked to fill out voluntary pre-prepared feedback forms, detailing their experience of using our RPM platform throughout the monitoring period. For HALO-S and HALO-Trak studies, patients were asked to report usability issues wearing the physical device, using the app, general usability fatigue due to illness and data synchronisation technical issues. Further ease-of-use scores for wearing the device, using the app and completing a PROM were also collected from HALO-Trak responders. All findings are presented in the results section.

## HALO-S

HALO-S (Home and Locally Observed after Surgery) [53] was a prospective observational study designed in the aftermath of the COVID-19 pandemic to monitor patients for 30 days following radical cystectomy surgery. Focus was on short-term patient recovery, aiming to test the feasibility and patient compliance of wearable-based RPM and QoR-15 PROM collection in the immediate postoperative and post-discharge periods. It is the sequel to DREAMPath [54] which measured patient compliance with a multi-device remote monitoring kit after discharge from hospital following major surgery. During the COVID-19 pandemic the UCLH Cancer Hub experienced a reduction in staffing resources due to the redeployment clinical staff to the frontline, thus affecting how patients were managed post-discharge. To maintain standard of care, patients were provided with pulse oximeters on discharge, and a daily conversation with a member of the surgical team for a period after discharge from hospital. However, a one-off oximeter reading has its limitations in detecting an early functional decline and surgical complications, motivating the HALO-S study to test the feasibility of HALO-X for higher resolution RPM.

## HALO-Trak

HALO-Trak [55] was a 12-month multi-centre observational cohort study designed to monitor patients undergoing systemic chemotherapy, immunotherapy or hormone therapy for advanced haematological cancer. The study collected EORTC QLQ-C30 PROMs [56], cytokine profiling, stool and blood sample data in addition to the wearable and QoR-15 PROM data. This study demonstrated a proof of concept for aggregating RPM data collected from outside the hospital with data collected within the hospital using a FHIR data egress microservice. Aggregated datasets are the foundations to building statistical models for use in proactive care such as the prediction of clinical outcomes (response to therapy, risks such as hospital readmission and survival). The study aimed to determine the feasibility of longitudinal digital data capture and exploratory biomarker development. All patients were receiving standard of care therapies, recruited from oncology clinics at participant sites once diagnosis of advanced haematological cancers were established.

## DISCUS

DISCUS [57] is an existing randomised phase II clinical trial investigating whether shorter chemotherapy duration improves quality of life without worsening efficacy, by comparing three versus six cycles followed by Avelumab. A feasibility sub-study was created to evaluate the HALO-X platform's ability to collect QoR-15 PROMs and wearable patient data during the trial's chemotherapy cycles. The DISCUS sub-study recruits from Spain, France and the UK, enabling us to evaluate HALO-X's internationalisation features, such as its capacity to handle multiple time zones and UI text translation. Remote RPM deployment away from our immediate clinical teams was used to gain experience in remote clinic operational pain points. DISCUS [57] is an existing randomised phase II clinical trial investigating whether shorter chemotherapy duration improves quality of life without worsening efficacy, by comparing three versus six cycles followed by Avelumab. A feasibility sub-study was created to evaluate the HALO-X platform's ability to collect QoR-15 PROMs and wearable patient data during the trial's chemotherapy cycles. The DISCUS sub-study recruits from Spain, France and the UK, enabling us to evaluate HALO-X's internationalisation features, such as its capacity to handle multiple time zones and UI text translation. Remote RPM deployment away from our immediate clinical teams was used to gain experience in remote clinic operational pain points.

## Declarations

## Data Availability

The data that supports this study is not publicly available because it was collected from patients in clinical studies subject to ethical, legal and privacy restrictions. Due to these constraints, we are unable to share this data publicly.

## Code Availability

The HALO-X platform codebase is proprietary and commercially owned by Ethern Health Ltd. Due to this constraint, we are unable to share this code publicly.

## Funding Declaration

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## Authors Contributions

RS designed, developed, tested, debugged, implemented, documented, deployed and maintained the HALO-X platform software and cloud infrastructure. YL, RS, ID carried out data aggregation, cleaning, transformation and analysis. DS, ID, RS did wearable testing and analysis. YL, RS, DS developed figures, charts and visualisations. RS, GC developed interoperability, system integration, cloud security/resources and trusted research environment strategies. PK, JK developed/implemented clinical study design and ethics. FJ, TP developed/implemented RCT sub-study design and ethics. HK, HM, PW, FJ managed clinical operations, managed patient contact and clinical data collection. GC, JK managed funding, project administration and collaboration partnerships. RS prepared, wrote and edited this manuscript according to guidelines. RS, ID, YL, GC reviewed the complete manuscript before final edits. All authors reviewed final proofs before publications.

## Competing Interests

RS, GC, PK, ID and JK are shareholders and/or directors of Ethern Health Ltd., within which the HALO-X platform was developed.

## Ethics Approval

HALO-S (REC ref: 20/WA/0221)

HALO-Trak (REC ref: 22/SW/0161)

DISCUS sub-study (REC ref: 21/LO/0694)

## Consent to Participate

Informed consent was obtained from all patients recruited into HALO-S, HALO-Trak and DISCUS sub-study.

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## Figures

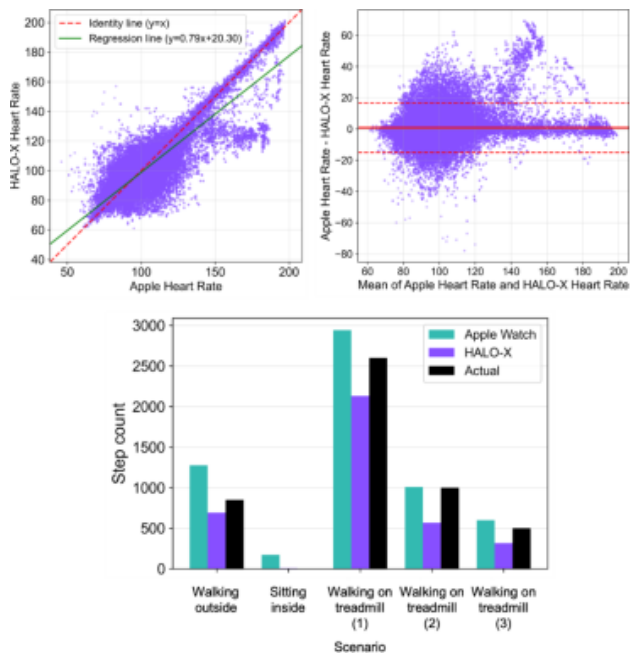


**Figure 1**

Correlation plot (top-left), Bland-Altman plot (top-right) for the Apple Watch and HALO-X heart rate BPM values (rounded to nearest integer during export). Maximum heart rates were achieved with a 19-year-old male subject undergoing extreme exercise. Step count comparison for multiple user activities (bottom).

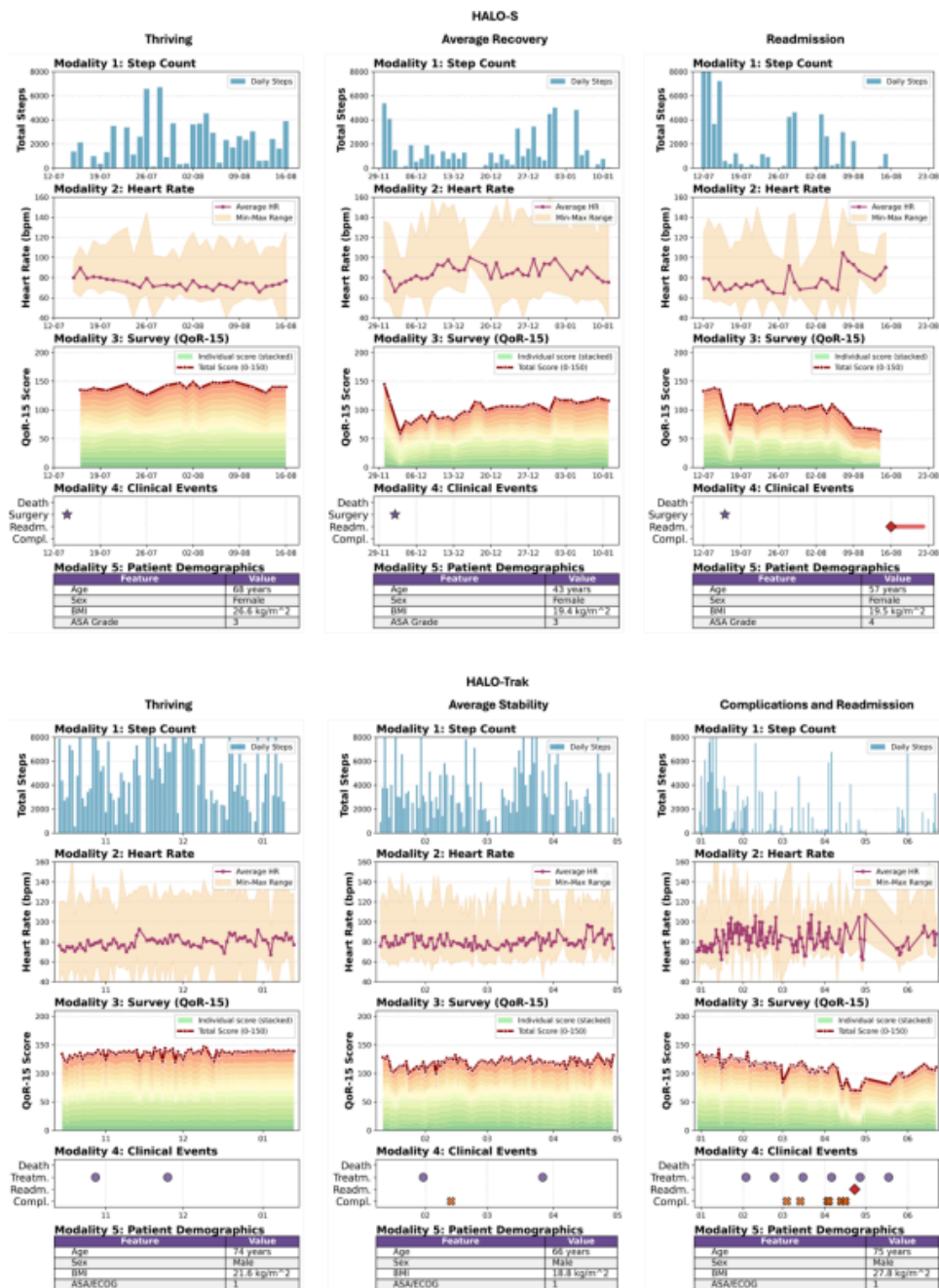


Figure 2

Aggregated multimodal data sets for selected patients. HALO-S (top, time axis DD-MM) and HALO-Trak (bottom, time axis MM); thriving (left), average recovery/stability (middle) and readmission/complications (right).

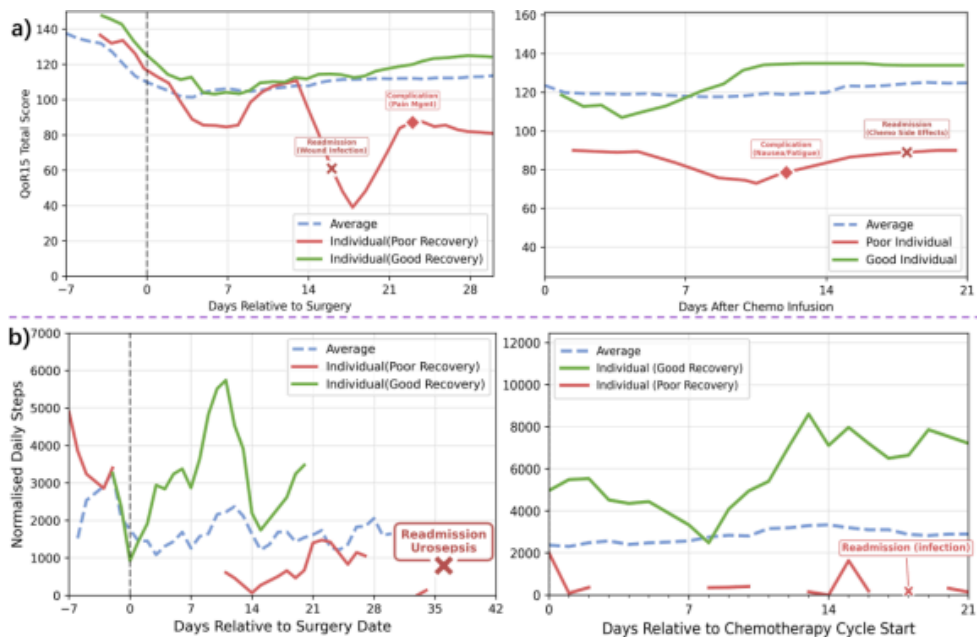


Figure 3

Quality of recovery (QoR-15) questionnaire score trajectories (top) and step count trajectories (bottom) in HALO-S (left; radical cystectomy) and HALO-Trak (right; 21 days following chemotherapy infusion). Cohort average recovery (dotted blue), alongside individual cases with poor recovery (red) and good recovery (green).

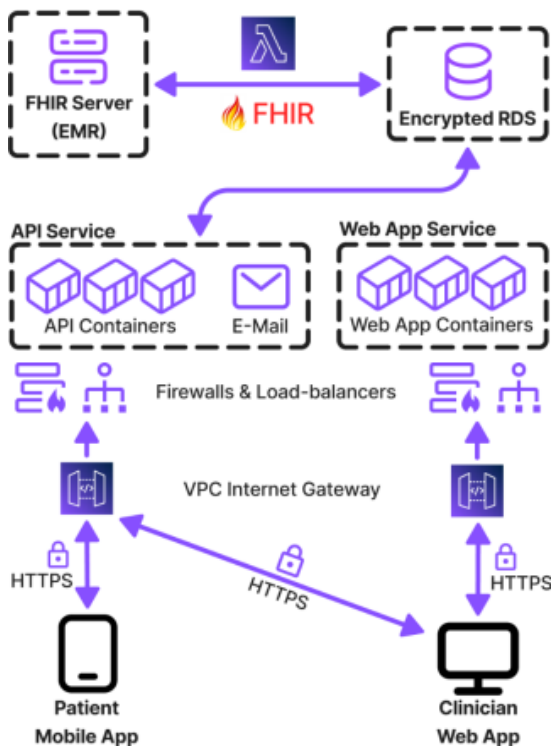


Figure 4

HALO-X system network architecture: patient mobile app, clinician web app, backend API and FHIR microservice data egress.

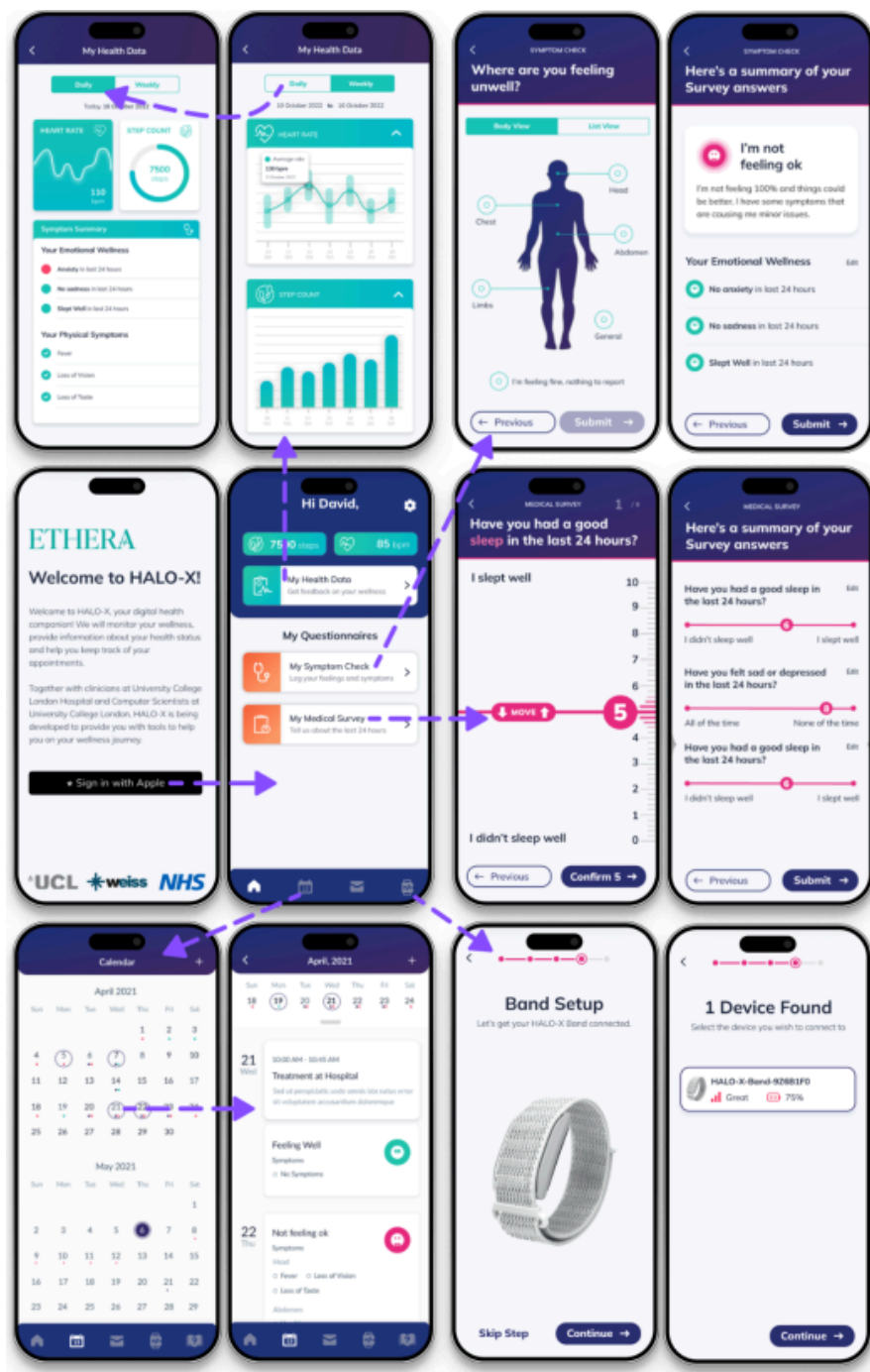


Figure 5

Patient-facing app, navigating from the home screen.



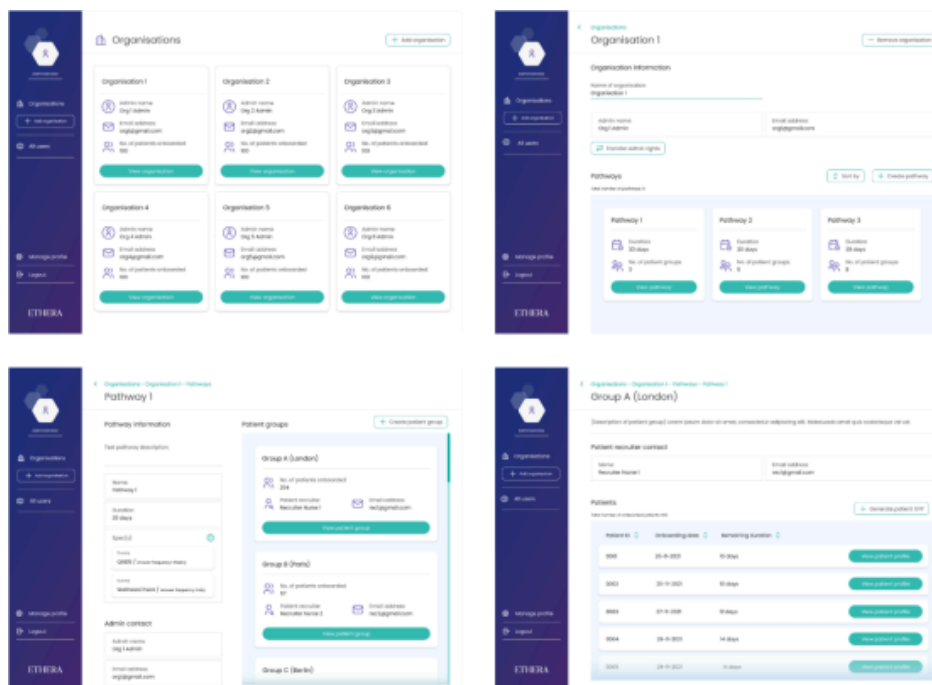


Figure 8

Clinician web app: *Organisations, pathways and patient groups.*



Figure 9

Patient onboarding flow, in-person with a nurse recruiter. When a patient is on-boarded into a study in the patient app, a unique pseudo-anonymous patient ID is created to uniquely identify the patient. The nurse recruiter records this ID in the patient's clinical notes (hospital-side), used later for joining any RPM data sent into the hospital/research environment.

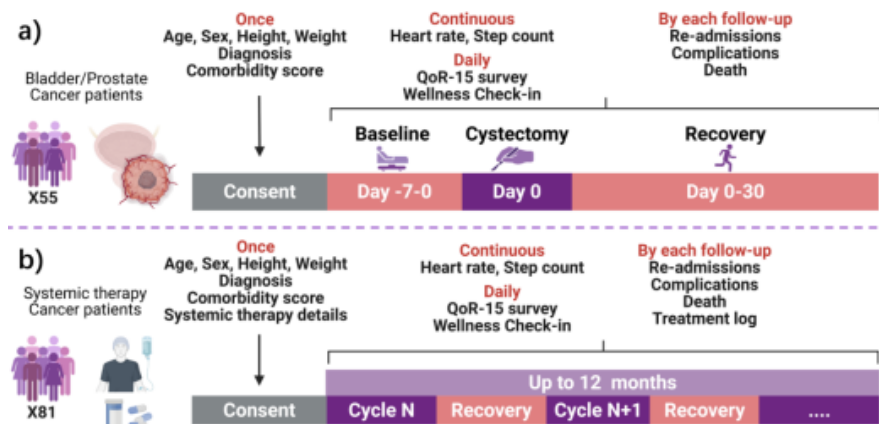


Figure 10

a) HALO-S clinical study design: 30-day post-operative wearable and daily PROM data collection along with clinical outcomes. b) HALO-Trak clinical study design: up to 12-month timeline of wearable and daily PROM data collection along with clinical outcomes.

