CASE STUDY

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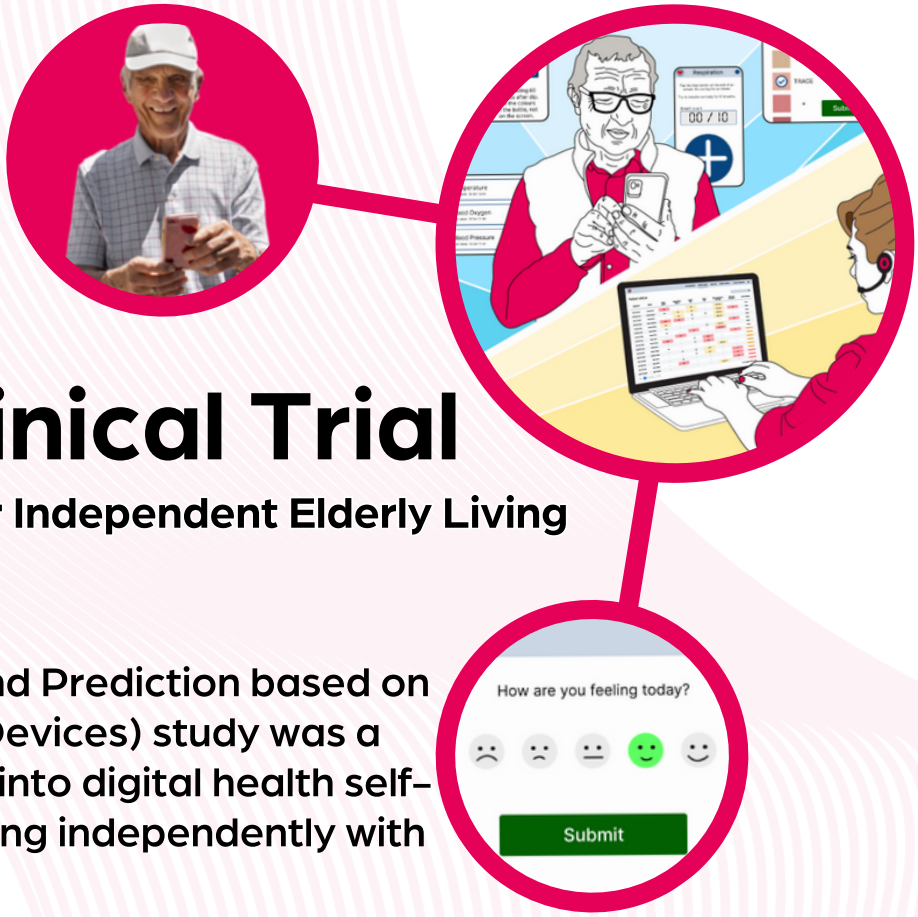


# SerPICoD Clinical Trial

## Digital Health Monitoring for Independent Elderly Living

## Overview

**The SerPICoD (Service Demand Prediction based on Information from Connected Devices) study was a groundbreaking investigation into digital health self-monitoring by older people living independently with health conditions.**

**Commissioned by NHS England and conducted by Camgenium through Hertfordshire and West Essex Integrated Care Board, this study achieved unusually high compliance rates to the self-monitoring regime with a cohort of 600 participants aged 65 to 95. It successfully overcame barriers resulting from digital inclusivity and technology adoption issues. Camgenium's Xenplate, no code platform was used to develop the patient app and clinical trial management system with the user-friendly system being a key driver in the success of the study.**

## Study Purpose & Innovation

The SerPICoD study was designed to address the challenge of providing improved long-term healthcare support for patients aged over 65 living independently with health conditions. The primary research hypothesis tested whether information captured by participants self-monitoring could predict demand for healthcare provision and prevent the crises that strip away independence and result in expensive emergency admissions by enabling healthcare providers to identify early signs of deterioration.

The study's innovative approach differed significantly from traditional condition-specific monitoring programmes. Rather than selecting participants based on specific diseases, SerPICoD used proxies for risk of exacerbation, including recent unscheduled care attendance, multiple clinical domains from Quality and Outcomes Framework (QOF), and medium to high frailty scores. This methodology made the findings applicable across diverse elderly populations with multiple comorbidities.

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## Technological Innovation, Digital Inclusivity and Technology Adoption

As part of the clinical trial design, significant care was taken in designing the participant app and trial management technology to enable elderly patients to self-monitor long-term. The success of this approach was evidenced by the excellent compliance rates of over 90% to the self-monitoring regime.

People aged 65-95 years typically have lower familiarity and comfort with technology than the general population, and this was a clear challenge that had to be addressed through the study design. The participant app was specially designed to be easy to use even with poor eyesight or fine motor control. It was designed to connect automatically to a wide range of measurement devices (such as blood pressure meters and pulse oximeters) via Bluetooth and it supported multiple measurement types. It gave participants a simple interface through which they could answer questions about how well they were feeling and provided helpful information about the equipment and the study. The study team developed protocols for training participants on the technology and for participant support, all managed through a comprehensive clinical trial system.

Participants used relatively low-cost standard medical devices. Participants with digital skills were encouraged to install the study app on their own phones to reduce deployment costs.
However, some participants found this too challenging and so were given pre-configured, locked-down smartphones with paired measurement devices as a set of equipment ready to use.

The study also included a support service, which was driven by the trial management system developed on Camgenium's GxP compliant software platform, Xenplate. The system ensured that participants were correctly onboarded and trained. It also identified any people who were struggling with the technology so that they could be given the additional support they needed. All participants were onboarded, trained and supported by telephone; none received a visit. The telephone system was integrated into the study management system and all calls were recorded as part of the study record and audit trail.

The clinical trial management system was developed using Camgenium's secure GxP compliant Xenplate platform. The Xenplate system has extensive functionality and can be rapidly configured to meet exact requirements. It enabled the team to manage all aspects of the study including compliance management, device and asset management, and data collection and management as well as those described above. The Reassure app issued to participants was an integral part of the system, and was used to capture measurements and other participant reported data.

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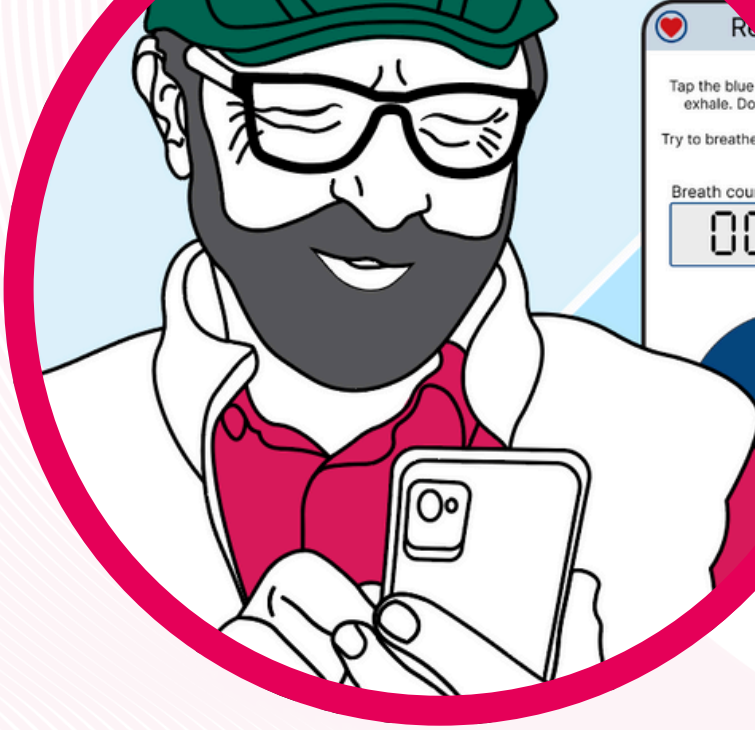
Using the Xenplate platform, it proved straightforward to adapt the research management system as the study progressed to ensure it was always providing the functionality needed by the team. This agile approach was crucial in adapting the system for the amended protocol that was used for the second of the two trial phases. It also ensured that unforeseen challenges could be managed as they manifested. As an auditable system, not only was all usage and data collected in compliance with the requirements of Good Clinical Practice, all changes to the system itself were automatically recorded, meeting compliance requirements.

## Exceptional Compliance Achievement

Despite the implementation challenges and the demanding nature of the monitoring regime, the study achieved remarkable compliance rates that exceeded expectations for elderly populations using digital health technologies.

Over 90% of all required measurements were taken throughout the study period, representing exceptional adherence to a relatively onerous self-monitoring regime. Phase 2 participants were asked to monitor twice daily for twelve weeks in accordance with NICE guidance. (NICE recommends twice daily monitoring of patients at risk of deterioration.) This frequency represented a significant daily commitment from participants.

The study's dropout rate was extraordinarily low at only 7%, particularly given the age range and health of participants, with just 36 out of 515 failing to complete participation in the study. This retention rate is significantly higher than that typically achieved in digital health intervention studies in elderly populations.




## Inclusive Participation Success

The study successfully demonstrated that digital health monitoring could be digitally inclusive across diverse elderly populations. Participants ranged in age from 65 to 95 years, with 27.8% over 80 years old in Phase 2. All participants had significant comorbidities, and many had medium to high frailty scores, representing the most challenging demographic for technology adoption.

Socio-economic diversity was achieved through strategic surgery selection, providing representation across affluent areas and areas of deprivation. The cohort included participants from various ethnic backgrounds, though formal ethnicity assessment was not conducted.

Remarkably, compliance appeared to be independent of age, health condition, social deprivation and technical proficiency. This finding challenged common assumptions about digital divide barriers and demonstrated the effectiveness of the study's inclusive design approach.

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## Effective Support Infrastructure

The study's success was underpinned by a carefully designed support infrastructure using non-clinical Research Assistants who provided telephone-based technical support tailored to the needs of each individual participant. This stratified support model proved highly effective, with some participants requiring minimal assistance while others needed more intensive support.

The median number of calls was eleven per participant over the study period, though there was considerable variation with some participants requiring significantly more support. Calls were made for a variety of purposes besides support that included initial on-boarding, training, to completing research questionnaires. Importantly, analysis showed that neither technical proficiency nor age significantly affected the number of support calls required, indicating that the inclusive design measures were effective.

Research Assistants in fact provided multiple functions: teaching participants about the study and how to use the technology, providing technical support and troubleshooting technical problems, providing accountability for measurement taking, and offering social support. This multifaceted approach contributed significantly to sustained engagement.

## Technology Design Success Factors

Several specific design elements contributed to the compliance rates. The L2S2 Reassure app was designed for simplicity, using large buttons and clear interfaces appropriate for elderly users.

Where possible, devices connected via Bluetooth to minimise manual data entry and transcription errors.

Participants were provided with certified medical devices including blood pressure monitors, pulse oximeters, peak flow meters, and thermometers, selected according to their specific health conditions. The device selection was personalised based on clinical review of participant medical records by the study's Chief Medical Officer.

Participants were also asked to provide self-assessed measures including breathing speed (measured by tapping the app in time with breathing) and perception of health using a simple Likert scale with facial expressions. These "free" measurements that didn't require sensors proved valuable in detecting exacerbation.

## Multi-Stakeholder Collaboration Complexity

The study required complex collaboration arrangements with multiple GP surgeries across diverse geographical and socio-economic areas. The selection of surgeries was strategic; two surgeries were chosen specifically because they served significant numbers of patients from areas of deprivation and ethnic minorities, ensuring representative cohort diversity.

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## Lessons Learned and Future Implementation

The study identified several critical success factors for digital health monitoring in elderly populations. Technology must be designed to be simple and easy of use, and alternatives should be provided for participants who are unable to use their own smartphone to run an app. Technical support must be provided via telephone with escalation according to individual needs, and support staff require training in both technical and social engagement skills.

Device selection should be personalised based on clinical assessment of participant conditions, and regular review processes should ensure only devices with extremely simple operation are provided. The study also highlighted the value of tiered provision of equipment and support according to individual need.

## Early detection capabilities

The study successfully demonstrated that some exacerbations, particularly infections, could be identified from data captured in the ten days before the exacerbation occurred.
While statistical confidence was limited due to cohort heterogeneity and data limitations, these findings suggested that daily, simple self-measurements could provide an affordable early warning system for population-scale rollout.

## Participant Benefits and Behavioural Changes

The study documented significant additional benefits beyond clinical monitoring. Sixteen percent of participants reported changing to healthier behaviours as a result of self-monitoring, with one-third of this subset using the monitoring data to drive improvements in their healthcare.

Forty-three percent of participants improved their awareness of their health and its relationship to lifestyle factors. Some participants (just under 5%) acted on monitoring data by contacting their GP, who modified their healthcare accordingly, potentially preventing some exacerbations.

Many participants reported enjoying the self-monitoring process and expressed desire to continue monitoring after study completion, with some purchasing devices to enable ongoing self-monitoring.

## Service Transformation Potential

The study demonstrated clear potential for transforming existing NHS services through provision of an inclusive long-term monitoring service with stratified technology and support. The proposed service model could provide early detection of exacerbations, enable triaged intervention, collect valuable longitudinal health data, and empower service users to monitor and understand their health.

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## Recommendations for Scale-Up or for Future Studies

For scale-up, the study recommended several improvements including app enhancements, replacement of configured smartphones with specially developed simpler devices, and regular reviews of all equipment to ensure optimal usability. A clinical service model should include regular clinical feedback to participants, longitudinal data access for clinicians, and integration with existing healthcare delivery systems.


Cost-effectiveness analysis indicated that the service could be provided at relatively low cost for the majority of participants or patients, with stratified support to ensure that resource is concentrated where it is most needed.

The inclusive design approach, combining simple technology with stratified telephone support, all coordinated through an integrated trial management system, proved effective across diverse populations regardless of age, technical proficiency, or socio-economic background.

## Summary

The study successfully demonstrated that elderly people with complex health conditions can achieve exceptional compliance with demanding digital health monitoring regimes when they are provided with appropriately designed technology and support services. This study achieved compliance rates exceeding 90% with dropout rates of only 7%.

Most significantly, the study demonstrated that such monitoring systems can provide early detection capabilities while empowering participants to better understand and manage their health, offering substantial potential for healthcare transformation and cost reduction through prevention of emergency admissions.

The study's success challenges conventional assumptions about digital divide barriers in elderly populations and provides a robust evidence base for population-scale implementation of digital health monitoring.