The University of Manchester

Health Research from Home




HEALTH RESEARCH FROM HOME

# DATA COLLECTION PLATFORM GUIDE

*Health Research from Home is funded by the Medical Research Council (MRC) [grant number MR/Y003624/1]*

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# 01

# Introduction

Selecting a digital data collection platform for research can be challenging, with a wide range of tools and platforms available that differ in their capabilities, governance arrangements, technical requirements and suitability for different study designs.

This guide is intended to help researchers identify, compare and evaluate platforms that may support data collection, participant engagement, study management and research delivery.

The guide is organised into several sections, each designed to support a different stage of the assessment process:

- **Before engaging with platform providers** helps researchers define their study requirements and prepare a clear specification before exploring potential platforms.
- **Selecting a digital data collection platform** outlines the main factors that may influence platform selection, including study design, participant needs, data requirements, governance considerations and resource implications.
- **At-a-glance feature comparison table** provides a high-level comparison of key platform features to help researchers quickly identify platforms that may meet their study requirements. It is intended as a starting point for evaluation rather than a definitive assessment. Researchers should use the table alongside the detailed platform profiles and assessment criteria to explore functionality, governance, technical requirements and suitability in more depth.
- **Platform profiles** summarise the characteristics, capabilities, strengths and limitations of individual platforms to support comparison.
- **Glossary** explains commonly used terms and concepts that researchers may come across.

Researchers may choose to read the document from start to finish or use individual sections as needed. Those at the early stages of study planning may find it helpful to start with the “Before engaging with platform providers” and “Key considerations” sections, while researchers with a defined set of requirements may wish to use the assessment criteria and platform profiles to compare potential solutions.

# 02

## Before engaging with digital data collection platform providers

Before approaching platform providers, it is helpful to have a clear understanding of your study requirements.
The questions below can help you define what you need from a platform and assess whether it is suitable for your study.

- [ ] Have I clearly defined the study objectives and research questions?
- [ ] Have I identified the study design (for example, pilot, feasibility, longitudinal vs interventional , direct-to-participant or researcher-facilitated)?
- [ ] Have I defined the participant population, eligibility criteria and recruitment approach?
- [ ] Have I identified what data will be collected? Does it need to be actively reported (e.g. tracked symptoms, text surveys), active tasks (e.g. sit-stand test, tap test, audio recordings), passive or a combination?
- [ ] Have I considered the type, format and expected volume of data (for example, surveys, wearable data, images, audio, video or sensor data)?
- [ ] Have I assessed the sensitivity of the data and any privacy, information governance or regulatory requirements?
- [ ] Have I identified any requirements for data storage, processing, sharing or integration with other systems or datasets?
- [ ] Have I determined what devices, technologies or third-party platforms are required? For example, do participants need an app, device, wearable or web-only access?
- [ ] Have I considered participant and researcher support requirements?
- [ ] Have I identified any requirements for monitoring, reporting, audit trails or data quality assurance?
- [ ] Have I identified the approvals required, such as ethics, sponsor, NHS or information governance approvals?

- [ ] Have I established any budget, procurement or funding constraints?
- [ ] Have I considered study timelines, including platform setup, testing, recruitment and follow-up?
- [ ] Have I defined the minimum requirements a platform must meet to be considered suitable for the study?

# 03

# Selecting a digital data collection platform

### Governance, privacy and compliance

Consider whether the platform can meet the governance, privacy and compliance requirements of your study. Requirements may vary depending on the type, volume and sensitivity of the data being collected and managed. Gather information on data controller and processor roles, information governance requirements, consent models, audit trails, access controls, retention and deletion policies, anonymisation processes and data sharing arrangements. This information can help determine whether the platform is suitable for your study and support ethics and governance approvals. Confirm whether the platform has been used in NHS, clinical trial or other regulated research settings, and what further assurance may be needed within your organisation.

### Hosting and data location

Consider whether the hosting arrangements are appropriate for your study and the type, volume and sensitivity of data being collected. Check where the platform and data would be hosted, for example locally, institutionally, in a commercial cloud or by a managed service provider. Confirm who maintains the infrastructure, where data are stored, whether UK or EU hosting is available, and whether the data location meets funder, sponsor, NHS or university requirements.

### Implementation and support requirements

Assess the practical effort needed to set up and run the platform. Consider procurement processes, technical skills, configuration effort, staff training, user support, study onboarding, maintenance, upgrades, supplier support and realistic implementation timescales before committing.

**Participant experience**

Consider what participation would feel like for the people taking part, ideally involving patients or potential participants in evaluating platforms. Check whether they need to self-enrol, install an app, use a device or wearable, respond to reminders, complete frequent surveys, provide passive data or use the platform offline. Consider accessibility, language options, digital exclusion and the likely impact on recruitment and retention.

**Integration and interoperability**

Check whether the platform can connect with the systems and data sources the study needs, such as wearable devices, smartphone sensors, electronic health records, Apple Health, Android Health Connect, APIs, statistics packages, dashboards or institutional identity management systems. Confirm which integrations are already available and which would need development (and at what cost).

**Data standards and validated instruments**

Check how data are structured, coded and exported, and whether they meet the standards required by the study and receiving systems, for example Fast Healthcare Interoperability Resources (FHIR), relevant clinical terminologies, common data models or agreed metadata standards. Confirm whether questionnaires, patient-reported outcome measures and other assessments use validated instruments, approved versions and appropriate scoring methods, and whether licences or permissions are required.

**Outputs, access and analysis**

Clarify what researchers will get out of the platform and how they will access it. Check export formats, access permissions, dashboards, reports, provision of metadata, data quality checks, missing-data alerts, analysis readiness and whether platform data can be linked with other study datasets.

**Scale and study complexity**

Match the platform to the scale and complexity of the study. Consider whether it is intended for pilots, single-site studies, multi-site studies, longitudinal studies, high-frequency data collection, large cohorts, decentralised trials or international projects. Check any limits on participant numbers, sites, devices, forms, data volume or data frequency.

**Regulated trial suitability**

If the study is a clinical trial, medical device study, sponsor-led study or regulated trial, confirm whether the platform can meet the required standard before selecting it. For example, depending on the study, the platform may need to support Good Clinical Practice (GCP) through documented validation for its intended use, audit trails recording changes to trial data, controlled user access and secure retention of records for inspection, alongside meeting sponsor quality requirements and applicable data protection law, including UK GDPR.

# 04

## Directory of digital patient-generated health data (PGHD) collection platforms

At-a-glance feature comparison table

*Note that these ratings are based on public information reviewed and require study-specific confirmation.*

# 05

## Platform profiles: End-to-End Digital Research Platforms

End-to-end digital research platforms are integrated software solutions that support multiple stages of the research lifecycle using smartphones and/or wearables. Typically, they provide functionality for participant recruitment, eligibility screening, electronic consent, data collection, wearable integration, participant engagement, study management, data storage, and data export or analysis within a single platform or ecosystem.

A further section follows detailing research frameworks and tools that support specific stages of the research lifecycle.

## Beiwe




Contact: hdawood@hsph.harvard.edu is listed for the Beiwe Service Center and Onnela Lab pages.
URL:
- Beiwe Service Center
- Beiwe Service Center - Technology
- GitHub
- Paper - Beiwe: A data collection platform for high-throughput digital phenotyping

**What is it?**
Beiwe is an open-source smartphone-based digital phenotyping research platform developed by the Onnela Lab at Harvard T.H. Chan School of Public Health. It supports active and passive data collection through native Android and iOS apps, an AWS-backed back end, a web-based study management portal and Forest analytics for Beiwe data.

**Supported devices**
- Android smartphones through a native Beiwe Android application.
- iOS smartphones through a native Beiwe iOS application.
- AWS-backed web infrastructure for study management, data processing and storage.

**Supported data types**
- Active participant input, including text surveys, audio recordings and associated metadata.
- Passive smartphone sensor data, including GPS, accelerometer and gyroscope data.
- Phone log and usage data, including communication logs where supported and approved.
- Raw sensor and phone-use data with configurable sampling, upload frequency, data connection rules and survey logic.

**Benefits:**
- Purpose-built for smartphone-based digital phenotyping in academic research.
- Collects raw smartphone sensor and usage data, supporting transparency, reproducibility and re-analysis.
- Highly configurable study settings include sensors, sampling frequency, upload frequency, GPS noise and survey skip logic.
- Beiwe Service Center offers access to the platform as a service, so research teams do not need to set up and maintain their own version of the open-source software.

**Limitations:**
- Standard service pricing, contract terms and support service levels are not published.
- Self-hosted implementation requires technical capability to deploy and maintain AWS-based infrastructure.
- Data collection depends on smartphone operating system permissions, background data collection limits, battery use, participant device compatibility and participant adherence.

**Best-fit research use**

- Academic digital phenotyping studies using participants' own smartphones.
- Mental health, behavioural health, social behaviour, mobility and longitudinal studies requiring passive smartphone sensor and usage data.
- Studies needing configurable active surveys alongside background passive data collection.
- Projects where reproducible raw data collection matters more than off-the-shelf summary measures.

**Example applications**

- Smartphone-based assessment of disease progression in people with amyotrophic lateral sclerosis (ALS). Publication: Design and results of a smartphone-based digital phenotyping study to quantify ALS progression
- Digital phenotyping studies investigating behaviour, mobility, social interaction and mental health using passive smartphone sensor and usage data. Overview: Digital Phenotyping and Beiwe Research Platform.

**Costs and contracts**

Beiwe is open source, and the Beiwe Service Center offers platform access as a service. Standard pricing, contract terms, implementation costs and service levels are not published. Researchers would need to confirm costs and responsibilities with the Beiwe Service Center or plan for internal technical deployment and maintenance.

**Governance, privacy and compliance**

Study-specific review would be needed for consent, data minimisation, participant acceptability, data controller and processor roles, NHS information governance, data-sharing, retention, international transfer, ethics approval and sponsor requirements. Published platform materials reviewed do not confirm UK-specific information governance compliance or inspection readiness.

**Hosting and data location**

The open-source Beiwe back end is based on Amazon Web Services infrastructure, including S3, EC2, Elastic Beanstalk and RDS/PostgreSQL. Specific data centre locations, UK or EU hosting options, backup arrangements and contractual hosting responsibilities are not confirmed in the sources reviewed.

**Implementation and support requirements**

Implementation requires study configuration, app deployment for Android and iOS, participant onboarding, sensor and survey configuration, AWS-backed infrastructure, data processing workflows and analytics planning. The Beiwe Service Center can provide access to the platform as a service. Standard implementation timescales, training routes and support service levels are not published.

| | |
|---|---|
| **Integration and interoperability** | Beiwe connects smartphone app data with an AWS-backed back-end system and Forest analytics. Study teams can configure data collection settings and analyse Beiwe data using Python-based tools. Detailed institutional identity management options, EHR integration, wearable integration and standard export specifications were not found in public sources. |
| **Outputs, access and analysis** | Beiwe collects raw sensor and phone-use data. Forest provides a Python library for analysing Beiwe data and can integrate with the AWS back end for scalable on-demand analytics. Tableau API support is listed for customisable workbooks and dashboards. Export formats, metadata completeness, missing-data alerting and analysis-readiness should be confirmed for the intended deployment. |
| **Scale and study complexity** | Beiwe is designed for high-volume smartphone-based digital phenotyping and scalable AWS-backed deployment. Published materials describe use across multiple research studies and support for secure, scalable, customisable study deployment through the Beiwe Service Center. General limits on participants, sites, studies, data volume, data frequency or study duration were not found. |
| **Regulated trial suitability** | Beiwe has been used in medical and academic research studies and is designed for research-grade digital phenotyping. The sources reviewed do not confirm Good Clinical Practice compliance, 21 CFR Part 11 compliance, UKCA or CE status, clinical safety case arrangements, inspection-readiness or validation status for a specific regulated trial. Researchers should confirm suitability against the intended study, sponsor requirements, regulatory expectations, institutional requirements and deployment documentation. |

## DAISER

Contact: Research and pricing enquiries: use the "Book an appointment" option on DAISER's website.
URL:
- Website
- About DAISER

**What is it?**
DAISER is a digital health platform for building digital health services and applications. It includes modular components, native AI integration, wearable and diagnostic connections, conversational AI, external data sources, APIs, web and mobile deployment, and regulated digital health pathways.

**Supported devices**
- Web, mobile or custom environments.
- Wearables, diagnostics, sensors and external data sources can be connected or integrated.
- The ASPIRE Study app, developed by DAISER Ltd, is available for iPhone, iPad and Android and includes Apple Health, Google Fit and Oura Ring integration.

**Supported data types**
- Digital health data that can be collected, structured and analysed within a research environment.
- Connected health data from wearables, diagnostics, sensors and APIs.
- AI-enabled user journeys, conversational AI and image recognition are available within DAISER's platform materials.
- The ASPIRE Study app lists patient-reported outcome surveys, physical symptoms, lifestyle habits, maternal wellbeing, sleep cycles, heart rate variability and movement as study data types.

**Benefits:**
- Supports configurable modular digital health services without requiring users to have a software engineering background.
- Supports AI integration, sensors, image recognition, wearables, diagnostics, APIs and automated processes.
- DAISER is positioned as regulation-ready, with pre-configured regulatory and application approval processes.

**Limitations:**
- Standard pricing, contract terms and service levels are not published.
- Detailed technical documentation, API specifications, hosting details and export formats were not found.
- Regulation-ready and regulated pathway claims require study-specific confirmation against sponsor, ethics, NHS, university and regulator requirements

**Best-fit research use**

- Digital health research programmes that need configurable web or mobile applications rather than a completely custom software build.
- Studies or services combining participant engagement, wearables, diagnostics, sensors, conversational AI or external data sources.
- Research-to-service translation where teams need to move from concept, to prototype, to deployable digital health application.
- Longitudinal research or care pathway projects that need structured digital health data and participant-facing applications.

**Example applications**

- ASPIRE (Advancing Stillbirth Prevention through Innovative Risk Evaluation) a multi-site longitudinal cohort study of first-time mothers funded through the Wellcome Leap InUtero programme. The study uses the DAISER platform to collect participant-reported outcomes, wearable data and other real-world health measures to support the development of predictive tools for pregnancy complications such as pre-eclampsia, fetal growth restriction and gestational diabetes. Link to app: ASPIRE app
- South Yorkshire Digital Health Hub projects such as Smart-Health, where DAISER is being used to help translate digital health research into participant-facing technologies and support the development of digital health innovations aimed at addressing population health needs and health inequalities across South Yorkshire. Website: Smart-Health | Smart-Health | The University of Sheffield

**Costs and contracts**

DAISER invites users to book an appointment or contact the team, but standard pricing, licence costs, contract terms, implementation costs and service levels are not published.

**Governance, privacy and compliance**

DAISER is positioned as secure, regulation-ready and built for digital health services, with references to regulated pathways and pre-configured regulatory and application approval processes. The ASPIRE Study app listing says participant data are mapped to a unique Participant ID, patient-identifiable information is not stored on application servers, information is encrypted and data are stored by the clinical study team. Study-specific review would still be needed for consent, data controller and processor roles, NHS information governance, sponsor requirements, data-sharing, retention, clinical safety, software as a medical device classification and regulatory suitability.

**Hosting and data location**

The hosting model, data centre location, UK or EU hosting options, backup arrangements and contractual hosting responsibilities are not confirmed in the sources reviewed.

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|---|---|
| **Implementation and support requirements** | The implementation model is assess, build and deploy. Assessment covers definition, design and prototyping. Build activities include configuring modular components against regulatory standards and design specifications. Deployment includes rapid launch with pre-configured regulatory and application approval processes. Standard implementation timescales, training packages, support service levels and customer responsibilities are not published. |
| **Integration and interoperability** | DAISER includes external data sources, wearables, diagnostics, APIs, sensors, image recognition, conversational AI and automation. The ASPIRE Study app lists Apple Health, Google Fit and Oura Ring integration. Technical integration documentation, API specifications, identity management options and data standards were not found. |
| **Outputs, access and analysis** | DAISER supports collection, structuring and analysis of digital health data, transforming episodic research data into longitudinal 24/7 insights and building a data foundation for digital care. Standard export formats, researcher dashboard details, access-permission workflows, metadata specifications, analysis-readiness information and missing-data alert configuration were not found. |
| **Scale and study complexity** | DAISER supports rapid deployment of digital health services and applications, including web, mobile and custom environments. The South Yorkshire Digital Health Hub partnership provides a planned deployment example across multiple clinical services. General limits on participants, sites, applications, devices, data volume and data frequency were not found. |
| **Regulated trial suitability** | DAISER uses terms such as regulation-ready, Class I regulated and Class II regulated for different service layers. The sources do not confirm validation status, inspection-readiness, Good Clinical Practice alignment, 21 CFR Part 11 compliance, UKCA or CE status, clinical safety case arrangements or suitability for a specific regulated trial. Researchers should confirm these points against the intended study, sponsor requirements and deployment documentation. |

## Empatica




Contact: Research and pricing enquiries via Empatica's Talk to our team form, selecting "Empatica Health Monitoring Platform"
URL:
- Website
- Empatica Health Monitoring Platform
- Empatica - Research Studies
- Empatica - Clinical Trials
- Empatica - Embrace Plus

**What is it?**
Empatica provides medical-grade wearables, digital biomarkers and a health monitoring platform for remote patient monitoring, clinical trials, academic research and clinical care. The Empatica Health Monitoring Platform combines EmbracePlus or EmbraceMini devices, a companion mobile app, Empatica Cloud and a Care or Care Lab Portal for participant management, data access and biomarker monitoring.

Participants wear EmbracePlus or EmbraceMini and use a compatible smartphone app to transfer data to Empatica Cloud. EmbracePlus pairs with the companion app through Bluetooth and includes in-app onboarding for correct wear. Data can be temporarily stored on the device or smartphone when connectivity is unavailable and then synchronised when the device reconnects.

**Supported devices**
- EmbracePlus, a wrist-worn medical wearable with PPG, accelerometer, gyroscope, temperature and EDA sensors.
- EmbraceMini, used within Empatica's health monitoring platform and Parkinson's monitoring offer.
- Compatible Android or iOS companion devices running Care App or Care Lab App for Bluetooth synchronisation and data transfer.
- Internet browser access to Care Portal or Care Lab Portal for study management, participant monitoring and data access.

**Supported data types**
- Raw sensor data from EmbracePlus, including PPG, accelerometer, gyroscope, temperature and EDA.
- Digital biomarkers and digital measures, including sleep, activity, cardiovascular and neurological measures.
- Physiological parameters and movement data collected continuously in real-world settings.
- Remote patient monitoring outputs, including participant compliance, wearing time, biomarker visualisation and downloadable raw sensor and digital biomarker data.

**Benefits:**

- Integrated platform combining wearable devices, a companion app, cloud infrastructure and a web portal for study management and data access.
- FDA-cleared and CE-certified or CE MDR certified platform materials are available for clinical trials and health monitoring.
- Supports continuous remote data collection from everyday life, including validated digital biomarkers and raw physiological data.
- Academic study features include anonymised participant data access, live tracking of wearing time, study set-up, participant management and data downloads.

**Limitations:**

- Standard pricing, enterprise licence costs, contract terms and service levels are not publishedStudy feasibility depends on device availability, participant smartphone compatibility, Bluetooth pairing, internet access and participant willingness to wear the device.
- Regulated trial use requires study-specific confirmation of validation package, sponsor requirements, regulatory expectations, data protection, information governance and trial-specific deployment documentation.

**Best-fit research use**

- Clinical trials, decentralised trials and hybrid trials needing remote collection of physiological data, digital biomarkers and raw wearable data.
- Academic research needing physiological and movement monitoring across real-world settings, multiple participants, locations and timeframes.
- Sleep, physical activity, cardiovascular, neurological and movement disorder research using digital biomarkers and raw sensor data.
- Remote patient monitoring and clinical care pathways.

**Example applications**

- Home-based monitoring of vasomotor symptoms in people receiving androgen deprivation therapy for prostate cancer, using EmbracePlus, the Empatica Care app and Empatica Cloud. Study record: BioWEAR: A Feasibility Study of Biometric Measurements Via Wearable Smart Watch Technology for Evaluation of Vasomotor Symptoms in Patients Treated With Androgen Deprivation Therapy for Prostate Cancer.
- Multicentre, six-month remote monitoring of people with chronic heart failure using EmbracePlus physiological, activity and sleep measures to support alerts, teleconsultations and assessment of clinical outcomes. Protocol: SMART-CARE: AI-Based Monitoring System for Chronic Heart Failure With Advanced Wearable and Mini-Invasive Devices.
- Longitudinal collection of continuous electrodermal activity, heart rate, skin temperature and activity data using EmbracePlus to develop personalised models for predicting migraine attacks. Publication: Migraine attack prediction using wearable biosensor data.

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| **Costs and contracts** | Academic users can request a quote through Empatica's research studies page, and the quote is valid for 30 days. Empatica also advertises a 25% academic discount. Standard clinical trial pricing, enterprise licence costs, contract terms, implementation costs and service levels are not published. |
| **Governance, privacy and compliance** | Empatica lists certification against international standards for information security management (ISO/IEC 27001:2022) and medical device quality management (ISO 13485). These certifications do not, on their own, confirm suitability for a specific UK research study. Empatica privacy materials identify Empatica S.r.l. as data controller for specified Embrace and app services and describe collection of registration, physiological and technical information. Study-specific review would still be needed for consent, controller and processor roles, ethics, NHS information governance, data-sharing, retention, validation, auditability and sponsor requirements. |
| **Hosting and data location** | Empatica Cloud securely stores collected data and makes it available through the Care or Care Lab Portal, or for direct download. Academic support documentation identifies AWS S3 bucket access for downloading raw sensor and digital biomarker data. Specific data centre locations, UK or EU hosting options, backup arrangements and contractual hosting responsibilities are not confirmed in the sources reviewed. |
| **Implementation and support requirements** | Implementation requires study set-up in the Care or Care Lab Portal, participant management, device provisioning, pairing with the companion app, sensor mode selection, participant onboarding, data transfer monitoring and data access set-up. Enterprise support materials include data collection basics, device and app instructions, study management, troubleshooting and advanced data access. Standard implementation timescales, training packages and service levels are not published. |

| | |
|---|---|
| **Integration and interoperability** | The platform connects Empatica devices to a companion app, Empatica Cloud and Care or Care Lab Portal. Clinical trial materials refer to cloud-to-cloud options for using a sponsor's own cloud while combining Empatica hardware and software for data collection and streaming. Detailed API documentation, export specifications, institutional identity management options and integration set-up requirements were not found. |
| **Outputs, access and analysis** | Care Portal or Care Lab Portal supports participant management, participant monitoring, wearing-time tracking, digital biomarker visualisation and data access. Data Access Keys provide credentials for downloading raw sensor and digital biomarker data from AWS S3 for further analysis. Standard export specifications, metadata completeness, researcher dashboard configuration and missing-data alert options should be confirmed for the intended deployment. |
| **Scale and study complexity** | Empatica positions the platform for clinical trials, decentralised and hybrid trials, academic research and clinical care. Clinical trial materials state that the platform is scalable across studies and geographies, supports simultaneous data collection from thousands of devices and multiple language support, and has been implemented in more than 120 industry-sponsored trials. General limits on participants, studies, devices, data volume or data frequency were not found. |
| **Regulated trial suitability** | Empatica materials state FDA-cleared and CE-certified or CE MDR certified status for the Empatica Health Monitoring Platform and EmbracePlus, and list FDA 510(k) clearance identifiers for EmbracePlus as part of the platform. Legal and compliance materials list ISO 13485 and ISO/IEC 27001 certifications. The sources reviewed do not confirm Good Clinical Practice compliance, 21 CFR Part 11 compliance, inspection-readiness or validated electronic source data status for a specific regulated trial. Researchers should confirm suitability against the intended study, sponsor requirements, regulatory expectations and deployment documentation. |

## Evidation

**What is it?**
Evidation is a real-world health data company that connects directly with individuals to collect longitudinal, multimodal real-world data. Its Research & Engagement Platform supports participant engagement, protocol compliance, patient-reported outcomes, surveys, connected device data and health-record data collection.

Contact: Research and pricing enquiries via Evidation's Contact Us form.
URL:
- Website
- Research platform
- About the App

**Supported devices**
- Wearables and health apps that can be linked by Evidation members, including Fitbit, Apple Watch, Garmin, Apple Health, Google Health, Dexcom, Withings and Samsung Health.
- Additional device and platform integrations are described as expanding, including Peloton, Polar and Ultrahuman.
- Medical records can be connected where members choose to do so.

**Supported data types**
- Multimodal real-world data, including clinical data, demographic and social context, conditions and treatment experience, patient-reported outcomes, molecular data from biosamples and digital measures from wearables.
- Active data including ePROs, surveys, programme interactions and health questions.
- Passive data from connected devices and wearables.
- Consumer health data categories may include health-related conditions, symptoms, diagnoses, testing, treatments, biometric measurements and information from connected third-party apps and services, depending on the service and user choices.

**Benefits:**

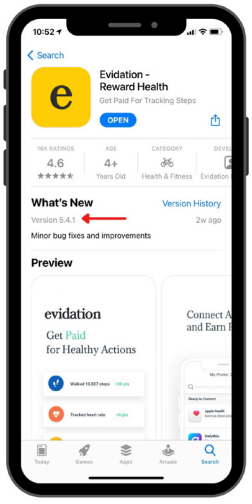
- Programmes commonly report participant retention rates above 90% and protocol compliance rates above 80%, according to Evidation's Research & Engagement Platform page.
- Supports low-burden active and passive real-world data capture, configurable to the study activity schedule.
- The Evidation Community includes around 5 million members participating through consented data sharing and research engagement, according to Evidation's public materials.
- Evidation's published research page listed 58 publications and abstracts at the time reviewed.

**Limitations:**

- Public materials reviewed do not provide standard pricing, contract terms or service levels for research customers.
- Public materials reviewed focus primarily on Evidation-managed or Evidation-licensed programmes and do not describe a self-hosted open-source research platform.
- Privacy notices state that different services, health programmes and sponsored programmes may be subject to specific informed consent terms and disclosures, so study-specific due diligence would still be needed.

## Best-fit research use

- Large-scale, longitudinal real-world evidence programmes that need direct participant engagement and repeated measurement over time.
- Studies combining patient-reported outcomes, surveys, connected device data, health records and contextual real-world data.
- Remote or app-enabled studies involving recruitment, onboarding, eConsent, retention monitoring and ongoing participant engagement.
- Digital health evidence generation, patient insights, recruitment and real-world studies for life sciences and digital health customers.






**Example applications**

- Large decentralised cardiovascular study involving more than 34,000 people aged 65 or over, combining app activities, Apple Watch data and authorised healthcare claims. Evidation collaborated with Johnson & Johnson and Apple to deliver remote study operations and the participant-facing digital experience. Publication: Does early detection of atrial fibrillation reduce the risk of thromboembolic events? Rationale and design of the Heartline study.
- Decentralised prospective study of more than 18,000 adults examining whether passively collected Apple Watch, Garmin or Fitbit data, symptom surveys and at-home PCR testing could identify respiratory viral infections. Participants connected their wearable to the Evidation platform and completed remote activities over ten weeks. Study record: Wearable Assisted Viral Evidence (WAVE) Study.
- Cohort Profile: Our Future Health, a peer-reviewed profile of the UK longitudinal population health programme, which aims to recruit up to five million adults. Evidation was selected to provide participant-platform technology, including the participant-facing app, engagement functions and collection of longitudinal real-world data such as surveys and wearable measures. Article: Our Future Health welcomes Evidation as new technology provider to enhance volunteer experience – Our Future Health



**Costs and contracts**

Evidation's public platform and customer pages invite organisations to contact Evidation or work with them, but do not provide standard pricing, licence costs, implementation costs, contract terms or service levels.

**Governance, privacy and compliance**

The model is consent-first, and members control what personal information they share, with whom and for how long. Privacy notices say health programmes may have their own informed consent terms, disclosures or authorisations. The personal information collected depends on the service used and choices made by the individual. Evidation uses industry-standard encryption and safeguards, according to its public privacy materials. Researchers would still need study-specific review of consent, controller and processor roles, data-sharing, retention, international transfer, sponsor requirements and applicable UK information governance requirements.

**Hosting and data location**

Evidation privacy notices include sections on location of personal information, but the public materials reviewed do not provide enough detail to confirm hosting model, data centre location, UK or EU hosting options, backup arrangements or hosting responsibilities for a specific customer research programme.

**Implementation and support requirements**

Planning and set-up include configuring and branding the programme experience, configuring participant profiles and testing the experience before launch. Programme delivery can include ongoing monitoring, programme-level analytics, actionable insights and data delivery. Public sources reviewed do not give standard implementation timescales, training requirements or support service levels.

**Integration and interoperability**

The platform can integrate active patient-reported data, passive data from connected devices, electronic health records, claims data and medical records that members authorise access to. App materials list examples of wearable and health app connections. Public sources reviewed do not provide technical integration documentation, API details, institutional identity management options or implementation specifications.

**Outputs, access and analysis**

Ongoing reporting can support programme health monitoring, programme-level analytics, actionable insights and data delivery. Public materials also refer to scientific insights, publications, real-world evidence generation and model development using longitudinal multimodal data. Public sources reviewed do not provide standard export formats, metadata specifications, missing-data alert configuration or researcher access-permission workflows.

**Scale and study complexity**

Evidation connects with around 5 million people and supports programmes involving tens of thousands of engaged patient populations, according to its public materials. Public examples include programmes across multiple geographies and the Heartline study, which involved more than 30,000 participants aged 65 or over. Public sources reviewed do not provide general limits on participants, sites, forms, devices, data volume or frequency.

**Regulated trial suitability**

Evidation public materials describe real-world studies, research programmes, eConsent, participant engagement and evidence generation, but do not state that the platform is validated for regulated clinical trials or provide inspection-readiness, Good Clinical Practice or 21 CFR Part 11 documentation. Researchers should confirm suitability against sponsor, regulator, ethics and institutional requirements before selection.

## Eureka




Contact: Research and study set-up enquiries: info@eurekaplatform.org, or use the enquiry form on Eureka's Get in Touch page.
URL:
- The Eureka Research platform
- Information about Eureka
- About the Research Platform

**What is it?**
Eureka is a non-profit digital research platform from the University of California San Francisco for online, mobile and hybrid medical research studies. It supports electronic consent, online and app-based surveys, wearable and mobile device data collection, electronic health record integration through FHIR, study management, secure cloud storage, raw data access and reports.

**Supported devices**
- Web access for online study activities, participant enrolment, surveys and study management.
- iOS and Android mobile apps for participant-facing study activities.
- Smartphones, wearable devices, apps and other connected data sources can contribute study data where configured.
- Electronic health record integration is available through FHIR where supported by the study and institution.

**Supported data types**
- Eligibility screening, electronic consent and enrolment data.
- Online questionnaires, surveys and other patient-generated data.
- Data from apps, devices, wearables, smartphones and electronic medical records.
- Coordinator-entered data, flexible automated reminders, raw data exports and custom reports.

**Benefits:**

- Supports online, mobile and hybrid research studies from enrolment through data collection and reporting.
- Offers a participant-facing mobile and web study experience, electronic consent, questionnaires, reminders and study management tools.
- Can support recruitment from a large existing participant community or from a study's own participants.
- Large Eureka-built studies include Health eHeart and COVID-19 Citizen Science, which together enrolled nearly 400,000 participants.

**Limitations:**

- Standard pricing, contract terms, implementation costs and service levels are not published.
- Detailed API documentation, export specifications, institutional identity management details and UK hosting options were not found.
- Regulated trial use would need study-specific confirmation of validation status, sponsor requirements, audit expectations, data protection, information governance and deployment documentation.

**Best-fit research use**

- Online, mobile or hybrid medical research studies needing remote enrolment, eConsent, surveys and participant engagement.
- Large-scale direct-to-participant cohort studies using web and mobile data collection.
- Studies collecting data from wearables, mobile devices, apps, electronic health records and participant-reported surveys.
- Studies that need a managed digital research platform rather than a self-built app and data infrastructure.

**Example applications**

- Large-scale remote recruitment into the Eureka-built Health eHeart cohort, with nearly 194,000 patients invited by email and Eureka supporting online registration, consent and longitudinal digital participation in cardiovascular research. Publication: Email-Based Recruitment Into the Health eHeart Study: Cohort Analysis of Invited Eligible Patients.
- Entirely digital population study launched through Eureka to collect repeated information on COVID-19 symptoms, behaviours and disease occurrence, using targeted recruitment, eConsent, recurrent surveys, smartphone-based measurements, participant engagement and real-time feedback. Protocol: The COVID-19 Citizen Science Study: Protocol for a Longitudinal Digital Health Cohort Study.
- Remote app-based trial in 499 people with symptomatic atrial fibrillation, with Eureka supporting mobile enrolment, randomisation, daily self-reporting, smartphone electrocardiogram data and personalised n-of-1 testing of participant-selected triggers. Publication: Individualized Studies of Triggers of Paroxysmal Atrial Fibrillation: The I-STOP-AFib Randomized Clinical Trial.

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| **Costs and contracts** | Pricing, licence costs, implementation costs, contract terms and service levels are not published. The public site invites researchers to book a demo or contact the team with a study idea. |
| **Governance, privacy and compliance** | Eureka is described by UCSF as a cloud-based, HIPAA-compliant research platform created at UCSF and approved by UCSF IT Security. The participant privacy policy says each study has a specific description of the data collected and how data will be used, that identity is not shared without permission, and that participants can choose whether to join each study based on the informed consent. Study-specific review would still be needed for UK ethics, consent, data controller and processor roles, NHS information governance, data-sharing, retention, international transfer, validation, auditability and sponsor requirements. |
| **Hosting and data location** | Eureka uses secure, HIPAA-compliant cloud storage. Specific cloud provider, data centre location, UK or EU hosting options, back-up arrangements and contractual hosting responsibilities are not confirmed in the sources reviewed. |
| **Implementation and support requirements** | Implementation requires study configuration for eligibility, eConsent, enrolment, surveys, reminders, participant experience, study management roles, data reports and any wearable, device, app or EHR integrations. Eureka provides consultation from a multi-expert team. Standard implementation timescales, training packages, support service levels and customer responsibilities are not published. |
| **Outputs, access and analysis** | Eureka can collect data from apps, devices, wearables, smartphones and electronic medical records, and UCSF describes EHR integration via FHIR. Detailed API documentation, identity management implementation details, integration set-up requirements and export specifications were not found. |

**Scale and study complexity**

Eureka supports online, mobile and hybrid studies, including remote recruitment, study management, electronic consent, data collection and reporting. UCSF describes rapid remote recruitment from more than 400,000 already-engaged participants or from a study's own new participants. General limits on participants, sites, forms, studies, data volume and data frequency were not found.

**Regulated trial suitability**

Eureka is described as a HIPAA-compliant research platform approved by UCSF IT Security for online, mobile and hybrid research studies. The sources reviewed do not confirm Good Clinical Practice compliance, 21 CFR Part 11 compliance, UKCA or CE status, clinical safety case arrangements, inspection-readiness or validation status for a specific regulated trial. Researchers should confirm suitability against the intended study, sponsor requirements, regulatory expectations, institutional requirements and deployment documentation.

## Evinova



Contact: Research and pricing enquiries via Evinova's Contact Us form.
URL:
- Website
- Unified Trial Solution
- Evinova Platform
- Trust Center

**What is it?**
Evinova is a health-tech business within AstraZeneca that provides digital health solutions for clinical trial sponsors, contract research organisations, clinical trial site care teams and patients. Its products and services include an AI-enabled clinical development platform, study design and optimisation, portfolio management, consulting and Unified Trial Solution for digital and decentralised trials. Unified Trial Solution brings trial participation from home into one app, with single sign-on for patients and sites. It supports remote assessments, connected devices, telehealth, ePRO/eCOA, remote patient monitoring, home supply and medication management, reminders and multilingual support through a patient-friendly interface.

**Supported devices**
- Smartphones, tablets and computers for multimodal data capture.
- Connected devices and telehealth for remote assessments and real-time health insights.
- Patient-managed app combining patient-reported outcomes, connected devices and personalised coping tips within remote patient monitoring modules.

**Supported data types**
- Patient-reported outcomes and eCOA data, including pre-configured eCOA instruments and custom questionnaires with automated calculations and compliance reporting.
- Remote measurements, digitally enabled endpoints, connected device data and telehealth data.
- Remote patient monitoring data, including symptoms, biovital values, smart notifications, analytics, documentation, reports and data visualisation.
- Clinical development and operational data for protocol authoring, study design, costing, start-up, trial execution and portfolio management.

**Benefits:**

- Supports digital and decentralised clinical trials through a unified platform for patients, sites and sponsors.
- Supports remote assessments, connected devices, telehealth, ePRO/eCOA integration, remote patient monitoring, home supply and medication management.
- Multilingual support is available in more than 115 language locales across more than 50 countries.
- The technology had already been used in multiple AstraZeneca-sponsored clinical trials in more than 40 countries at launch.

**Limitations:**

- Standard pricing, licence costs, contract terms, implementation costs and service levels are not published.
- Detailed public technical documentation, API specifications, export formats and institutional identity management details were not found.
- Regulated trial use would need study-specific confirmation against sponsor requirements, validation evidence, inspection-readiness, data protection, information governance and ethics requirements

**Best-fit research use**

- Sponsor-led clinical trials that need digital, hybrid or decentralised trial delivery.
- Studies needing remote patient monitoring, patient-reported outcomes, connected devices, telehealth, home assessments or digital endpoints.
- Clinical development teams needing AI-supported protocol authoring, study design, costing, planning, start-up, trial execution or portfolio management.
- Life sciences organisations, biotechnology companies and contract research organisations seeking enterprise digital trial solutions.



**Example applications**

- I-SPY 2.2 breast cancer platform trial, an adaptive platform trial for people with newly diagnosed, locally advanced breast cancer. Evinova's remote patient monitoring module is being used for one treatment arm to collect daily information from home and alert study teams to early symptoms of interstitial lung disease. Published I-SPY2.2 treatment papers predate and do not evaluate this Evinova implementation, so the platform use is supported by the official study announcement rather than those clinical-results papers. Article: Evinova and Quantum Leap Healthcare Partner to Incorporate Real-Time Remote Patient Monitoring into Breast Cancer Platform Trial
- Phase III chronic obstructive pulmonary disease outcome study, a large multinational trial delivered through the AstraZeneca digital trial technology that underpins Evinova's Unified Trial Solution. The participant app, site portal, remote visits, home drug supply, patient-reported outcomes and event-driven notifications enabled around 60% of visits to take place from home. The peer-reviewed 6R framework paper provides the stronger evidence source for the underlying digital implementation and reported operational benefits. Case study: How a fully connected trial platform delivered 2× faster recruitment in a Phase III COPD study
- Implementation of digital health technology in clinical trials: the 6R framework, a peer-reviewed account of AstraZeneca's implementation of the digital trial technologies that underpin Evinova. Across clinical trial deployments, the approach combined remote data capture, connected devices and patient-facing digital tools to reduce in-person visits, improve participant experience and support faster, less burdensome trial delivery. Publication: Implementation of digital health technology in clinical trials: the 6R framework



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| **Costs and contracts** | Pricing, licence costs, implementation costs, contract terms and service levels are not published. The Evinova website invites prospective customers to contact the company or book a demo. |
| **Governance, privacy and compliance** | The Evinova Trust Center lists NIST CSF, GDPR, ISO/IEC 27001 and SOC 2 under its compliance materials. It also lists security and privacy material including a security whitepaper, privacy risk assessment SOP, personal data breach SOP, data subject request process, subprocessors, international data access and safeguards, customer audit rights, access monitoring, audit logging, product architecture, incident response and business continuity/disaster recovery materials. Study-specific review would still be needed for sponsor requirements, consent, data controller and processor roles, information governance, data-sharing, retention, validation, auditability and inspection readiness |
| **Hosting and data location** | Evinova Trust Center materials list isolated customer data tenants, encryption at rest, customer-managed encryption keys, TLS 1.3 encryption in transit, Amazon Web Services cloud service providers and geographic location of data. Specific data centre locations, UK or EU hosting options, backup arrangements and contractual hosting responsibilities are not confirmed in the sources reviewed. |
| **Implementation and support requirements** | Implementation would require enterprise-level trial configuration, including study design, digital strategy, participant and site workflows, connected devices, eCOA configuration, remote patient monitoring modules, reporting and governance workflows. Evinova also offers consulting services for digital health strategy, regulatory consulting, AI-powered patient recruitment, access and endpoint validation. Standard implementation timescales, training packages, customer responsibilities and support service levels are not published. |

**Integration and interoperability**

Evinova supports ePRO/eCOA integration, connected devices, telehealth, remote patient monitoring and multimodal data capture across smartphones, tablets and computers. Its platform page also lists single sign-on compatible with SAML 2.0 and OAuth 2.0. Detailed API documentation, export specifications, integration set-up requirements and institutional identity management implementation details were not found.

**Outputs, access and analysis**

Sponsor-facing features include real-time insights, site operations monitoring, patient data monitoring, compliance reporting, smart notifications, advanced analytics, documentation and reports, data visualisation and portfolio-level reporting and governance. Standard export formats, metadata specifications, researcher dashboard configuration and missing-data alert options were not found.

**Scale and study complexity**

Evinova is intended for enterprise-scale clinical development and global clinical research. The technologies had already been used in multiple AstraZeneca-sponsored clinical trials in more than 40 countries at launch. Unified Trial Solution materials also state support across more than 50 countries and more than 115 language locales. General limits on participants, sites, studies, devices, data volume and data frequency were not found.

**Regulated trial suitability**

Evinova is explicitly focused on clinical trial sponsors, contract research organisations, trial site care teams and patients. Its Trust Center lists compliance, security, privacy, audit logging, access monitoring, product architecture, incident response and business continuity materials. The sources reviewed do not confirm validation status, Good Clinical Practice compliance, 21 CFR Part 11 compliance, UKCA or CE status, clinical safety case arrangements or inspection-readiness for a specific regulated trial. Researchers should confirm suitability against the intended study, sponsor

## MindLAMP



Contact: Not found.
Consultation is available through the mindLAMP Core interest form.
URL:
- MindLAMP
- About MindLAMP
- MindLAMP Core
- Privacy

**What is it?**
MindLAMP is an open-source digital phenotyping platform from the Division of Digital Psychiatry at Beth Israel Deaconess Medical Center and Harvard Medical School. It supports mobile health research and clinical care through a participant app, researcher or clinician dashboard, database and Cortex analytics pipeline. The platform can collect smartphone sensor data, surveys, cognitive games, psychoeducation and self-management activities.

**Supported devices**
- Native iOS and Android apps for participants.
- Web application access through dashboard.lamp.digital.
- Smartphone sensors, including GPS, accelerometer, device motion, device state, steps, activity recognition and related passive sensing streams.
- Apple HealthKit and Google Health Connect data where participants provide permissions.
- Connected wearables are supported through health platform integrations where configured.

**Supported data types**
- Passive smartphone sensor data including GPS, accelerometer, screen state, device motion, steps, nearby devices, telephony, analytics and activity recognition.
- Health platform data including sleep, heart rate, heart rate variability, respiratory rate, blood pressure, blood glucose, oxygen saturation, body temperature, workouts and nutrition where supported.
- Configurable surveys, ecological momentary assessments, cognitive games, voice recordings, educational content, mood tracking, journaling and self-management activities, including guided breathing.
- Derived behavioural features through Cortex, including sedentary behaviour, home time, screen usage and sleep-related measures.

**Benefits:**

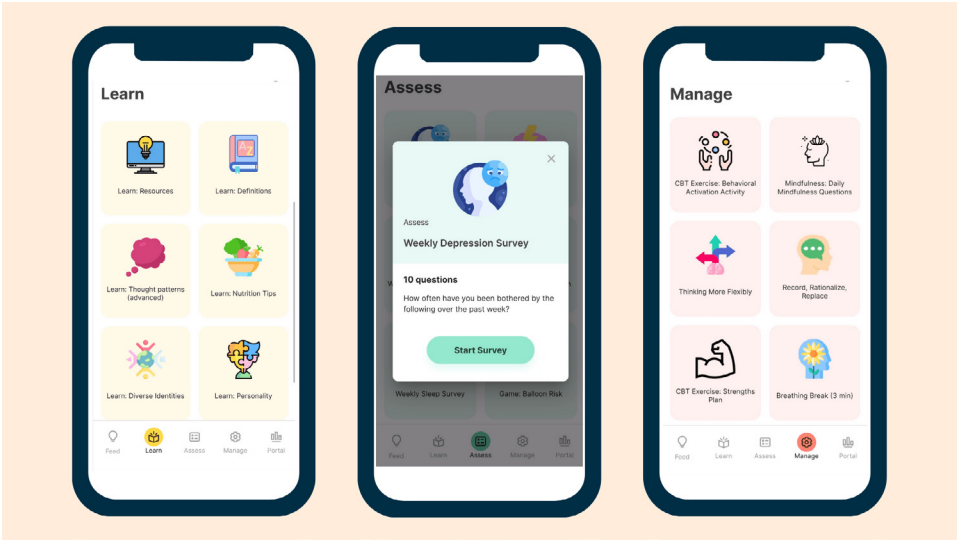
- Purpose-built for digital mental health, behavioural research and digital phenotyping.
- Supports both participant-facing intervention content and passive sensor collection in one app.
- Includes dashboards for study configuration, participant scheduling, near-real-time monitoring and engagement tracking.
- Open-source code, API documentation and Cortex analytics support reproducible digital phenotyping research.
- mindLAMP Core provides a supported deployment pathway with consultation, configuration, training and ongoing support.

**Limitations:**

- Standard pricing, contract terms and service levels are not published.
- Self-deployment requires technical capability to host, configure, maintain and secure the platform.
- Passive data quality depends on participant permissions, device compatibility, operating system behaviour, background collection limits, battery use and adherence.

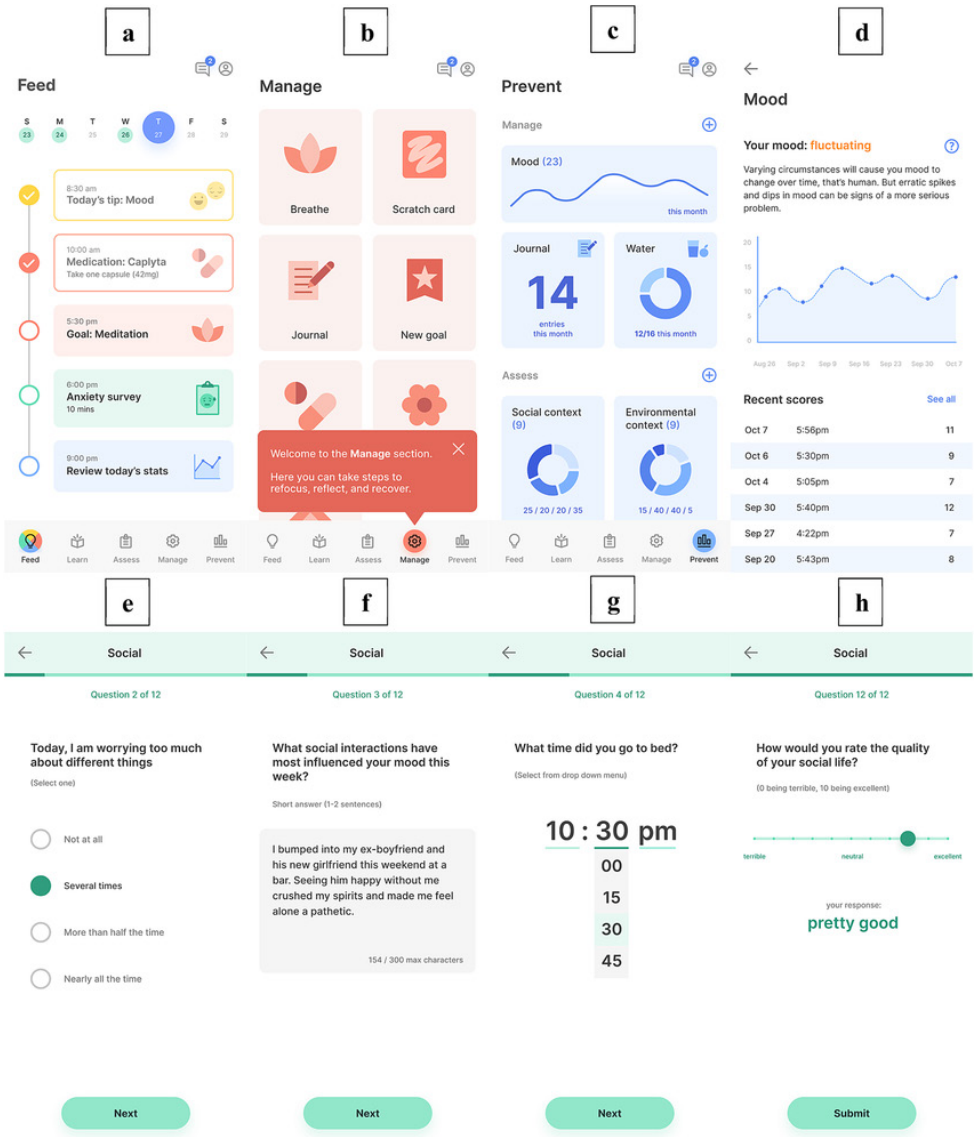
**Best-fit research use**

- Academic digital mental health studies using smartphone sensing, surveys and participant-facing self-management tools.
- Digital phenotyping studies needing passive sensing, ecological momentary assessment, cognitive games and behavioural feature extraction.
- Clinical research programmes where researchers need both engagement tools and near-real-time dashboards.
- Multi-site behavioural, mental health or neuropsychiatric studies needing configurable app content, dashboards and analytics.



## Example applications

- Mental health prediction and personalised interventions in college students. A prospective study used mindLAMP surveys and smartphone sensor data to test mental health symptom prediction and personalised app interventions. Publication: Digital Phenotyping Data to Predict Symptom Improvement and Mental Health App Personalization in College Students: Prospective Validation of a Predictive Model.
- Remote cognitive assessment in schizophrenia. A global multi-site pilot study used mindLAMP cognitive tasks to assess the feasibility, validity and reliability of remote cognitive assessment in people with schizophrenia at sites in the United States and India. Publication: Mobile cognitive remote assessment of schizophrenia: a global multi-site pilot study.
- Digital mental health tool usability in older adults. A four-week study used mindLAMP for passive smartphone sensing and nightly surveys in older adults, examining training needs, adherence and usability factors relevant to digital mental health research with older populations. Publication: Barriers and facilitators to usability of a smartphone-based digital mental health tool in older adults: Insights from a secondary analysis of mindLAMP.



**Costs and contracts**

mindLAMP is open source. mindLAMP Core provides customised deployment proposals with pricing, timeline and configuration details after consultation. Standard pricing, contract terms, implementation costs and service levels are not published.

**Governance, privacy and compliance**

The mindLAMP privacy materials say the Division of Digital Psychiatry at Beth Israel Deaconess Medical Center will not access data without prior consent and permission. Self-deployed users have sole control and ownership of data consumed or produced by the LAMP platform. The platform does not by default request, use or store personally identifiable information, and the documentation strongly recommends against using user-facing utilities to collect it. Study-specific review would still be needed for UK ethics, consent, data minimisation, participant acceptability, controller and processor roles, NHS information governance, data-sharing, retention, international transfer, security review and sponsor requirements.

**Hosting and data location**

Data can be hosted by the research organisation or by mindLAMP Core in a private and secure manner, depending on the deployment route. Specific data centre locations, UK or EU hosting options, backup arrangements and contractual hosting responsibilities are not confirmed in the sources reviewed.

**Implementation and support requirements**

Implementation requires project configuration, app set-up, participant groups, activity scheduling, surveys, cognitive games, sensor permissions, push notifications, dashboards, data access, analytics planning and hosting decisions. mindLAMP Core can support configuration, training and data collection. Participant burden, accessibility, language options and digital exclusion should be assessed for each deployment. Standard implementation timescales, training packages and full support service levels are not published.

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| **Integration and interoperability** | mindLAMP integrates smartphone app data, passive sensors, Apple HealthKit, Google Health Connect and connected wearables where configured. The platform includes API documentation and SDKs for programmatic access. Institutional identity management options, electronic health record integration and UK health-system integrations were not found. |
| **Outputs, access and analysis** | The dashboard provides near-real-time participant data, engagement visibility and a Data Portal. Participants can view visualisations of their own activity or sensor data in the app. The database indexes data chronologically using the LAMP Protocol. Cortex transforms raw sensor data into daily behavioural features and supports analysis and visualisation. Export formats, metadata completeness, missing-data alerting and analysis-readiness should be confirmed for the intended deployment. |
| **Scale and study complexity** | mindLAMP materials report use across 13 countries, 10 languages and more than 120 publications. mindLAMP Core reports support for more than 50 active sites worldwide. The platform is positioned for projects ranging from small pilots to multi-site consortia. General limits on participants, sites, studies, devices, data volume and data frequency were not found. |
| **Regulated trial suitability** | mindLAMP is used in clinical research and care, including deployments with IRB approval. The sources reviewed do not confirm Good Clinical Practice compliance, 21 CFR Part 11 compliance, UKCA or CE status, clinical safety case arrangements, inspection-readiness or validation status for a specific regulated trial. Researchers should confirm suitability against the intended study, sponsor requirements, regulatory expectations, institutional requirements and deployment documentation. |

## MyDataHelps

Contact: use https://ca-reevolution.com/contact-us/ to request a demo.
URL:
- Website
- My Data Helps Support
- Developer Center
- Privacy Info

**What is it?**
MyDataHelps is CareEvolution's digital clinical trial and research platform for building and managing remote, hybrid and digital health studies. It supports digital recruitment, eConsent, surveys, ecological momentary assessments, wearable and device data collection, electronic health record data, automated notifications, participant engagement, data exports and developer APIs.

**Supported devices**
- MyDataHelps app access through iOS, Android and web.
- Apple Health, Health Connect, Google Health, Google Fit, Garmin, Oura, Omron and other supported data services where configured.
- Fitbit data are supported through device data services, with Fitbit moving towards Google Health for some integrations.
- Electronic health record data can be collected where participants connect compatible health records.

**Supported data types**
- eConsent, survey data, ecological momentary assessments, ePRO, ClinRO and performance outcome data.
- Wearable, device and app data, including activity, heart rate, sleep, nutrition, weight, blood pressure, oxygen saturation and movement-related data where supported.
- Electronic health record data, claims data and participant-reported health information where enabled and permissioned.
- Environmental and contextual data, including weather and air quality, where configured.



**Benefits:**

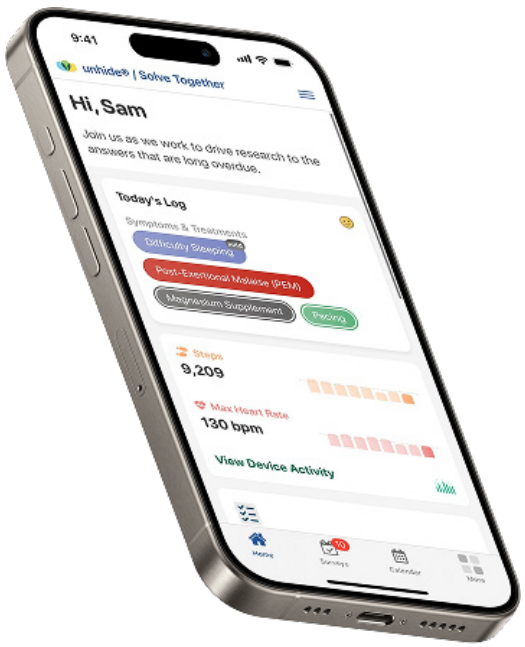
- No-code and code-optional study configuration supports faster study build and launch.
- Supports digital recruitment, eConsent, survey delivery, wearable and EHR data, automated notifications and return of results.
- Integrates with REDCap and NIH Common Data Elements for study configuration and validated instruments.
- Used in large research programmes including the
- Framingham Heart Study, NIH's All of Us Research Program and the
- RECOVER COVID Initiative.

**Limitations:**

- Standard pricing, contract terms, implementation costs and full service levels are not published.
- Actual sensor data availability depends on participant device, permissions, app settings and linked accounts.
- Regulated trial use would need study-specific confirmation of validation evidence, sponsor requirements, audit expectations, data protection, information governance and deployment documentation.

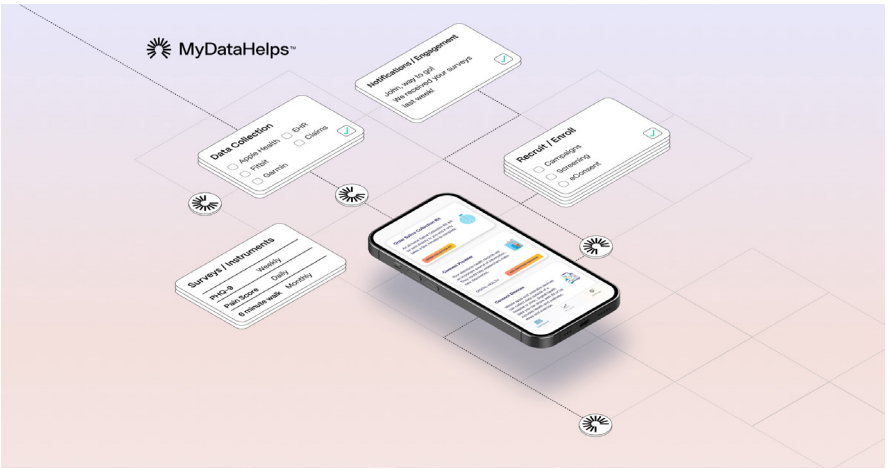
**Best-fit research use**

- Remote, hybrid or digital clinical trials needing digital recruitment, consent, surveys and longitudinal data collection.
- Studies combining participant-reported outcomes, ecological momentary assessments, wearable data, EHR data and claims data.
- Large-scale population health, precision health and decentralised research programmes that need participant engagement and repeated measurement.
- Projects needing a configurable platform plus APIs, SDKs or custom participant experiences.



Example applications

- Electronic Framingham Heart Study: smartphone and wearable monitoring within a cardiovascular cohort. The study used a MyDataHelps-based smartphone app, Apple Watch and a connected blood pressure monitor to collect repeated surveys, activity measures and cardiovascular data remotely. It added everyday digital measurements to the established Framingham Heart Study, supporting comparison with cardiovascular measures collected at the research centre. The published implementation study assessed app usability and survey completion. Publication: Design, deployment, and usability of a mobile system for cardiovascular health monitoring within the electronic Framingham Heart Study.
- DETECT: combining smartphone surveys and wearable data for infectious disease research. Scripps Research used MyDataHelps to collect smartwatch and activity-tracker data alongside self-reported symptoms and diagnostic test results. The initial publication reported 30,529 enrolled participants and investigated whether wearable measures improved discrimination between symptomatic participants reporting positive or negative COVID-19 tests. The diagnostic analysis involved a much smaller subset, so total enrolment should not be interpreted as the model-validation sample. Publication: Wearable sensor data and self-reported symptoms for COVID-19 detection. Platform confirmation: Scripps Research DETECT study announcement.
- Fitbit and app feasibility study: physical activity support for cancer survivors. A three-month feasibility study combined Fitbit activity tracking with the MyDataHelps app in a diverse group of cancer survivors. Usability surveys and interviews assessed acceptability and implementation. Publication: Usability and Implementation Considerations of Fitbit and App Intervention for Diverse Cancer Survivors: Mixed Methods Study.
- NIH All of Us Research Program: remote enrolment in large-scale precision health research. The NIH All of Us Research Program uses MyDataHelps for its direct volunteer pathway, enabling people recruited outside healthcare provider organisations to enrol remotely, provide eConsent, complete electronic assessments and choose to share electronic health record data. The platform supports longitudinal research and recruitment of populations traditionally underrepresented in biomedical research. Case study: Facilitating precision medicine research through the All of Us Research Program.



**Costs and contracts**

A MyDataHelps Designer account is free to start. Standard enterprise pricing, licence costs, implementation costs, contract terms and full service levels are not published. Prospective customers can try the platform or contact CareEvolution.

**Governance, privacy and compliance**

CareEvolution's trust materials list NIST SP 800-53 Rev. 5, HITRUST e1 certification, HIPAA compliance, FDA 21 CFR Part 11 controls, NIH Authorization to Operate, the Digital Medicine Society Seal, GDPR and Data Privacy Framework standards, and CARIN Code of Conduct alignment. The MyDataHelps privacy policy says participant data are not sold, not used for advertising and securely stored in the United States by CareEvolution. Study-specific review would still be needed for UK ethics, consent, data controller and processor roles, NHS information governance, data-sharing, retention, international transfer, validation, auditability and sponsor requirements.

**Hosting and data location**

MyDataHelps privacy materials say participant data are securely stored in the United States by CareEvolution. Specific UK or EU hosting options, backup arrangements and contractual hosting responsibilities are not confirmed in the sources reviewed.

**Implementation and support requirements**

Implementation requires project configuration in MyDataHelps Designer, including surveys, eConsent, participant recruitment routes, SMS, email or push notifications, sensor and EHR data settings, data exports, participant management and any API or SDK development. Participant device compatibility, permissions, accessibility, language options, notification burden and digital exclusion should be confirmed for each deployment. Standard implementation timescales, training packages and full support service levels are not published.

**Integration and interoperability**

MyDataHelps integrates with wearable, device, app and EHR data services including Apple Health, Health Connect, Google Health, Google Fit, Garmin, Oura, Omron, Fitbit, weather and air quality services. Device Data APIs, SDKs and developer documentation are available for custom workflows and data access. Institutional identity management implementation details and UK health-system integration requirements should be confirmed for the intended deployment.

**Outputs, access and analysis**

Data exports can be configured for study data, sensor data and EHR data. Developer materials describe device data APIs and data export resources, including CSV, JSON and Parquet formats in public platform summaries. Participants can view signed consent documents and, where configured, receive returned results or insights. Export content, metadata completeness, access permissions, missing-data alerting and analysis-readiness should be confirmed for each deployment.

**Scale and study complexity**

CareEvolution materials report use by more than 2 million research and public health participants, more than 200,000 connected wearables or devices and more than 55,000 connected EHRs. MyDataHelps is positioned for large-scale digital clinical trials, population health studies and public health programmes. General limits on participants, sites, studies, devices, data volume and data frequency were not found.

**Regulated trial suitability**

CareEvolution trust materials list FDA 21 CFR Part 11 controls for electronic records, audit trails and signatures, alongside NIH Authorization to Operate and HITRUST certification. The materials do not confirm validation status, inspection-readiness, Good Clinical Practice compliance, UKCA or CE status, clinical safety case arrangements or suitability for a specific regulated trial. Researchers should confirm suitability against the intended study, sponsor requirements, regulatory expectations, institutional requirements and deployment documentation.

## RADAR-base

Contact: radar-base@kcl.ac.uk or radar-base@thehyve.nl.
URL: Website

**What is it?**
RADAR-base (Remote Assessment of Disease And Relapses) is an open-source platform for remote, continuous and scalable health data collection. It integrates data from smartphones, wearables, mobile apps and Internet of Things devices, and supports real-time collection, processing, storage, management and sharing of data with researchers.

**Supported devices**
- Smartphones, with the phone as the main hub for data routing and collection.
- Wearable devices and mobile technologies.
- Connected devices and data sources listed in the RADAR-base supported devices documentation and data source catalogue.
- Internet of Things devices.

**Supported data types**
- Active data provided by participants through the aRMT app, including questionnaires, active tasks and challenges.
- Passive data collected in the background from phone sensors and connected wearable devices through the pRMT app.
- Examples of passive phone data include movement, location, audio, calls and texts, and app usage.

**Benefits:**
- Open source, with components available under an Apache 2 licence.
- Supports active and passive data collection through dedicated mobile applications.
- Designed with extensibility, flexibility and scalability in mind, using a plugin-based architecture.
- Can be deployed on premise or in the cloud using Docker or Kubernetes, and The Hyve offers managed deployment, hosting, support, development and training.

**Limitations:**
- Self-hosting requires technical expertise to configure, secure and maintain the platform.
- Data availability varies by operating system and device; additional integrations may require development.
- Connectivity, battery optimisation and authentication issues can interrupt passive collection, requiring monitoring and participant support.

**Best-fit research use**

- Remote, continuous and scalable health data collection using smartphones, wearables, mobile apps and Internet of Things devices.
- Studies requiring active and passive data collection, including questionnaires and background sensor data.
- Remote monitoring studies that need access to a RADAR-base deployment hosted in-house, in the cloud or through a managed service.
- Use cases listed by The Hyve include remote cardiac rehabilitation, digital markers for Alzheimer's disease, autistic characteristics and co-occurring difficulties, psoriasis treatment and research, and migrant health and well-being.

**Example applications**

- PAPrKA (Physical Activity Patterns after Knee Arthroplasty): understanding activity before and after knee replacement. Led by the University of Manchester with King's College London and support from the National Joint Registry, this UK study used RADAR-base to link retrospective physical activity data from smartphones and wearable devices with survey responses and knee replacement records. It aimed to identify real-world activity patterns and improve understanding of longer-term recovery. Protocol: PAPrKA: Physical Activity Patterns after Knee Arthroplasty, Health Research from Home.
- RADAR-MDD (Remote Assessment of Disease and Relapse in Major Depressive Disorder): longitudinal smartphone and wearable monitoring of depression. This multi-country cohort used RADAR-base to combine smartphone monitoring, Fitbit data and repeated assessments to investigate depression and relapse. It provides an example of sustained active and passive data collection in a condition-specific cohort, rather than a representative general-population sample. The published implementation paper reports recruitment, retention and data availability. Publication: Remote Assessment of Disease and Relapse in Major Depressive Disorder (RADAR-MDD): recruitment, retention, and data availability in a longitudinal remote measurement study.
- RADAR-Engage: improving engagement with symptom tracking in major depressive disorder. This King's College London-led randomised trial assessed whether in-app components could improve engagement with symptom tracking through RADAR-base. It used active and passive remote measurement, including questionnaires, smartphone sensor data and wearable data. Protocol: Exploring the Effects of In-App Components on Engagement With a Symptom-Tracking Platform Among Participants With Major Depressive Disorder (RADAR-Engage).
- RALPMH (Remote Assessment of Lung Disease and Impact on Physical and Mental Health): monitoring the effects of chronic lung disease. This UK prospective observational study used RADAR-base to investigate physical and mental health effects. Participants completed app-based questionnaires and provided passive smartphone and wearable data to assess symptoms, behaviour and physiological measures remotely. Protocol: Remote Assessment of Lung Disease and Impact on Physical and Mental Health (RALPMH).

**Costs and contracts**

RADAR-base components are available as open-source software under an Apache 2 licence. The Hyve describes RADAR-base as a Service as an all-inclusive, fully managed option for remote patient-monitoring studies, and also offers deployment, hosting and support, development and training. Specific pricing, contract terms and service levels should be discussed with the RADAR-base team.

**Governance, privacy and compliance**

Participants can securely share health data with clinicians and researchers, and centralised security controls are available for user roles, participant access and device authorisations. Researchers should confirm specific compliance standards, audit evidence, retention controls, anonymisation processes and regulated inspection readiness. Local ethics, data protection, information governance and data-sharing review would still be needed for a study deployment.

**Hosting and data location**

RADAR-base can be deployed on premise or in the cloud using Docker or Kubernetes. The Hyve also states that it can host RADAR-base in a secure and private cloud environment or on premise. Researchers should confirm specific data centres, UK or EU data location options, backup arrangements or contractual hosting responsibilities.

**Implementation and support requirements**

RADAR-base deployment requires technical set-up and configuration using Docker or Kubernetes, depending on the deployment route. Participants can be enrolled through the RADAR-base Management Portal. The Hyve offers managed deployment, hosting and support, development and training. Public sources reviewed do not provide standard implementation timescales, training requirements or support service levels.

**Integration and interoperability**

RADAR-base is designed to integrate data streams from a range of sources, including smartphones, wearables, mobile apps and Internet of Things devices. RADAR-base documentation describes a plugin-based architecture and APIs that can be extended to support additional devices and data sources. Specific integrations should be checked against the current supported devices documentation and data source catalogue before study selection.

**Outputs, access and analysis**

RADAR-base provides live dashboards, exporting raw data for analysis, and output formats including AVRO, JSON and CSV. Structured data uses Apache Avro and near real-time data streaming using Apache Kafka. Researchers should confirm analysis-readiness, complete metadata availability, access approval workflows or missing-data alert configuration for every deployment.

**Scale and study complexity**

RADAR-base is scalable and suitable for continuous remote health data collection. The current RADAR-base home page shows headline figures for use cases, disease areas and study participants. Researchers should confirm limits on participant numbers, sites, devices, data volume or data frequency.

**Regulated trial suitability**

RADAR-base is an open-source platform designed to support remote clinical trials by collecting continuous data from wearables and mobile applications. The Hyve describes it as suitable for remote research studies and virtual clinical trials. Researchers should confirm validation status, inspection-readiness, Good Clinical Practice compliance, electronic consent compliance and suitability for a specific regulated trial against sponsor requirements and deployment documentation.

## Studypages Data



Contact: Initial research and pricing enquiries via the Studypages Data website's "Request a demo" option.
URL:
- Studypages Data
- Electronic data capture
- Studypages website
- Security
- Privacy policy

**What is it?**
Studypages Data, formerly Teamscope, is a web and mobile data collection platform for clinical and research teams. It supports secure electronic data capture, case management, online surveys, patient-reported outcomes, offline data collection, analytics and data export.

**Supported devices**
- Web access for form design, case management, reporting, analytics and administration.
- iOS and Android mobile apps for data collection, including offline data capture.
- Smartphones and tablets can collect and sync data when internet access becomes available.

**Supported data types**
- Structured electronic data capture forms, case records and longitudinal follow-up data.
- Patient-reported outcomes, daily diary studies, experience sampling and online survey responses.
- Files uploaded into the secure cloud, including medical images or study documents where configured.
- Audit trail, reminders, analytics, saved views, formulas, branching logic, permissions, webhooks and API-enabled data workflows.

**Benefits:**
- Supports web, iOS and Android data collection, including offline collection and later synchronisation.
- Supports clinical trials, patient registries, ePRO, daily diary studies, experience sampling and online surveys.
- Includes branching logic, reminders, audit trail, group-level permissions, analytics, saved views, webhooks and API access.
- Can be used as part of the wider Studypages clinical research platform, which connects recruitment, enrolment, engagement and study conduct workflows.

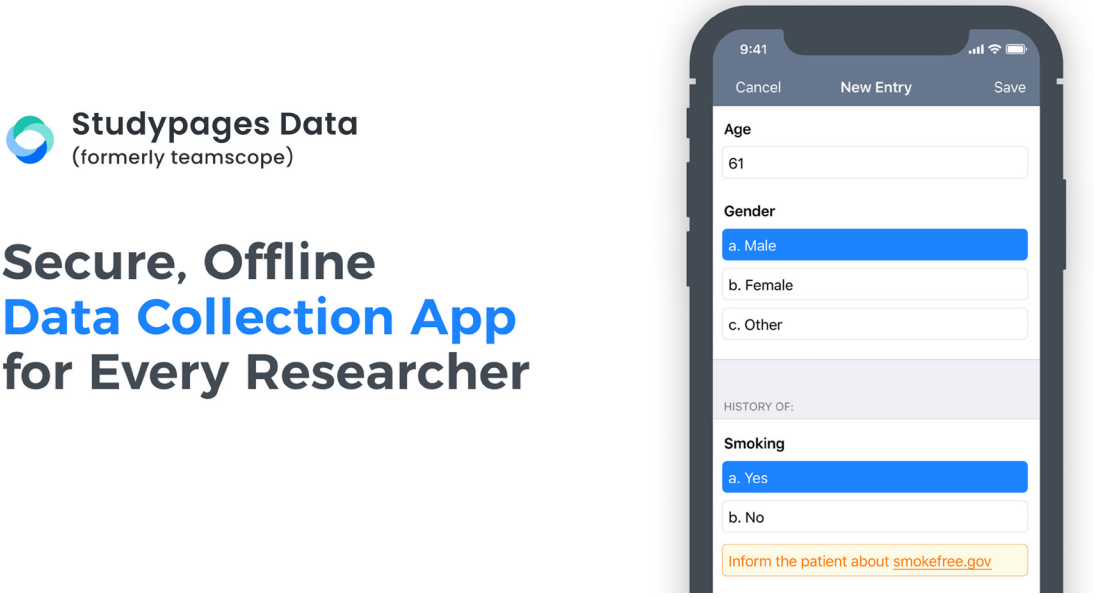
**Limitations:**
- Standard enterprise pricing, contract terms and full service levels are not published.
- Single sign-on and two-factor authentication are listed as forthcoming on the Studypages Data feature list, so availability should be confirmed before selection.
- Regulated trial use would need study-specific confirmation of validation status, sponsor requirements, audit expectations, data protection, information governance and deployment documentation.

**Best-fit research use**

- Clinical research studies needing secure electronic data capture with forms, cases, reminders, audit trail and exports.
- Studies needing offline data collection in community, field or low-connectivity settings.
- Patient registries, PRO studies, daily diary studies, experience sampling and online surveys.
- Trials or studies already using the wider Studypages platform for recruitment, enrolment, communication and clinical operations.

**Examples applications**

No named population health study using Studypages Data, formerly Teamscope, to combine smartphone sensing and wearable data collection was identified in the public sources reviewed. Its mobile questionnaires, daily diaries, experience sampling and offline forms may support participant-reported data collection. Platform information: Electronic Data Capture for Clinical Research.



**Costs and contracts**

Studypages Data pricing is available by contacting the Studypages team through the request-a-demo route. Technical support is available by email, with weekday responses within 24 hours and an average response time of 6 hours. Standard enterprise pricing, licence costs, implementation costs, contract terms and full service levels are not published.

**Governance, privacy and compliance**

Studypages encrypts data in transit with TLS 1.2 and encrypts data at rest with AES. Security materials list independent penetration, threat and vulnerability testing, user access controls with single sign-on and MFA, security awareness training, third-party audits, continuous monitoring and an information security programme aligned with SOC 2 and HIPAA criteria. The privacy policy identifies the customer as the controller or business for customer data and says Studypages is not the controller or owner of customer data. The Studypages Data GDPR Data Processing Agreement identifies Yuzu Labs PBC as processor where a customer acts as controller. Study-specific review would still be needed for ethics, consent, controller and processor roles, NHS information governance, data-sharing, retention, validation, auditability and sponsor requirements.

**Hosting and data location**

Studypages Data stores data in a secure Amazon Web Services facility in Frankfurt, Germany. Specific UK hosting options, backup arrangements and contractual hosting responsibilities are not confirmed in the sources reviewed.

**Implementation and support requirements**

Implementation requires form design, case structure, user permissions, reminders, branching logic, data export configuration, mobile app set-up and any webhooks or API integration needed by the study. Technical support can help with form building and custom integrations. Standard implementation timescales, training packages and full support service levels are not published.

**Integration and interoperability**

Studypages Data includes webhooks and API access in its feature list, and the wider Studypages platform includes an integration layer for connecting trial technologies such as electronic data capture, safety reporting, ePRO and eConsent. Detailed API documentation, identity management implementation details and export specifications were not found.

**Outputs, access and analysis**

Studypages Data includes saved views, analytics, reporting filters, graph sharing and raw data export. Teamscope  electronic data capture materials show case management, filters, sorting, columns and custom reports for identifying data issues and segmenting patients. Standard export specifications, metadata completeness, dashboard configuration and missing-data alert options should be confirmed for the intended deployment.

**Scale and study complexity**

The wider Studypages platform supports traditional, hybrid and fully virtual trials, including recruitment, enrolment, study conduct, site onboarding and clinical operations. Studypages Data supports clinical trials, patient registries, ePRO studies and online surveys. General limits on participants, sites, forms, studies, data volume and data frequency were not found.

**Regulated trial suitability**

Studypages Data materials state compliance with HIPAA, GDPR and Good Clinical Practice, and the Teamscope ELECTRONIC DATA CAPTURE page states HIPAA, FDA, GDPR and 21 CFR Part 11 compliance. UC Davis guidance describes Studypages as a HIPAA-compliant, 21 CFR Part 11-validated, web-based clinical research study management and participant engagement platform for its local deployment. Validation status, inspection-readiness and regulated trial suitability should still be confirmed against the intended study, sponsor requirements, institutional deployment and contract documentation.

# 06

# Platform Profiles: Patient-Generated Health Data (PGHD) platforms without full end-to-end support

Research frameworks and infrastructure are technologies that provide specific components, tools, standards, or technical foundations for digital research studies but do not generally support the complete research lifecycle on their own. They typically require additional systems or services for activities such as recruitment, consent, participant management, or study operations.

## Apple ResearchKit




Contact: Researchers exploring a study using Apple devices and ResearchKit can start with Apple's Investigator Support Program and research FAQs. Programme applications are submitted to research_proposals@apple.com.
URL:
- Apple Developer ResearchKit documentation
- Apple Open Source ResearchKit
- ResearchKit developer documentation

**What is it?**
ResearchKit is an Apple open-source framework for building iOS research apps. It provides predesigned screens and transitions to help developers design and build engaging custom research apps that let people participate in medical research studies.

**Supported devices**
- iPhone and other iOS devices, as ResearchKit is used to build native iOS research apps.
- Apple Health data can be requested where appropriate, with participant permission.

**Supported data types**
- Onboarding information, including study introduction, eligibility screening, permission steps and consent.
- Participant-entered survey and questionnaire data.
- Active task data, including measurements captured outside the clinic.
- Health and fitness data through Apple Health, where access is requested and granted by the participant.

**Benefits:**

- Provides predesigned screens and transitions for building research app experiences.
- Supports onboarding, eligibility screening, informed consent, surveys and active tasks.
- Can work with CareKit and Apple Health where appropriate.

**Limitations:**

- Pricing, implementation timescales, hosting routes, service levels and research governance responsibilities were not found.

**Best-fit research use**

- Studies that need a custom iOS research app with participant onboarding, eligibility screening and consent.
- Research using surveys, scheduled tasks or active tasks to capture measurements outside the clinic.
- Research and care app pilots where ResearchKit is used alongside CareKit.
-
- Example applications
- • GlaxoSmithKline rheumatoid arthritis feasibility study: remote collection of daily symptoms. This US study used a ResearchKit smartphone app to enrol and obtain consent from people with rheumatoid arthritis and collect daily patient-reported symptoms in real-world settings. It assessed recruitment, retention, adherence and the feasibility of remote symptom collection. Publication: Using a ResearchKit Smartphone App to Collect Rheumatoid Arthritis Symptoms From Real-World Participants: Feasibility Study.
- • Back on Track: tracking decision-making after anterior cruciate ligament rupture. This multilingual observational study used a ResearchKit app for remote recruitment, consent and repeated surveys following acute anterior cruciate ligament rupture. It demonstrated international app distribution, secure data transfer and sustained participant data collection. Publication: "Back on Track": A Mobile App Observational Study Using Apple's ResearchKit Framework.
- • Asthma Mobile Health Study: large-scale remote monitoring of asthma. This fully remote study used a ResearchKit app for recruitment, electronic consent, surveys, device data, geolocation and environmental information. It enrolled 7,593 participants and collected longitudinal data over six months. Publication: The asthma mobile health study, smartphone data collected using ResearchKit.

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| **Costs and contracts** | ResearchKit materials describe the framework and design guidance, but do not provide pricing, contracting routes, implementation costs or service-level information. |
| **Governance, privacy and compliance** | ResearchKit helps make the consent process concise and friendly, while still allowing developers to incorporate legal requirements or requirements set by an institutional review board or ethics review board. Its guidance recommends simple, straightforward language, digestible consent sections and allowing participants to view the full consent form before agreeing. Developers should seek appropriate legal advice and ensure the app complies with applicable App Store guidelines, including consent requirements. |
| **Hosting and data location** | ResearchKit does not provide a hosted study database. The research organisation and app developer must arrange data storage, transfer, security, backups and retention. Data location, including any UK or EU hosting, depends on the infrastructure or service selected for the study. |
| **Implementation and support requirements** | ResearchKit is a developer framework for building custom native iOS apps, so implementation would require app development capability. Onboarding should clearly introduce the study, assess eligibility, request permissions and obtain consent before access to personal data is granted, where appropriate. Developer guidance, sample code and learning resources are available. |
| **Integration and interoperability** | ResearchKit can work with CareKit and Apple Health, including the ability to request access to health and fitness data with participant permission. |
| **Outputs, access and analysis** | ResearchKit supports collection of participant survey responses, active task measurements and health data with permission. |
| **Scale and study complexity** | ResearchKit is intended to enable broad participation in medical research studies, but limits or guidance on participant numbers, number of sites, data volume, study duration or operational scale were not found. |
| **Regulated trial suitability** | ResearchKit guidance refers to legal, institutional review board, ethics review board and App Store consent requirements, but does not state whether ResearchKit is validated, inspection-ready or suitable for a specific regulated clinical trial. |

## Apple SensorKit



Contact: Researchers interested in using SensorKit should start with Apple's Accessing SensorKit Data page for research requirements and the study access application process.
URL:
- About SensorKit
- Configuring your project for SensorKit
- Accessing SensorKit Data

**What is it?**
Apple SensorKit is a developer framework for accessing selected raw sensor data and derived metrics from an iPhone or paired Apple Watch in approved research-study apps. It requires Apple approval, a private SensorKit entitlement and user permission before sensor data can be read.

**Supported devices**
- iPhone running iOS 14.0 or later.
- Paired Apple Watch where supported SensorKit data are available.
- Mac Catalyst and compatible iPad or iPhone apps running in visionOS are not supported for SensorKit calls.

**Supported data types**
- Steps, accelerometer and rotation-rate data, wrist detection, ambient light and routine travel or commute information.
- Device usage, keyboard metrics, media events, Messages usage, phone usage, visits, speech metrics, face metrics and wrist temperature where supported.
- ECG, PPG, heart rate, odometer, Siri speech metrics and wrist temperature are included in SensorKit update materials.

**Benefits:**
- Provides access to selected iPhone and paired Apple Watch sensor data and derived metrics for approved research-study apps.
- Uses system-level permission prompts and granular user approval for sensor access.
- Can complement ResearchKit app workflows where a custom iOS research app needs richer passive sensor or usage data.

**Limitations:**
- Access is limited to approved research studies and requires a private Apple entitlement.
- Sensitive data types may affect participant acceptability, onboarding completion and storage requirements.
- Standard pricing, implementation support, hosting arrangements, export workflows and service levels are not published.

**Best-fit research use**

- Approved iOS research-study apps that need sensor or device usage data from an iPhone or paired Apple Watch.
- Studies where SensorKit data are central to the research hypothesis and justified in the consent process.
- Studies using ResearchKit-style participant onboarding and consent alongside passive sensor or usage data collection.

**Example applications**

- SensorKit and mindLAMP pilot: exploring digital biomarkers for mental health. This UK-linked study involved researchers from the University of Oxford and University of Manchester. It used SensorKit through mindLAMP to collect one week of opt-in phone usage, Messages usage, visits, device usage and ambient light data from one person with depression. The study compared these outputs with existing digital phenotyping sources to assess their potential as mental health biomarkers. Publication: Exploring the Potential of Apple SensorKit and Digital Phenotyping Data as New Digital Biomarkers for Mental Health Research.
- Intern Health Study pilot: assessing the feasibility and acceptability of passive monitoring. This longitudinal pilot in US medical residents used SensorKit through MyDataHelps to collect optional passive iPhone and Apple Watch usage and sensor data. It assessed enrolment, retention and participant acceptability, identifying differences in opt-in rates that may have implications for equitable digital research participation. Publication: Feasibility and acceptability of collecting passive phone usage and sensor data via Apple SensorKit.
- Intern Health Study: investigating passive digital measures of physician wellbeing. The study uses SensorKit to collect optional keyboard, device usage, Messages usage, phone usage, visits, ambient light and Apple Watch wrist-state data. Participants choose which data types to share and can withdraw SensorKit permissions while remaining in the wider study. Study information: Intern Health Study Apple SensorKit FAQs.



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| **Costs and contracts** | SensorKit pricing, contract terms, implementation costs, hosting costs and service levels are not published in the sources reviewed. Use requires Apple approval, a private entitlement and app development capability. |
| **Governance, privacy and compliance** | SensorKit requires Apple approval for the research-study app, a private entitlement and user permission. The app must clearly disclose how SensorKit data will be used, identify essential information for the study and include the study purpose, requested sensors and privacy policy URL in the app metadata. When sensor access is first requested, the system presents a sheet explaining the study and the information collected. Participants approve access for individual sensor data types and can change these permissions in Settings. Study-specific review would still be needed for ethics, consent, data minimisation, data protection, NHS information governance, retention, data-sharing and participant acceptability. |
| **Hosting and data location** | SensorKit provides access to device sensor data within an approved app; researchers would need to define the study data storage, transfer, security and retention arrangements. |
| **Implementation and support requirements** | Implementation requires an approved research-study app, a SensorKit entitlement, manual provisioning, Xcode configuration, sensor-specific entitlements, study metadata, privacy policy URL, consent materials and app development capability. Standard implementation timescales, central support routes and training packages are not published. |
| **Integration and interoperability** | SensorKit integrates at iOS app level through Apple's SensorKit framework and SRSensorReader. Integration with study systems, dashboards, cloud storage, institutional identity management and electronic health records is not described in the sources reviewed and would need to be designed by the study team or app developer. |

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| **Outputs, access and analysis** | SensorKit provides query access to recorded data through fetch requests and recorded sample results. |
| **Scale and study complexity** | SensorKit is most suitable for custom research-study apps where approved sensor data are necessary to answer the study question. Limits on participants, study sites, devices, data volume, data frequency and study duration are not published in the sources reviewed. Storage and infrastructure requirements may increase because SensorKit can generate sensitive and high-volume data. |
| **Regulated trial suitability** | SensorKit is limited to approved research uses and does not publish validation status, Good Clinical Practice compliance, 21 CFR Part 11 compliance, UKCA or CE status, clinical safety case arrangements or inspection-readiness for a specific regulated trial. Researchers should confirm suitability against the intended study, sponsor requirements, regulatory expectations and deployment documentation. |

## AWARE Framework



Contact: team@aware-framework.com
URL:
- Website
- GitHub
- Source code
- Article

**What is it?**
AWARE Framework is an open-source mobile sensing framework for logging, sharing and reusing mobile context information. It supports smartphone-based research by collecting hardware, software and human-generated data through mobile sensors, plugins and study configuration tools. AWARE is primarily an Android app, with iOS support also available.

**Supported devices**
- Android smartphones through the AWARE client.
- iOS devices through AWARE iOS support and related open-source repositories.
- Apple Watch and other Apple platforms may be supported through newer iOS, watchOS and sensor repositories where configured.
- External devices and plugins can be used where researchers configure or develop the relevant support.

**Supported data types**
- Hardware sensor data, including accelerometer, gyroscope, magnetometer, gravity, rotation, location, barometer, proximity and related phone sensor streams.
- Software and phone-use data, including battery, network, calls, screen events, memory, Wi-Fi, timezone and related contextual streams where permitted.
- Human-generated data through experience sampling and ecological momentary assessment plugins.
- Plugin-based extensions, including Fitbit, OpenWeatherMap, ambient noise and other configured sensors or services.

**Benefits:**
- Open source and available on GitHub under the Apache Software License 2.0.
- Purpose-built for smartphone sensing, digital phenotyping, experience sampling and mobile context research.
- Plugin architecture supports extensibility and custom sensor modules.
- Widely used in academic mobile sensing research and associated with over 200 academic papers according to public project materials.

**Limitations:**
- AWARE is framework infrastructure rather than a complete end-to-end research operations platform.
- Android app distribution is not through Google Play because the app uses permissions that current developer guidelines do not allow for Play Store publication.

**Best-fit research use**

- Academic smartphone sensing and digital phenotyping studies requiring passive mobile context data.
- Studies using ecological momentary assessment, experience sampling and passive sensing in naturalistic settings.
- Research teams with technical capability to configure, host, extend and maintain mobile sensing infrastructure.
- Projects where open-source flexibility and sensor-level control are more important than a managed commercial platform.

**Example applications**

- SmartSense-D: assessing digital phenotyping in young people with depression. This eight-week Australian pilot involved young people aged 16 to 25 with major depressive disorder. It combined AWARE smartphone sensing, actigraphy and ecological momentary assessments to assess safety, feasibility and acceptability. Publication: SmartSense-D: A safety, feasibility, and acceptability pilot study of digital phenotyping in young people with major depressive disorder.
- StudentSense: tracking smartphone use and student mental health. This seventeen-week Australian study followed 151 university students. It used AWARE to collect passive smartphone data, including screen activity, app use, location and keyboard measures, alongside repeated assessments of depression, anxiety, stress, loneliness and wellbeing. Publication: StudentSense: Primary outcomes of a smartphone digital phenotyping study of university students in Australia.
- "Leave your smartphone out of bed": examining smartphone use and sleep quality. This Finnish study combined smartphone application-use data collected through AWARE with sleep and physiological measures from a wearable ring in 75 participants. It examined associations between smartphone use in bed and sleep latency, awake time, heart rate and heart rate variability. Publication: "Leave your smartphone out of bed": quantitative analysis of smartphone use effect on sleep quality.



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| **Costs and contracts** | AWARE is available as open-source software under the Apache Software License 2.0. Any costs would relate to local hosting, development, configuration, maintenance, support and governance activity |
| **Governance, privacy and compliance** | AWARE can collect sensitive mobile context data, including location, communication-related metadata, app or device usage, ambient data and experience sampling responses depending on configuration. Study-specific review would be needed for consent, data minimisation, participant acceptability, data controller and processor roles, NHS information governance, data-sharing, retention, international transfer, security review and sponsor requirements. Published materials reviewed do not confirm UK-specific information governance compliance or inspection readiness. |
| **Hosting and data location** | Hosting depends on local deployment choices. AWARE-compatible deployments can use configured servers and databases, and AWARE client repositories describe integration with MySQL. Specific hosting models, data centre locations, UK or EU hosting options, backup arrangements and contractual hosting responsibilities are not confirmed in the sources reviewed. |
| **Implementation and support requirements** | Implementation requires technical set-up of the client, study dashboard or configurator, sensor and plugin selection, permissions, participant onboarding, data upload, server or database configuration, security review and analytics workflow. Standard implementation timescales, training packages and support service levels are not published. |
| **Integration and interoperability** | AWARE uses a plugin-based architecture for sensors, services and external data sources. Public repositories include multiple sensor modules and configurator tools. Detailed institutional identity management options, electronic health record integration and standardised export specifications were not found |

**Outputs, access and analysis**

AWARE captures mobile context data for local storage, upload and analysis depending on deployment. AWARE-related tools include dashboards, narrators and R Shiny visualisation components. Export formats, metadata completeness, missing-data alerting and analysis-readiness should be confirmed for the intended deployment.

**Scale and study complexity**

AWARE is designed for scalable mobile context research and has been widely adopted in academic studies. Actual scale depends on hosting architecture, device mix, sensor configuration, upload frequency, data volume, participant adherence and technical support capacity. General limits on participants, sites, studies, data volume or data frequency were not found.

**Regulated trial suitability**

AWARE is an open-source research framework for mobile sensing and digital phenotyping. The sources reviewed do not confirm Good Clinical Practice compliance, 21 CFR Part 11 compliance, UKCA or CE status, clinical safety case arrangements, inspection-readiness or validation status for a specific regulated trial. Researchers should confirm suitability against the intended study, sponsor requirements, institutional requirements and deployment documentation.

## REDCap




Contact: redcap@vumc.org for central REDCap queries. REDCap Mobile App support is listed as redcapapp@vumc.org. Researchers should also check whether their organisation already has a local institutional REDCap service and support route.
URL: Website

**What is it?**
REDCap, or Research Electronic Data Capture, is a secure web application for building and managing online surveys and databases. It supports online or offline project design, secure web-based data entry, audit trails, multi-site access, automated exports to Excel, PDF and common statistical packages, ad hoc reporting, branching logic, file uploads, calculated fields, a scheduling module and health-record interoperability through FHIR services where available.

**Supported devices**
- Web browsers using the REDCap web application over a secure web connection.
- REDCap Mobile App on iPhone, iPad, Android phone or Android tablet for offline data collection.
- The REDCap Mobile App must be used alongside REDCap itself and cannot be used as a standalone system.
- Health-record interoperability is described through FHIR services within an electronic health record, where available locally.

**Supported data types**
- Online surveys and research databases.
- Structured data entered through forms, including branching logic, calculated fields and file uploads.
- Offline data collected through the REDCap Mobile App, including text and structured data, photos, videos, signatures and audio.
- Audit trail and user activity data.
- Structured clinical data imported through FHIR-based clinical data interoperability services, where supported locally.

**Benefits:**

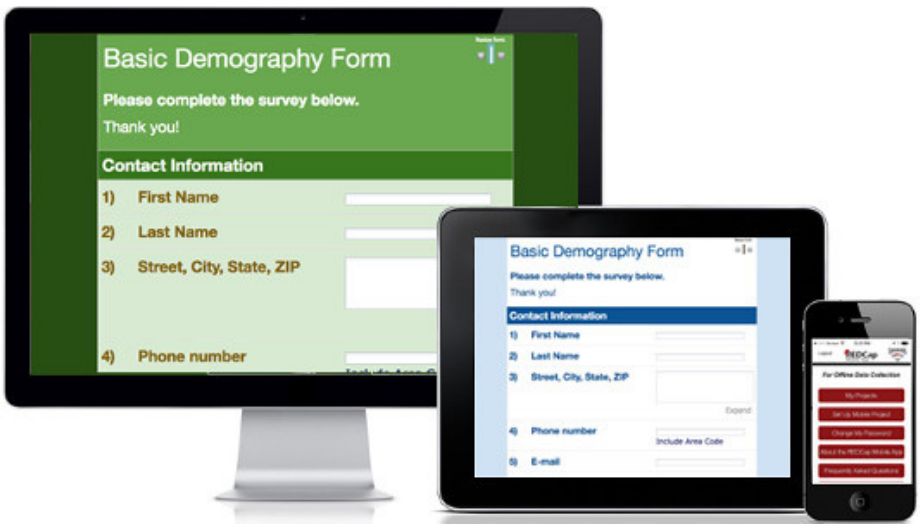
- REDCap is available at no cost for REDCap Consortium partners.
- REDCap is secure and web-based, with authentication and data logging.
- REDCap supports multi-site access, audit trails, automated export procedures, ad hoc reporting, branching logic, file uploading and calculated fields.
- REDCap Mobile App supports offline data collection on iPhone, iPad and Android phones or tablets.

**Limitations:**

- Each REDCap Consortium partner site is independently responsible for software installation, maintenance and user support.
- REDCap is not available for individual personal use.
- The REDCap central team states that it is unable to provide demonstrations, phone support, personalised consultations or webinars.

**Best-fit research use**

- Research studies and operational projects that need secure online surveys or databases.
- Multi-site databases or surveys where researchers need access from multiple sites and institutions.
- Projects needing configurable forms, branching logic, file uploads, calculated fields, reports, scheduling and exports to common statistics packages.
- Studies needing offline data collection in environments with poor or no internet connectivity, using the REDCap Mobile App as a companion to an institutional REDCap server.
- Regulated clinical research may need study-specific confirmation of institutional governance, validation and sponsor requirements.



**Example applications**

- Oxford Clinical Trials Research Unit: electronic consent across UK clinical studies. The unit used REDCap to support electronic consent across 35 UK clinical studies over six years, with nearly 12,000 participants aged 8 to 80 consented through the system. The implementation included on-site and remote consent, multimedia participant information and purpose-built external modules to support consent workflows. Publication: Lessons learnt from the implementation of electronic consent (eConsent) and its use across a large portfolio of trials in a UK academic clinical trials unit.
- REFINE: developing a neuropsychiatric database and research register. This UK feasibility study uses REDCap to create a de-identified neuropsychiatric database and research register for people with intellectual disabilities and epilepsy across specialist services in England and Wales. It will capture clinical-record data for around 600 people and consented participant and consultee information for the research register. Protocol: Neuropsychiatric research databases for people with intellectual disabilities and epilepsy (REFINE): a feasibility study protocol.
- IMPACT: collecting multicentre data to validate a meningioma prognostic model. This UK-led international study used REDCap to support standardised collection of clinical and imaging data for external validation and recalibration of a prognostic model for incidental meningioma. It aimed to include 1,500 patients and involved NHS and university centres in Liverpool, Oxford, Manchester, Leeds and Cambridge alongside international sites. Paper: External validation and recalibration of an incidental meningioma prognostic model – IMPACT: protocol for an international multicentre retrospective cohort study.



**Costs and contracts**

REDCap software is available at no cost for REDCap Consortium partners. Non-profit organisations can join the consortium and install or administer REDCap on their local servers. Each partner site is independently responsible for software installation, maintenance and user support. REDCap Cloud is described as a third-party company that offers fee-based hosting in a custom version of REDCap.
Non-profit organisations can join the global REDCap Consortium. The consortium provides access to community support tools, administrator support, shared instruments, training materials, external modules, webinars, committees and annual REDCap meetings.

**Governance, privacy and compliance**

REDCap provides technical capabilities that support compliant data collection and management, including audit trails, user authentication, role-based access controls, configurable workflows and permissions, logging and traceability of user activity, and support for electronic consent and signature workflows. REDCap is not a pre-certified regulatory system and compliance depends on system capabilities, institutional governance and study-specific implementation. Researchers should confirm local approvals, consent, retention, data-sharing, security review and sponsor or funder requirements.

**Hosting and data location**

Standard REDCap can be installed or administered by a REDCap Consortium partner on local servers, and each partner site is independently responsible for software installation, maintenance and user support. Public sources reviewed do not specify hosting arrangements, data location, backup arrangements or security controls for any individual institutional REDCap service. REDCap Cloud is a fee-based hosting option in a custom version of REDCap.

**Implementation and support requirements**

REDCap projects can be designed online using the Online Designer or offline using a data dictionary template in Microsoft Excel that can be uploaded later into REDCap . REDCap can move from conception to production-level database or survey in less than one day and installation can be quick, but each consortium partner site is independently responsible for installation, maintenance and user support. The REDCap Mobile App is intended for data collectors working offline, with data synchronised to the institutional server when internet access becomes available; offline participant self-entry should not be assumed. Researchers should confirm local build processes, administrator support, training, governance review and implementation timescales, along with accessibility, languages for participant-facing materials, reminder burden and the intended participant workflow.

**Integration and interoperability**

REDCap supports interoperability with health records through FHIR web services inside an electronic health record, which can pull structured data into REDCap using OAuth2 authorisation. REDCap also provides automated export procedures to Excel, PDF and common statistical packages including SPSS, SAS, Stata and R. Public sources reviewed do not confirm which integrations are enabled at any individual institution, so researchers should check local REDCap configuration and support.

**Outputs, access and analysis**

REDCap provides automated export procedures for downloads to Excel, PDF and common statistical packages, including SPSS, SAS, Stata and R. REDCap also includes ad hoc reporting tools, audit trails, data logging and role-based access controls. Researchers should confirm local export settings, access permissions, data dictionary use, metadata needs, missing-data processes and analysis-readiness before study set-up

**Scale and study complexity**

REDCap databases and surveys can be used by researchers from multiple sites and institutions. REDCap supports online and offline data capture for research studies and operations. Public sources reviewed do not provide enough detail to confirm limits on participant numbers, projects, forms, records, sites, data volume or data frequency for every deployment. Researchers should confirm local institutional capacity and study-specific requirements.

**Regulated trial suitability**

REDCap is a configurable research platform used in clinical, translational and academic research environments operating under regulatory, privacy and compliance requirements. REDCap is not a pre-certified regulatory system and compliance is achieved through system capabilities, institutional governance and study-specific implementation. REDCap Cloud describes its electronic data capture product as a validated, cloud-based clinical data management system for regulated clinical research, with 21 CFR Part 11 compliant electronic records and signatures. Researchers should confirm sponsor requirements, institutional validation, audit controls, electronic consent processes and inspection readiness before selecting a platform.

# 07

## Glossary

| Term | Definition |
|---|---|
| Active | Data that require participant input, such as completing surveys, symptom diaries, questionnaires or study tasks. |
| Active task | A structured activity completed by a participant using a device, such as a walking assessment, tapping task or sit-to-stand test. |
| Cohort | A study that follows a defined group of participants over time to investigate outcomes, experiences or exposures. |
| Decentralised clinical trial | A clinical trial in which some or all study activities are conducted remotely rather than at a traditional research site. |
| Digital biomarker | A measure derived from digital devices or sensors that may provide information about health, behaviour or functioning. |
| Digital phenotype | The collection and analysis of data from personal digital devices to understand behaviour, health or wellbeing in real-world settings. |
| Ecological momentary assessment (EMA) | Brief, repeated questions that participants answer during everyday life about their symptoms, experiences or behaviours at that moment or shortly beforehand. For example, an app might prompt participants several times a day to record pain, mood, fatigue or current activity, rather than asking them to recall the whole week. 'Ecological' refers to real-life settings, and 'momentary' means at or close to the time the experience occurs. |

| Term | Definition |
|---|---|
| End-to-end digital research platform | A platform that supports multiple stages of the research lifecycle, such as recruitment, consent, data collection, participant management and data access. |
| Hybrid study or trial | A study that combines remote and site-based research activities. |
| Longitudinal | A study that collects data from participants repeatedly over a period of time. |
| Participant engagement | Activities designed to recruit, communicate with, support and retain participants throughout a study. |
| Passive data collection | Data collected automatically by devices, apps or sensors with little or no active participant input. |
| Patient-reported outcome measure (PROM) | A questionnaire or assessment completed directly by participants about their health, symptoms or quality of life. |
| Pilot study | A small-scale preliminary study used to assess feasibility and refine study procedures before a larger study. |
| Real-world data | Health-related data collected outside traditional controlled research settings, including routine healthcare, apps and wearable devices. |
| Remote patient monitoring | Collection and review of participant data while participants remain outside a clinic or research site. |
| Sponsor | The organisation responsible for initiating, managing and overseeing a research study. |

## Data, technology and interoperability

| Term | Definition |
|---|---|
| API | A mechanism that allows different software systems to exchange information and functionality. |
| Common data model | An agreed structure and set of conventions used to organise data consistently across systems or datasets. |
| Data standard | An agreed format, structure, terminology or method for recording and exchanging data. |
| Electronic health record | A digital record of an individual's health and care information. |
| FAIR Data Principles | Principles that promote data being Findable, Accessible, Interoperable and Reusable. |
| Fast Healthcare Interoperability Resources (FHIR) | A standard for exchanging healthcare information between different systems. |
| Internet of Things (IoT) | Connected devices that collect and exchange data over a network. |
| Interoperability | The ability of systems, applications or devices to exchange and use information effectively. |
| Metadata | Information describing a dataset, such as how, when and by whom data were collected. |
| Open source | Software made available with source code that can be inspected, modified and redistributed in accordance with its licence. |
| Software Development Kit (SDK) | A collection of tools and resources used to develop applications or integrate services. |
| System integration | The connection of multiple systems or technologies so they can exchange information and work together. |
| Webhook | An automated method by which one system sends information to another when a specified event occurs. |
| Wearable device | A device worn by a participant that collects information such as activity, sleep, heart rate or other physiological measures. |
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## Governance, privacy and information security

| Term | Definition |
|---|---|
| Anonymisation | The process of removing or altering information so that individuals cannot be identified. |
| Audit trail | A record of who accessed, modified or deleted data and when those actions occurred. |
| Cloud hosting | Hosting of software or data using remote infrastructure provided by a cloud service provider rather than local servers. |
| Data controller | The organisation that determines why and how personal data are processed. |
| Data minimisation | The principle of collecting and processing only the data necessary for a defined purpose. |
| Data processor | An organisation that processes personal data on behalf of a data controller. |
| Data retention | The period for which data are stored before deletion, archiving or further review. |
| Data sensitivity | The degree of protection required for data based on factors such as identifiability, confidentiality and potential harm if disclosed. |
| Data sovereignty | The principle that data are subject to the laws and governance requirements of the country in which they are stored or processed. |
| Encryption at rest | Protection applied to data while stored on a system or device. |
| Encryption | Protection applied to data while being transferred between systems or locations. |
| Information governance | The framework of policies, processes and controls used to manage information securely, legally and appropriately. |
| International data transfer | The movement of personal data between countries or jurisdictions. |
| Managed service | A platform or infrastructure that is operated and maintained by a third-party provider. |

| Term | Definition |
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| Multi-factor authentication (MFA) | An authentication method requiring more than one form of verification before access is granted. |
| Personally identifiable information (PII) | Information that can identify an individual directly or indirectly. |
| Platform provider | The organisation responsible for developing, hosting, supporting or maintaining a platform. |
| Pseudonymisation | Replacing identifying information with unique codes while retaining a separate mechanism for re-identification when necessary. |
| Role-based access control (RBAC) | Restricting access to systems or data according to a person's role or responsibilities. |
| Scalability | The ability of a platform to support increasing numbers of users, participants or data without significant performance issues. |
| Subprocessor | A third party engaged by a data processor to undertake part of the processing activity. |
| UK GDPR | The United Kingdom's legal framework governing the processing of personal data. |

## Clinical trials, regulation and quality assurance

| Term | Definition |
|---|---|
| 21 CFR Part 11 | United States regulations governing electronic records and electronic signatures used in regulated environments. |
| CE marking | A marking indicating that a product meets applicable European regulatory requirements. |
| Clinical | A measure describing or reflecting how a participant feels, functions or survives. |
| Clinical trial | A research study involving human participants that evaluates health-related interventions or healthcare approaches. |
| Clinician-reported outcome (ClinRO) | An assessment completed by a trained healthcare professional based on observation or examination. |
| eConsent (electronic consent) | The process of obtaining and recording participant consent using electronic systems. |
| Electronic case report form (eCRF) | A digital form used to collect protocol-required data during a clinical trial. |
| Electronic clinical outcome assessment (eCOA) | A clinical outcome assessment collected using electronic systems. |
| Electronic data capture (EDC) | A system used to collect, manage and store research data electronically. |
| Electronic patient-reported outcome (ePRO) | Information reported directly by participants through electronic systems such as apps, websites or tablets. |
| Good Clinical Practice (GCP) | An internationally recognised quality standard for the design, conduct, recording and reporting of clinical research involving human participants. |
| Inspection readiness | The state of being prepared for sponsor, regulatory or quality assurance inspections. |
| Medical device | A product, device or software intended for a medical purpose that may be subject to medical device regulation. |

| Term | Definition |
| --- | --- |
| Medical Device Regulation (MDR) | The regulatory framework governing the assessment and use of medical devices. |
| Performance outcome | A measurement obtained when a participant performs a defined task according to specified instructions. |
| Regulated research | Research that must comply with specific legal, regulatory, sponsor or quality requirements. |
| Software validation | Documented evidence demonstrating that a system performs as intended and is suitable for its intended use. |
| UKCA marking | A conformity marking used for certain products placed on the market in Great Britain. |
| Validated system | A system supported by documented evidence showing that it performs consistently and reliably for its intended purpose. |