For Academia

Mi-Trial supports academic research with study apps to help participants stay informed, organised, and engaged throughout their study journey. The Mi-trial app offers a single repository for all of a participant's study information. Mi-trial provides clear study scheduling and timely communication to reduce missed visits, support protocol adherence, and minimise administrative burden.

Background

Mi-Trial, the clinical trial companion app, was developed out of many years of experience of working with trial participants and delivering clinical trials. Mi-Trial was developed to address a range of unmet needs for three cohorts: **study participants**, **trial organisations or units**, and **Trial sponsors**. Mi-trial has been successfully deployed in academic studies and offers a unique and powerful tool to aid study participants and teams. We are committed to value-for-money partnership with academic researchers, using our proven platform.

Mi-Trial Product Overview

- Flexible scheduling tool which enables research teams to set up a broad range of study schedules, milestones, and activities.
- The visits and appointments are mapped for each participant, allowing tracking and schedule modifications where needed.
- Participants can view all events, notifications and appointment instructions through the **Personal Study Plan**, which syncs with calendar apps. This allows the participant to keep informed, track their progress and minimise protocol deviations.
- The **Documents** feature enables participants to access important supporting information such as Trial Summary or Participant Information Sheets.
- Notifications can be pre-configured and edited in the study visit design. Custom, ad-hoc communications or notifications can be sent to specific participants through the web portal.
- Notifications are currently presented in-app and via push notification if the participant enables this. Email / SMS / post notification functionality can be added.
- Regulatory and Ethically approved for use in UK clinical trials.

Mi-Trial was conceived by clinical researchers working on and delivering clinical trials and developed in partnership with the **Medicines Evaluation Unit (MEU)**. Professors Alex Horsley and Jacky Smith are both **clinical academics** working in Respiratory medicine (cystic fibrosis and cough research respectively) and between them have led and designed dozens of clinical trials.

The other partner is the SME **ELAROS**, a Sheffield-based developer of medical apps, already partnered with a number of different NHS organisations and currently rolling out **autonom-e**, a customisable digital solution for the remote assessment, triage, monitoring, management, rehabilitation, and education of patients with a range of long-term conditions built on the **C19-YRS Long COVID symptom app**.

Case Study (The CF-Tracker Study)

Mi-trial is providing the study app for a **major new study** investigating the causes of lung infections in people with **Cystic Fibrosis**. The CF-Tracker study is sponsored by the University of Manchester and funded by the **CF Trust** and the medical charity **LifeArc** as part of the work of the **Pulse-CF Innovation Hub** they fund at **University of Manchester**.

In order to support the study, Mi-trial has provided a **standalone** version of the app, **rebadged** and **branded** as the **CF-Tracker app**. This contains all the usual features of Mi-trial, as well some additional features. The study involves sending home samples and questionnaires every 2 weeks, so the **diary function** and **reminders** are an essential part of this. In this version, Mi-trial have added an extra feature: the app provides a unique link to a **Patient Reported Outcome Measure (PROM)**. The PROM is hosted on **SnapSurvey**, so makes use of their extensive experience and **well-established information governance**. The app provides a link that only goes live during the assessment window, and links out seamlessly on the phone to the CF-Tracker branded PROM, with hidden fields linking to the responders study ID.

Creating this version of Mi-trial **adds another layer of functionality to Mi-trial**. It was also essential to the CF-Tracker study, which is now up and running in **18 UK CF centres**. Patient feedback has been really positive and the team are delighted with their new **study-specific app**.

Find out more: **https://www.pulse-cf.com/tracker-study**

Pulse CF Innovation Hub

Funded by

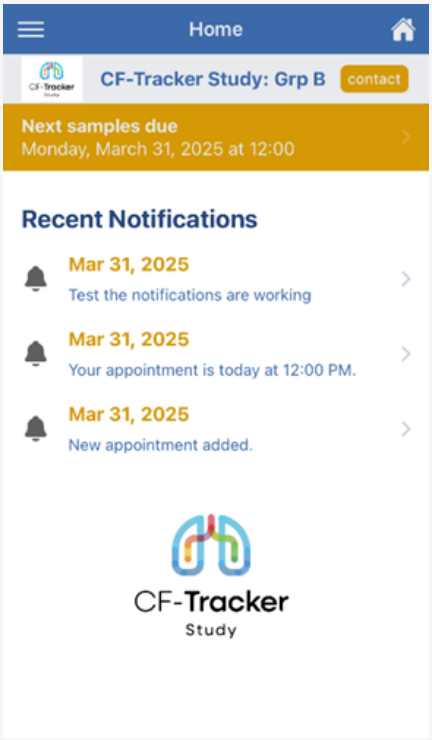
LifeArc

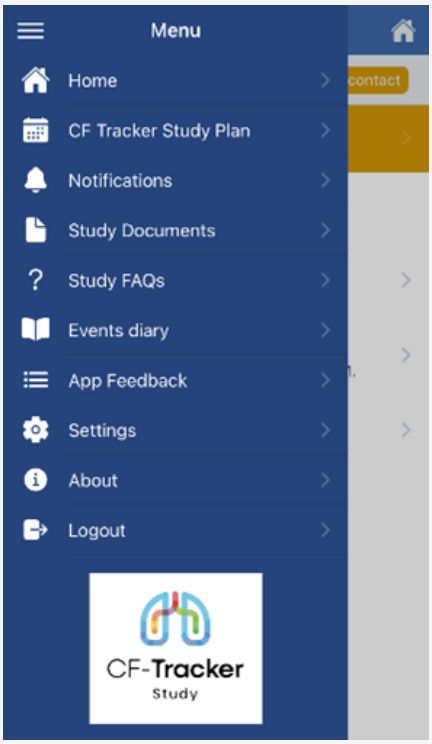
Cystic Fibrosis Trust

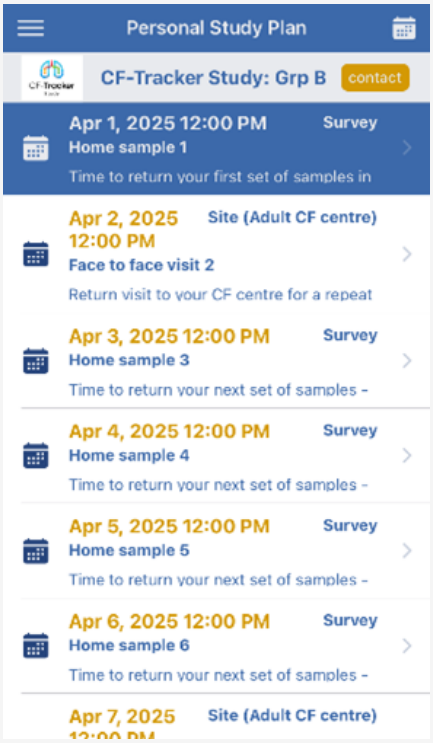
Case Study (The CF-Tracker Study)

Participants have the option of using the **CF-Tracker study app**, downloadable from **Android** or **Apple**. The app:

- Includes all study information to access easily.
- Shows diary of reminders and notifications.
- Provides a link to the questionnaire for that week.



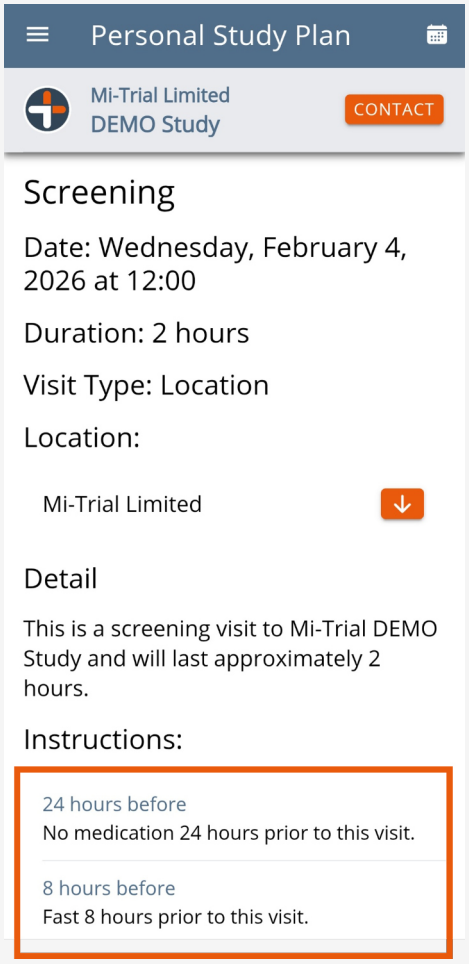


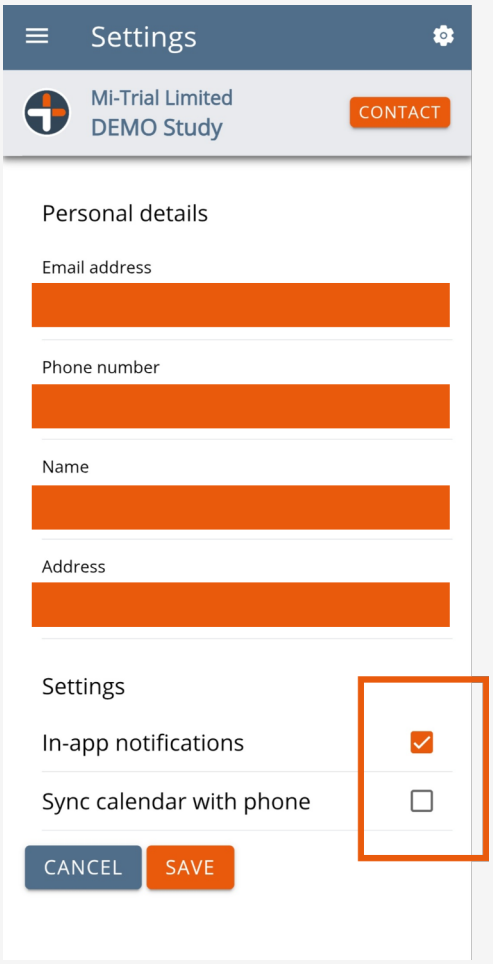


Mi-Trial (App)

Participant view of an event in their **Personal Study Plan**. Note the two instructions which will also populate the **Notifications** page and also send as push-notifications if the participant has these enabled. SMS / Email notifications functionality can be added.

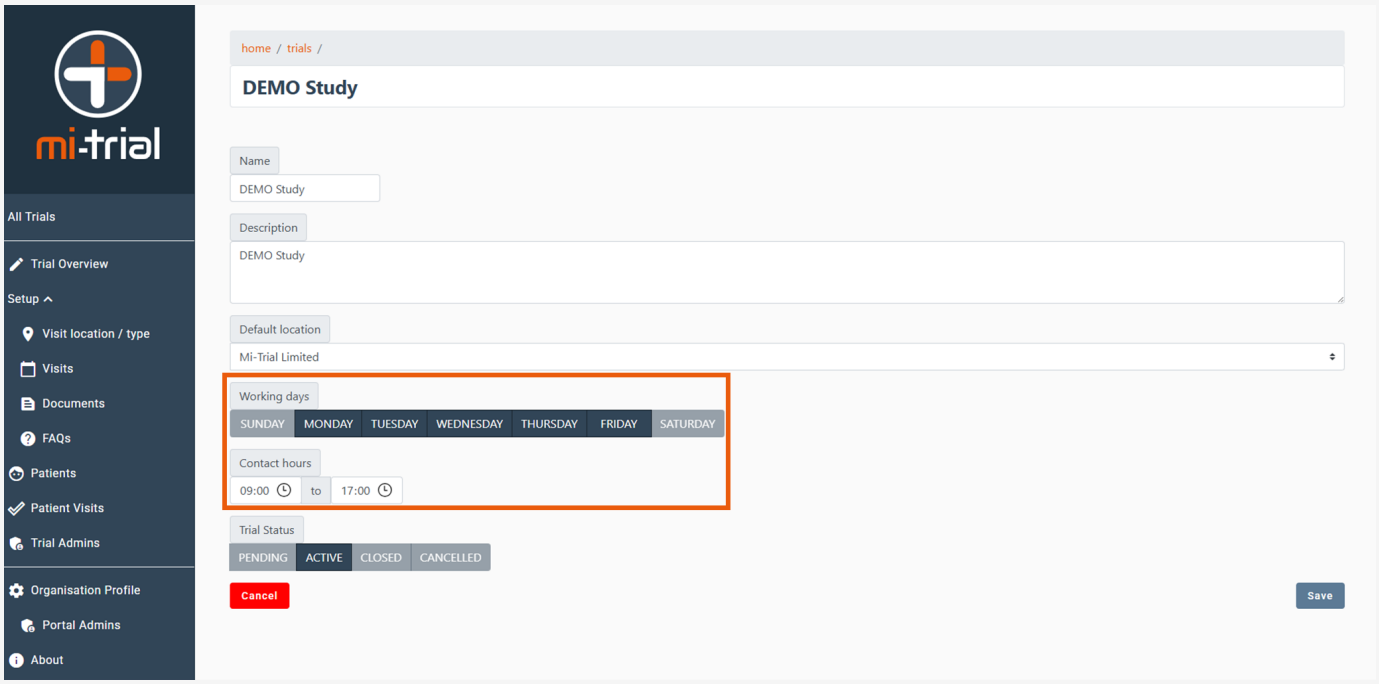
A **web app** version is also available to access off the mobile.



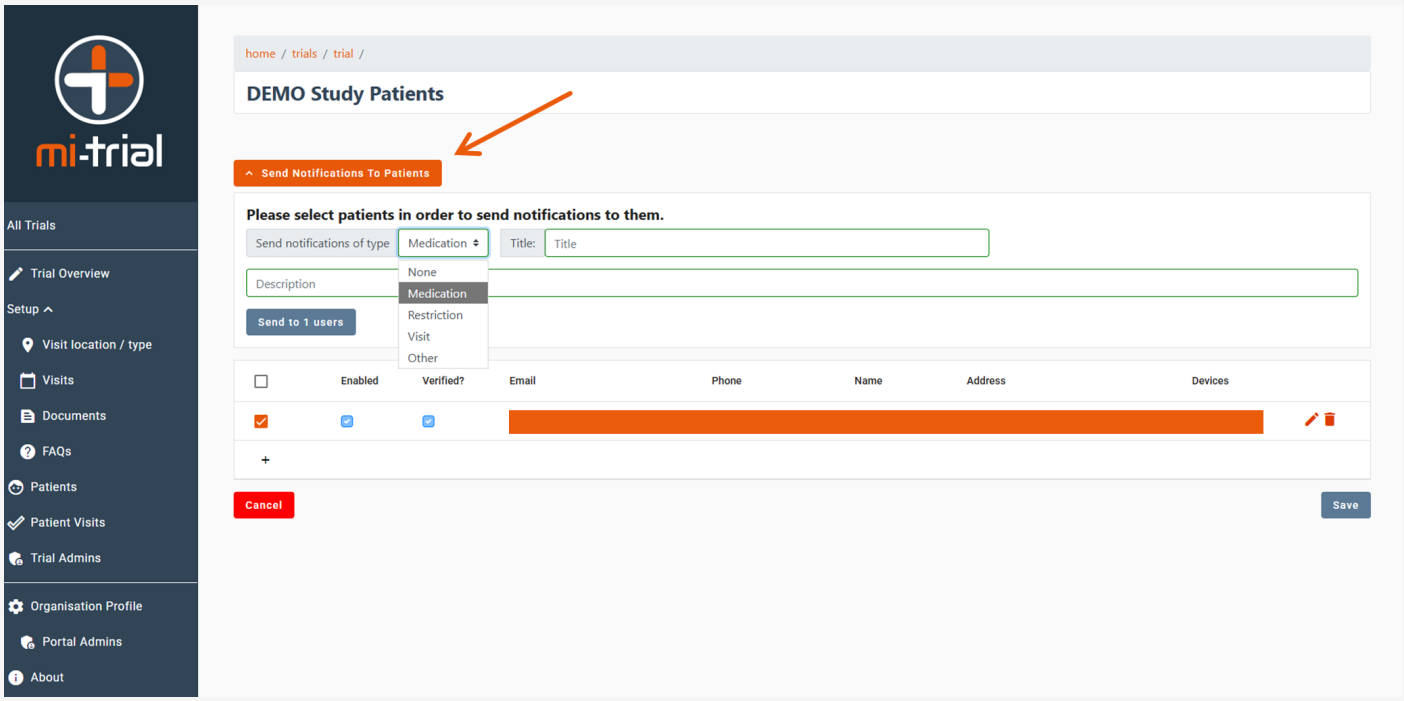


Mi-Trial (Web Portal)

Trial Setup view, where the trial organisation configures settings. Working days and contact hours feed into the scheduling algorithm to help determine the most time-efficient visit times, whilst maintaining protocol and valid date ranges.



Patients menu in Portal mode, where the trial organisers can send bespoke / custom notifications to specific patients.

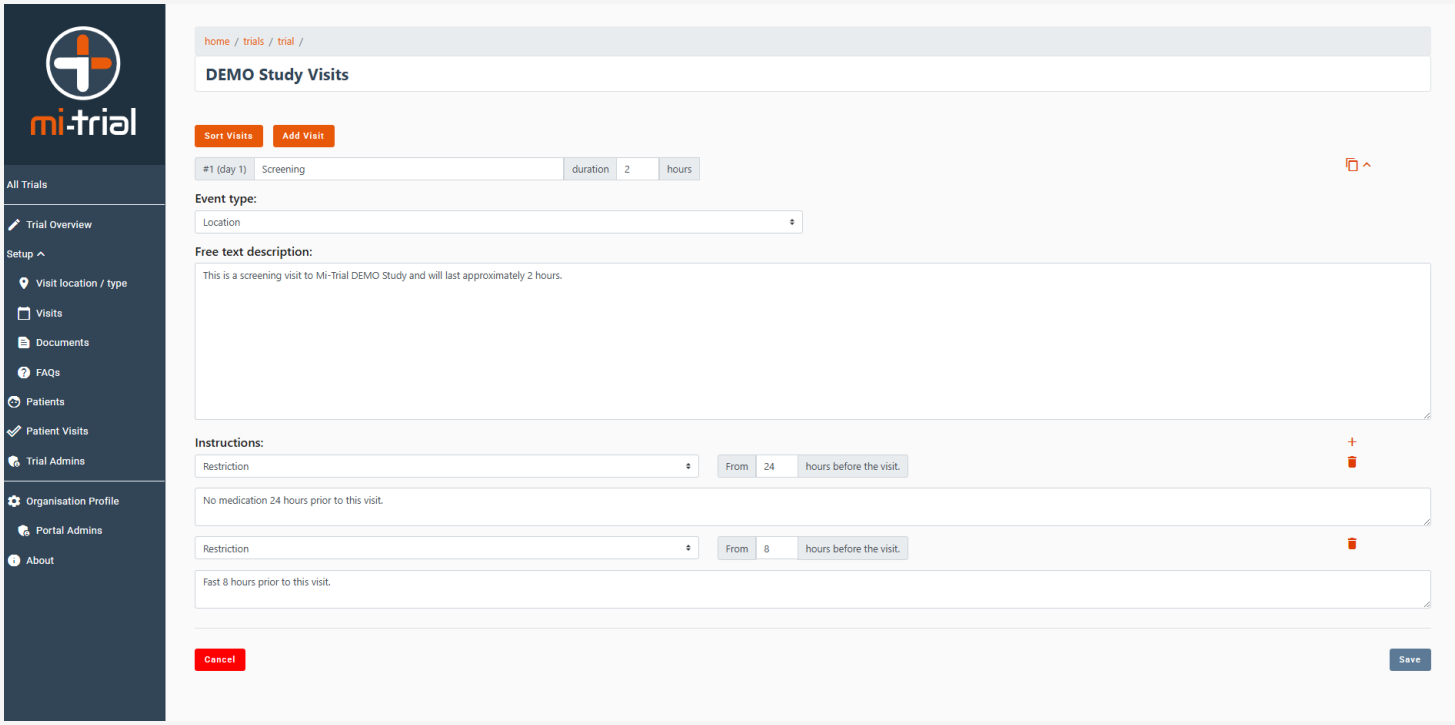


Mi-Trial (Web Portal)

Mi-trial is managed from the **Web Portal**. This is a secure (2FA) portal where the research team can set up the study schedule and planned notifications. The team can add **documents** for patients to access from the app, and develop their own **FAQs**.

New patients are added to the study in the Portal, which automatically populates the **visit schedule**. This can be manually changed if needed.

The portal allows the team to see all active study participants, to send them **personalised or global messages**, and to see which participants have upcoming visits. Different levels of access mean that local teams can add participants, and the central team can monitor recruitment.



Assurance

Mi-Trial has been designed specifically to support use in **academic research studies** and has been developed in-line with established regulatory, data protection, and information governance requirements. It is intended to act as a participant-facing study coordination and communication tool, operating alongside and **not replacing** existing clinical, research, or data capture systems.

UK GDPR

Mi-Trial operates in accordance with data protection principles. Key features include:

- Data minimisation: only data required for study delivery and coordination is collected.
- Clear participant-facing privacy information within the app.
- Defined roles / responsibilities between study sponsor, research site, and platform provider.
- No secondary use of participant data.

Mi-Trial does not use participant data for purposes outside the delivery of the approved study. Supporting documentation (Privacy Notice, Privacy Policy, Terms & Conditions, Patient and Clinician EULAs) is available to support ethics, R&D, and information governance review.

US CFR 21 Part 11

Mi-Trial has been developed in line with the principles of CFR 21 Part 11 relating to electronic records and auditability. This includes:

- Controlled user access and permissions.
- Secure system authentication.
- Comprehensive audit logging of relevant system actions. Mi-Trial maintains audit logs for key system activities, including: study configuration changes, user actions within the researcher portal, and updates to participant study schedules and instructions.
- Documented development, testing, and validation activities.

Hosting

Mi-Trial is hosted on secure, UK-based infrastructure appropriate for health and academic research use. The platform incorporates:

- Role-based access controls.
- Secure authentication for research staff and participants (MFA).
- Separation between participant-facing and researcher-facing environments.
- Controlled deployment and change management processes.
- Access to the Mi-Trial portal is restricted to authorised study personnel only.

Cost

Mi-Trial is provided to academic research studies using a study-based costing model designed to support grant-funded research. Costs are proportionate to the **scale and complexity** of each study and are suitable for inclusion within standard academic funding applications.

Pricing is typically based on the duration of the study, the number of participants and sites involved, and the level of study configuration and support required. Study costs may include initial study setup and configuration, participant and research team access to the Mi-Trial platform, and ongoing technical support for the duration of the study.

Mi-Trial costs can be included within grant applications as a digital study support or infrastructure cost. A detailed, study-specific costing breakdown can be provided to support grant submissions, sponsor approvals, and local R&D or finance review.

Our **modular design** and proven track record means we can provide rapid, low-cost options immediately as well as more complex study-specific apps faster and cheaper than competitors.

For further information please contact **hello@mi-trial.com**.

Frequently Asked Questions (FAQs)

What types of studies is Mi-Trial suitable for?
Mi-Trial can be used in interventional and observational academic studies, including NIHR-supported research, single- and multi-centre studies, and longitudinal or hybrid digital studies. The platform is condition-agnostic and configurable per study.

Does Mi-Trial replace EDC platforms?
No. Mi-Trial does not collect research outcome data and is not an EDC or PRO platform. It is designed to operate alongside existing systems, focusing on study scheduling, participant instructions, reminders, and engagement.

How is Mi-Trial used by participants?
Participants access Mi-Trial via a mobile app where they can view a personalised study plan, receive reminders and instructions, access study documents, and find contact details for the research team. This helps participants understand what is expected and when.

How is Mi-Trial used by research teams?
Research teams use a secure web-based portal to configure study schedules and visits, manage participant communications, and monitor progress against the study plan. Access is role-based and restricted to authorised study staff.

Contact Details

For further details or queries, please contact us at
hello@mi-trial.com

Request a demo:
https://forms.office.com/e/vGtkStS8Ff

Electric Works
Sheffield Digital Campus
3 Concourse Way
Sheffield
S1 2BJ

+44 (0)114 286 6219

www.mi-trial.com

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