



Supporting Children to Better Health

Accelerating Paediatric Clinical Trials



We use innovation to accelerate paediatric clinical trials through an integrated participant support and clinical trial management system.



The Problem

According to the FDA, 25-40% of paediatric clinical trials fail to establish data to determine the safety and effectiveness of the study intervention⁽¹⁾. This leads to off-label or unlicensed paediatric prescriptions - reported to be as high as 79% and 35% respectively⁽²⁾. Trial failure is in part explained by the inherent complexities of running a paediatric clinical trial - including challenges in recruitment, adherence to trial protocol and retention of participants.

Paediatric clinical trial challenges

- **Poor recruitment**
\$1200, Average cost of a failed recruitment
- **Early withdrawal**
20% of patients withdraw from clinical trials
- **Low adherence**
50% adherence to prescribed medication
- **Delays**
80% Of clinical trials are delayed
- **Lost revenue**
\$8M lost revenue each day delayed

References:

1: Pediatric Clinical Trials Market Analysis – Coherent Market Insights (2020). Online: Pediatric Clinical Trials Market Size, Trends, Shares, Insights, Forecast - Coherent Market Insights

2 - Rajeshwari Gore, Preeta K. Chugh*, Chakra D. Tripathi, Yangshen Lhamo and Sandhya Gautam, "Pediatric Off-Label and Unlicensed Drug Use and Its Implications", Current Clinical Pharmacology (Discontinued) 2017; 12(1) . <https://doi.org/10.2174/1574884712666170317161935>

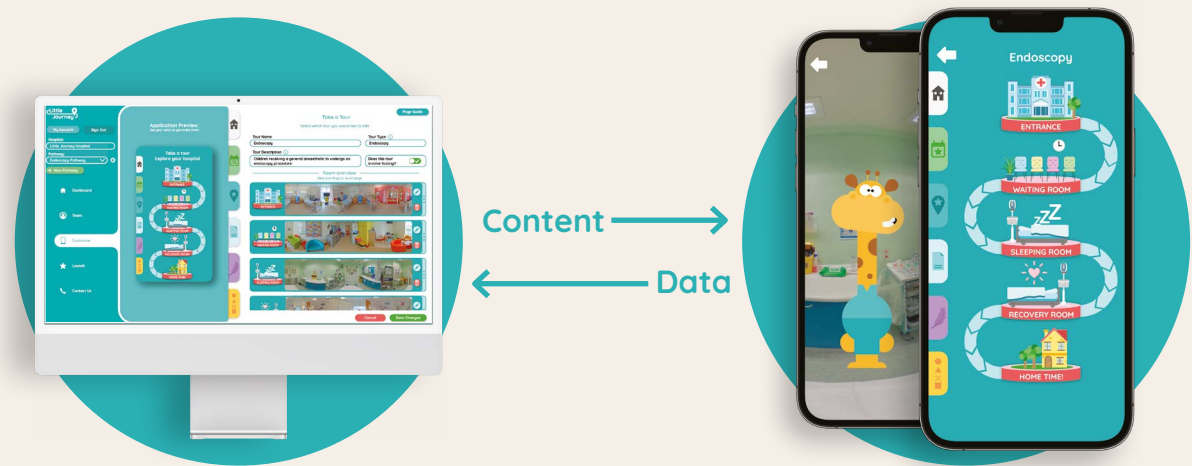


Our Solution

Little Journey is a clinical trial support and management platform designed to optimise trial participant engagement and improve trial completion rates; it comprises a participant-facing smartphone app and accompanying web-portal accessed by research staff, trial Sponsors and CROs.

The Little Journey smartphone app is a digital companion tool that informs, supports, and engages children and families end-to-end throughout the trial process, all from the comfort and safety of their own home. It delivers interactive content tailored to the child's age, trial progress and hospital site.

The Little Journey Clinical Trial web-portal, accessed by research staff and CRO's, enables teams to collaborate in configuring app content relevant to each site and to monitor trial progress.



Configured and controlled by Healthcare & Research Organisations

Used and loved by children & families

Background Research

Peri-procedural anxiety is common, affecting 50-75% of children and 33% of adults.^(1,2)

It is the leading complaint before surgery⁽²⁾ and results in poor patient experiences, reduced satisfaction with care and worse mental and physical health outcomes.⁽³⁾

Psychological preparation reduces anxiety but face-to-face provision is expensive and time consuming.⁽⁴⁾

Families may be reluctant to participate in a clinical trial involving multiple procedures or hospital visits to avoid the potential for exacerbating distress in their child. Accessible support, starting before screening, empowers families in making the correct choice for them.



1. Kain ZN, Mayes LC, Caramico LA Preoperative preparation in children: a cross-sectional study. J Clin Anesth 1996; 8: 508-14. 2. Walker EM, Bell M, Cook TM, Grocott MP, Moonesinghe SR Patient reported outcome of adult perioperative anaesthesia in the United Kingdom: a cross-sectional observational study. Br J Anaesth 2016; 117: 758-66. 3. Kain ZN, Mayes LC, Caldwell-Andrews AA, Karas DE, McClain BC Preoperative anxiety, postoperative pain, and behavioral recovery in young children undergoing surgery. Pediatrics 2006; 118: 651-8. . 4. Kain ZN, Caldwell-Andrews AA, Mayes LC, et al. Family-centered preparation for surgery improves perioperative outcomes in children: a randomized controlled trial. Anesthesiology 2007; 106: 65-74.



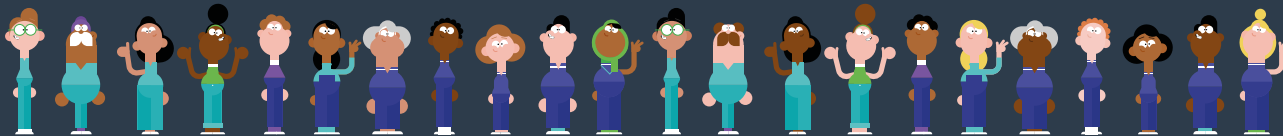
An Award Winning Participant-facing App

The Little Journey smartphone app provides accessible, multi-faceted support for both child and caregiver end-to-end - from screening through to trial completion.

With features to engage and support participants and their families through their trial journey, the Little Journey app addresses common challenges faced in paediatric clinical trials. Improvements in participant recruitment, retention, and adherence results in cost and time savings for trial sites, CRO's and Industry Sponsors.

Tailored information is delivered at key time points along a participant's trial journey, enhancing their comprehension and retention of understanding. Peri-procedural psychological preparation, including virtual tours and relaxation guides, aids the development of problem and emotion-focussed coping strategy formation, reducing anxiety and improving participant retention.

Languages, Localisation & Globalisation



Little Journey is currently available in 16 languages, including: English, French, Portuguese, Greek, Lithuanian, American, Spanish, Russian, Italian and Vietnamese; and features a diverse range of characters for you to select from.



A Configurable Web-portal for Research Staff

The Little Journey Clinical Trial web-portal, accessed by research staff and CROs, enables teams to collaborate in configuring app content relevant to each site and to monitor trial progress.

The Little Journey web portal enables configuration of app content to specific trial protocols; research teams at each site can customise information relevant to their local patient pathways and policies. Data feedback allows the monitoring of engagement and usage to enhance and improve the support provided. Research teams can adapt individual care for participants based on feedback provided.

Tailored procedure preparation content for:

- Surgery
- COVID-19 Swab
- Phlebotomy
- Endoscopy
- Clinical Trials

Coming Soon:

- MRI Scans
- Intensive Care
- Neo-natal Intensive Care



Configurable Modules

Little Journey has four configurable modules for use within clinical trials.

These include:

- 01 - Preparation & Support
- 02 - Clinical Trial Information
- 03 - Medication Gamification
- 04 - Data Collection



Module - 01

Preparation & Support



Module 1 - Preparation & Support

Our information modules prepare and empower caregivers in supporting their child during the clinical trial journey. Specific articles can be customised by site staff via the clinical trial portal meaning information is tailored to protocol requirements and local hospital guidelines.

Families can track upcoming appointments, reflect on previous trial interactions and request rescheduling of appointments via an interactive appointment scheduler module. This also ensures that information is delivered at times relevant to trial progress.

Age-tailored, interactive virtual tours explain what will happen and who families will meet during each trial visit. These include 360 degree images of the actual rooms visited, uploaded by local research sites via the Little Journey portal.

Prepare:

- Customisable age tailored virtual tours
- Therapeutic games
- Snippet information articles
- Fasting guidelines
- Checklist
- Coping guides

Distract:

- Distraction games
- Relaxation animations
- Low sensory environments

Support:

- Appointment scheduling
- Hospital contact information
- Nudges and reminders

Key Benefits

For Sponsors & CROs

- Reduction in on-the-day cancellations
- Time saving for site staff
- Leads to cost savings for both local hospital, CRO and Sponsor
- Reduction in protocol deviations
- Improves participant retention

For Sites & Staff

- Reduction of on-the-day cancellations
- Time saving for site staff
- Patients are better prepared and informed
- Ability to tailor care to individual participant and family needs

For Participants & Families

- Easily accessible information
- Reduced procedural anxiety and stress
- Distraction therapy provided whilst undergoing procedures
- Helps to develop coping strategies

Module - 02

Clinical Trial Information

Module 2 - Clinical Trial Information

Digitised, trial-specific information, including clinical trial support documents, is delivered according to the Schedule of Assessments.

Information is delivered to the participants device at key time points, preparing children and families for upcoming appointments.

Features for families:

- Digitised patient information leaflets
- Interactive clinical trial timeline
- Trial specific information articles
- Local research site contact details
- Information guides

Features for staff:

- Appointment tracker
- Schedule management

Key Benefits

For Sponsors & CROs

- Track and monitor trial progress
- Improved retention
- Empowers participants and families
- Increases adherence

For Sites & Staff

- Reduced participant and family anxiety
- Increased confidence in the informed consent process

For Participants & Families

- Easy to understand information
- Better awareness of trial activities
- More informed decision making



Module - 03

Medication Gamification



Module 3 - Medication Gamification

Gamified medication system that monitors and tracks drug adherence of investigational product (IP) and supports children through the process of taking their medication throughout the trial.

Features for families:

- Interactive gamification encouraging the taking of medication
- Digitised rewards
- Customised notification reminders
- Trial specific emergency protocol information

Features for research teams:

- Remote monitoring of adherence to IP

Key Benefits

For Sponsors & CROs

- Near real-time monitoring of compliance
- Ability to provide additional support from site if needed
- Reduced protocol deviations
- Ability to foresee IP issues and intervene to provide solution

For Sites & Staff

- Improved medication compliance
- Easy to manage medication tracking

For Participants & Families

- Keep track of daily medication
- Daily rewards for taking medication

Module - 04

Data Collection



Module 4 - Data Collection

Bespoke remote data capture systems tailored to trial protocol and the schedule of assessments.

Little Journey enables easy capture of electronic patient reported outcome measures specific to trial protocol. This includes the ability for participants to record and reflect on previous trial appointments. Standard feedback and reporting methodologies are available as well as custom built questionnaires. Explicit consent is provided for this data collection through the informed consent form and linked to a unique six-digit code entered within the app post-consent.

Features for families:

- Accessible feedback forms

Features for research teams:

- Data collection dashboard
- Customised data collection forms

Key Benefits

For Sponsors & CROs

- Data collection
- Digitised source data
- Reduction in data queries

For Sites & Staff

- Simplified method of data collection and analysis
- Reduced paper trail
- Learn from participant feedback and tailor care according to individual needs

For Participants & Families

- Improved participant satisfaction with care
- Easy to complete feedback
- Engaging user interface

Benefits for Your Sites

Little Journey use has proven benefits for healthcare organisations including:

- Organisational cost benefits - £3.50 and £6.00 cash/non-cash releasing savings for healthcare organisations and society respectively for every £1 invested.
- Reduced unplanned admissions
- Decreased on-the-day cancellations (42% reduction)
- Improved staff/resource utilisation
- Improved patient compliance with care (e.g. reduced pre-medication rates)

Patient Benefits

With a 97% satisfaction rate from more than 450 app store reviews, Little Journey improves patient's experience of care, satisfaction and health outcomes:

- Reduced anxiety - 32% reduction in anxiety!
- Decreased fasting times by 1 hour for liquids and 2 hours for solids before surgery
- Faster post-operative recovery time (1.74% QALY improvement from using Little Journey)
- Fewer missed days of school/work
- Development of positive health behaviours transitioning to adulthood



Feedback

Valued by healthcare professionals,
loved by patients and families!

We used the Little Journey app to help a 9 year old girl recently who was very anxious and has autism. Her previous procedures have been a real challenge due to this. After the patient downloaded and used the app, it was a much less stressful situation, simply due to the immersive distraction she experienced from playing with the app.

Dr Alyson Walker
Consultant Paediatric Anaesthetist

“We think the app is a really good idea. We hadn’t really discussed the operation with Freddie yet as we weren’t quite sure what to say or how best to go about it, so the app really helps with that.

Parents of Freddie, aged 5

“Amazing app, helped to show my daughter what she would experience, took a little of the anxiety away. Very easy to use and very informative.

iOS App Store Review

The Little Journey innovations are outstanding and a perfect example of patient-centred healthcare design. Little Journey’s goal of improving children’s experience of hospital is of paramount importance to us at NHS England.

Dr Jacqueline Cornish
NHS England National Clinical Director for Children, Young People and Transition to Adulthood.



Clinical Trial eSupport & Research Management Tool Setup

Protocol Overlay

Oversight tool for CROs to track progress and identify issues early

Configuration to sites

Web portal & research management system for clinical & research staff

CRA Support

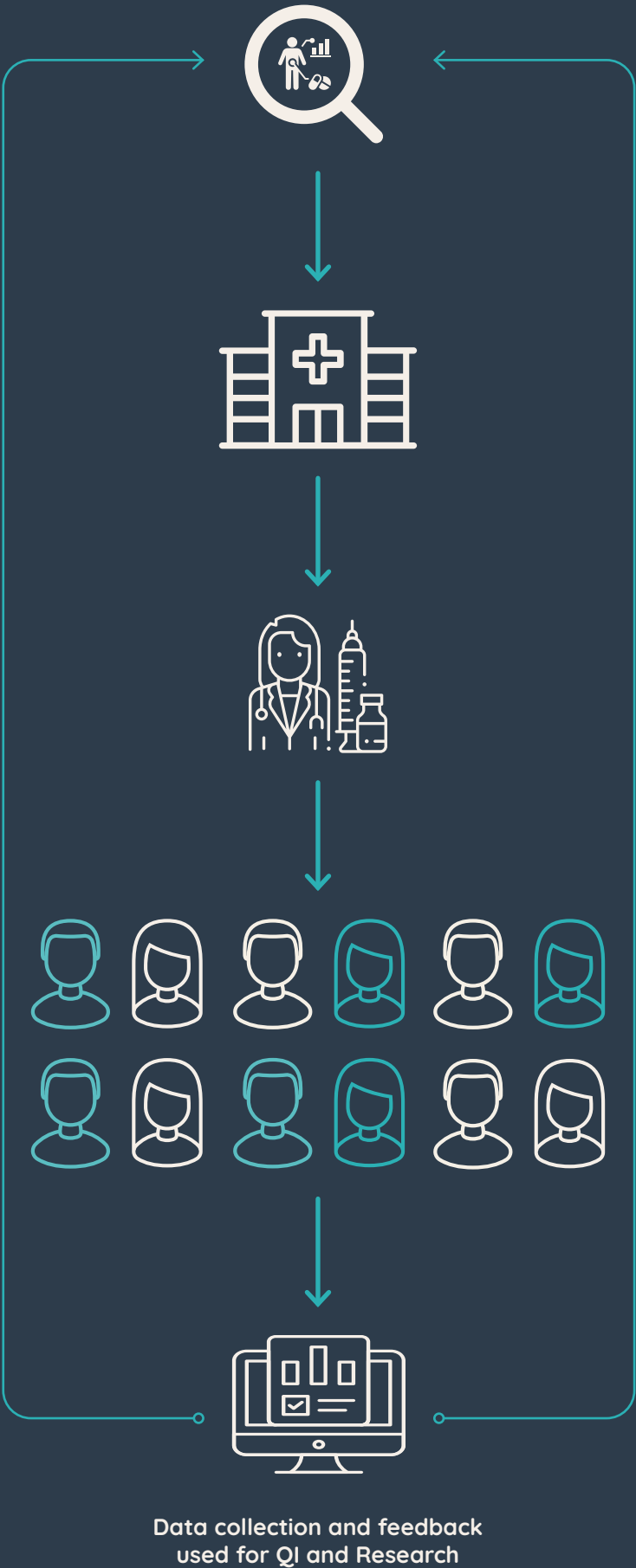
Little Journey provide ongoing support during the whole trial period, not just setup.

Tailored to end user

Free to download smartphone app

24 hour Portal Access

Platform available 24/7 to either configure local pathways or monitor trial progress



Pricing & Quotations

For a confidential discussion on how Little Journey could create a bespoke proposal, fully tailored to your clinical trial protocol, please contact us at: hello@littlejourney.health



Book a Demo

To arrange a platform demo please visit www.littlejourney.health





Download Little Journey for free
and experience it for yourself.



Find out more at



www.littlejourney.health