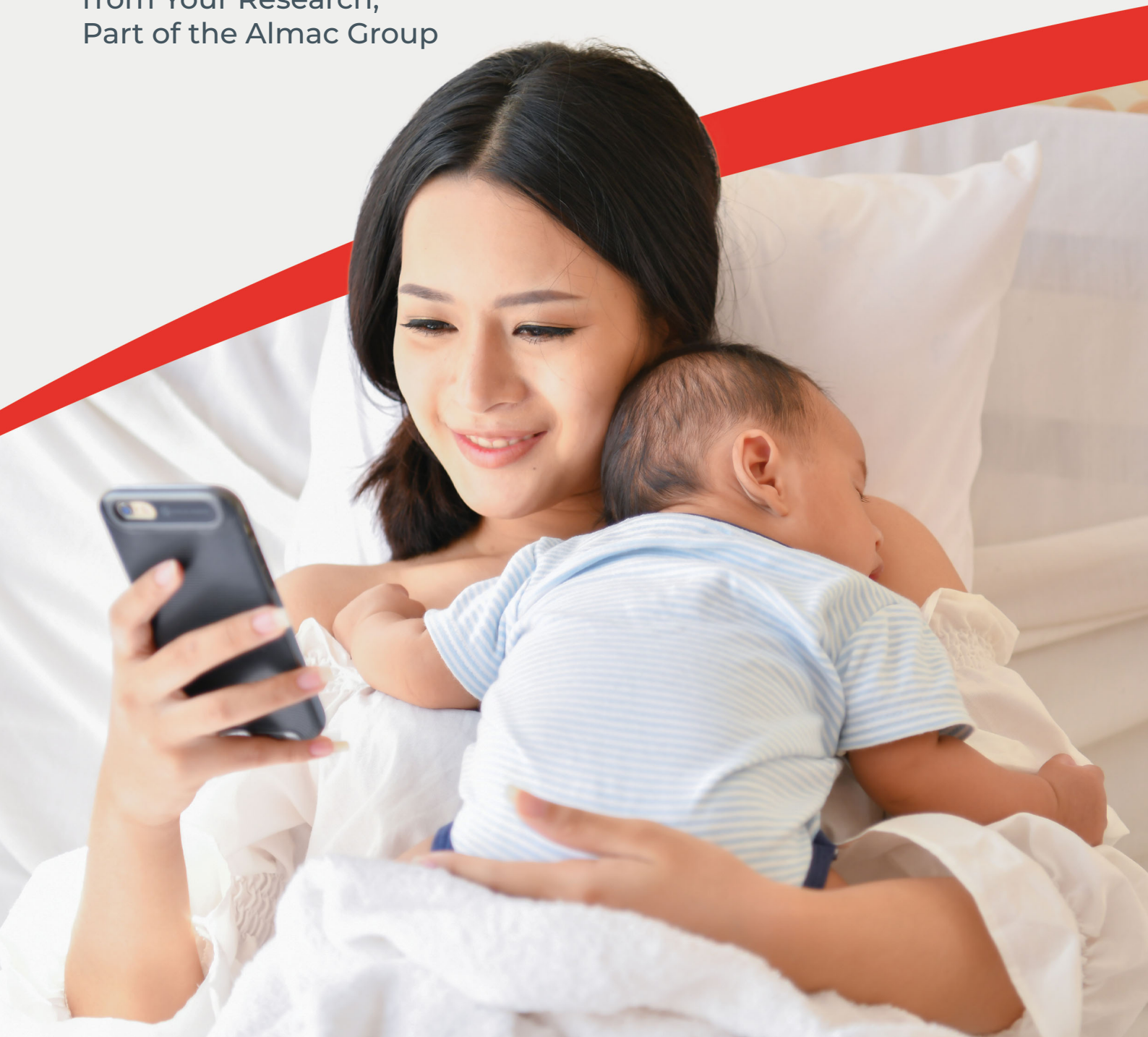


Cardiff University advances neonatal respiratory research with **eCOA Solution**

from Your Research,
Part of the Almac Group



Study: BALLOON Trial
Sponsor: Cardiff University
Location: United Kingdom

Solution: eCOA via RespiRecord App
Participants: 542
Duration: 3.5 years

Challenge

Prematurely born babies face significant increased risk of chest infections after discharge from the neonatal unit due to underdeveloped lungs and immune systems. Frequent infections can lead to repeated medical visits and hospitalisations during early life. Cardiff University is evaluating if Bactek—a novel daily oral spray—can reduce infection rates and improve long-term respiratory outcomes in this vulnerable population.

With 542 participants across 12 – 18 sites in the UK, the BALLOON trial required a digital solution that could enable seamless, real-time symptom tracking by caregivers, ensure data integrity, and scale efficiently over a 3.5-year study period.

Solution

Cardiff University selected **Your Research, part of the Almac Group**, to provide an eCOA platform delivered through the **white-label RespiRecord App**, supporting all electronic Clinical Outcome Assessments (eCOA) in the BALLOON study.

Key features of the solution included:



Participant management

Centralised enrolment and oversight of 542 families across 12 – 18 UK sites.



eCOA via RespiRecord App

Real-time, caregiver-reported symptom tracking through a mobile interface, improving data quality and timeliness.



Custom configuration based on PROTEA study

The solution leveraged a previously validated architecture from the PROTEA study, with tailored adaptations to support the BALLOON protocol.



Compliant EU hosting

Data securely stored within GDPR-compliant European infrastructure.



End-to-end support

Full implementation support, including 2nd line technical support and ongoing system maintenance, delivered by Your Research's dedicated team.

Impact

The integration of the eCOA platform has enabled Cardiff University to:

- Collect high-quality, longitudinal respiratory data directly from caregivers.
- Monitor symptom trends across a dispersed population with ease.
- Reduce administrative burden for sites through automated workflows and centralised participant tracking.

“By the parents using the RespiRecord App for the BALLOON study, we hope to capture data in real time which should help us manage the trial participants more effectively, including reporting of treatment compliance and collection of outcome data.”

Sailesh Kotecha, Cardiff University

About the sponsor

Cardiff University is a leading UK research institution committed to improving healthcare outcomes through innovative science and collaborative trials. The BALLOON trial exemplifies their work in neonatal health and early-life immune interventions.

<http://balloon-trial.uk>
<https://www.cardiff.ac.uk>

About the eCOA platform

The **RespiRecord App**, powered by **Your Research, part of the Almac Group**, is a custom-configured mobile platform for real-time participant symptom reporting and eCOA data capture.

<https://respirecord.com>

About the vendor

Your Research B.V. was an independent provider of digital clinical solutions at the time of initiating the BALLOON trial. Since then, the company has been acquired by **Almac Group** and now forms an integral part of **Almac Clinical Technologies' eClinical Solutions** portfolio. Your Research, now part of the Almac Group, continues to deliver intuitive, regulator-ready tools—including eCOA, eConsent, and participant engagement platforms—supporting global clinical trials with scalable, high-quality technology.

<https://www.almacgroup.com/clinical-technologies/your-research/>

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