

Franciscus Hospital drives preterm infant respiratory research with **eCOA**

Solution from Your Research,
part of the Almac Group



Study: PROTEA Trial
Sponsor: Franciscus Gasthuis & Vlietland
Solution: eCOA & remote data capture via white-label app

Location: The Netherlands
Participants: 500
Duration: 1 year + 1 year follow-up

CHALLENGE

Each year, around 10,000 infants are born prematurely (30–36 weeks' gestation) in the Netherlands. These babies are significantly more vulnerable to respiratory tract infections (RTIs) and wheezing in their first year of life due to underdeveloped lungs and immune systems. Current treatment options are limited, and no preventive interventions are approved for this at-risk group.

Franciscus Hospital initiated the **PROTEA trial** to determine whether **OM-85 (Broncho-Vaxom)**—a bacterial extract with immune-priming effects—could reduce the frequency and severity of respiratory symptoms in this vulnerable population. The trial required a fully decentralised, tech-enabled approach to accommodate parents of young participants, remote monitoring, and multi-site recruitment.

SOLUTION

Your Research, part of the Almac Group, was selected to deliver a patient-centric eCOA and participant management platform for this decentralised, two year-long study. A white-labelled mobile app was deployed to enable seamless caregiver reporting and treatment compliance tracking.

Key features of the solution included:



White-label app for eCOA & compliance

Weekly and daily symptom reporting, reminders for treatment days, and secure communication with study teams, all tailored to non-technical caregivers of infants.



Integrated sample collection tracking and notifications

Optional prompted biological sampling (blood, saliva, nasal swabs, stool) scheduled alongside remote or in-home study visits, reducing burden on families.



Participant management

Central oversight of now 200, with an aim of 500, enrolled preterm infants across multiple hospitals in the Netherlands.



Compliant EU hosting & data security

All data securely stored in GDPR-compliant infrastructure with strict access controls.



Decentralised trial enablement

Caregiver training, digital informed consent support, and home-based data collection (including lung function data, if opted in).



Longitudinal follow-up capability

Post-intervention health tracking extended to 24 months via digital questionnaires.

OUTCOMES AND KEY RESULTS

These metrics reflect strong participant engagement, minimal attrition, and high data volume, demonstrating the feasibility and success of running decentralised infant studies at scale.

Metric	Result
Compliance	88%
Dropout rate	7.8%
Study sites	20
Total assessments	13,455
Signed ICFs	196



By digitising the participant journey, the PROTEA trial achieved:

Scalable remote monitoring

Parents of 200 infants used the app to record symptoms, receive study instructions, and maintain contact with the clinical team—eliminating the need for frequent in-person visits or paper diaries.

Reduced site burden

Study visits were reduced to three touchpoints, all optionally conducted via video. Clinical staff reported greater confidence in data quality and fewer logistical challenges.

Enhanced data collection

Real-world adherence to OM-85 treatment cycles and symptom recording was effectively maintained through automated app reminders and intuitive interfaces.

“With Your Research’s platform, we enabled hundreds of families to participate from home—while still collecting high-quality, real-time data from some of the most fragile patients in research.”

— Dr. G.A. Tramper, Principal Investigator, PROTEA Trial

About the sponsor

Franciscus Gasthuis & Vlietland is a leading clinical and research hospital in the Netherlands. Through investigator-initiated studies like PROTEA, it advances care pathways and interventions for vulnerable patient groups, including neonates and preterm infants.

<https://www.franciscus.nl>

About the eCOA platform

The **white-labelled mobile app**, developed by **Your Research, part of the Almac Group**, supports decentralised trial models through intuitive caregiver reporting, remote monitoring, and integrated sample logistics.

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

About the vendor

At the time of the PROTEA trial’s initiation, **Your Research B.V.** was an independent digital health technology provider based in the Netherlands. Since then, it has been acquired by the **Almac Group** and now forms a core part of **Almac Clinical Technologies’ eClinical Solutions**. Your Research continues to deliver innovative, regulator-ready platforms that reduce site burden, empower patients, and improve trial data integrity.

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

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