



The POPART Trial sponsor: University College Dublin (UCD)



University College Dublin is the sponsor of the [POPART trial](#) funded by the [PedCRIN](#) project and it has employed PedCRIN services for the expansion of the POPART trial into other European countries (Belgium, Czech Republic, Italy, Portugal, Norway, Sweden) .

[UCD](#) is one of Europe's leading research-intensive universities; an environment where undergraduate education, masters and PhD training, research, innovation and community engagement form a dynamic spectrum of activity. The international standing of UCD has grown in recent years. It is currently ranked within the top 1% of higher education institutions worldwide. UCD is also Ireland's most globally engaged university with over 30,000 students drawn from 136 countries, including almost 4,000 students based at locations outside of Ireland.

We had the pleasure to speak to UCD about their experience of working with PedCRIN as a **sponsor**:

Could you please summarize the goal of the POPART trial? What need does this trial intend to tackle?

Up to **10% of babies** are born prematurely. **Premature babies** are at high risk of developing respiratory distress syndrome (RDS). Many premature babies with RDS have respiratory failure and are **intubated** and **ventilated**. Intubating and ventilating babies is invasive, unpleasant, expensive and associated with **adverse outcomes**. **Surfactant** is an effective treatment for RDS that is given to intubated babies. The POPART trial is examining





whether **giving surfactant into the oropharynx of premature babies** at birth for them to aspirate reduces the proportion of babies who are intubated for respiratory failure in the first 5 days of life.

Which challenges have emerged when designing the trial? And during the implementation?

Surfactant has a characteristic milky white appearance and **there is no placebo** that is safe for babies to aspirate. Also, several caregivers (midwife, obstetrician and neonatologist) are present at the moment that a premature baby is born. This makes it extremely **difficult to mask group assignment**, either by using a placebo or sham intervention. Once open, the trial protocol has proven relatively straightforward to implement. The greatest challenges to opening the trial were the **time it took to apply to and receive approval from Ethics Committees** and Competent Authorities in participating countries and the time taken to agree contracts between the sponsor and participating sites.

How have you considered the experience of the parents during this trial?

We received help with the **design of the study** and **study materials** (parent information leaflet and consent form) from the representative group for parent of premature babies in Ireland.

What challenges have you faced during recruitment?

Many preterm babies are born with little advance notice and **often outside of regular working hours**. This places a responsibility for informing the families of potentially eligible infants on treating clinicians. We are very fortunate to have and deeply appreciate the support of clinicians at participating sites, without whom this study could not work.

How many centers are participating in the study? How were these selected?

There are **8 participating sites** in 5 countries (2 sites in Ireland, 2 in Norway, 2 in Czech Republic, 1 in Belgium, 1 in Sweden). **The Chief Investigator had previously collaborated with the Principal Investigators (PIs) at many sites**, while new collaborations were established with PIs at other sites through relationships with other researchers.

As a POPART trial sponsor, what are University College Dublin's main duties?

Main duties have included **oversight of all sponsorship duties for the trial**. This has included: protocol finalization support for the study, monitoring as well as overarching monitoring oversight and training for all CRAs, provision of training on sponsor processes and materials, POPART database creation and training, central pharmacovigilance, core regulatory affairs support, DSMB co-ordination, provision of GCP training and site support for sites including site readiness and ongoing support.





What kind of services did you receive from PedCRIN?

European **coordination** between sponsor and PedCRIN/ECRIN partner CTUs, local CTU support provided for: regulatory and ethics submissions, monitoring, translations, obtaining insurance.

Do you think that the trial would have been conducted in other European countries without PedCRIN's support? What is the added value (if any) of working with PedCRIN?

Yes, the trial would have been conducted. However, **PedCRIN has provided significant local support from experienced staff for the conduct of the POPART trial within the European region** which has helped things be completed smoothly and **in accordance with local requirements**.

Would you like to work with PedCRIN in future?

Yes!

We have had a **good experience with ECRIN support for our clinical trial, as sponsor and particularly as an academic sponsor**, it has been very useful to have the expertise ECRIN has been able to provide and we would be happy to work with ECRIN again should we have another Europe-wide clinical trial.

We have been particularly **impressed with the work ECRIN staff** have done for the study. They have done an amazing job supporting the POPART trial. We would be most happy to collaborate with them again should the opportunity arise.

