TREOCAPA
a c4c study

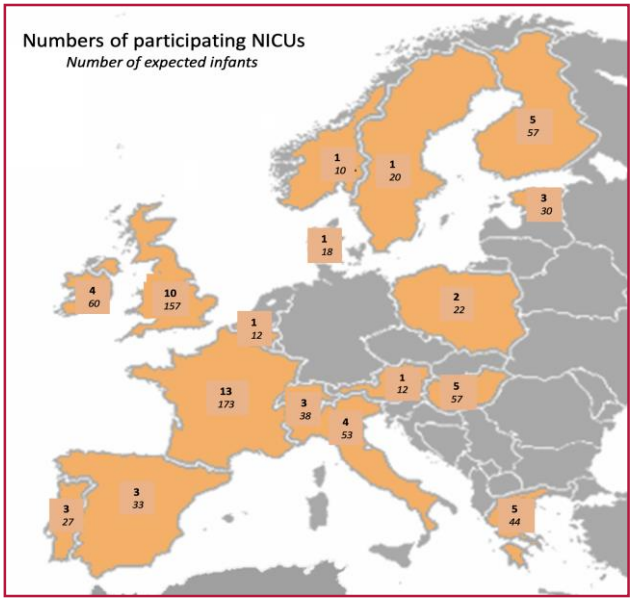
Powered by conect4children (COLLABORATIVE NETWORK FOR EUROPEAN CLINICAL TRIALS FOR CHILDREN) and Inserm

Prophylactic **TRE**atment **O**f the du**C**tus **A**rteriosus in **P**reterm infants by **A**cetaminophen

Dear national hubs,
Dear investigators,

We are delighted to announce that TREOCAPA protocol has been approved by the c4cTrial Commissioning Committee.

With **17 countries** and **65 investigation centers** participating in the TREOCAPA trial, we plan to have our **first patient enrolled by May 2020**! The project has been submitted on December 11th, 2019 to the European VHP (Voluntary Harmonisation Procedure applied to multinational clinical drug trials conducted in EU Member States).



Phase II (4 countries – 11 centers)	Phase III (17 countries - 65 centers)
Objective: to define the minimum effective dose of acetaminophen to close the ductus arteriosus before or at day 7 in preterm infants of 23-26 weeks of gestation **Target number of patients to be enrolled**: 30 patients of 23-26 weeks of gestational age.	**Objective**: to demonstrate an increase in surviving without severe morbidity at 36 weeks of post menstrual age (or at discharge if it occurs before) from 50% (placebo group) to 60% in group receiving a prophylactic treatment by acetaminophen during the first 5 days of life. **Target number of patients to be enrolled:** 398 patients of 27-28 weeks of gestational age and 396 patients of 23-26 weeks of gestational age.

Save the date!

You are invited to the **TREOCAPA Kick Off Meeting** scheduled on March 30, 2020 in **Paris**.

Your TREOCAPA team

TREOCAPA is a study co-developed with parents and their European representatives.

EFCNI european foundation for the care of newborn infants

This study is funded by the c4c project. Find out more here: https://conect4children.org/

efpia imi innovative medicines initiative

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 777389. The Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.