

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

Dear Investigators, dear National Hubs,

After the success of the Treocapa Kick Off meeting on June 16 with more than 150 participants, we are glad to announce that the first Site Initiation Visit is scheduled on **October 5, 2020** at the University Hospital in Nantes, France. Additionnal participating sites in Europe are also planned to open during the months of October and November 2020.

Regulatory approvals updates:

- ✓ Approval by NCAs have been received in 12 countries out of 17,
- ✓ Approvals for both NCAs and ECs have been received in 6 countries out of 17.

After France, the first countries to open their investigation sites will be Denmark, Estonia, Finland, Hungary and Portugal.

Training on monitoring activities:

Four training sessions on monitoring activities will be organized by the sponsor. The distribution of countries on training dates was made based on regulatory and administrative status progress of participating sites.

Clinical Project Manager & Clinical Research Associate in charge of the monitoring activities are requested to participate.



More news!

- ✓ 5 trial short training courses are now available for research teams on c4c Academy website :
 - Phase II Protocol Training*
 - Phase III Protocol Training*
 - Guidelines for cardiac echo realization*
 - Guidelines for cerebral echo realization*
 - eCRF Training*
- ✓ Both eCRF Phase II and III are finalized
- ✓ IMP production starts the week of Sept 14-18



1st session: September 21	Denmark, Sweden, Norway, Hungary
2 nd session: September 28	Belgium, Estonia, Portugal, Finland
3rd session: To be defined	Spain, Switzerland, Italy, Ireland
4th session: To be defined	UK, Greece, Austria, Poland

Your TREOCAPA team

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

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