

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



Dear investigators, dear all,
First, we wish you all the best for this new year. Recruitment has been maintained during this period thanks to all of you! We would be very grateful if you could maintain this level of involvement in the TREOCAPA study!
With 43 sites now open to recruitment in 14 countries, the TREOCAPA phase III study is progressing well with **424 patients** enrolled to date, 12 countries having included at least 1 preterm infant (see flags)

TREOCAPA'S LATEST NEWS

1. Protocol Amendment

The amendment n3 has been submitted in all countries (except in Spain) and is already approved for some countries. The main modification is the extension of the inclusion period : **the inclusion period will end in April 2024**, i.e 14 additional months from now.

2. DSMB and Safety Analysis

Thank you for your help during the retrospective review of AE/SAE, **no new risks or safety concerns were identified** from the analysis performed at the end of last year. No alarming signals were emerging from the close gastro-intestinal complications follow-up neither. The safety profile is consistent with usual observation in the study population. The recommendation of the DSMB meeting held on January, 2023 was to continue the study without changes.

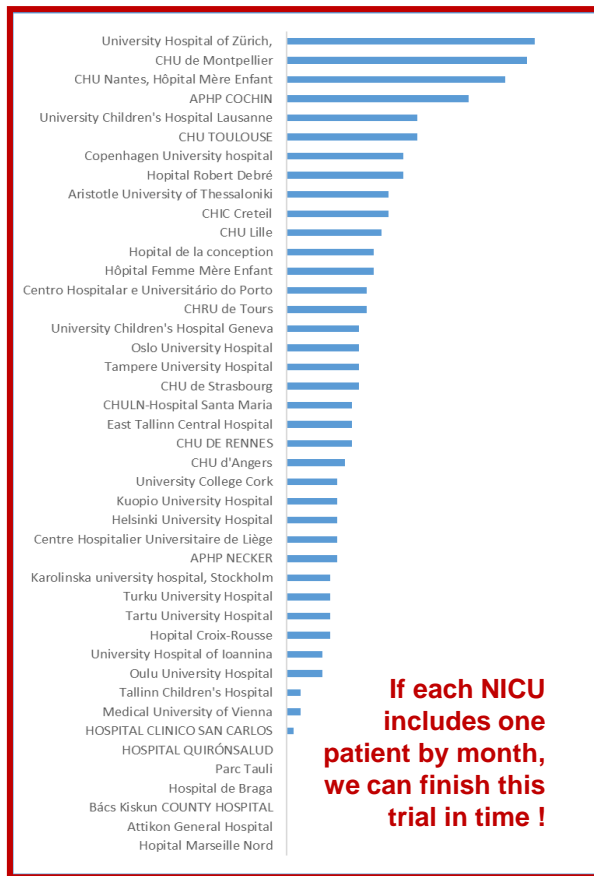
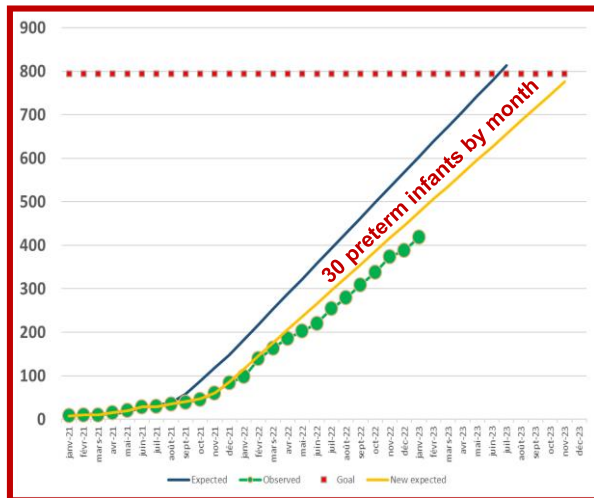
3. IMP

A new production campaign of 300 new kits in total with expiry date on March 2024 is ongoing.

4. Follow-up study

We responded to two French funding calls.

- The first, to collect follow-up data using an online parent questionnaire (PARCA-R plus additional questions) was successful and we will be contacting shortly with more info.
- The second, to have in-person (Bayley) assessments, was limited to French participants but is through to a second stage. We will keep you updated!



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/>