

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

Dear Investigators, dear National Hubs,

The sponsor received a response from the European VHP (Voluntary Harmonisation Procedure applied to multinational clinical drug trials conducted in EU Member States) on March 5, 2020.

During the first round of review, in February 2020, the sponsor had addressed 23 questions raised by the reviewers and the protocol was modified accordingly. In their second response received on March 5, the reference National Competent Authority (NCA) requested the sponsor to submit a new version of the protocol that better describes all changes resulting from the VHP review.

Consequently, the new Schedule is defined as follows:

**March 13, 2020** : Responses due to the reference NCA

**March 23, 2020** : Final approval by the reference NCA

**March 23 – April 13, 2020** : National Regulatory submission to the NCA & EC

**Main changes in protocol following to VHP review are:**

- 1 - sodium intake from dilutions and purge must be limited as much as possible**
- 2 - AST/ALT level must be checked after administration of dose 1 and dose 10 of IMP in both phases**



### **TREOCAPA Kick Off Meeting**

*In the light of the growing concern about COVID-19, we thought it was important to keep you informed about the health situation in France, and its impact on the organisation of the TREOCAPA Kick Off Meeting which will take place on March 30 in Paris.*

*For the moment, congresses with less than 1.000 participants are not cancelled in France. Infected cases are grouping in clusters and Paris is not concerned. Our event is, therefore, currently maintained.*

*We will continue to closely monitor the COVID-19 epidemic in France and we will keep you regularly informed of the evolution of the situation as well as the different alternatives (i.e. teleconferences,) that could be proposed.*

**Your TREOCAPA team**

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

**EFONI**  
european foundation for  
the care of newborn infants

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