

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

Dear Investigators, dear National Hubs,
Here are some news from Treocapa!

As of today, **26 sites in 6 countries** (Belgium, Estonia, Finland, France, Portugal and Switzerland) have received green light from the sponsor to start patient inclusions. These 26 sites will be fully active for patient recruitment after the summer break (Sept. 2021).

Phase II study:

A dose increase was validated by the DSMB members on July 9.
The dose to be administered to infants of 23-26 weeks of gestation currently is : **25 mg/kg loading dose then 10 mg/kg/6hours during 5 days**

Inclusions status:

Phase II : 25 inclusions / Target : 30 patients
Phase III : 28 inclusions / Target : 794 patients

Pharmacovigilance : Non-serious adverse events reporting

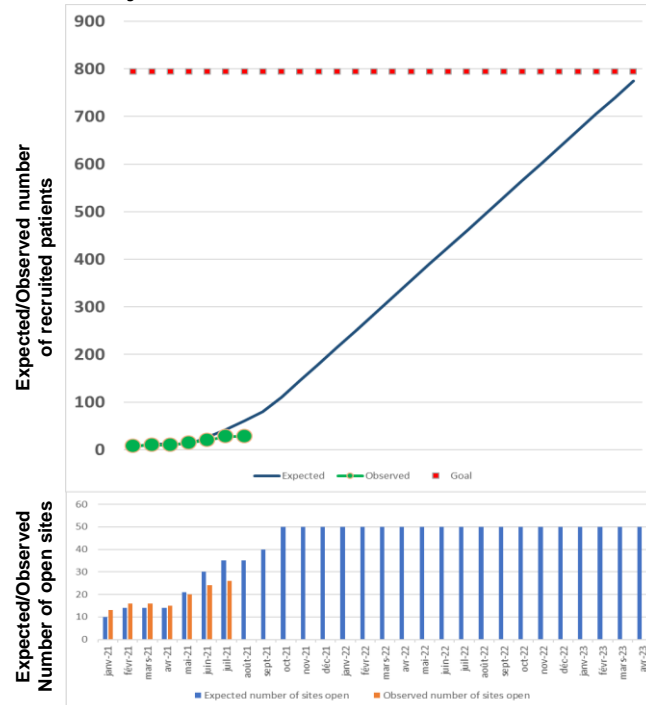
In very preterm and often critically ill infants, a lot of clinical signs and laboratory parameters could be abnormal. Abnormal laboratory parameters assessed as a usual event due to prematurity could be considered as a non-reportable event because these are related to the studied population.

However, we remind investigators that any signs or laboratory parameters considered as abnormal or unusual in terms of nature, incidence, severity or outcome or which cannot be explained or considered as expected by prematurity, should be reported as AE regardless of the causal relationship with the product.

Examples of reportable AEs, but not limited to :

- Event basically and/or temporally **related to the IMP**
- Laboratory value that indicate **liver or renal dysfunction** (elevated ALT, AST, GGT, Creatinine, Urea)
- Elevated conjugated bilirubin**: > 20% of total bilirubin
- Severe hypoglycaemia**: blood glucose < 1.5 mmol/l
- Coagulation disorder** in the context of haemorrhagic syndrome: low platelet count < 50 /nl, abnormal coagulation screen

Projection of inclusions Phase III :



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/>