

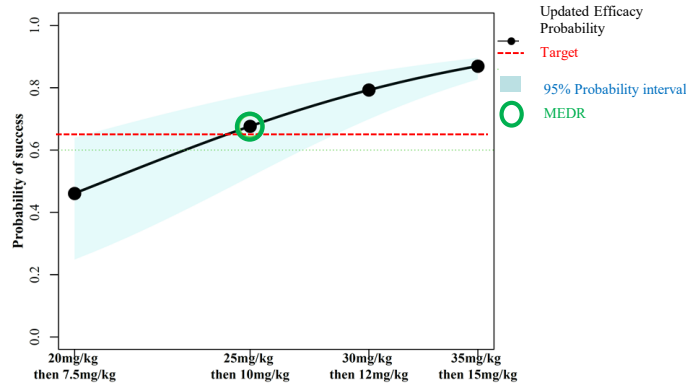
Prophylactic **TRE**atment **O**f the du**C**tus **A**rteriosus in **P**reterm infants by **A**cetaminophen

Dear Investigators, Dear all,

We are delighted to announce that the **DSMB** and **Trial Steering Committee** granted approval to proceed with the **recruitment of 23-26 weeks of GA infants in Phase III**.

Phase II Primary Analysis indicated that according to the continual reassessment model, the dose giving a probability of success closest to the target (60%) is level 2.

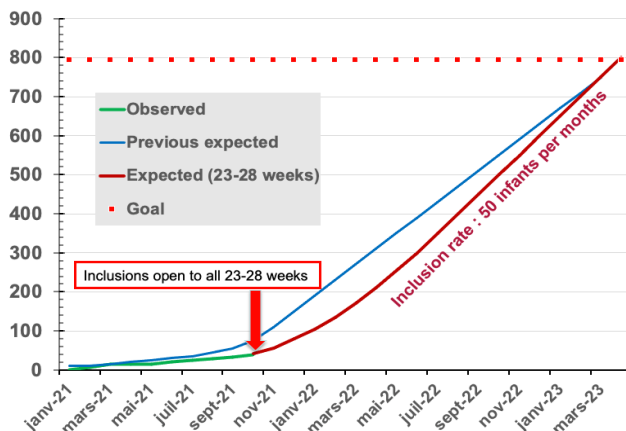
Thus, the loading dose of 25mg/kg followed by maintenance dose of 10mg/kg should be the minimum effective dose regimen (MEDR) for the 23-26 weeks GA.



The two age groups of infants will receive different dosages of paracetamol :

- **27-28W GA : 20 mg/kg loading dose then 7.5 mg/kg/6hours during 5 days**
- **23-26W GA : 25 mg/kg loading dose then 10 mg/kg/6hours during 5 days**

Goal to reach Phase III recruitment target : 1 to 2 inclusions per month in each NICU participating in TREOCAPA



NEXT STEPS:

- Hold a **Kick-Off Meeting for Phase III** with 23-28 weeks inclusions (date to be confirmed in November 2021)
- Open remaining sites as soon as possible
- Recover our recruitment backlog

NEW TRAINING VIDEOS!

Our PPI partner, EFCNI, has developed a training course on **approaching parents for recruitment of their child** into the TREOCAPA study. Six short videos are available for investigational teams:

- 1- What preterm birth means for parents
- 2- Timing and environment
- 3- Language
- 4- Showing empathy
- 5- Leaving hospital
- 6- Personal parent testimony

Check the course out on the c4c Academy Platform: <https://www.academyc4c.com/>

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/>