

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

Dear investigators, dear all,

First, we hope you all had a great summer holidays !

We would like to thank the sites that participated in maintaining a minimum of inclusions during the summer, we obtained 20 inclusions in July and 23 in August.

The pace of inclusion has dropped a bit in the summer, **we are counting on you** please to maintain a minimum of

1 inclusion / month / site to reach our goal of **794 patients**, there are **only 8 months left** !

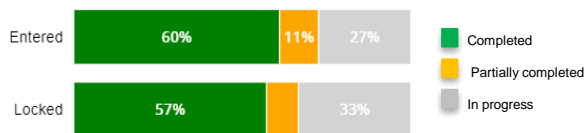


The mid-term Interim Analysis

The results of the mid-term interim analysis of the first 397 patients have been presented to the DSMB members on July 13, 2023, and forwarded to the **Steering committee** members. Good news : their decision was to continue the trial without any changes. Thanks to all for your involvement in filling in the eCRF ! The same challenge must be overcome with the next interim analysis of the 595 patients included recently !

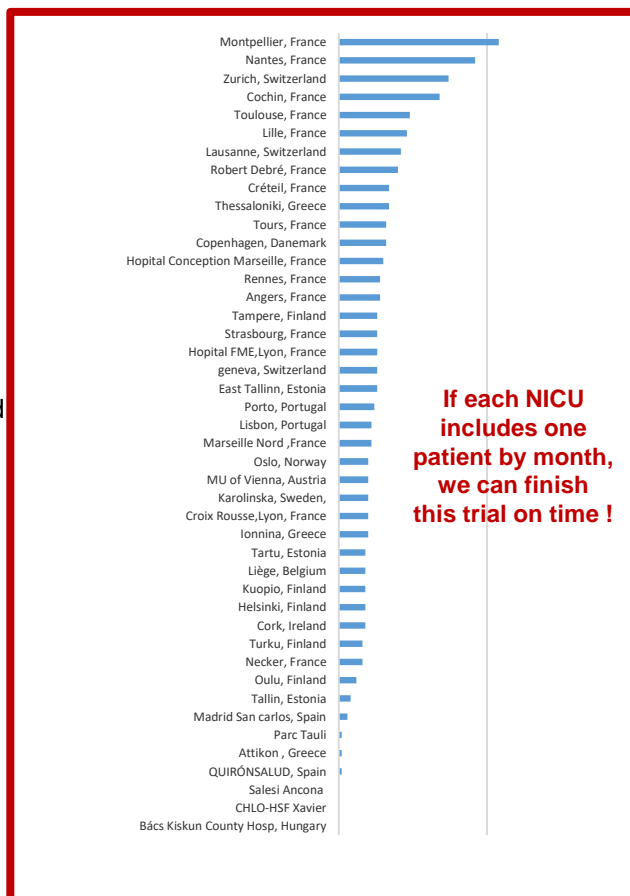
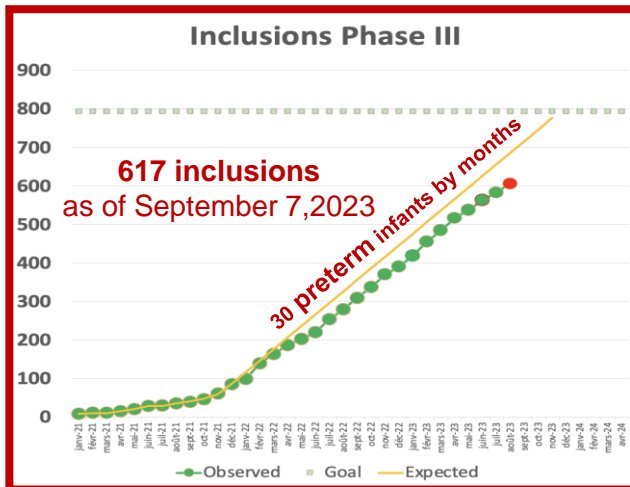
The next Interim Analysis of 595 patients

As for the previous analysis and to conduct it in the required deadlines, we need **all** patient records to be **completed** as much as possible and the pages **locked**, please.



TREOCAPA's Safety Analyses

Gastrointestinal complications are still closely monitored. In this context, the 7th Quarterly Report was sent to the DSMB in August 2023. Analysis and discussion on recent digestive cases have been performed with the DSMB members. Great news: no specific signal due to IMP has been confirmed and the decision was to continue the trial without any changes.



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/>