This project (RIA2019PD-2887) is part of the EDCTP2 programme supported by the European Union

PedMAb: going for dual !

Phase I/II study to determine Safety and Pharmacokinetics of subcutaneous administration of potent and broad anti HIV-1 neutralizing monoclonal antibodies (bNAb), given to HIV-1 exposed neonates and infants.

EDCTP2 grant RIA2019PD – 2887. Funding period: 1 May 2021 – 31 December 2025.

The PedMAb Consortium's aim is to ensure the development of a promising HIV-prevention strategy with broad anti-HIV-1 bNAbs to reduce postnatal transmission of HIV via breast milk, which continues to contribute to residual HIV pediatric infection in low-middle income, high HIV prevalence settings (https://pedmab.w.uib.no/about/ and https://pedmab.samrc.ac.za/).

In 2024 the PedMAb consortium achieved three important targets:

I. Completed the five arms of the PedMAb1 trial with the dose escalation of the long acting version of the two HIV bNAbs CAP256V2.LS and VRC07-523LS administered to neonates.
II. Administered two bNAbs at the same time to HIV at-risk neonates for the first time ever worldwide.
III. Delivered a course on "Introduction to Clinical Trials and Biostatistics".

The PedMAb consortium met for its third annual meeting in Durban, South Africa on June 3-5, 2024. Similar to the previous year, the meeting was held at the South African Medical Research Council (SAMRC) and at the SAMRC Chatsworth Clinical Research Site located at the R.K. Khan Hospital. The meeting brought together the entire PedMAb Consortium, from Milan, Italy, Montpellier, France, Bergen, Norway and South Africa. Partners reviewed trial progress, including the 2024 achievements, and further developed technical approaches.

The PedMAb1 trial has successfully completed the first five arms with dose escalation from 5 to 20 mg/kg of CAP256V2LS, and 20 and 30 mg/kg of VRC07-523LS administered subcutaneously to HIV exposed and negative infants within 96 hours of birth. Eight neonates for each arm were fully enrolled and the last participants completed the 6 months follow-up visits in May 2024. Both bNAbs did not show safety concerns. This, together with the analysis of the pharmacokinetics of the study products, has supported the revision of the protocol and the administation of a fixed dose regimen of the two bNAbs close to birth and a second dose after 3 months. On June 4th 2024 for the first time ever the PedMAb clinical trial team administered two bNAbs at the same time to HIV at-risk neonates, which assures a large coverage of different circulating HIV-clades.

Aware that biostatistics is an essential pillar for planning, conduction and analysis of clinical trials the PedMAb consortium organised a 1-week course on Introduction to clinical trials and biostatistics (11-15 March 2024) in Durban, South Africa for project members and staff members from SAMRC. Around 30 participants enjoyed and appreciated the course that was composed of aspects of running and analysing clinical trials alternating with Stata hands-on exercises.

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The PedMAb Team at the South African MRC clinical research site at Chatsworth, Durban, South Africa.

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The PedMAb 1 participants at the 6 months exit visit.