

DATURA

Determination of Adequate **T**uberculosis Regimen in Adults and adolescents hospitalised with HIV-associated severe immune suppression (NCT04738812)



The Datura project is funded by the EDCTP2 programme (Grant RIA2018-CO-2515) supported by the European Union and Inserm-ANRS. Inserm-ANRS is the sponsor of the research (ANRS 12424 Datura) and the funder of the Asian component.

What is Datura?

Datura is an international randomised clinical trial assessing whether an intensified tuberculosis treatment increases survival in hospitalised severely immunosuppressed HIV-infected adults and adolescents in sub-Saharan Africa and South-East Asia.

Participants are recruited in Cambodia, Cameroon, Guinea, Mozambique, Uganda and Zambia.

Datura is registered in ClinicalTrials.gov: [NCT04738812](https://clinicaltrials.gov/ct2/show/study/NCT04738812)

Joint meeting in July 2024 in Montpellier with Project Steering Committee / Independent Data & Safety Monitoring Board

The first Datura **joint** Project Steering Committee (PSC) and Independent Data & Safety Monitoring Board (DSMB) meeting has been hosted by the PCCEI (international coordinating trial unit) at Montpellier, France from 7 to 9 July 2024.



At a time that **695 participants were being randomized** in the clinical trial, around 40 people, members of the 2 committees together with representatives of all participating countries (Cambodia, Cameroon, France, Guinea, Mozambique, Norway, Uganda and Zambia) and leaders of the six work packages were able to attend this meeting.

Led by Dr. Paula Munderi, Chair of the PSC, Prof. Peter Godfrey-Faussett, Chair of the DSMB, and the two project coordinators, Dr. Didier Laureillard and Prof. Francois-Xavier Blanc, the meeting aimed to assess the trial progress two years after the start of inclusions, discuss the current challenges in recruitment and present preliminary data about pharmacokinetics.

As conclusion, the DSMB recommended that as **many participants as possible be recruited until December 2024** to maximise the chances of achieving a significant difference in all-cause mortality between the two arms.

Datura Newsletter 2025-1

July 2025

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Funding of nested study: BADASSE

A nested study, named BACteriological DATura Sub-StudiEs (BADASSE), aiming to determine bacterial biomarkers predicting treatment outcome is led by prof. Nicolas Veziris. It has been granted funding by the ANRS MIE, and it includes a PhD scholarship for Dr Moussa Condé from Guinea.

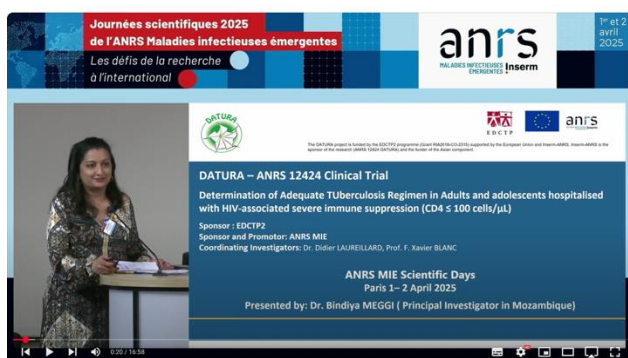
Finalisation of DATURA inclusions in December 2024

Participant enrollment in the DATURA trial started in April 2022 and was completed in December 2024 with 907 randomised participants. Participants will continue to be followed until their final trial visit, which will occur 48 weeks after the initiation of TB treatment. The last visit of the last participant is expected on November 2025.

ANRS MIE scientific days, April 1-2, 2025

Dr Bindiya MEGGI, Principal Investigator in Mozambique, has presented the baseline characteristics of the 907 enrolled participants during the scientific days organized by the ANRS MIE (sponsor of the trial) on April 2.

<https://www.youtube.com/watch?v=VKCqbZy9GfA&list=PLcLbqg1xI8etXFIprpYfPLot4ZRC5268N&index=37>



Next steps

A new Project Steering Committee meeting will take place ONLINE October 3rd 2025. Each site will be closed after the last participant's final visit and the final data monitoring. Results of the trial are expected by mid-2026 with dissemination meeting organised in each participating country.

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