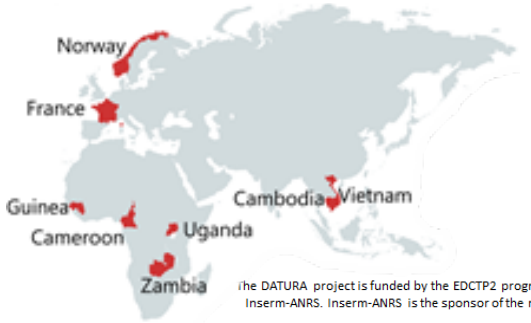
DATURA

Determination of **A**dequate **TU**berculosis **R**egimen in **A**dults and **a**dolescents hospitalised with HIV-associated severe immune suppression (NCT04738812)



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What is DATURA?

DATURA is a clinical trial assessing whether an intensified initial TB treatment phase increases survival in hospitalised, HIV-infected adults and adolescents in sub-Saharan Africa and South-East Asia.
DATURA is registered in ClinicalTrials.gov : NCT04738812

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- About Datura
- Clinical Sites
- Participants
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DATURA & COVID-19

COVID-19 has made most DATURA missions more difficult. Many DATURA researchers are clinicians and were thus drafted into service to help with national efforts to fight the pandemic in their respective countries. In addition, many medical facilities were re-prioritised as COVID-19 treatment centres.

This has resulted in delays in many aspects of the start-up phase of the project. The project coordinators are monitoring the situation in each participating country very carefully. Not being able to travel is also a serious handicap, but there have been many meetings using digital platforms, despite internet irregularities in some locations.

Cameroon (Jamot Hospital)

Cambodia (National Clinic for AIDS, Dermatology and STDs)

Guinea (Ignace Deen National Hospital)

Datura Clinical Sites

Zambia (University Teaching Hospital)

Vietnam (Pham Ngoc Thach Hospital)

Uganda (Mbarara Regional Referral Hospital)

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DATURA Kick-off Meeting: 14-15 Sept. 2020

The DATURA project kick-off meeting (KOM) took place both face-to-face and by teleconference. More than 30 participants from 4 continents were able to attend, despite many being clinicians specialising in infectious and pulmonary diseases, who are in great demand managing the COVID-19 cases in their home institutions.

Participants included project partners from 4 different African regions (Cameroon, Guinea, Uganda and Zambia), 2 European countries (France and Norway) and 2 Asian countries (Cambodia and Vietnam) as well as 5 external experts (from North America, Europe and Africa) and the community representative (from Africa) of the Project Steering Committee (PSC). In addition, there were representatives from the Inserm-ANRS-sponsor, and the EDCTP officer.

Goal

Led by Dr. Paula Munderi, Chair of the PSC, and the two project coordinators, Dr. D. Laureillard and Pr. FX Blanc, the KOM goal was to finalise and validate the project protocol and other key documents.

Input from external experts

There were good exchanges and discussions between the participants. The extensive experience of the external members, particularly in the field of high dose rifampicin (Pr. M. Boeree, Netherlands), anti-TB and ARV drug-drug interactions (Pr. K Dooley, USA), ethics (Pr. J.A Singh, South-Africa), HIV research (Dr. P. Munderi, Uganda) as well as of the community representative (J. Gapiya-Niyonzima, Burundi) and experts from the DATURA team in TB treatment (Pr. N. Véziris, France), immunology (Pr. L. Weiss, France) and pharmacology (Dr. G. Peytavin, France), provided crucial input for the revising of both the protocol and the information forms for the trial participants. The presence of Pr. F. Bonnet, the fifth external expert of the PSC and the coordinator of the INTENSE-TBM project of the EDCTP2 programme, opened the way for potential future collaboration between the two projects.

Next steps

As a follow-up to the KOM, the validated protocol and trial participant information documents were submitted to the Data and Safety Monitoring Board 28.10.2020. The Board members include Prof. Peter Godfrey-Fausset (UNAIDS), Prof. Anthony D. Harries (The Union), Dr. Riitta Dlodlo (The Union), Dr. Adrienne Shapiro (University of Washington, USA), and Delphine Gabillard (University of Bordeaux, France). The next step is that these documents will undergo ethical approval processes in each participating country.

Official start: 1 May 2020

The **E**uropean and **D**eveloping Countries **C**linical **T**rials **P**artnership (EDCTP) signed the grant on **14 April 2020.** The agreement entered into force on this day.
The project will last 54 months. Patient inclusions will begin in the latter half of 2021.

In 2020 DATURA obtained supplementary grants from the French National Agency for Research on AIDS (ANRS) , an autonomous Inserm agency (Inserm is the French National Institute for Health and Medical Research). This grant made it possible to expand the DATURA trial to include two countries from South-East Asia.

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