IMPAACT4TB PROJECT UPDATES

December 2021

IMPAACT4TB remains Unitaid’s key investment in TB prevention, creating important synergies with other Unitaid-funded projects. This flagship project continues to sustain its strategic value and generate momentum towards scale-up of short-course preventative therapy with strong collaboration towards scale-up with PEPFAR and Global Fund.

GLOBAL ENGAGEMENT AND SUPPLY CHAIN 3HP FDC SUPPLIER:

- Finalizing an amendment to the Commercialization and Ceiling Price Agreement and executing a Volume Guarantee Agreement (VGA) with MedAccess.
- Establishing a potential price decrease in 2022 depending on volume uptake through facilitation of VGA.
- Start-up of a nitrosamine impurity coordination Task Team to ensure a unified communication hub for all stakeholders.
- Working with 2nd generic supplier to continue development of RPT formulations for 3HP, 1HP, Paediatrics and extend supply security.

CONTINUED ENROLLMENT ON 3HP

- Resumption of 3HP delivery after a pause of about 6 months following the impurity issue (longest period in Malawi).
- All countries but Tanzania have 3HP as a recommended preventive treatment regimen for PLHIV and children in approved national guidelines.
- Training and Skills Development completed in most countries with the product. The slow roll-out of training in South Africa (Global Fund-funded). Tanzania delayed but still anticipated buy-in from the Tanzania government impacted the planned training and TA provision. The Brazilian government has independently purchased and received patient courses of rifapentine. The MOH has loaned 500 units of rifapentine to begin I4TB while the MOU awaits approval highlighting the government’s commitment to the national scale-up of 3HP.

EVIDENCE GENERATION

- **DOLPHIN TOO- South Africa** - drug is on-site, and enrollment began (in August) study teams can recruit, transport, screen, and enrol participants safely.
- **CAT** - Study implementation has begun in all three countries as of 6 August 2021. **Malawi** started April 2021, **Zimbabwe** started June 2021, **Mozambique** August 2021 start.
- **The cost-effectiveness and modelling** team has published three papers: (1) cost-effectiveness of 3HP vs 1HP for TB preventive therapy in settings such as the I4TB countries (Ferguson et al, JIAS 2020; e25623); (2) cost-effectiveness of a 12-country intervention to scale up TPT (Shin et al, JIAS 2020; e25629); and (3) cost-effectiveness of scaling up TPT for child contacts (Jo et al, eClinical Medicine 2021; 31:1007007).
- **CHIP- ETHIOPIA**: Data collection is currently ongoing for phase 1 (pre-trial) interviews. **SOUTH AFRICA**: Final approval for version 7.0 (with the changed South African site) were obtained in July 2021.