

Tafenoquine Roll-oUt Study (TRuST)

FACTSHEET

About TRuST

The Tafenoquine Roll-oUt Study (TRuST) was the first real-world, observational study to assess the feasibility of providing appropriate relapse-prevention treatment with tafenoquine (TQ) or primaquine based on G6PD test results. The study, co-sponsored by the Brazilian Ministry of Health (MoH) and MMV, was conducted in the municipalities of Manaus, Amazonas (AM), and Porto Velho, Rondônia (RO) and was launched in September 2021. TRuST was led by two malaria researchers and their associated institutes in Brazil: Dr. Marcus Lacerda from Dr. Heitor Vieira Dourado Tropical Medicine Foundation (FMT-HVD) and Dr. Dhelio Pereira, Tropical Medicine Research Centre of Rondônia (CEPEM).

The study assessed the feasibility of introducing a new *P. vivax* treatment protocol with point-of-care G6PD testing and single-dose tafenoquine. TRuST was implemented in two phases by the MoH and the State and Municipal health secretariats in Manaus and Porto Velho. The first phase started in September 2021 and was conducted in nine higher- and medium-level health facilities. In February 2022, the study was expanded to 40 lower-level facilities in the same municipalities following the recommendation by the Independent Study Oversight Committee based on the review of the first interim analysis. The last patient was recruited in study on 31st August 2022. A qualitative research study known as 'QualiTRuST' was conducted by researchers at FMT-HVD alongside TRuST to understand the perspectives of health workers and patients on the introduction and use of the new tools.

In December 2022, the results of the first and second interim analysis of TRuST were included in a comprehensive dossier, along with the results from QualiTRuST, cost-effectiveness and budget impact analysis and other tafenoquine and G6PD-related scientific evidence, that was submitted to the National Commission for the Incorporation of Technologies (CONITEC) in the national health system (SUS) requesting the incorporation of single-dose TQ and the STANDARD™ G6PD test into the SUS.

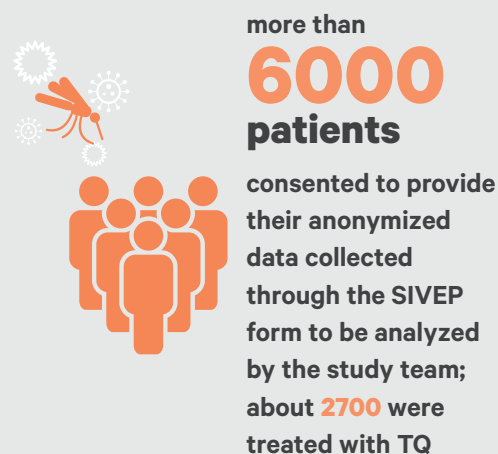
Key results: new tools can be appropriately incorporated within the health services

The primary objective of TRuST was to investigate whether patients with *P. vivax* aged ≥16 years were treated with tafenoquine according to the appropriate level of G6PD enzyme activity.

TRuST Key Figures



9 higher- and medium-level
40 lower-level



TRuST and Quali-TRuST Key conclusions

- ✓ The level of compliance with the new treatment protocol of providing tafenoquine based on appropriate levels of G6PD activity was above 99% and was consistent across higher/medium- and lower-level healthcare facilities.
- ✓ The healthcare providers were able to routinely test patients for G6PD activity before providing radical cure with tafenoquine or primaquine.
- ✓ Routine testing for G6PD activity before providing radical cure was feasible at different levels of the Brazilian health system.
- ✓ Healthcare providers and patients reported the use of a single dose for radical cure as a positive development, contributing to improving malaria treatment.
- ✓ Patients with previous infections of *P. vivax* highlighted the benefit of the reduced pill count and shorter treatment.
- ✓ As with any new intervention, there was a steep learning curve for healthcare providers to incorporate G6PD testing in health units' routine. The initial challenges with the G6PD test were overcome with training and practice.
- ✓ Brazil's health surveillance system is robust and enables the linkage of surveillance, hospitalization, and mortality data to monitor adverse events related to antimalarials.
- ✓ These results suggest that the training provided for health workers on the use of tafenoquine was appropriate. Training was delivered by the State and Municipal Health Secretariats and the study team, focusing on how to use the G6PD test and provide the appropriate treatment based on the MoH guidelines.

LATEST DEVELOPMENTS



TRuST results were key in supporting Brazilian MoH's decision to become the first malaria-endemic country in the world to adopt tafenoquine and quantitative G6PD testing as part of Brazil's protocol to treat vivax malaria patients. The study's results as well as the operational lessons learned from the experience of rolling out the new treatment during the study implementation are helping to guide the Malaria National Program strategy to scale up the use of tafenoquine and quantitative G6PD testing in the country. Moreover, this evidence generated in Brazil is being shared with relevant malaria stakeholders globally and regionally - including the World Health Organization (WHO) and the Pan American Health Organization (PAHO) - and is contributing to the global discussion on innovation and malaria elimination.



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