The TRuST study will be implemented in two phases and will take approximately 12 months to complete.

1st phase
approximately 3 months duration

Higher-level health facilities
referral hospitals, hospita and emergency care units, polyclinics

10

in Manaus and Porto Velho

Training of health care providers (HCP) and provision of G6PD tests and TQ to P. vivax malaria patients will be initially limited to 10 higher-level health facilities (referral hospitals, hospitals, emergency care units, polyclinics) – 6 in Manaus and 4 in Porto Velho.

If the interim results are deemed unsatisfactory, the ISOC may recommend not to extend the study until improvements are made to the educational programme and/or additional HCP support is implemented.

2nd phase
approximately 9 months duration

An additional interim analysis will be conducted on data from 600 P. vivax patients ≥16 years old at lower-level facilities once data from 600 P. vivax patients ≥16 years old have been entered in the study database. An additional interim analysis will be conducted to decide whether the study can be extended to lower-level health facilities. The recommendation will be made by an Independent Study Oversight Committee (ISOC) and the decision by the study sponsors (the Ministry of Health and MMV).

An additional interim analysis will be conducted on data from 600 P. vivax patients ≥16 years old at lower-level facilities once data from 600 P. vivax patients ≥16 years old have been entered in the study database.

Final results will be reviewed and endorsed by the ISOC.

After staff have been trained, G6PD semiquantitative tests and TQ will be supplied to these health care facilities by the municipal health authorities.

Once data from 600 P. vivax patients ≥16 years old have been entered in the study database, an interim analysis will be conducted to decide whether the study can be extended to lower-level health facilities. The recommendation will be made by an Independent Study Oversight Committee (ISOC) and the decision by the study sponsors (the Ministry of Health and MMV).

If recommended by the ISOC and approved by the sponsors, the study will be extended to lower-level health facilities (basic health units, basic family health units and primary care units) and additional higher-level health facilities. After staff have been trained, G6PD semiquantitative tests and TQ will be supplied to additional health facilities by the municipal health authorities.

An additional interim analysis will be conducted on data from 600 P. vivax patients ≥16 years old at lower-level facilities if entered in the study database.