



# National Institute of Malaria Parasitology and Entomology (NIMPE)

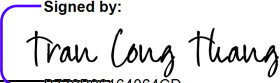
## Statistical Analysis Plan (SAP)

### SAP Revision History

STUDY FULL TITLE	A mixed-method operational research study on the use of tafenoquine and G6PD testing for radical cure of Plasmodium vivax malaria in passive and active case detection in Vietnam
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TRIAL PRINCIPAL INVESTIGATOR	Dr. Phuc Bui Quang National Institute of Malaria Parasitology and Entomology (NIMPE), Vietnam
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Effective date	09 December 2025


## 1. Signatures

**I give my approval for the attached SAP entitled “Operational feasibility of appropriate radical cure of Plasmodium vivax with tafenoquine or primaquine after semi quantitative G6PD testing in Ethiopia: a mixed methods study” Dated 09/12/2025**  
**Statistician (Author)**

Name: Thang Tran  
Signature:   
Date: December 16, 2025

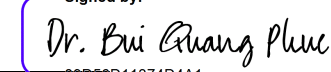
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## 2. Abbreviations and Definitions

Abbreviation	Definition
AHA	Acute hemolytic anemia
CI	Confidence interval
CQ	Chloroquine
CRF	Case report form
CRO	Contract research organization
EC	Ethics committee
eCRF	Electronic case report form
FDA	Food and Drug Administration
G6PD	Glucose-6-phosphate dehydrogenase
GCP	Good clinical practice
HCP	Health care provider
ICF	Informed consent form
ICH	International conference on harmonization
IRB	Institutional review board
P. vivax	Plasmodium vivax
PI	Principal investigator
PQ	Primaquine
SAP	Statistical analysis plan
TQ	Tafenoquine
WHO	World Health Organization

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### **3. Introduction**

#### **3.1. Preface**

This statistical analysis plan (SAP) is a document that specifies the data analysis that will be performed on VivAction project dataset. It serves as a comprehensive guide for the analysis, presenting a clear and organized approach to data analysis that ensures the reliability and validity of the results.

SAPs typically outline the steps needed to prepare TQ feasibility study data for analysis, the methods to use, and sample size used in this project, data sources, and any assumptions or limitations of the analysis. The appropriate statistical techniques for analysing the data and specify the analysis details, such as sample size and data sources. It should also include the strategy for presenting and interpreting the results.

#### **3.2. Scope of the analyses**

The main purpose of this study is to evaluate the operational feasibility of providing TQ and PQ after G6PD testing at different levels of the health services, in order to inform potential policy change, malaria strategy, and introduction planning. These data will inform what resources and implementation strategies are needed to ensure that patients benefit from optimal vivax malaria case management and best clinical practices.

This statistical analysis plan (SAP) will give more detailed descriptions of the endpoints in the study and the corresponding analyses. The SAP will explain how to analyse the data set entitled “A mixed-method operational research study on the use of tafenoquine and G6PD testing for radical cure of Plasmodium vivax malaria in passive and active case detection in Vietnam.”

### **4. Study goals and objectives**

#### **4.1. Study Goal**

The goal of this study is to assess whether the use of tafenoquine after semi-quantitative G6PD testing for radical cure of Plasmodium vivax malaria is operationally feasible based on the revised algorithm in Vietnam, a country approaching elimination.

## 4.2. Study Objectives and Endpoints

<p><b>Study Objectives and Endpoints</b></p>	<p><b><u>Primary objective:</u></b></p> <p>1. Assess adherence to a revised case management including both TQ and PQ for <i>P. vivax</i> malaria</p>	<p><b><u>Primary endpoint:</u></b></p> <p>1.1 Proportion of <i>P. vivax</i> infected individuals that are correctly treated with TQ based on the revised algorithm as an aggregate and within each of three case finding strategies.</p> <p>1.2 Proportion of <i>P. vivax</i> and mixed <i>P. vivax</i> infected individuals that are correctly treated with PQ based on the revised algorithm as an aggregate and within each of three case finding strategies.</p>
	<p><b><u>Secondary objectives:</u></b></p> <p>2. Determine the capacity of the health system to safely implement RC after G6PD testing in different case finding strategies</p> <p>3. Assess the quality and effectiveness of training and supervision strategies through competency testing, and training and supervision evaluations</p> <p>4. Explore barriers and facilitators to adding TQ to the treatment algorithm within different case finding strategies</p> <p>5. Determine the costs associated with introducing a single dose RC.</p>	<p><b><u>Secondary endpoints:</u></b></p> <p>2.1 Proportion of non-eligible patients that receive RC</p> <p>2.2 Proportion of patients experiencing acute hemolytic anemia (AHA) during the patient follow-up period</p> <p>3 Health care provider knowledge and skills regarding G6PD testing and RC over time as determined by a competency assessment</p> <p>4 Patients, health care provider and supervisors’ perceptions of and experience with the new RC algorithm, specifically TQ, as reported in interviews and focus group discussions</p> <p>5.1 Total monetary cost of including G6PD testing and single dose cure compared across case finding strategies</p> <p>5.2 Per patient monetary cost of including G6PD testing and single dose cure compared across case finding strategies.</p>

	<p>6. Monitor the frequency of recurrences in study participants</p> <p>7. Monitor Serious Adverse Events (SAE) in study <i>P.vivax</i> patients receiving RC</p> <p><b><u>Exploratory objectives:</u></b></p> <p>1. Monitor moderate and severe adverse events in study <i>P.vivax</i> patients receiving RC</p>	<p>6.1 Number of recurrences of <i>P.vivax</i> identified by study participants until Day 29, in total and stratified by treatment type.</p> <p>7.1. Number of <i>P. vivax</i> patients reporting serious adverse events after TQ and PQ administration until Day 29.</p> <p>7.2. Frequency and severity of each serious adverse event reported after TQ and PQ administration until Day 29.</p> <p><b><u>Exploratory endpoints:</u></b></p> <p>1.1 Number of <i>P. vivax</i> patients reporting moderate and severe adverse events after TQ and PQ administration until Day 29.</p> <p>1.2. Frequency and severity of each moderate and severe adverse event reported after TQ and PQ administration until Day 29.</p>
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## 5. Study design

This study was a longitudinal, uncontrolled, low-interventional study, that used a mix of methods, including the quantitative assessments of case management data, qualitative assessments (individual interviews, focus group discussions), and a costing component that compares costs across case-finding strategies to evaluate the operational feasibility of introducing new tools in the management of vivax patients. The intervention included a revised case management algorithm that incorporated G6PD testing with the SD Biosensor G6PD Test, followed by liver- and blood-stage treatment as indicated and follow-up at 2,3,4, 8, 15 and 29 days. The intervention package also included training of health care providers responsible for routine malaria case management, as well as stakeholder engagement and involvement.

Operational feasibility of the implementation package (detailed below) will be measured across multiple dimensions: HCP capacity and adherence to revised case management algorithms, patient follow-up and safety, modified training and supervision strategies, patient and provider perceptions, and costs. These dimensions will be investigated through a mixed-method approach that will include a quantitative component that assesses adherence to case management guidelines at the patient and provider levels, a qualitative component, a process evaluation component, and a cost analysis component. The data and information generated through these different components will collectively help assess the operational feasibility of providing RC after G6PD testing.

This study aims to introduce a revised case management algorithm and other adaptations to routine malaria service delivery required for the successful implementation of new tools. This intervention will include the following components:

- A G6PD test used to screen for G6PD deficiency and inform radical cure treatment options
- TQ, a single dose radical cure treatment option

This intervention will be implemented at the health facility level, serving as a demonstration of the revised case management algorithm in a subset of health facilities. This entails that all vivax patients visiting the study facilities will be treated according to the revised treatment algorithm.

## **6. Data management and analysis**

### **6.1. Data management**

The different objectives and methods outlined in previous sections entail that study data will be collected through different standard forms and reports, outlined in the data management plan. Dedicated electronic databases will be designed to record all the data to be collected as per the quantitative and process evaluation components of the study. This database conforms to 21 CFR Part 11 requirements. Only authorized, trained personnel will have access to this database. This includes data entry personnel, study sponsor staff (PATH), as well as staff from sponsor delegates. Automated data checks will be built in the electronic database so that inconsistencies in the data and out-of-range values are flagged upon entry. In case of abnormal values, discrepancies or inconsistencies, the data entry personnel will query the study HF for clarification or correction. Any change or correction to the original forms will be documented appropriately. Specific processes for data quality control and data management will be described in the Data Management Plan. After completion of data cleaning and database lock, the database will be shared with the key stakeholder including the National Malaria Control Program and other national implementation partners in accordance with the data sharing agreements in the respective agreements and contracts. The study data and documents will be kept under restricted and secured access by the local implementing partners up until 2 years after study end, or longer if required by local regulations. After this retention period, study data and documents will be destroyed.

### **6.2. Analysis sets**

Enrolled population - All eligible *P.vivax* patients including mixed infection with *P.vivax* who provided consent for study participation regardless of receiving RC or not.

Full analysis population for safety analysis: All subjects in the enrolled population who received RC. This population is considered the primary analysis population for all safety objectives.

Qualitative analysis: A deductive approach using content analysis was used to identify emerging themes from interview. Coding frameworks were developed a priori using the overarching logic model and modified and added to as new themes on the use, perceptions and experiences of the treatment algorithm emerge.

### **6.3. Adherence component**

The quantitative endpoints will be informed by data collected through the following study forms: a CRF completed for each individual patient and AHA report form to be completed for every suspected or confirmed AHA; data will either be directly collected in study-specific forms or transcribed from existing forms currently in use in the study facilities. AE/SAE to be completed for SAE and moderate/severe AEs; data will either be directly collected in study-specific forms or transcribed from existing forms currently in use in the study facilities. HCPs enrolled in the study will be responsible for data collection. Prior to study start, all HCPs who have agreed to participate will be trained on how to fill in the study-specific forms. Data collection in the AHA, AE/SAE report forms will be under the responsibility of the PI and his/or delegate. Paper/electronic CRF and AHA, AE/SAE forms will be used, and those will be collected at regular intervals by dedicated study staff. The data contained within these paper forms will be entered into a dedicated study database by trained data entry personnel of NIMPE. Participants' identifiable information will not be collected on either of these forms. The quantitative endpoints will be informed by data collected through the following study forms: a CRF completed for each individual patient and an AHA report form to be completed for every suspected or confirmed AHA.

### **6.4. Qualitative study**

Study data will be collected through in-depth interviews (IDIs), and/or focus group discussions (FGDs). An adapted implementation framework will be used to guide the development of questionnaires and data analysis. FGDs if any will be used to review some of the processes and discuss how to improve them. IDIs will be used to investigate a topic in depth with key informants. In-depth interviews and FGDs will be recorded. In informal conversations, or in occasions where participants do not want to be recorded, written notes will be used to generate a summary. The recordings will be stored under restricted access according to local policies, for a minimum period of 2 years after study completion. After that period, they will be destroyed.

### **6.5. Costing component**

Standardized cost data-collection instruments would be developed with clear definitions and instructions regarding of how the costs should be calculated, what should / should not be included, as well as preferred data sources. Objective data sources, such as invoices, training logs and payment, will be used as far as possible. Sources will be carefully recorded so that

the costs can be validated. This will ensure consistency in data collected across multiple sites. All costs will be calculated in local currency to minimize the impact of exchange rate fluctuations. The cost per patient will be evaluated by considering the cost of the commodities used for that patient (including any additional tests needed for re-testing and quality assurance) as well as health system costs such as supervision. The training costs will be a one-off cost. These monetary costs will be considered separately, over the course of the study period

## **7. Covariate definitions**

### **7.1. Demographics and Baseline Characteristics**

Baseline characteristics will be described for the HCP and will include but is not limited to age, biological sex, education level, professional category, years of experience managing malaria patients, facility level and role in case management.

Baseline characteristics will be described for patients and will include but is not limited to age (by category), biological sex, pregnancy status, breastfeeding status,. The history of past malaria infection within the last 6 months will be described and will include but is not limited to: number of days since last infection, diagnostic tests performed (malaria microscopy and/or rapid diagnostic test (RDT)), microbial type, and treatment received.

### **7.2. Current Malarial Illness**

Present malaria condition will be described for the patient population and will include but is not limited to: presence of malaria symptoms, diagnosis of malaria by either microscopy or rapid diagnostic test (RDT), whether G6PD test was performed and reasons if not performed, G6PD categorical result, haemoglobin (Hb) test result, type and dosage of blood stage treatment, patient counselling regarding AHA and follow-up visit, type and dosage of liver stage treatment, type and dosage of any other drugs used.

### **7.3. Follow-up Visit**

The following measures will be described for the follow-up/end of treatment visit: if follow up visit was done, the type of visit, timing of the visit, including any variance from when the patient was visited or attended follow-up outside of the per protocol window, if patient

completed treatment, reason for treatment discontinuation, and whether the patient was lost to follow-up.

#### 7.4. Adverse Events

Incidence of suspected and/or confirmed Acute Haemolytic Anaemia (AHA), SAE and moderate/severe AEs will be described. In cases of suspected or confirmed AHA, the initial and repeat G6PD results, the Hb difference between baseline and repeated results and clinical presentation will be described. Actions taken, relationship to TQ and PQ and outcome will be described, symptoms and signs of AHA including dark urine, fatigue, dizziness, shortness of breath, back pain, yellowing of the skin, pallor, tachycardia, fever, nausea/vomiting, other adverse events, and any actions taken for the adverse events. The number of patients experiencing at least one Acute Haemolytic Anaemia (AHA) event will be described.

Other Serious Adverse Events (SAE) unrelated to AHA will also be captured. The number of each of the adverse events collected in the eCRF will be described

#### 7.5. Laboratory Values

The following laboratory values will be described at time points prior to treatment, at the time of the event, and after the event, if collected: Hemoglobin (g/dL) (Hb), Hematocrit (%), BUN, Creatinine (mg/dL), Total Bilirubin (mg/dL), Conjugated Bilirubin (mg/dL), Alanine aminotransferase (ALT) (IU/L), and Aspartate aminotransferase (AST) (IU/L).

## 8. Analyses

### 8.1. Descriptive analysis

Quantitative (continuous) variables will be described by the number of observations, mean, standard deviation (SD), median, extreme values (minimum and maximum). Quantitative (categorical) variables will be described by the absolute and relative (%) frequency of each response categories. The percentages will be calculated based on the respective analysis set or the number of non-missing observations (i.e., the number of patients assessed) in the respective analysis set where applicable. For categorical variables with at least one missing observation, a category of 'missing' will be added to document the number of missing observations. The percentages of missing observations will not be applicable for the categorical variables, summarized by relative (%) frequency, based on the number of patients

assessed. If there is no missing observation, a category of 'missing' may not be added. Means and medians will be rounded to one decimal more than that with which the original data are recorded. The standard deviation will be rounded to two decimals more than the original data. Minimum and maximum will be reported with the same number of decimals with which the original data are recorded. Percentages will be rounded to one decimal place. Confidence intervals for means and percentages will be calculated when appropriate and will be 2-sided at the 95% level unless otherwise specified.

## 8.2. Treatments

Radical cure and intended treatment duration will be presented using descriptive summary statistics. The study population will be segmented by treatment received.

## 8.3. Primary analyses

The number and percentage of *P. vivax* patients treated in accordance with the appropriate level of G6PD enzyme activity, age and contra-indication will be summarized using descriptive statistics for the analysis population and in the radical cure subgroups of interest.

In the first 2 weeks of study implementation, due to the un expected delay of TQ importation, then 5 enrolled *P. vivax* patients were eligible for TQ but could not receive this medication; instead they were given 7-day PQ. These 5 patients would be classified as receiving correct RC. The reasons were well documented in the paper CRFs.

## 8.4. Secondary analyses

The number and percentage of *P. vivax* patients aged  $\geq 6$  months treated or not with daily PQ in accordance with the appropriate level of G6PD enzyme activity will be summarized using descriptive statistics for the analysis population and in the subgroups of interest. Patient characteristics (age, gender, , weight, malaria history, malaria diagnosis, hemoglobin, pregnancies and breast-feeding status, G6PD activity) of patients treated with TQ and of patients treated with PQ will be presented using descriptive statistics. Confirmed drug-induced AHA will be presented overall, by anti-malarial drug received, and by G6PD test results, using descriptive summary statistics: number and percentage of patients who experienced at least one AHA, number of AHA in total and per patient, hemoglobin level, AHA symptoms, treatments, hospitalizations and outcomes, training of HCP(s) who performed the G6PD test and provided the anti-malarial treatment.

## 8.5. Interim Analyses

As the implementation duration of this study was short (planned for 4-6 months but actual duration was only in 10 weeks) then there was no interim analysis planned for this study. There was no ad-hoc interim analysis as there was no concern about the safety and/or study implementation.

## 8.6. Final Analyses

Based on epidemiological trends and the short duration of study enrollment, number of P. vivax cases is likely to be diagnosed and treated within the study period and about 20-30 patients are likely to be treated according to the revised treatment algorithm. A final analysis will be conducted at the end of the study.

The mock tables and figures for final analysis are provided in the annex 1 and annex 2 respectively of this SAP.

## 9. Reference

1. Statistical Analysis Plan WWARN Primaquine for Radical Cure of Plasmodium vivax and Plasmodium ovale: A pooled analysis investigating the tolerability, safety and efficacy of primaquine in paediatric patients compared with adults Version 1.3
2. Supplement to: Brito M, Rufatto R, Murta F, et al. Operational feasibility of Plasmodium vivax radical cure with tafenoquine or primaquine following point-of-care, quantitative glucose-6-phosphate dehydrogenase testing in the Brazilian Amazon: a real-life retrospective analysis. *Lancet Glob Health* 2024; 12: e467–77

## Annex 1: Mock Tables

**Table 1. Baseline characteristics of patients enrolled in the study by overall**

**Note:** Because there only 21 patients enrolled into study (18 in Quang Tri province and 3 in Lai Chau province) then it is not necessary to do descriptive analyse by site/province)

Categories	Results	Remark
N		
Age (mean, SD)		Min: .... Max: .....
Gender:		
Male		
Female		
Ethnic:		
Facility type, n (%)		
Regional hospital (former district hospital)		
Commune health station		
Patient finding method, n (%)		
Active case detection		
Passive finding		
Current malaria symptom		
Hemoglobin g/dL (mean, SD)		
G6PD status <sup>2</sup> , n (%)		
Normal ( $\geq 6.1$ U/g Hb)		
Intermediate (4.1-6.0) U/g Hb)		
Deficiency ( $\leq 4.0$ U/g Hb)		
G6PD activity (U/g Hb), mean, (SD)		
Breastfeeding Status, n (%)		
Yes		
No		
Unknown		
Pregnancy status, n (%)		
Yes		
No		
Unknown		

Vivax mono-infection, n (%)		
Diagnostic method <sup>3</sup> , n (%)		
Microscopy & RDT		
Microscopy only		
RDT only		
Day 2 follow-up completed, n (%)		
Day 3 follow-up completed, n (%)		
Day 4 follow-up completed, n (%)		
Day 8 follow-up completed, n (%)		
Day 15 follow-up completed, n (%)		
Day 29 follow-up completed, n (%)		

**Table 2. Baseline characteristics of patients enrolled in the study by treatment arm**

	<b>TQ</b>	<b>PQ</b>	<b>No PQ or TQ</b>
	N=	N=	N=
<b>Age (mean and range)</b>			
<5yrs			
5-16			
≥16yrs			
<b>Sex n (%)</b>			
Male			
Female			
Unknown			
<b>Malaria diagnosis n (%)</b>			
P. vivax			
Mixed infection			
Other			

**Table 3. Baseline characteristics of HCPs enrolled in the study by overall and by active sites**

**Note:** as only Quang Tri and Lai Chau provinces enrolled patients into study then the characteristics of HCPs will be analyzed by overall and by active sites of Quang Tri and Lai Chau

	Overall	Quang Tri	Lai Chau	Notes
N				
Age (mean, SD)				
Male, n (%)				
Facility type, n (%)				
Commune health station				
District hospital/health center				
Provincial CDC				
Professional category, n (%)				
Medical doctor				
Health officer				
Nurse				
Laboratory technician				
Pharmacist				
Other <sup>1</sup>				
Highest level of education, n (%)				
Medical degree				
Degree (BSc/BA)				
Master's degree				
Other <sup>2</sup>				
Years of experience in malaria case management (mean, SD)				
Years of experience at the current facility (mean, SD)				

**Table 4. G6PD activity status classification with result by SD Biosensor by overall and sites**

	<b>Overall</b>	<b>Male</b>	<b>Female</b>
Normal			
Intermediate			
Deficiency			
<i>Total</i>			

**Table 5. Participants correctly treated with RC under the new treatment algorithm by overall and active sites**

	<b>Overall</b>	<b>Quang Tri</b>	<b>Lai Chau</b>	<b>Notes</b>
n/N (%)				
Radical cure, n/N (%)				
TQ				
PQ				
- 7-day PQ				
- 14-day PQ				
- 8-week PQ				
No RC				
Facility type, n/N (%)				
Regional Medical center (former district hospital)				
Commune Health station				

Abbreviations: n, number of participants correctly treated; N, total participants; PQ, primaquine; TQ, tafenoquine.

**Table 6. Participants incorrectly treated with RC under the new treatment algorithm by overall and active sites**

	<b>Overall</b>	<b>Quang Tri</b>	<b>Lai Chau</b>	<b>Notes</b>
n/N (%)				
Radical cure, n/N (%)				
In correct TQ prescription				
In correct PQ prescription				
- 7-day PQ				
- 14-day PQ				
- 8-week PQ				
In correct No RC				
Facility type, n/N (%)				
Regional Medical center (former district hospital)				
Commune Health station				

**Table 7. Number of patients with malaria recurrence by treatment arm**

	<b>TQ</b>	<b>PQ</b>	<b>No PQ or TQ</b>
	N=	N=	N=
Number and recurrence case with <i>P. vivax</i>			
Number and recurrence case with <i>P. faciparum</i>			
Number and recurrence case with other malaria species			

**Table 8. Number of patients with AHA/SAE, moderate and severe AEs in the study by treatment arm**

	<b>TQ</b>	<b>PQ</b>	<b>No PQ or TQ</b>
	N=	N=	N=
Number and percentage of patients with any sign/symptom of AHA			
Number and percentage of patients with suspected AHA			
Number and percentage of patients with confirmed AHA			
Number and percentage of patients with suspected AHA			
Number and percentage of patients with SAE			
Number and percentage of patients with moderate AE			
Number and percentage of patients with severe AE			

**Table 9. AHA symptoms/signs reported by patients for each RC in each follow-up visits during study participation**

<b>Tafenoquine</b>						
	<i>Day 2</i>	<i>Day 3</i>	<i>Day 4</i>	<i>Day 8</i>	<i>Day 15</i>	<i>Day 29</i>
<b>Total symptoms reported</b>						
Dark urine						
Fatigue						
Dizziness						
Shortness of breath						
Back pain						
Yellowing of skin						
Pallor						
Rapid heart rate						
Fever						
Nausea/vomiting						
Other						

<b>Primaquine</b>						
	<i>Day 2</i>	<i>Day 3</i>	<i>Day 4</i>	<i>Day 8</i>	<i>Day 15</i>	<i>Day 29</i>
<b>Total symptoms reported</b>						
Dark urine						
Fatigue						
Dizziness						
Shortness of breath						
Back pain						
Yellowing of skin						
Pallor						
Rapid heart rate						
Fever						
Nausea/vomiting						
Other						

**Table 10. G6PD activity status classification with result by SD Biosensor by overall and by gender**

	<b>Overall</b>	<b>Male</b>	<b>Female</b>
Normal			
Intermediate			
Deficiency			
<i>Total</i>			

**Table 11. G6PD activity status classification with result by SD Biosensor by overall and by sites**

	<b>Overall</b>	<b>Quang tri</b>	<b>Lai Chau</b>
Normal			
Intermediate			
Deficiency			
<i>Total</i>			

**Table 12: Anemia classification with result by SD Biosensor by overall and sites**

	<b>Overall</b>	<b>Quang Tri</b>	<b>Lai Chau</b>
Normal			
Mild			
Moderate			
Severe			
<i>Total</i>			

## **Annex 2: list of Figures**

- Figure 1: Patient age distribution by category
- Figure 2: G6PD activity distribution by overall and sex in enrolled patients
- Figure 3: G6PD activity distribution by overall and sex in identified patients
- Figure 4: RC distribution in enrolled patients
- Figure 5: Anaemia classification with result by SD Biosensor by overall and sites
- Additional figures if required.