Local Study Server DATA GUIDE

Kingdom of Swaziland National Malaria Control Program

SVR001 Data guide

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Introduction

Data secured on the prompt tablets and local server is coded; this document provides a detailed key with reference to each column for better analysis of the coded data.

Purpose

This SOP outlines the procedures for browsing and locating a recorded patient's records on the tablet computers.

Responsible Personnel

Administrators with access to the server data for export to XML/CSV.

Procedures

- 1. Log onto the local server with assigned pass code.
- 2. Select "Download/Export" icon.
- 3. Select desired icon for export.
- 4. Open exported data in Excel etc.
- 5. Use this guide to analyze the data.

Note: for security reasons, you are encouraged log out immediately if you no longer need to use the server.

1: Eligibility

Column: svr id

Intent: Server Unique Identifier.

Purpose: System Level Tracking/Voids Duplicate

Question Number: N/A

Column: dateAdded

Intent: Date Record was entered on server.

Purpose: Study Level Tracking

Question Number: 1

Column: q1

Intent: Capture age estimate.

Purpose: Study Level Questionnaire

Question Number: 1.1
Question: Age >1 year

Decode Key

Yes	1
No	2

Column: q2

Intent: Capture malaria diagnosis confirmation.

Purpose: Study Level Questionnaire

Question Number: 1.2

Question: Confirmed malaria diagnosis?

Decode Key

Yes	1
No	2

Column: q3

Intent: Capture follow-up agreement.
Purpose: Study Level Questionnaire

Question Number: 1.3

Question: Agrees to follow-up phone calls and/or visits

Decode Kev

Yes	1
No	2

Column: q4

Intent: Capture intention to move.
Purpose: Study Level Questionnaire

Question Number: 1.4

Question: No intention to move (leave Swaziland) during the

follow-up period of 14 days at minimum.

Yes	1
No	2

Intent: Capture informed consent confirmation.

Purpose: Study Level Questionnaire

Question Number: 1.5

Question: Has provided written, informed consent

Decode Key

Yes	1
No	2

Column: q6

Intent: Capture Hemoglobin.

Purpose: Study Level Questionnaire

Question Number: 1.6

Question: Hemoglobin > = 8 g/dL or Hematocrit > 25%

Decode Key

Yes	1
No	2

Column: q7

Intent: Capture absence of severe malaria.

Purpose: Study Level Questionnaire

Question Number: 1.7

Question: Absence of severe malaria, defined as the presence of suspect (clinical) symptomatic malaria with one or two of the following clinical manifestations: prostration, impaired consciousness, respiratory distress, multiple convulsions, circulatory collapse, pulmonary oedema, abnormal bleeding, jaundice, and hemoglobinuria Decode Key

Yes	1
No	2

Column: q8

Intent: Capture absence of known allergies.

Purpose: Study Level Questionnaire

Question Number: 1.8

Question: Absence of known allergies to study medications (PQ)

Decode Key

Yes	1
No	2

Column: q9

Intent: Capture gender.

Purpose: Study Level Questionnaire

Question Number: 1.9

Question: Is this patient male or female?

Male	M
Female	F

Column: childbearing_age

Intent: Case question (if female) to question 1.9 (q9)

Purpose: Study Level Questionnaire

Question Number: 1.9.1

Question: Is this patient of childbearing age [15 - 49

years]?
Decode Key

Yes	1
No	2

Column: breast feeding

Intent: Case question (if yes) to question 1.9.1

(childbearing age)

Purpose: Study Level Questionnaire

Question Number: 1.9.2

Question: Is the patient currently breast-feeding?

Decode Key

Ī	Yes	1
	No	2

Column: q10

Intent: Case question (if yes) to question 1.9.2

(breast feeding)

Purpose: Study Level Questionnaire

Question Number: 1.10

Question: Is the patient pregnant?

Decode Key

Yes	1
No	2
Uncertain	3
N/A	4

Column: q10_isTested

Intent: Case question (if no or uncertain) to question 1.10

(q10)

Purpose: Study Level Questionnaire

Question Number: N/A

Question: Has she agreed to a pregnancy test?

Decode Key

Yes	1
No	2

Column: q10_ pregnant

Intent: Case question (if yes) to question q10 isTested

Purpose: Study Level Questionnaire

Question Number: N/A

Question: Was the test positive for pregnancy?

Yes	1
No	2

Intent: Capture eligibility criteria compliance.

Purpose: Study Level Questionnaire

Question Number: 1.11

Question: Has the individual met all the eligibility criteria

for the study? Decode Kev

<u> </u>	
Yes	1
No	2

Column: q11a

Intent: Capture inclusion to study.
Purpose: Study Level Questionnaire

Question Number: 1.11a

Question: Has the individual been included in the study?

Decode Key

2	
Yes	1
No	2

Column: no 2

Intent: If the individual has not been included.

Purpose: Study Level Questionnaire

Question Number: 1.12

Question: If the individual has not been included in the

study, give the reason

Column: no 4

Intent: If the individual has not been included.

Purpose: Study Level Questionnaire

Question Number: N/A

Question: Participant's Study ID Number

Column: hemoglobin measure

Intent: Capture Hemoglobin measure in q/dl.

Purpose: Study Level Questionnaire

Question Number: N/A

Column: tabletId

Intent: Tablet Identifier Number.
Purpose: System Level Tracking

Question Number: N/A

Column: interviewer

Intent: User Identifier (Name).

Purpose: System/Study Level Tracking

Column: dateModified

Intent: Date record was last updated/modified.

Purpose: System Level Tracking

2: Patient Data

Column: svr id

Intent: Server Unique Identifier.

Purpose: System Level Tracking/Voids Duplicate

Question Number: N/A

Column: patientid

Intent: Patient Unique Identifier - Patient Barcode (QR Code)

Number.

Purpose: Study Level Tracking

Question Number: N/A

Column: dateAdded

Intent: Date Record was entered on server.

Purpose: Study Level Tracking

Question Number: 1

Column: hemoglobin

Intent: Hemoglobin measure in g/dl.
Purpose: Study Level Questionnaire

Question Number: N/A

Column: healthFacility

Intent: Health Facility where patient initially presented.

Purpose: Study Level Questionnaire.

Question Number: 3

Decode Key

RFM	RFM
Good Shepherd	Good Shepherd

Column: familyName

Intent: Capture last name.

Purpose: Study Level Questionnaire

Question Number: 4

Column: fname

Intent: Capture first name.

Purpose: Study Level Questionnaire

Question Number: 5

Column: nationality, nationalityOther

Intent: Capture nationality/country name.

Purpose: Study Level Questionnaire

Question Number: 6

<u> </u>	
Swaziland	1
Mozambique	2
South Africa	3
Other	4

Column: countryOfResidence

Intent: Capture country of residence.
Purpose: Study Level Questionnaire

Question Number: 7

Question: Is Swaziland your country of residence?

Decode Key

Yes	1
No	2

Column: age

Intent: Capture patient age.

Purpose: Study Level Questionnaire

Question Number: 8

Column: ageType

Intent: Capture patient age type (months or years).

Purpose: Study Level Questionnaire

Question Number: 8

Decode Key

Months	М
Years	Y

Column: sex

Intent: Capture patient gender.

Purpose: Study Level Questionnaire

Question Number: N/A

Decode Key

Male	M
Female	F

Column: mobile1

Intent: Capture patient primary mobile number.

Purpose: Study Level Questionnaire

Question Number: 10

Column: mobile2

Intent: Capture patient secondary mobile number.

Purpose: Study Level Questionnaire

Question Number: 11

Column: pregnant

Intent: Capture patient pregnancy status.

Purpose: Study Level Questionnaire

Question Number: N/A

Question: Is patient pregnant?

Yes	1
No	2
Not Applicable	NULL/BLANK

Column: weight

Intent: Capture patient weight in kilograms.

Purpose: Study Level Questionnaire

Question Number: 9

Column: q12

Intent: Capture patient family history of hemolysis.

Purpose: Study Level Questionnaire

Question Number: 12

Question: Does this patient have a family history of hemolysis

(severe anemia)?

Decode Key

Yes	1
No	2
Uncertain	3
Not Answered	NULL/BLANK

Column: q12a

Intent: Case question (if yes) to question 12 (q12)

Purpose: Study Level Questionnaire

Question Number: N/A

Question: If yes, was it in response to?

Decode Key

Medication	1
Food	2
Infection	3
Other	4
Not Answered	NULL/BLANK

Column: q12a other

Intent: Case question (if other) to question 12a (q12a)

Purpose: Study Level Questionnaire

Question Number: N/A

Column: q13

Intent: Capture patient family history of G6PD deficiency.

Purpose: Study Level Questionnaire

Question Number: 13

Question: Does this patient have a family history of G6PD

deficiency?
Decode Key

Yes	1
No	2
Uncertain	3
Not Answered	NULL/BLANK

Intent: Capture patient blood transfusion history.

Purpose: Study Level Questionnaire

Question Number: 14

Question: Has this patient ever had a blood transfusion?

Decode Key

Yes	1
No	2
Not Answered	NULL/BLANK

Column: q15

Intent: Capture diagnostic test type.
Purpose: Study Level Questionnaire

Question Number: 15

Question: Diagnostic test type?

Decode Key

RDT	1
Microscopy	2
Both	3
Not Answered	NULL/BLANK

Column: q16

Intent: Capture malaria diagnosis.
Purpose: Study Level Questionnaire

Question Number: 16
Question: Diagnosis

Decode Kev

Pf	1
Pv	2
Mixed	3
Other	4
Not Answered	NULL/BLANK

Column: q16 other

Intent: Case question (if other) to question 16 (q16)

Purpose: Study Level Questionnaire

Intent: Capture antimalarial prescribed.

Purpose: Study Level Questionnaire

Question Number: 17

Question: Antimalarial Prescribed:

Decode Key

AL	1
Oral QN	2
IM QN	3
SP/Fandisar	4
CQ	5
Other	6
Unknown	7
Not Answered	NULL/BLANK

Column: q17 other

Intent: Case question (if other) to question 17 (q17)

Purpose: Study Level Questionnaire

Question Number: N/A

Column: q17a

Intent: Capture dose.

Purpose: Study Level Questionnaire

Question Number: 17a

Question: Dose Decode Key

20mg/120mg	1
Other	2
Not Answered	NULL/BLANK

Column: q17a other

Intent: Case question (if other) to question 17a (q17a)

Purpose: Study Level Questionnaire

Question Number: N/A

Column: q17b

Intent: Capture number of tablets per dose.

Purpose: Study Level Questionnaire

Question Number: 17b

Question: # of tablets per dose

Column: q17c

Intent: Capture number of doses per day.

Purpose: Study Level Questionnaire

Question Number: 17c

Question: # of doses per day

2 doses	1
Other	2
Not Answered	NULL/BLANK

Column: q17c other

Intent: Case question (if other) to question 17c (q17c)

Purpose: Study Level Questionnaire

Question Number: N/A

Column: q17d

Intent: Capture number of doses per day.

Purpose: Study Level Questionnaire

Question Number: 17d Question: # of days

Decode Key

3 days	1
Other	2
Not Answered	NULL/BLANK

Column: q17d other

Intent: Case question (if other) to question 17d (q17d)

Purpose: Study Level Questionnaire

Question Number: N/A

Column: q18a

Intent: Capture Primaquine dose prescribed and # of days.

Purpose: Study Level Questionnaire

Question Number: 18a Question: Daily dose

Decode Key

7.5mg	1
Other	2
Not Answered	NULL/BLANK

Column: q18a other

Intent: Case question (if other) to question 18a (q18a)

Purpose: Study Level Questionnaire

Question Number: N/A

Column: q18b

Intent: Capture Primaquine dose prescribed and # of days.

Purpose: Study Level Questionnaire

Question Number: 18b

Question: # of PQ tablets taken per day

Decode Key

7.5mg	1
Other	2
Not Answered	NULL/BLANK

Column: q18b other

Intent: Case question (if other) to question 18b (q18b)

Purpose: Study Level Questionnaire

Column: q18c

Intent: Capture Primaquine dose prescribed and # of days.

Purpose: Study Level Questionnaire

Question Number: 18c

Question: For how many days

Decode Key

1 day	1
Not Answered	NULL/BLANK

Column: **g6pd**

Intent: Capture G6PD.

Purpose: Study Level Questionnaire

Question Number: 24

Question: G6PD Test performed?

Decode Key

Yes	1
No	0
Not Answered	NULL/BLANK

Column: g6pd_test_type
Intent: Capture G6PD.

Purpose: Study Level Questionnaire

Question Number: 25

Question: G6PD test type? Default Answer: CareStart

Column: q26

Intent: Capture G6PD.

Purpose: Study Level Questionnaire

Question Number: 26

Question: G6PD Test result?

Decode Key

Normal	1
Deficient	2
Invalid	3
Not Answered	NULL/BLANK

Column: bloodspot_taken
Intent: Capture bloodspot.

Purpose: Study Level Questionnaire

Question Number: N/A

Question: N/A

Default Answer: unknown

Column: guardian

Intent: Capture guardian name for patients younger than 18.

Purpose: Study Level Questionnaire

Question Number: N/A
Question: Guardian Name

Column: tabletId

Intent: Tablet Identifier Number.
Purpose: System Level Tracking

Question Number: N/A

Column: interviewer

Intent: User Identifier (Name).

Purpose: System/Study Level Tracking

Question Number: N/A

Column: dateModified

Intent: Date record was last updated/modified.

Purpose: System Level Tracking

Question Number: N/A

Column: day7

Intent: Determine day 7 based on date added.

Purpose: System/Study Level Tracking

Question Number: 2

Question: Scheduled day 7 visit

Column: status

Intent: Determine if patient is included in study and if

patient appears on patient list.

Purpose: System/Study Level Tracking

Question Number: N/A

Decode Key

Active (Included in	1
study)	
Inactive (Not	0
included in study)	

Column: callAttempts

Intent: Number of call attempts for to patient via tablet

Purpose: Study Level Tracking

Question Number: N/A
Default Answer: 0

3: Adverse Events

Column: svr id

Intent: Server Unique Identifier.

Purpose: System Level Tracking/Voids Duplicate

Question Number: N/A

Column: patientid

Intent: Patient Unique Identifier - Patient Barcode (QR Code)

Number.

Purpose: Study Level Tracking

Question Number: N/A

Column: dateAdded

Intent: Date Record was entered on server.

Purpose: Study Level Tracking

Question Number: 1

Column: type

Intent: Capture type of adverse event.
Purpose: Study Level Questionnaire

Question Number: 1

Question: Type of adverse event:

Decode Key

Rash	1
Nausea	2
Vomitting	3
Anemia	4
Dark Urine	5
Diarrhea	6
Other*	7

Column: type_other

Intent: Case question (if other) to question 1 (type)

Purpose: Study Level Questionnaire

Question Number: N/A

Question: Describe other type of event

Column: onsetDate

Intent: Date the AE started.
Purpose: Study Level Tracking

Question Number: 2 Question: Onset Date

Column: resolvedDate

Intent: Date the AE was resolved.
Purpose: Study Level Tracking

Question Number: 6

Question: Date Resolved

Column: severityGrade

Intent: Capture severity of adverse event.

Purpose: Study Level Questionnaire

Question Number: 3

Question: Severity Grade

Decode Key

-	
Mild	1
Moderate	2
Severe	3
Life-threatening	4

Column: actionsTaken

Intent: Capture actions taken to address adverse event.

Purpose: Study Level Questionnaire

Question Number: 4
Question: Actions Taken

Decode Key

Prescribed drug	1
Hospitalization	2
None	3
Blood Transfusion	4
Other**	5

Column: actionsTaken other

Intent: Case question (if other) to question 4 (actionsTaken)

Purpose: Study Level Questionnaire

Question Number: N/A

Question: Describe other actions taken

Column: isRelated

Intent: Capture adverse event relation to PQ.

Purpose: Study Level Questionnaire

Question Number: 5

Question: Is Adverse Event Related To PQ?

<u> </u>	
Unrelated	1
Unlikely	2
Possible	3
Probable	4
Definite	5

Column: aeOutcome

Intent: Capture adverse event outcome.
Purpose: Study Level Questionnaire

Question Number: 7

Question: Outcome of Adverse Event:

Decode Key

_	
Recovered/resolved	1
Recovered/resolved	2
with sequelae	
Recovering/resolving	3
Not recovered/not	4
resolved	
Fatal	5
Unknown	6

Column: isSerious

Intent: Capture nature of AE.

Purpose: Study Level Questionnaire

Question Number: 1.2

Question: Serious Adverse Event?

Decode Key

Yes	1
No	0

Column: tabletId

Intent: Tablet Identifier Number.
Purpose: System Level Tracking

Question Number: N/A

Column: interviewer

Intent: User Identifier (Name).

Purpose: System/Study Level Tracking

Question Number: N/A

Column: dateModified

Intent: Date record was last updated/modified.

Purpose: System Level Tracking