SEVUSMART

FORM 1: SCREENING

SEVUSMART- ID *(Add post enrolment)* | Child's Initials | Clinic/ Hospital No.

Age: Y Y M M ☐ Male ☐ Female | Date of Birth D D M M M Y Y Y Y | Site: ☐ Kilifi ☐ Nchelenge

Admission Date D D M M M Y Y Y Y | Admission Time (24hr) H H M M | Form Filled Date D D M M M Y Y Y Y

1. ELIGIBILITY CRITERIA AT SCREENING

Please complete the SEVUSMART Screening Log for all patients with Severe Malaria.

A. Inclusion Criteria (all Yes boxes must be ticked for the child to be eligible)	**Yes**	**No**
i. Is the child aged 3 months to 12 years?	☐	☐
ii. Does the child have *Plasmodium falciparum* malaria (blood film) ?	☐	☐
iii. Clinical evidence of severe malaria: *impaired consciousness: coma (inability to localize painful stimulus) or prostration (inability to sit unsupported for those above 6 months) or deep breathing*	☐	☐
iv. Lactate >2 mmol/L	☐	☐
v. Is there a guardian or parent willing and able to provide consent?	☐	☐
B. Exclusion Criteria (all No boxes must be ticked for the child to be eligible)	**Yes**	**No**
i. Clinical evidence or a history of a bleeding /coagulation disorder.	☐	☐
ii. A comorbidity which clinician believes has a significant risk of poor outcome e.g. malignancy, end-stage renal failure, major cardiac condition	☐	☐
iii.Thrombocytopenia (Platelet count <25×10/L)	☐	☐

2. PHYSICAL EXAMINATION AT SCREENING

A. Details of physical examination:

i. Weight (kg) kg kg . g	ii. Heart rate (bpm)	iii. Axillary temperature (°C) .
iv. Height/Length (cm) cm cm cm . mm	v. Blood pressure S S S / D D D	vi. Oxygen Sats (%)
vii. MUAC (cm) .	viii. Respiration rate (brpm)	ix. Capillary refill time (sec.)
x. Weak radial pulse volume ☐ Yes ☐ No	xi. Temperature gradient ☐ Yes ☐ No	**Blantyre coma score (BCS)**

xiii. Eyes (movements directed?) ☐ 0 Not directed ☐ 1 Directed score

xiv. Motor (response to pain) ☐ 0 No response ☐ 1 Withdraws ☐ 2 Localizes painful stimuli score

xv. Verbal ☐ 0 No response ☐ 1 Moan ☐ 2 Meaningful cry score

Total Score

3. ELIGIBILITY

	YES (enrol)	**NO**
i Are all inclusion criteria in 1A and NONE of the exclusion criteria in 1B met (all grey boxes ticked)	☐	☐

Completed by: Name	Signature	Date
		D D M M M Y Y Y Y

SEVUSMART	FORM 2: CONSENT & ENROLMENT	Page 1 of 1 V2.0 16-May-2023

SEVUSMART- ID *(Add post-enrolment)* | Child's Initials | Clinic/ Hosp No.

Age: Y Y M M ☐ Male ☐ Female | Date of Birth D D M M M Y Y Y Y | Site: ☐ Kilifi ☐ Nchelenge

Admission Date D D M M M Y Y Y Y | Admission Time (24hr) H H M M | Date form completed D D M M M Y Y Y Y

1. CONSENT

A. Was written consent obtained ?	☐ Yes ☐ No	If Yes: Date: D D M M M Y Y Y Y	Time (24hr): H H M M
*If written consent was obtained **after** enrolment, please complete Section 4 below instead when written consent obtained*			
B. Was verbal assent sought?	☐ Yes ☐ No	If Yes: Date: D D M M M Y Y Y Y	Time (24hr): H H M M

***Do NOT** proceed with enrolment if **NO** to **BOTH** questions. Please document on Screening Log.*

2. ENROLMENT

A. Patient has been enrolled to: *Tick one*

SEVUPARIN

1.5mg/kg/dose ☐ 3.0mg/kg/dose ☐ 4.0mg/kg/dose ☐ 4.5mg/kg/dose ☐ 5.0mg/kg/dose ☐ 6.0 mg/kg/dose ☐

B. Time of enrolment (24hr): H H M M

3. POST-ENROLLMENT CONSENT

A. Was post-enrolment written consent taken and the Consent Form completed and signed after enrolment?

☐ No: consented before enrolment ☐ No: consent declined	☐ No: died before consent obtained ☐ No: absconded before consent obtained	☐ Yes: please date and sign below

Date D D M M M Y Y Y Y | Time (24hr) H H M M | Initials of person taking written consent:

SEVUSMART- ID	Child's initials	Clinic/Hospital No
	Site: ☐ Kilifi ☐ Nchelenge	Date form Completed: D D M M M Y Y Y Y

1. CLINICAL DETAILS AT ADMISSION

A. Clinical History of THIS illness	*Please tick ONE box per question*		
	Yes	**No**	**Don't Know**
i. History of fever	☐	☐	☐
ii. If yes, duration of fever	☐☐☐ Days		
iii. History of cough	☐	☐	☐
iv. Increased work of breathing (in-drawing or deep breathing)	☐	☐	☐
v. Vomiting	☐	☐	☐
vi. Diarrhoea (> 3 loose motions in last 24 hours)	☐	☐	☐
vii. If diarrhoea = yes, is this bloody	☐	☐	☐
viii. Haemoglobinuria (red or cola coloured urine)	☐	☐	☐
ix. If haemoglobinuria = yes, when did it start	☐☐ days ago		
x. Has there been seizures in this illness	☐	☐	☐
xi. If yes, did any last more than 30 minutes	☐	☐	☐
xii. Inability to sit up right unsupported (prostrate)	☐	☐	☐
B. Treatment in THIS illness	**Yes**	**No**	**Don't Know**
i. Admitted for over 24 hours into another hospital	☐	☐	☐
ii. Number of doses of IV or IM quinine /artesunate received before enrolment	☐☐ Doses		
iii. Received oral anti-malarials in the last week prior to admission	☐	☐	☐
iv. Received an anticonvulsant prior to admission	☐	☐	☐
v. If yes, which anticonvulsant s (can tick more than one)	☐ Phenobarbitone ☐ Diazepam ☐ Don't know		
vi. If phenobarbitone or diazepam, what was the route of administration	☐ Oral ☐ I.M ☐ ☐ I.V		
vii. Received oral antibiotics in last week prior to admission	☐	☐	☐
C. Past history - BEFORE this illness	**Yes**	**No**	**Don't Know**
i. Two or more hospital admissions in the last year	☐	☐	☐
ii. Previously received a blood transfusion (ever)	☐	☐	☐
iii. Did the child have epilepsy	☐	☐	☐
iv. If yes, is the child on regular anticonvulsants	☐	☐	☐
v. Was the child able to sit without support before this illness	☐	☐	☐
vi. Was the child able to walk without help before this illness	☐	☐	☐

SEVUSMART- ID	Child's initials	Clinic/Hospital No

Site: ☐ Kilifi ☐ Nchelenge

Date form Completed: D D M M M Y Y Y Y

1. CLINICAL DETAILS AT ADMISSION CONT.

D. About the child's family	Please tick ONE box per question		
i. Number of siblings			
ii. Father's ethnic group and code	_____		
iii. Mother's ethnic group and code	_____		
iv. Both parents still alive	☐ Both alive	☐ One alive	☐ Both died
v. Homestead where child lives	☐ Urban	☐ Semi-urban	☐ Rural
vil. child sleep under a bed net/mosquito net	☐ Yes	☐ No	☐ Don't know

E. Clinical examination	Please tick ONE box per question		
i. Airway maintained	☐ Spontaneously	☐ With positioning	☐ With adjunct (guedel)
ii. Shallow / irregular breathing	☐ Yes	☐ No	☐ Not assessed
iii. In-drawing	☐ Yes	☐ No	☐ Not assessed
iv. Deep breathing	☐ Yes	☐ No	☐ Not assessed
v. Crackles	☐ Unilateral	☐ Bilateral	☐ None ☐ Not assessed
vi. Sunken eyes	☐ Yes	☐ No	☐ Not assessed
vii. Decreased skin turgor	☐ Yes	☐ No	☐ Not assessed
viii. Cold hands or feet only	☐ Yes	☐ No	☐ Not assessed
ix. Liver size >2cm below costal margin	☐ Yes	☐ No	☐ Not assessed
x. Splenomegaly (gross ≥ 5 cm)	☐ Not palpable	☐ Enlarged	☐ Gross
xi. Jaundice	☐ Yes	☐ No	☐ Not assessed
xii. Very severe wasting	☐ Yes	☐ No	☐ Not assessed
xiii. Signs of kwashiorkor (symmetrical oedema)	☐ None	☐ Pretibial	☐ Hands/legs ☐ Generalized
xiv. Generalized lymphadenopathy	☐ Yes	☐ No	☐ Not assessed
xv. Flaky paint dermatitis	☐ Yes	☐ No	☐ Not assessed
xvi. Oral candidiasis	☐ Yes	☐ No	☐ Not assessed

F. Neurological	Please tick ONE box per question		
i. Inability to sit up right unsupported (prostrate)	☐ Yes	☐ No	☐ Not assessed
ii. Fitting currently?	☐ Yes	☐ No	☐ Not assessed
iii. Neck stiffness	☐ Yes	☐ No	☐ Not assessed
iv. Bulging Fontenelle (infants only)	☐ Yes	☐ No	☐ Not assessed
v. Pupil symmetry	☐ Equal	☐ Unequal	
vi. Divergent gaze	☐ Yes	☐ No	☐ Not assessed
vii. Abnormal motor posturing	☐ Yes	☐ No	☐ Not assessed
viii. Does the child have bruxism? (grinding teeth)	☐ Yes	☐ No	☐ Not assessed

SEVUSMART- ID	Child's initials	Clinic/Hospital No

Site: ☐ Kilifi ☐ Nchelenge

Date form Completed: D D M M M Y Y Y Y

2. ADMISSION SAMPLES

	Volume (9ml)	Real time test/ Storage	Real time results & form to be completed Sample storage required & form to be completed
EDTA (purple top)	1 x 0.5ml	FBC	Form 7 Real Time Blood Tests
Malaria microscopy	1 slide (thin and thick smear)	Microscopy for malaria parasites	Form 7 Real Time Blood Tests
Blood Culture (BACTEC)	2-3ml	Microbiology	Form 8 Microbiology & Urine Results
Lithium heparin (green top)	2 x 2ml	Biochemistry and plasma storage	Form 7 Real Time Blood Tests
Sodium Citrate (Blue top)	1x 2mls	APTT	Form 4 Sevuparin and Coagulation Tests

Please fill in the header and clinic sections of Forms 6 and 7 and send along with the samples to the laboratories.

4. WARD TESTS AT ADMISSION

Please use some of the blood drawn as part of the admission bloods (above) to run the following ward tests.

A. Ward tests and results:

i. Haemoglobin g/dl	ii. Lactate mmols/L	iii. Blood glucose mmols/L	iv. Glucose given?
.	.	.	☐ Yes ☐ No

v. HIV test result: ☐ Positive ☐ Negative ☐ Not done

☐ Tested today positive ☐ Tested today negative ☐ Tested today invalid

vi. Blood gas pH . Bicarb . PCO_2 . Base deficit$_{(ecf)}$. Base deficit$_{(b)}$.

5. WORKING DIAGNOSIS

A. What is the working (initial) diagnosis for this patient? *Tick all that apply*

☐ Severe malaria	☐ Developmental delay/cerebral palsy	
☐ Sepsis/septicemia	☐ Recurrent hemoglobinuria	☐ Hepatitis
☐ LRTI - all types	☐ Encephalopathy	☐ Gastroenteritis (>3 watery stools/24hr)
☐ Severe anaemia (Hb <6g/dL)	☐ Meningitis - all types	☐ Urinary tract infection
☐ Malnutrition	☐ Sickle cell anaemia	☐ Pyrexia of unknown origin
☐ HIV/AIDS	☐ Sickle cell crisis	☐ Hemoglobinuria

☐ Other; provide further details: _____

6. PRESENTATION

A. What type of healthcare facility did the child <u>first</u> present to for this illness?

☐ This hospital ☐ Level I ☐ Level II ☐ Level III ☐ Level IV ☐ Private hospital/clinic

B. If <u>not</u> this hospital:

i. Date presented at other facility: D D M M M Y Y Y Y

Ii. Time presented at other facility (24 hr): H H M M

iii. Date referred from other facility: D D M M M Y Y Y Y

iv. Time referred from other facility (24 hr): H H M M

v. How far away is the facility they first presented to from this hospital (estimated km): K M

Completed by (Doctor): Name	Signature	Date
		D D M M M Y Y Y Y

SEVUSMART

FORM 4:
SEVUPARIN and COAGULATION TESTS (APTT)

v2.0 16-May-2023

SEVUSMART ID

Child's initials

Site: ☐ Kilifi ☐ Nchelenge

Clinic/Hospital No.

Date of form D D M M M Y Y Y Y

1. SEVUPARIN / APTT

SEVUPARIN

TIMEPOINT	DATE / TIME OF SEVUPARIN DOSE	INITIALS
0 Hour (Adm)	D D M M M Y Y Y Y H H M M	
8 Hours	D D M M M Y Y Y Y H H M M	
16 Hours	D D M M M Y Y Y Y H H M M	

***** Collect sample for PK at these timepoints

COAGULATION TESTS

	DATE / TIME OF APPT SAMPLE	APTT RESULTS(Secs)	ACT RESULTS(Secs)	INITIALS
0 Hour	D D M M M Y Y Y Y H H M M	.	.	
1 Hours	D D M M M Y Y Y Y H H M M *	.	.	
9 Hours	D D M M M Y Y Y Y H H M M *	.	.	
24 Hours	D D M M M Y Y Y Y H H M M	.	.	

2. ASSESSMENT OF SUBLINGUAL MICROCIRCULATION

TIMEPOINT	DATE / TIME OF ASSESSMENT	INITIALS
Before **0 Hour** Sevuparin dose	D D M M M Y Y Y Y H H M M	
Before **8 Hour** Sevuparin dose	D D M M M Y Y Y Y H H M M	

TIMEPOINT	DATE / TIME OF ASSESSMENT	INITIALS
After **8 Hour** Sevuparin dose	D D M M M Y Y Y Y H H M M	
1-2 Hours after **16 Hour** Sevuparin dose	D D M M M Y Y Y Y H H M M	

Form checked and signed by: Name	Initials	Date
		D D M M M Y Y Y Y

SEVUSMART

FORM 5: BEDSIDE OBSERVATIONS

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Site: ☐ Kilifi ☐ Nchelenge

SEVUSMART- ID

Child's initials

Clinic/ Hospital No.

Form 4 should be completed at the prescribed timepoints from time of enrolment. Actual time should be recorded at the time vitals are taken. DO NOT pre-fill the times.

	0 mins	30 mins	1 hour	2 hours	4 hours	8 hours	12 hours	17 hours	24 hours	48 hours
Date of Enrolment D D M M M Y Y Y Y	D D M M M	D D M M M	D D M M M	D D M M M	D D M M M	D D M M M	D D M M M	D D M M M	D D M M M	D D M M M
Actual time of observation (24hr)	H H M M	H H M M	H H M M	H H M M	H H M M	H H M M	H H M M	H H M M	H H M M	H H M M
A. Heart rate (beats/min)										
B. Capillary refill time (seconds)										
C. Axillary temperature, °C	.	.	.	.	.	.	.	.	.	.
D. Weak pulse	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
E. Systolic blood pressure (*999 = can't read)*	S S S	S S S	S S S	S S S	S S S	S S S	S S S	S S S	S S S	S S S
F. Diastolic blood pressure	D D D	D D D	D D D	D D D	D D D	D D D	D D D	D D D	D D D	D D D
G. Respiratory distress (*in-drawing or deep breathing)*	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
H. Oxygen saturation (%) *(999 = can't read)*										
I. Respiratory rate (breaths/min)										
J. Receiving oxygen	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
K. Conscious	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
L. Blantyre coma score	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
M. Vomiting	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
N. Passing dark or red urine	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
O. Blood glucose level (mmol/L)	See admission values	.		.	.	.	.			
P. Hypoglycaemia treated				☐ Yes ☐ No		☐ Yes ☐ No	☐ Yes ☐ No			
Q. Haemoglobin (g/dL)		.	.	.	.	.	.	.	.	.
R. Blood lactate (mmol/L)			.	.	.	.	.	.	.	.
Nurse's initials										

SEVUSMART

FORM 6: ADDITIONAL BEDSIDE OBS

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Site: ☐ Kilifi ☐ Nchelenge

SEVUSMART- ID

Child's initials

Clinic/ Hospital No.

Form 5 should be completed at any other time points outside the time points in form 4 whenever the clinical team feels the clinical condition of the participant warrants it.

Date	D D M M M	D D M M M	D D M M M	D D M M M	D D M M M	D D M M M	D D M M M	D D M M M	D D M M M	D D M M M	D D M M M
Actual time of observation (24hr)	H H M M	H H M M	H H M M	H H M M	H H M M	H H M M	H H M M	H H M M	H H M M	H H M M	H H M M
A. Heart rate (beats/min)											
B. Capillary refill time (seconds)											
C. Axillary temperature, °C	.	.	.	.	.	.	.	.	.	.	.
D. Weak pulse	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
E. Systolic blood pressure (*999 = can't read)*	S S S	S S S	S S S	S S S	S S S	S S S	S S S	S S S	S S S	S S S	S S S
F. Diastolic blood pressure (*999 = can't read)*	D D D	D D D	D D D	D D D	D D D	D D D	D D D	D D D	D D D	D D D	D D D
G. Respiratory distress (*in-drawing or deep breathing)*	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
H. Oxygen saturation (%) *(999 = can't read)*											
I. Respiratory rate (breaths/min)											
J. Receiving oxygen	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
K. Conscious	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
L. Blantyre coma score	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
M. Vomiting	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
N. Passing dark or red urine	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
O. Blood glucose level (mmol/L) (Optional)	.	.	.	.	.	.	.	.	.	.	.
P. Hypoglycaemia treated	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Q. Haemaglobin (g/dL) (Optional)	.	.	.	.	.	.	.	.	.	.	.
R. Blood lactate (mmol/L) (Optional)	.	.	.	.	.	.	.	.	.	.	.
Nurse's initials											

SEVUSMART

FORM 7: REAL TIME BLOOD TESTS

SEVUSMART ID | | | | | | |

Child's initials | | | |

Clinic/Hospital No | | | | | | | | | |

Date of form D D M M M Y Y Y Y

Child's age Y Y M M

Child's gender ☐ Male ☐ Female

Site: ☐ Kilifi ☐ Nchelenge

1. SAMPLE DETAILS

Form header and sample details to be completed in clinic by person requesting test.

A. Sample details: ☐ Admission ☐ 24 hours ☐ Day 7 ☐ Unscheduled

Sample type	Sample Date	Sample time (24hr)
☐ EDTA ☐ Lithium Heparin	D D M M M Y Y Y Y	H H M M

B. Test (s) requested:

i. EDTA - please run the following *(tick all required)*	☐ Haematology
iii. Lithium heparin tube - please run the following	☐ Biochemistry

Requested by (clinic staff): Name	Signed	Date Requested
		D D M M M Y Y Y Y

Form either to be completed in the laboratory and returned to clinic (along with a copy of the results wherever possible), or in the clinic using the results sent by the laboratory.

2. HAEMATOLOGY - FULL BLOOD COUNT

A. Please tick here if haematology was requested but could not be run, and provide reason: ☐ Not done

_____

B. Haematology (FBC) test results:

Test	Result	Unit *Circle if choice*	Not Done	Comments
i. WBC	•	10^3/µL or 10^9/L	☐	
ii. RBC	•	10^6/µL or 10^{12}/L	☐	
iii. Hb (from FBC) or Haemocue if FBC not possible	•	g/dL	☐	
iv. Haemocrit	•	%	☐	
v. MCV	•	fL	☐	
vi. MCH	•	Picograms	☐	
vii. MCHC	•	g/dL	☐	
viii. Platelets	•	10^3/µL or 10^9/L	☐	
ix. Lymphocytes	•	10^3/µL or %	☐	
x. Neutrophils	•	10^3/µL or %	☐	
xi. Granulocytes	•	10^9/L or %	☐	
xii. Monocytes	•	10^9/L or %	☐	

SEVUSMART ID	Child's initials	Clinic/Hospital No
	Date of form	D D M M M Y Y Y Y

Sample details: ☐ Admission ☐ 24 hours ☐ Day 7 ☐ Unscheduled

3. BIOCHEMISTRY AND INFLAMMATORY MARKERS

A. Please tick here if biochemistry was requested but could not be run, and provide reason: ☐ Not done

_____

B. Biochemistry test results:

Test	Result	Unit *Circle if choice*	Not Done	Comments
i. Sodium		mmol/L	☐	
ii. Potassium		mmol/L	☐	
iii. Creatinine		µmol/L or mg/dl	☐	
iv. Glucose		mmol/L	☐	

Completed by: Name	Signed	Date Completed
		D D M M M Y Y Y Y

SEVUSMART ID

Child's initials | **Clinic/Hospital No**

Date of form D D M M M Y Y Y Y

Site: ☐ Kilifi ☐ Nchelenge

1. MALARIA INVESTIGATIONS

Timepoint	Sample date /time	Test	Result	Not Done	Comments	Initials
Admission		**i. Malaria Blood Film**	☐ Positive ☐ Negative ☐ Invalid	☐		
		ii. Malaria Pigment	☐ Yes ☐ No	☐		
	D D M M M Y Y Y Y H H M M	If positive: ☐ *P. falciparum* Schizonts present ☐ Yes ☐ No		☐		
		If the slide is positive:	Parasite count ☐ per 200 WBC ☐ per 500 RBC ☐ per 1000 RBC			
Hour 8/9		**i. Malaria Blood Film**	☐ Positive ☐ Negative ☐ Invalid	☐		**Initials**
		ii. Malaria Pigment	☐ Yes ☐ No	☐		
	D D M M M Y Y Y Y H H M M	If positive: ☐ *P. falciparum* Schizonts present ☐ Yes ☐ No		☐		
		If the slide is positive:	Parasite count ☐ per 200 WBC ☐ per 500 RBC ☐ per 1000 RBC			
Hour 24		**i. Malaria Blood Film**	☐ Positive ☐ Negative ☐ Invalid	☐		**Initials**
		ii. Malaria Pigment	☐ Yes ☐ No	☐		
	D D M M M Y Y Y Y H H M M	If positive: ☐ *P. falciparum* Schizonts present ☐ Yes ☐ No		☐		
		If the slide is positive:	Parasite count ☐ per 200 WBC ☐ per 500 RBC ☐ per 1000 RBC			
Hour 36		**i. Malaria Blood Film**	☐ Positive ☐ Negative ☐ Invalid	☐		**Initials**
		ii. Malaria Pigment	☐ Yes ☐ No	☐		
	D D M M M Y Y Y Y H H M M	If positive: ☐ *P. falciparum* Schizonts present ☐ Yes ☐ No		☐		
		If the slide is positive:	Parasite count ☐ per 200 WBC ☐ per 500 RBC ☐ per 1000 RBC			

SEVUSMART ID	Child's initials	Clinic/Hospital No

Date of form D D M M M Y Y Y Y Site: ☐ Kilifi ☐ Nchelenge

Timepoint	Sample date/time	Test	Result	Not Done	Comments	Initials
Hour 48		**i. Malaria Blood Film**	☐ Positive ☐ Negative ☐ Invalid	☐		
		ii. Malaria Pigment	☐ Yes ☐ No	☐		
	D D M M M Y Y Y Y H H M M	If positive: Schizonts present	☐ *P. falciparum* ☐ Yes ☐ No	☐		
		If the slide is positive:	Parasite count ☐ per 200 WBC ☐ per 500 RBC ☐ per 1000 RBC			
Hour 72		**i. Malaria Blood Film**	☐ Positive ☐ Negative ☐ Invalid	☐		**Initials**
		ii. Malaria Pigment	☐ Yes ☐ No	☐		
	D D M M M Y Y Y Y H H M M	If positive: Schizonts present	☐ *P. falciparum* ☐ Yes ☐ No	☐		
		If the slide is positive:	Parasite count ☐ per 200 WBC ☐ per 500 RBC ☐ per 1000 RBC			

Completed by: Name	Signed	Date Requested
		D D M M M Y Y Y Y

SEVUSMART ID	Child's initials	Clinic/Hospital No
	Date of form D D M M M Y Y Y Y	Site: ☐ Kilifi ☐ Nchelenge

1. MALARIA INVESTIGATIONS AT FOLLOW UP

Day 7		**i. Malaria Blood Film**	☐ Positive ☐ Negative ☐ Invalid	☐	**Initials**
D D M M M Y Y Y Y H H M M		**iii. Malaria Pigment**	☐ Yes ☐ No	☐	
		If positive: Schizonts present	☐ *P. falciparum* ☐ Yes ☐ No	☐	
		If the slide is positive:	Parasite count ☐ per 200 WBC ☐ per 500 RBC ☐ per 1000 RBC		
Day 28		**i. Malaria Blood Film**	☐ Positive ☐ Negative ☐ Invalid	☐	**Initials**
D D M M M Y Y Y Y H H M M		**ii. Malaria Pigment**	☐ Yes ☐ No	☐	
		If positive: Schizonts present	☐ *P. falciparum* ☐ Yes ☐ No	☐	
		If the slide is positive:	Parasite count ☐ per 200 WBC ☐ per 500 RBC ☐ per 1000 RBC		

Completed by: Name	Signed	Date Requested
		D D M M M Y Y Y Y

SEVUSMART

FORM 9: MICROBIOLOGY & URINE RESULTS

SEVUSMART ID	Child's initials	Site: ☐ Kilifi ☐ Nchelenge
	Clinic/ Hospital No.	Date of form: D D M M M Y Y Y Y

Visit: ☐ 0 Days (At admission) ☐ Day 1 ☐ Day 7 ☐ Day 28 ☐ Extra - specify: ☐ Days ☐ Months

1. SAMPLE DETAILS

Please indicate below which samples are being sent along with this form.

A. Sample type and collection details:

Sample type	Sample vol	Test	Taken	Date sample taken
Blood culture (BACTEC)	2-3ml	Microbiology	☐ Yes ☐ No	D D M M M Y Y Y Y
Urine (If clinically indicated)	1-5ml	Dipstick	☐ Yes ☐ No	D D M M M Y Y Y Y
CSF (If clinically indicated)	3-6 drops	Bacteriology	☐ Yes ☐ No	D D M M M Y Y Y Y

Comments: _____

Requested by (clinic staff): Name	Signed	Date Requested
		D D M M M Y Y Y Y

Form either to be completed in the laboratory and returned to clinic (along with a copy of the results wherever possible), or in the clinic using the results sent by the laboratory.

2. MICROBIOLOGY

A. Were microbiology samples received in the laboratory? ☐ Yes ☐ No

Comments: _____

B. Microbiology results:
Blood culture

i. Was a pathogen isolated?	☐ No pathogen isolated	☐ Yes *Please provide details below*	ii. Hours to positivity: H H H . M M

iii. Isolated pathogen:

Comments: _____

B. Microbiology results: CSF
Was a CSF sample collected? ☐ Yes ☐ No
If yes:

i. Was a pathogen isolated?	☐ No pathogen isolated	☐ Yes *Please provide details below*

ii. Isolated pathogen:

Comments: _____

If pathogen (not contaminant) isolated please send the sample for storage.

SEVUSMART ID	Child's initials	Site: ☐ Kilifi ☐ Nchelenge
	Clinic/ Hospital No.	Date of form: D D M M M Y Y Y Y

3. URINE DIPSTICK

A. Was a urine sample received in the laboratory? ☐ Yes ☐ No

Comments: _____

B. Urine dipstick results: ☐ *Tick if too dark to read*

i. Hillman colour chart number (1-10) ☐☐

Test	Result *Please circle*						
ii. Glucose (mg/dL)	Neg.		100	250	500	1000	2000 or more
iii. Bilirubin	Neg.				Small +	Moderate ++	Large +++
iv. Ketone (mg/dL)	Neg.		Trace 5	Small 15	Moderate 40	Large 80	Large 160
v. Specific Gravity	1.000	1.005	1.010	1.015	1.020	1.025	1.030
vi. Blood	Non-Haemolyzed			Haemolyzed			
	Neg.	Trace	Moderate	Trace	Small +	Moderate ++	Large +++
vii. pH (mg/dL)	5.0	6.0	6.5	7.0	7.5	8.0	8.5
viii. Protein	Neg.	Trace		30 +	100 ++	300 +++	2000 or more ++++
ix. Urobilinogen (mg/dL)	Normal 0.2	Normal 1			2	4	8
x. Nitrite	Neg.					Positive Any form of uniform pink	
xii. Leukocytes	Neg.			Trace	Small +	Moderate ++	Large +++

Results completed by (lab staff): Name	Signature	Date
		D D M M M Y Y Y Y

SEVUSMART ID	Child's initials	Site: ☐ Kilifi ☐ Nchelenge
	Clinic/ Hospital No.	Date of form: D D M M M Y Y Y Y

Record all medications prescribed during admission.

1. MEDICATIONS PRESCRIBED

ANTIBIOTICS AND ANTIMALARIALS first then other drugs	Start Date	Days Presc.	End date	Dose	Units (e.g. mg)	Times /day
SEVUPARIN						
Infusion 1 (0 hr)	D D M M M 2 0 Y Y		D D M M M 2 0 Y Y			
Infusion 2 (8 hr)	D D M M M 2 0 Y Y		D D M M M 2 0 Y Y			
Infusion 3 (16 hr)	D D M M M 2 0 Y Y		D D M M M 2 0 Y Y			
Antibiotics	D D M M M 2 0 Y Y		D D M M M 2 0 Y Y			
	D D M M M 2 0 Y Y		D D M M M 2 0 Y Y			
	D D M M M 2 0 Y Y		D D M M M 2 0 Y Y			
Antimalarials	D D M M M 2 0 Y Y		D D M M M 2 0 Y Y			
	D D M M M 2 0 Y Y		D D M M M 2 0 Y Y			
	D D M M M 2 0 Y Y		D D M M M 2 0 Y Y			
Other drugs	D D M M M 2 0 Y Y		D D M M M 2 0 Y Y			
	D D M M M 2 0 Y Y		D D M M M 2 0 Y Y			
	D D M M M 2 0 Y Y		D D M M M 2 0 Y Y			

2. STAT DOSE MEDICATIONS

Drug	Start Date	Dose	Units (e.g. mg)	No. times	Comments
	D D M M M 2 0 Y Y				
	D D M M M 2 0 Y Y				
	D D M M M 2 0 Y Y				
	D D M M M 2 0 Y Y				
	D D M M M 2 0 Y Y				
	D D M M M 2 0 Y Y				

4. FLUIDS (INCLUDING TRANSFUSIONS)

Fluid/ Transfusion Given (indicate whole or settled cells)	Date Started	Time Started (24hr)	Date Ended	Time Ended (24hr)	Amount Infused (ml)
	D D M M M 2 0 Y Y	H H M M	D D M M M 2 0 Y Y	H H M M	
	D D M M M 2 0 Y Y	H H M M	D D M M M 2 0 Y Y	H H M M	
	D D M M M 2 0 Y Y	H H M M	D D M M M 2 0 Y Y	H H M M	
	D D M M M 2 0 Y Y	H H M M	D D M M M 2 0 Y Y	H H M M	
	D D M M M 2 0 Y Y	H H M M	D D M M M 2 0 Y Y	H H M M	

Form completed by: Name	Signature	Date
		D D M M M Y Y Y Y

SEVUSMART	FORM 11: DISCHARGE	Page 1 of 1 V2.0 16-May-2023

SEVUSMART ID | **Child's initials** | **Clinic/Hospital No**

Site: ☐ Kilifi ☐ Nchelenge **Date of form** (D D M M M Y Y Y Y)

i. Status at discharge ☐ Alive ☐ Dead ☐ Absconded

ii. If alive, date/time of discharge: (D D M M M Y Y Y Y) (H H M M)

iii. If dead, date/time of death: (D D M M M Y Y Y Y) (H H M M)

iv. If absconded, date/time last seen: (D D M M M Y Y Y Y) (H H M M)

If child absconded there is no need to complete the rest of this form. Please sign and send for data entry.

If the absconded child cannot be contacted by phone/lost to follow up complete ***Form 13: Lost to Follow Up & Withdrawal***

1. CONTACT DETAILS

A. Are the contact details of the child and carer still correct as on Source Doc A: Contact Details? ☐ Yes ☐ No

If no, please update Source Doc A: Contact Details

2. PHYSICAL EXAMINATION

i. Weight (kg) (kg kg . g) | ii. MUAC (cm) (cm cm . mm) | iii. Temperature (°C) (.)

iv. Height/Length (cm) (cm cm cm . mm) | v. Head circumference (if < 2 years) (cm cm . mm)

3. MEDICATIONS PRESCRIBED AT DISCHARGE

A. Were any medications prescribed at discharge? ☐ Yes ☐ No

Do NOT include: cough syrups/cold medications or creams. *If Yes, please add details below.*

Medication	Reason prescribed	Dose	Units (e.g. mg)	Frequ-ency	Date of prescription	No of days
					D D M M M 2 0 2 Y	
					D D M M M 2 0 2 Y	
					D D M M M 2 0 2 Y	
					D D M M M 2 0 2 Y	

4. FINAL DIAGNOSIS: TICK A;LL THAT APPLY

☐ Severe malaria—all types	☐ Sickle cell anaemia	☐ Hepatitis
☐ Sepsis/septicaemia	☐ Sickle cell crisis	☐ Gastroenteritis
☐ LRTI - all types	☐ Meningitis - all types	☐ Malnutrition
☐ Other chest syndrome	☐ HIV/AIDS	☐ Osteomylitis/Pyogenic arthritis
☐ Severe anaemia (Hb <6g/dL)	☐ Tuberculosis - all types	☐ Developmental delay/cerebral palsy
☐ Haemoglobinuria/dark urine recurrence	☐ Pyrexia of unknown origin	☐ Urinary tract infection
☐ Haemoglobinuria/dark urine first episode	☐ Urinary tract infection	☐ Encephalopathy

☐ Other; provide further details: _____

6. DATE OF NEXT VISIT

A. Which is the next scheduled visit? ☐ Day 7 ☐ Day 28

A. Date of next visit (D D M M M Y Y Y Y)

Completed by (Clinician): Name	Signature	Date

SEVUSMART ID	Child's initials	Site: ☐ Kilifi ☐ Nchelenge
	Clinic/ Hospital No.	Date of form: D D M M M Y Y Y Y

Visit:	☐ Day 7 ☐ Day 28	☐ Extra - specify	☐ Days ☐ Months

Did the patient attend the clinic for this visit?

☐ Yes ☐ No, missed original and rescheduled visits ☐ No, had a home visit

☐ No, had telephone visit

If no visit, what was the date the patient was last known to be alive? D D M M M Y Y Y Y

If the patient did not attend as scheduled, please contact the carer and rearrange the visit, but DO NOT COMPLETE THIS FORM at this point. If the child fails to attend and cannot be contacted by phone and/or does not attend a re-scheduled appointment, please attempt to trace the child at their home address and complete Form 15: Lost to Follow Up & Withdrawal.

1. CONTACT DETAILS

A. Are the contact details of the child and carer still correct as on Source Doc A: Contact Details? ☐ Yes ☐ No

If no, please update Source Doc A: Contact Details

2. PHYSICAL EXAMINATION

A. Details of physical examination:

i. Weight (kg)	ii. MUAC (cm)	iii. Temperature (°C)
kg kg . g	cm cm . mm	.
iv. Height/Length (cm)	**v. Head circumference (if < 2 years)**	☐ Not done (telephone visit)
cm cm cm . mm	cm cm . mm	

3. SYMPTOM CHECKLIST

A. Does the patient have any of the following symptoms now or since the last *scheduled* visit?

Symptom	Yes	No	Symptom	Yes	No
i. Fever *(if current, consider FBC, malaria film/RDT, blood culture)*	☐	☐	x. Poor appetite	☐	☐
ii. Pallor	☐	☐	xi. Moderate-severe dehydration	☐	☐
iii. Red or "Coca-Cola" urine	☐	☐	xii. Difficulty/fast breathing	☐	☐
iv. Jaundice/yellow eyes	☐	☐	xiii. New/worsening seizures	☐	☐
v. Bone or hand/foot pain	☐	☐	xiv. Other (specify):.....	☐	☐
vi. Abdominal aching/pain	☐	☐	xv. Other (specify):.....	☐	☐
vii. Cough	☐	☐	xvi. Other (specify):.....	☐	☐
viii. Vomiting	☐	☐	xvii. Other (specify):.....	☐	☐
ix. Diarrhoea	☐	☐	xviii. Other (specify):.....	☐	☐

4. OTHER MEDICATIONS

Use the section below to report any medications prescribed or taken since the last SEVUSMART visit.

A. Has the child been prescribed any medications since the last SEVUSMART review, or at this visit? ☐ Yes ☐ No
Do NOT include: cough syrups/cold medications or creams. *If Yes, please add details below.*

Medication	Reason prescribed	Dose	Units (e.g. mg)	Frequ-ency	Date of prescription	No of days prescribed
					D D M M M 2 0 2 Y	
					D D M M M 2 0 2 Y	
					D D M M M 2 0 2 Y	
					D D M M M 2 0 2 Y	
					D D M M M 2 0 2 Y	
					D D M M M 2 0 2 Y	
					D D M M M 2 0 2 Y	

5. CLINIC AND HOSPITAL USE

Has the child had any of the following since the last SEVUSMART review:

A. Admission to, or discharge from, hospital?	☐ Yes ☐ No *If yes, add details below and complete Form 14: Adverse Events*

Event Name	Event Code	Admission Date	Discharge Date (Tick if ongoing)	Grade
	.	D D M M M Y Y Y Y	D D M M M Y Y Y Y ☐	worst
	.	D D M M M Y Y Y Y	D D M M M Y Y Y Y ☐	worst

i. Has the child had any febrile disease requiring medical intervention?	☐ Yes	☐ No
ii. Has the child received anti-convulsants since the last visit? *(If yes, add details to Section 4)*	☐ Yes	☐ No
Iii. Has the child received antimalarial; since the last visit? *(If yes, add details to Section 4)*	☐ Yes	☐ No
iv. Has the child had any other illness requiring medical intervention not captured above *If yes, specify*_____	☐ Yes	☐ No

B. Any new, or worsening/resolution of an existing, Grade 3/4 adverse event or Serious Adverse Event or event potentially related to Sevuparin?	☐ Yes ☐ No *If yes, complete Form 14: Adverse Events*

6. FOLLOW UP SAMPLES

Sample:	Volume	Samples collected for:	Real time results & form to be completed
EDTA (purple top) ☐ **Day 7**	2 x 0.5ml	Malaria & FBC (If unwell) Storage	Form 7 Real Time Blood Tests
Lithium heparin ☐ **(Green top) Day 28**	1 x 4ml (D28)	Plasma storage	

Completed by: Name	Signed	Date Requested
		D D M M M Y Y Y Y

SEVUSMART ID	Child's initials	Visit Details: ☐ Day 28	Site: ☐ Kilifi ☐ Nchelenge
	Clinic/ Hospital No.	Date of form: D D M M M Y Y Y Y	

1. SYMPTOM CHECKLIST

A. Does the patient have any of the following symptoms now?

Symptom	Yes	No	Symptom	Yes	No
i. Visual problems:	☐	☐	iv. Abnormal behaviour:	☐	☐
ii. Hearing problems:	☐	☐	v. Abnormal movement / motor function:	☐	☐
iii. Abnormal speech production:	☐	☐	vi. Feeding difficulty:	☐	☐
vii. Abnormal comprehension	☐	☐	viii. Seizures after acute phase	☐	☐

viii. Complete below from Source Document E:

Gross motor: ☐ Pass ☐ Fail Fine motor: ☐ Pass ☐ Fail Communication: ☐ Pass ☐ Fail

ix. If child has failed any of the above: is this ☐ pre-existing or ☐ new

x. Any other symptoms:

xi. Parental report/ worries:

2. NEUROLOGICAL EXAMINATION

Details of neurological examination (Complete below from Source Document E):

Cranial nerve function			
i. Facial appearance	☐ Normal	☐ Uncertain	☐ Abnormal
ii. Eye movements	☐ Normal	☐ Uncertain	☐ Abnormal
iii. Auditory response	☐ Normal	☐ Uncertain	☐ Abnormal
iv. Visual response	☐ Normal	☐ Uncertain	☐ Abnormal
v. Sucking/swallowing	☐ Normal	☐ Uncertain	☐ Abnormal
Tone			
i. Right arm	☐ Normal	☐ Increased	☐ Low
ii. Left arm	☐ Normal	☐ Increased	☐ Low
iii. Trunk	☐ Normal	☐ Increased	☐ Low
iv. Right leg	☐ Normal	☐ Increased	☐ Low
v. left leg	☐ Normal	☐ Increased	☐ Low

SEVUSMART ID	Child's initials	Site: ☐ Kilifi ☐ Nchelenge
	Clinic/ Hospital No.	Date of form: D D M M M Y Y Y Y

2. NEUROLOGICAL EXAMINATION

vi. Right ankle	☐ Normal	☐ Increased	☐ Low
vii. Left ankle	☐ Normal	☐ Increased	☐ Low
Reflexes			
i. Right biceps tendon reflex	☐ Normal	☐ Absent	☐ Increased
ii. Left biceps tendon reflex	☐ Normal	☐ Absent	☐ Increased
iii. Right patellar tendon reflex	☐ Normal	☐ Absent	☐ Increased
iv. Left patellar tendon reflex	☐ Normal	☐ Absent	☐ Increased
Gait	☐ Normal	☐ Abnormal	☐ Unable to assess
Coordination	☐ Normal	☐ Abnormal	☐ Unable to assess

Completed by: Name	Signed	Date Requested
		D D M M M Y Y Y Y

SEVUSMART ID	Child's initials	Clinical/Hospital no
	Site: ☐ Kilifi ☐ Nchelenge	Date of form (D D M M M Y Y Y Y)

*Scan and send all **SAE** reports to trial coordinating centre SEVUSMARTSAE@kemri-wellcome.org within **24 hours** of identification of the adverse event.*

Date of birth (D D M M M Y Y Y Y)	Age (Y Y M M)	☐ Male	☐ Female
Date of re-enrolment (D D M M M Y Y Y Y)	Time of enrolment (24 hr) (H H M M)		

1. GENERAL INFORMATION

A. Event Number	B. Type of report			
	☐ Initial	☐ Follow-up/on-going	☐ Final/resolved/died/no further change	☐ Initial & final

C. If this is a follow-up or final report, please give date of initial report (D D M M M Y Y Y Y)

D. Is this a: (tick all that apply)		
	☐ Serious Adverse Event (any grade)	☐ Death. If died give date and time (24hr) of death (D D M M M Y Y Y Y H H M M)
	☐ Grade 3/4 Adverse event	

E. If SAE, by which criteria is the event considered to be serious? *Tick all that apply*

☐ Resulted in death (fatal) If fatal, where did the death occur: ☐ Hospital ☐ Home ☐ Other, specify……	☐ Persistent or significant disability or incapacity
☐ APPT>2.5 X ULN 1 hour post Sevuparin dose.	☐ Caused or prolonged hospitalisation (not elective hospitalisation for a pre-existing condition)
☐ Life threatening (actual risk of death at time of the event)	☐ Other important medical condition (a real, not hypothetical risk of, or requiring intervention to prevent, one of the outcomes listed above)

F. Were any of the following part of this event:

☐ Sudden decrease in oxygen saturations ☐ Yes ☐ No	☐ Evidence of gastric reflux/aspirate in the oropharynx ☐ Yes ☐ No
☐ De-novo coarse chest crepitations ☐ Yes ☐ No	

Event Name	Event Code	Start Date	End Date (tick if ongoing)	Grade
i.	.	D D M M M 2 0 2 Y	D D M M M 2 0 2 Y ☐	worst
ii.	.	D D M M M 2 0 2 Y	D D M M M 2 0 2 Y ☐	worst
iii.	.	D D M M M 2 0 2 Y	D D M M M 2 0 2 Y ☐	worst

2. DEATH (ONLY COMPLETE IF THE CHILD DIED)

A. **If the child died, what was the underlying cause of death in your opinion?** *Please explain and add code* . Death event code

_____

B. What was the relationship of the death to severe malaria?
☐ Definitely ☐ Probably ☐ Possibly ☐ Unlikely ☐ Unrelated

If Unlikely or Unrelated please give reasons:_____

3. RELATIONSHIP OF ADVERSE EVENT TO TRIAL INTERVENTION (COMPLETE FOR ALL EVENTS)

A. What is the relationship of the adverse event to the following:

i. Sevuparin	☐ Definitely	☐ Probably	☐ Possibly	☐ Unlikely	☐ Unrelated	☐ Can't assess	☐ N/A

SEVUSMART ID	Child's initials	Clinical/Hospital no
	Site: ☐ Kilifi ☐ Nchelenge	Date of form (D D M M M Y Y Y Y)

4. MEDICATIONS

A. Was the child taking any of the following medication at or within 30 days prior to the onset of the adverse event?
Please also list any additional drugs that the child was taking at or within 30 days of the onset of the adverse event

Concomitant Medication		Still taking at event onset?	Adverse event relationship to medication: Definitely/probably	Possibly	Unrelated/unlikely
i. Benzyl penicillin	☐ Yes ☐ No	☐ Yes ☐ No	☐	☐	☐
ii. Chloramphenicol	☐ Yes ☐ No	☐ Yes ☐ No	☐	☐	☐
iii. Paracetamol	☐ Yes ☐ No	☐ Yes ☐ No	☐	☐	☐
iv. Artesunate	☐ Yes ☐ No	☐ Yes ☐ No	☐	☐	☐
v. Ceftriaxone	☐ Yes ☐ No	☐ Yes ☐ No	☐	☐	☐
vi. Phenobarbitone	☐ Yes ☐ No	☐ Yes ☐ No	☐	☐	☐
vii. Diazepam	☐ Yes ☐ No	☐ Yes ☐ No	☐	☐	☐
viii. Sevuparin	☐ Yes ☐ No	☐ Yes ☐ No	☐	☐	☐
ix.		☐ Yes ☐ No	☐	☐	☐
x.		☐ Yes ☐ No	☐	☐	☐
xi.		☐ Yes ☐ No	☐	☐	☐

5. DESCRIPTION OF ADVERSE EVENT

A. Working Diagnosis .....

B. Clinical history, symptoms and signs .....

C. Clinical examination .....

D. Investigations: i. Malaria/RDT: | ii. Hb: | iii. WBC: | iv. Glucose: | v. Lactate: | vi. HIV:

vii. Other: .....

E. Management .....

F. Clinical Findings precipitating the event .....

	Name	Signature	Date
Form completed by (Dr/MO)			
Local RA notified by /on	☐ N/A		
To be completed by SEVUSMART Trial Coordinating Centre, Kilifi:			
Clinically reviewed by			

SEVUSMART	FORM 15: LOST TO FOLLOW UP & WITHDRAWAL	Page 1 of 1 v2.0 16-May-2023

SEVUSMART ID	Child's initials	Clinic/Hospital No
	Site: ☐ Kilifi ☐ Nchelenge	Date of form (D D M M M Y Y Y Y)

1. DETAILS OF LAST CONTACT WITH PATIENT

A. Date last seen in hospital/SEVUSMART clinic: (D D M M M Y Y Y Y)

B. Was this (tick one option below):

☐ During primary admission (absconded) | ☐ At discharge | ☐ 7 days (1 week) | ☐ 28 days (1 month) | ☐ Other - Specify ___ | ☐ Days ☐ Months

C. Date of last contact with SEVUSMART staff: (D D M M M Y Y Y Y) ☐ Telephone ☐ Home visit

2. DETAILS OF HOME VISIT

A. Date of this home visit: (D D M M M Y Y Y Y) ☐ N/A—no home visit

B. Was contact made with the patient at this visit?	☐ Yes	☐ No
C. Was contact made with anyone who could give information on the patient at this visit?	☐ Yes	☐ No

D. Why is the patient currently not attending clinic? (Tick <u>all</u> that apply)

☐ Moved to another area	☐ Transport problems	☐ No longer interested
☐ Moved to live with another carer/relative	☐ Work commitments of carer	☐ Child too ill to travel
☐ Social problems	☐ Died (complete Adverse Event Form 12)	
☐ Other, specify: _____		

E. Is the child/carer able to return to the clinic for regular assessment?	☐ Yes	☐ No
F. Does the patient definitely <u>not</u> intend to return for further SEVUSMART clinic visits?	☐ Yes	☐ No

3. CONSENT WITHDRAWAL

*If the child/carer no longer wants to attend further SEVUSMART visits, they can withdraw consent, with or without withdrawing consent for having future contact/medical records consulted to obtain clinical information for SEVUSMART. They should complete and sign a **Withdrawal of Consent Form**. Please record their decision below.*

A. Date Withdrawal of Consent Form signed: ☐ N/A—withdrawal not signed

B. Consent withdrawal (tick ONE):

☐ No longer wish to continue in the study or to attend SEVUSMART follow up visits but agree to be contacted in future (home visits or by telephone)

☐ No longer wish to continue in the study or to attend SEVUSMART follow up visits but agree to medical records being consulted in future to obtain clinical information for SEVUSMART.

☐ No longer wish to continue in the study or to attend SEVUSMART follow up visits and do not agree to being contacted in the future or to my child's medical records being consulted in future to obtain clinical information for SEVUSMART.

C. Reason (s) for withdrawal of consent (tick <u>all</u> that apply)

☐ Moved to another area	☐ Transport problems	☐ No longer interested
☐ Moved to live with another carer/relative	☐ Work commitments of carer	☐ Child too ill to travel
☐ Social problems	☐ Unwilling to disclose reason	
☐ Other, specify: _____		

Completed by: Name	Signature	Date
		(D D M M M Y Y Y Y)

SEVUSMART ID	Child's initials	Clinic/Hospital No
	Site: ☐ Kilifi ☐ Nchelenge	Date of form (D D M M M Y Y Y Y)

1. CLINICAL DETAILS AT RE-ADMISSION

A. Clinical History of THIS illness	Please tick ONE box per question		
	Yes	No	Don't Know
i. History of fever	☐	☐	☐
ii. If yes, duration of fever	☐☐☐ Days		
iii. History of cough	☐	☐	☐
iv. Increased work of breathing (in-drawing or deep breathing)	☐	☐	☐
v. Vomiting	☐	☐	☐
vi. Diarrhoea (> 3 loose motions in last 24hours)	☐	☐	☐
vii. If diarrhoea = yes, is this bloody	☐	☐	☐
viii. Haemoglobinuria (red or cola coloured urine)	☐	☐	☐
ix. If haemoglobinuria = yes, when did it start	☐☐ days ago		
x. Seizures in this illness	☐	☐	☐
xi. If yes, lasting more than 30 minutes	☐	☐	☐
xii. Inability to sit up right unsupported (prostrate)	☐	☐	☐
B. Treatment in THIS illness	**Yes**	**No**	**Don't Know**
i. Admitted for over 24 hours into another hospital	☐	☐	☐
ii. Number of doses of IV or IM quinine /artesunate	☐☐ Doses		
iii. Received oral anti-malarials in the last week?	☐	☐	☐
iv. Received an anticonvulsant prior to admission	☐	☐	☐
v. If yes,	☐ Phenobarbitone	☐ Diazepam	☐ Don't know
vi. If phenobarbitone or diazepam, what was the route of administration?	☐ Oral	☐ I.M ☐	☐ I.V
vii. Received oral antibiotics in last week	☐	☐	☐

C. Clinical examination	Please tick ONE box per question		
i. Airway maintained?	☐ Spontaneously	☐ with positioning	☐ with adjunct (guedel)
ii. Shallow / irregular breathing?	☐ Yes	☐ No	☐ Not assessed
iii. In-drawing	☐ Yes	☐ No	☐ Not assessed
iv. Deep breathing	☐ Yes	☐ No	☐ Not assessed
v. Crackles	☐ Unilateral	☐ Bilateral	☐ None ☐ Not assessed
vi. Sunken eyes	☐ Yes	☐ No	☐ Not assessed
vii. Decreased skin turgor	☐ Yes	☐ No	☐ Not assessed

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1. CLINICAL DETAILS AT RE-ADMISSION CONT.

C. Clinical examination continued	Please tick ONE box per question		
viii. Cold hands or feet only	☐ Yes	☐ No	☐ Not assessed
ix. Liver size >2cm below costal margin	☐ Yes	☐ No	☐ Not assessed
x. Splenomegaly (gross ≥ 5 cm)	☐ Not palpable	☐ Enlarged	☐ Gross
xi. Jaundice	☐ Yes	☐ No	☐ Not assessed
xii. Very severe wasting	☐ Yes	☐ No	☐ Not assessed
xiii. Signs of kwashiorkor (symmetrical oedema)	☐ None	☐ Pretibial	☐ Hands/legs ☐ Generalised
xiv. Generalised lymphadenopathy	☐ Yes	☐ No	☐ Not assessed
xv. Flaky paint dermatitis	☐ Yes	☐ No	☐ Not assessed
xvi. Oral candidiasis	☐ Yes	☐ No	☐ Not assessed
D. Neurological	*Please tick ONE box per question*		
i. Inability to sit up right unsupported (prostrate)	☐ Yes	☐ No	☐ Not assessed
ii. Is the child fitting currently	☐ Yes	☐ No	☐ Not assessed
iii. Neck stiffness	☐ Yes	☐ No	☐ Not assessed
iv. Bulging Fontenelle (infants only)	☐ Yes	☐ No	☐ Not assessed
v. Pupil symmetry	☐ Equal	☐ Unequal	
vi. Divergent gaze	☐ Yes	☐ No	☐ Not assessed
vii. Abnormal motor posturing	☐ Yes	☐ No	☐ Not assessed
viii. Does the child have bruxism? (grinding teeth)	☐ Yes	☐ No	☐ Not assessed
E. Blantyre Coma Scale	*Please tick ONE box per question*		
ii. Eyes (are eye movements directed)	☐ Not directed	☐ Directed	-
iii. Motor (response to pain)	☐ No response	☐ Withdraws	☐ Localizes pain
iv. Verbal	☐ No response	☐ Moan only	☐ Meaningful cry

2. BLOOD TESTS AT RE-ADMISSION

A. Blood tests and bedside test results:

Test	Results	Not done	Initials of person completing
i. Malaria Blood Film	☐ Positive ☐ Negative ☐ Invalid	☐	
If positive: *Tick all that apply.*	☐ *P. falciparum* ☐ *P. malariae* ☐ *P. ovale* ☐ *P. vivax*	☐	
If the slide is positive:	Parasite count ☐ per 200 WBC ☐ per 500 RBC ☐ per 1000 RBC		
ii. Haemoglobin	• g/dL	☐	
iii. Glucose	• mmol/L	☐	
Iv. Lactate	• mmol/L	☐	

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5. WORKING DIAGNOSIS

A. What is the working (initial) diagnosis for this patient? *Tick all that apply*

☐ Severe malaria	☐ Developmental delay/cerebral palsy	☐ Tuberculosis - all types
☐ Sepsis/septicaemia	☐ Recurrent haemoglobinuria	☐ Hepatitis
☐ LRTI - all types	☐ Encephalopathy	☐ Gastroenteritis (>3 watery stools/24hr)
☐ URTI - all types	☐ Meningitis - all types	☐ Urinary tract infection
☐ Other chest syndrome	☐ Sickle cell anaemia	☐ Pyrexia of unknown origin
☐ Severe anaemia (Hb <6g/dL)	☐ Sickle cell crisis	☐ Haemoglobinuria
☐ Malnutrition	☐ HIV/AIDS	

☐ Other; provide further details: _____

Completed by (Doctor): Name	Signature	Date
		D D M M M Y Y Y Y