Save the Children.

ITIP 2	VISIT 2	Page No
	ENROLLMENT	7

Participant Number T 2 – ___ – _____ **Visit date** DD/MMM/YYYY

Informed Consent

Staff initials: ___

Date and time of informed consent:	DD/MMM/YYYY HH:MM	1
Consented at:	1 KCH 2 Bwaila	2

Vaccination, Vitamin A and Deworming History

Staff initials: ___

At Birth

	Yes	No	Unknown		
BCG:	1	2	99	Date: DD/MMM/YYYY	3
OPV (0):	1	2	99	Date: DD/MMM/YYYY	4

6 Weeks

	Yes	No	Unknown		
OPV (1):	1	2	99	Date: DD/MMM/YYYY	5
Pentavalent (1):	1	2	99	Date: DD/MMM/YYYY	6
Pneumococcal (1):	1	2	99	Date: DD/MMM/YYYY	7
Rotavirus (1):	1	2	99	Date: DD/MMM/YYYY	8

10 Weeks 66 Not Applicable 9

	Yes	No	Unknown		
OPV (2):	1	2	99	Date: DD/MMM/YYYY	10
Pentavalent (2):	1	2	99	Date: DD/MMM/YYYY	11
Pneumococcal (2):	1	2	99	Date: DD/MMM/YYYY	12
Rotavirus (2):	1	2	99	Date: DD/MMM/YYYY	13

14 Weeks 66 Not Applicable 14

	Yes	No	Unknown		
OPV (3):	1	2	99	Date: DD/MMM/YYYY	15
Pentavalent (3):	1	2	99	Date: DD/MMM/YYYY	16
Pneumococcal (3):	1	2	99	Date: DD/MMM/YYYY	17

9 Months 66 Not Applicable 18

	Yes	No	Unknown		
Measles:	1	2	99	Date: DD/MMM/YYYY	19

Additional Vaccinations

Any additional vaccination(s):	1 Yes 2 No 99 Unknown	20
Description: _____	Date: DD/MMM/YYYY	21
Description: _____	Date: DD/MMM/YYYY	22
Description: _____	Date: DD/MMM/YYYY	23
Vitamin A supplement given in last 6 months:	1 Yes 2 No 99 Unknown 66 Not applicable	24
Date of last vitamin A:	DD/MMM/YYYY	25
Deworming done in last 6 months:	1 Yes 2 No 99 Unknown 66 Not applicable	26
Date of last deworming:	DD/MMM/YYYY	27

Participant Number

T 2 – ___ – ___

Socio-Demographics

Staff initials: ___

Age of mother:	___ years ***OR*** 99 Unknown	1
Mother`s highest level of education:	1 Primary; 2 Secondary; 3 Tertiary; 4 None; 99 Unknown	2
Father`s highest level of education:	1 Primary; 2 Secondary; 3 Tertiary; 4 None; 99 Unknown	3
Parents` monthly income:	MK___ ***OR*** 99 Unknown	4

Environmental Exposure

Staff initials: ___

How many children aged 0-10 years (including study child) live in the same household:	___ **OR** 99 Unknown	5
Does this child attend out of home care (nursery/preschool/family care/crèche)?	1 Yes; 2 No; 99 Unknown	6
Do any children in the home other than the child attend out of home care (nursery/preschool/family care/crèche)?	1 Yes; 2 No; 99 Unknown	7
Does anyone who lives in the same household as the child smoke cigarettes?	1 Yes; 2 No; 99 Unknown	8
What is the main source of drinking water?	1 Piped water (inside); 2 Piped water (outside); 3 Tube/Deep tube well; 4 Surface well/other well; 5 Surface water*; 6 Bottled/filtered water; 55 Other; specify: _____; 99 Unknown	9
In the last 24 hours, have you used soap and water to wash your hands?	1 Yes; 2 No	10
Does this child sleep under a mosquito net?	1 Always; 2 Usually; 3 Sometimes; 4 Never; 99 Unknown	11
Is there cooking/heating that produces smoke in the household?	1 Yes; 2 No; 99 Unknown	12
Is anyone with active tuberculosis disease residing in or visiting the same household as the child?	1 Yes; 2 No; 99 Unknown	13

* Pond/tank/lake/ river/stream

Save the Children.

ITIP 2	VISIT 2	Page No
	ENROLLMENT	9

Participant Number

T 2 – ___ – _____

Respondent Assessment

Staff initials: ___

Fast/difficult breathing:	1 Yes	2 No	99 Unknown	1
Chest-indrawing:	1 Yes	2 No	99 Unknown	2
Lethargy:	1 Yes	2 No	99 Unknown	3
Feeling cold to the touch:	1 Yes	2 No	99 Unknown	4
Poor feeding:	1 Yes	2 No	99 Unknown	5
Vomiting:	1 Yes	2 No	99 Unknown	6
Diarrhoea:	1 Yes	2 No	99 Unknown	7
If Yes; how many episodes:	___ in ___ days			8
Nasal blockage:	1 Yes	2 No	99 Unknown	9
Runny nose:	1 Yes	2 No	99 Unknown	10
Measles in the last 3 months:	1 Yes	2 No	99 Unknown	11
Currently breastfeeding:	1 Yes	2 No	99 Unknown	12
If Yes; exclusive breastfeeding:	1 Yes 2 No, complementary feeding started at ___ months 99 Unknown	66 Not applicable		13
If No; was the child breastfed:	1 Yes, complementary feeding started at ___ months 2 No 99 Unknown	66 Not applicable		14

Physical Examination

Staff initials: ___

Time of examination	HH:MM			15
Respiratory rate:	___ breaths/min	Oxygen saturation	___ %	16
Pulse rate:	___ beats/min	Axillary temperature:	___.___ °C	17

Interviewer Details

Interviewer signature: _____ Date: DD/MMM/YYYY 18

Staff initials: ___ 19

Participant Number T 2 – ___ – _____ **Visit date** DD/MM/YYYY

General Information

Staff initials: ___

Start time of visit:	HH:MM	1
Follow-up location:	1 KCH inpatient 2 KCH outpatient 3 Home 55 Other; please specify: _____	2
Relationship of respondent:	1 Mother 2 Father 55 Other; please specify: _____	3
Adult respondent's statement - "Since the last visit the child is":	1 Improving 2 Not changed 3 Deteriorating 99 Unknown	4

Physical Examination

Staff initials: ___

Respiratory rate:	___ breaths/min	Oxygen saturation	___ %	5
Pulse rate:	___ beats/min	Axillary temperature:	___.___ °C	6

Respondent Assessment

Staff initials: ___

Since the last visit, did the child have the following symptoms?

Fever:	1 Yes	2 No	99 Unknown	7
Cough:	1 Yes	2 No	99 Unknown	8
Fast/difficult breathing:	1 Yes	2 No	99 Unknown	9
Chest-indrawing:	1 Yes	2 No	99 Unknown	10
Lethargy:	1 Yes	2 No	99 Unknown	11
Feeling cold to the touch:	1 Yes	2 No	99 Unknown	12
Poor feeding:	1 Yes	2 No	99 Unknown	13
Vomiting:	1 Yes	2 No	99 Unknown	14
Diarrhoea:	1 Yes	2 No	99 Unknown	15
If Yes; how many episodes:	___ in ___ days			16
Nasal blockage:	1 Yes	2 No	99 Unknown	17
Runny nose:	1 Yes	2 No	99 Unknown	18

Participant Number

T 2 – ___ – _____

Clinician Assessment

Staff initials: ___

Does the child currently have the following symptoms?

Cough:	1 Yes	2 No	99 Unknown	2
Fast/difficult breathing:	1 Yes	2 No	99 Unknown	3
Chest-indrawing:	1 Yes	2 No	99 Unknown	4
Feeling cold to the touch*:	1 Yes	2 No	99 Unknown	5
Signs of dehydration*:	1 Yes	2 No	99 Unknown	6
Poor feeding:	1 Yes	2 No	99 Unknown	7
Diarrhoea:	1 Yes	2 No	99 Unknown	8
Nasal blockage:	1 Yes	2 No	99 Unknown	9
Runny nose:	1 Yes	2 No	99 Unknown	10

* If not currently hospitalized, please refer to hospital for further evaluation

Danger Signs and Treatment Failure Criteria

Staff initials: ___

Danger Signs*

Convulsions:	1 No convulsion	2 Reported convulsion (within 24 hours)	11
	3 Observed convulsion (now)		
Lethargic or unconscious:	1 Yes	2 No	12
Unable to drink or feed:	1 Yes	2 No	13
Vomits everything:	1 Yes	2 No	14
Stridor in calm child:	1 Yes	2 No	15

Respiratory Distress*

Grunting:	1 Yes	2 No	16
Nasal flaring:	1 Yes	2 No	17
Head nodding:	1 Yes	2 No	18
Severe chest-indrawing:	1 Yes	2 No	19
Other:	1 Yes	2 No	20
If Other; specify:	_____		21

* If not currently hospitalized, please refer to hospital for further evaluation

Participant Number

T 2 – ___ – _____

Danger Signs and Treatment Failure Criteria (Continued)

Other

Hypoxia (SaO_2 <90%):	1 Yes	2 No	1
Missing 3 or more doses due to vomiting:	1 Yes	2 No	2
Change in antibiotics:	1 Yes	2 No	3
Death:	1 Yes	2 No	4

Referral to Hospital

Staff initials: ___

If child is not in the hospital and required referral, was child referred?	1 Yes	2 No	3 In hospital	66 Not applicable	5
If No; specify:	_____				6

Interviewer Details

Interviewer signature: _____ Date: DD/MM/YYYY 7

Staff initials: ___ 8

Participant Number T 2 – ___ – ___ **Visit date** DD/MM/YYYY

General Information

Staff initials: ___

Start time of visit:	HH:MM	1
Follow-up location:	1 KCH inpatient 2 KCH outpatient 3 Home 55 Other; please specify: ___	2
Relationship of respondent:	1 Mother 2 Father 55 Other; please specify: ___	3
Adult respondent's statement - "Since the last visit the child is":	1 Improving 2 Not changed 3 Deteriorating 99 Unknown	4

Physical Examination

Staff initials: ___

Respiratory rate:	___ breaths/min	Oxygen saturation	___ %	5
Pulse rate:	___ beats/min	Axillary temperature:	___.___ °C	6

Respondent Assessment

Staff initials: ___

Since the last visit, did the child have the following symptoms?

Fever:	1 Yes	2 No	99 Unknown	7
Cough:	1 Yes	2 No	99 Unknown	8
Fast/difficult breathing:	1 Yes	2 No	99 Unknown	9
Chest-indrawing:	1 Yes	2 No	99 Unknown	10
Lethargy:	1 Yes	2 No	99 Unknown	11
Feeling cold to the touch:	1 Yes	2 No	99 Unknown	12
Poor feeding:	1 Yes	2 No	99 Unknown	13
Vomiting:	1 Yes	2 No	99 Unknown	14
Diarrhoea:	1 Yes	2 No	99 Unknown	15
If Yes; how many episodes:	___ in ___ days			16
Nasal blockage:	1 Yes	2 No	99 Unknown	17
Runny nose:	1 Yes	2 No	99 Unknown	18

Participant Number

T 2 – ___ – _____

Clinician Assessment

Staff initials: ___

Does the child currently have the following symptoms?

Cough:	1 Yes	2 No	99 Unknown	2
Fast/difficult breathing:	1 Yes	2 No	99 Unknown	3
Chest-indrawing:	1 Yes	2 No	99 Unknown	4
Feeling cold to the touch:	1 Yes	2 No	99 Unknown	5
Signs of dehydration:	1 Yes	2 No	99 Unknown	6
Poor feeding:	1 Yes	2 No	99 Unknown	7
Diarrhoea:	1 Yes	2 No	99 Unknown	8
Nasal blockage:	1 Yes	2 No	99 Unknown	9
Runny nose:	1 Yes	2 No	99 Unknown	10

Danger Signs and Treatment Failure Criteria

Staff initials: ___

Danger Signs*

Convulsions:	1 No convulsion	2 Reported convulsion (within 24 hours)	11
	3 Observed convulsion (now)		
Lethargic or unconscious:	1 Yes	2 No	12
Unable to drink or feed:	1 Yes	2 No	13
Vomits everything:	1 Yes	2 No	14
Stridor in calm child:	1 Yes	2 No	15

Respiratory Distress*

Grunting:	1 Yes	2 No	16
Nasal flaring:	1 Yes	2 No	17
Head nodding:	1 Yes	2 No	18
Severe chest-indrawing:	1 Yes	2 No	19
Other:	1 Yes	2 No	20
If Other; specify:	_____		21

* If not currently hospitalized, please refer to hospital for further evaluation

Participant Number

T 2 – ___ – _____

Danger Signs and Treatment Failure Criteria (Continued)

Other

Hypoxia (SaO_2 <90%):	1 Yes	2 No	1
Missing 3 or more doses due to vomiting:	1 Yes	2 No	2
Change in antibiotics:	1 Yes	2 No	3
Documented axillary temperature ≥ 38 ºC with chest-indrawing:	1 Yes	2 No	4
Death:	1 Yes	2 No	5

Referral to Hospital

Staff initials: ___

If child is not in the hospital and required referral, was child referred?	1 Yes	2 No	3 In hospital	66 Not applicable	6
If No; specify:	_____				7

Interviewer Details

Interviewer signature: _____ Date: DD/MM/YYYY 8

Staff initials: ___ 9

Participant Number T 2 – ___ – _____ **Visit date** DD/MM/YYYY

General Information

Staff initials: ___

Start time of visit:	HH:MM	1
Follow-up location:	1 KCH inpatient 2 KCH outpatient 3 Home 55 Other; please specify: _____	2
Relationship of respondent:	1 Mother 2 Father 55 Other; please specify: _____	3
Adult respondent's statement - "Since the last visit the child is":	1 Improving 2 Not changed 3 Deteriorating 99 Unknown	4

Physical Examination

Staff initials: ___

Respiratory rate:	___ breaths/min	Oxygen saturation	___ %	5
Pulse rate:	___ beats/min	Axillary temperature:	___.___ °C	6

Respondent Assessment

Staff initials: ___

Since the last visit, did the child have the following symptoms?

Fever:	1 Yes	2 No	99 Unknown	7
Cough:	1 Yes	2 No	99 Unknown	8
Fast/difficult breathing:	1 Yes	2 No	99 Unknown	9
Chest-indrawing:	1 Yes	2 No	99 Unknown	10
Lethargy:	1 Yes	2 No	99 Unknown	11
Feeling cold to the touch:	1 Yes	2 No	99 Unknown	12
Poor feeding:	1 Yes	2 No	99 Unknown	13
Vomiting:	1 Yes	2 No	99 Unknown	14
Diarrhoea:	1 Yes	2 No	99 Unknown	15
If Yes; how many episodes:	___ in ___ days			16
Nasal blockage:	1 Yes	2 No	99 Unknown	17
Runny nose:	1 Yes	2 No	99 Unknown	18

Participant Number

T 2 – ___ – _____

Clinician Assessment

Staff initials: ___

Does the child currently have the following symptoms?

Cough:	1 Yes	2 No	99 Unknown	2
Fast/difficult breathing:	1 Yes	2 No	99 Unknown	3
Chest-indrawing*:	1 Yes	2 No	99 Unknown	4
Feeling cold to the touch:	1 Yes	2 No	99 Unknown	5
Signs of dehydration:	1 Yes	2 No	99 Unknown	6
Poor feeding:	1 Yes	2 No	99 Unknown	7
Diarrhoea:	1 Yes	2 No	99 Unknown	8
Nasal blockage:	1 Yes	2 No	99 Unknown	9
Runny nose:	1 Yes	2 No	99 Unknown	10

* If not currently hospitalized, please refer to hospital for further evaluation

Danger Signs and Treatment Failure Criteria

Staff initials: ___

Danger Signs*

Convulsions:	1 No convulsion	2 Reported convulsion (within 24 hours)	11
	3 Observed convulsion (now)		
Lethargic or unconscious:	1 Yes	2 No	12
Unable to drink or feed:	1 Yes	2 No	13
Vomits everything:	1 Yes	2 No	14
Stridor in calm child:	1 Yes	2 No	15

Respiratory Distress*

Grunting:	1 Yes	2 No	16
Nasal flaring:	1 Yes	2 No	17
Head nodding:	1 Yes	2 No	18
Severe chest-indrawing:	1 Yes	2 No	19
Other:	1 Yes	2 No	20
If Other; specify:	_____		21

* If not currently hospitalized, please refer to hospital for further evaluation

Participant Number

T 2 – ___ – _____

Danger Signs and Treatment Failure Criteria (Continued)

Other

Hypoxia (SaO_2 <90%):	1 Yes	2 No	1
Missing 3 or more doses due to vomiting:	1 Yes	2 No	2
Change in antibiotics:	1 Yes	2 No	3
Persistence of chest-indrawing:	1 Yes	2 No	4
Axillary temperature ≥ 38 ºC:	1 Yes	2 No	5
Death:	1 Yes	2 No	6

Referral to Hospital

Staff initials: ___

If child is not in the hospital and required referral, was child referred?	1 Yes	2 No	3 In hospital	66 Not applicable	7
If No; specify:	_____				8

Interviewer Details

Interviewer signature: _____ Date: DD/MM/YYYY 9

Staff initials: ___ 10

Participant Number T 2 – ___ – ___ **Visit date** DD/MM/YYYY

General Information

Staff initials: ___

Start time of visit:	HH:MM	1
Follow-up location:	1 KCH inpatient 2 KCH outpatient 3 Home 55 Other; please specify: ___	2
Relationship of respondent:	1 Mother 2 Father 55 Other; please specify: ___	3
Adult respondent's statement - "Since the last visit the child is":	1 Improving 2 Not changed 3 Deteriorating 99 Unknown	4

Physical Examination

Staff initials: ___

Respiratory rate:	___ breaths/min	Oxygen saturation	___ %	5
Pulse rate:	___ beats/min	Axillary temperature:	___.___ °C	6

Respondent Assessment

Staff initials: ___

Since the last visit, did the child have the following symptoms?

Fever:	1 Yes	2 No	99 Unknown	7
Cough:	1 Yes	2 No	99 Unknown	8
Fast/difficult breathing:	1 Yes	2 No	99 Unknown	9
Chest-indrawing:	1 Yes	2 No	99 Unknown	10
Lethargy:	1 Yes	2 No	99 Unknown	11
Feeling cold to the touch:	1 Yes	2 No	99 Unknown	12
Poor feeding:	1 Yes	2 No	99 Unknown	13
Vomiting:	1 Yes	2 No	99 Unknown	14
Diarrhoea:	1 Yes	2 No	99 Unknown	15
If Yes; how many episodes:	___ in ___ days			16
Nasal blockage:	1 Yes	2 No	99 Unknown	17
Runny nose:	1 Yes	2 No	99 Unknown	18

Participant Number

T 2 – ___ – _____

Clinician Assessment

Staff initials: ___

Does the child currently have the following symptoms?

Cough:	1 Yes	2 No	99 Unknown	2
Fast/difficult breathing:	1 Yes	2 No	99 Unknown	3
Chest-indrawing*:	1 Yes	2 No	99 Unknown	4
Feeling cold to the touch:	1 Yes	2 No	99 Unknown	5
Signs of dehydration:	1 Yes	2 No	99 Unknown	6
Poor feeding:	1 Yes	2 No	99 Unknown	7
Diarrhoea:	1 Yes	2 No	99 Unknown	8
Nasal blockage:	1 Yes	2 No	99 Unknown	9
Runny nose:	1 Yes	2 No	99 Unknown	10

* If not currently hospitalized, please refer to hospital for further evaluation

Clinical Relapse Criteria

Staff initials: ___

Danger Signs*

Convulsions:	1 No convulsion	2 Reported convulsion (within 24 hours)	11
	3 Observed convulsion (now)		
Lethargic or unconscious:	1 Yes	2 No	12
Unable to drink or feed:	1 Yes	2 No	13
Vomits everything:	1 Yes	2 No	14

Respiratory Distress*

Grunting:	1 Yes	2 No	15
Nasal flaring:	1 Yes	2 No	16
Head nodding:	1 Yes	2 No	17
Severe chest-indrawing:	1 Yes	2 No	18
Other:	1 Yes	2 No	19
If Other; specify:	_____		20

Participant Number

T 2 – ___ – _____

Clinical Relapse Criteria (Continued)

Other

Hypoxia (SaO_2 <90%):	1 Yes	2 No	1
Fever (Axillary temperature ≥ 38 ºC):	1 Yes	2 No	2
Recurrence of signs of chest-indrawing pneumonia:	1 Yes	2 No	3
Other severe disease:	1 Yes	2 No	4
If Yes; specify:	_____		5
Death:	1 Yes	2 No	6

* If not currently hospitalized, please refer to hospital for further evaluation

Referral to Hospital

Staff initials: ___

If child is not in the hospital and required referral, was child referred?	1 Yes	2 No	3 In hospital	66 Not applicable	7
If No; specify:	_____				8

Clinical Outcome

Staff initials: ___

Clinical outcome after 14 days from diagnosis:	1 Clinically cured	
	1 Failed initial antibiotic treatment regimen	
	2 Did not fail initial antibiotic treatment regimen	
	2 Not cured	9
	1 Improving	
	2 Deteriorating	
	3 Stable (Prognosis unclear)	
	55 Other; please specify: _____	

Interviewer Details

Interviewer signature: _____ Date: DD/MM/YYYY 10

Staff initials: ___ 11

Study Product Log

Staff initials: ___

First dose administered by: 1 Study staff 2 KCH staff 3 Caregiver 1

First dose administered at: HH:MM 2

Randomization number: R ___ – _____ – ___ Pharmacist: _____ Verified by: _____ 3

Number of tablets dispensed at enrolment: ___ 4

Day	Treatment number	Dose **successfully**[$] administered: Yes	No	Unknown	Number of **doses**[#] attempted	Reason dose not administered:	Did the child vomit within 30 minutes of a dose? Yes	No	Un-known	N/A	Number of **doses**[#] where child vomited within 30 minutes	Docu-mented by:	
1	1	1	2	99	__ 66 N/A		1	2	99	66	__ 66 N/A	_____	5
	2	1	2	99	__ 66 N/A		1	2	99	66	__ 66 N/A	_____	6
2	1	1	2	99	__ 66 N/A		1	2	99	66	__ 66 N/A	_____	7
	2	1	2	99	__ 66 N/A		1	2	99	66	__ 66 N/A	_____	8
3	1	1	2	99	__ 66 N/A		1	2	99	66	__ 66 N/A	_____	9
	2	1	2	99	__ 66 N/A		1	2	99	66	__ 66 N/A	_____	10
4	1	1	2	99	__ 66 N/A		1	2	99	66	__ 66 N/A	_____	11
	2	1	2	99	__ 66 N/A		1	2	99	66	__ 66 N/A	_____	12
5	1	1	2	99	__ 66 N/A		1	2	99	66	__ 66 N/A	_____	13
	2	1	2	99	__ 66 N/A		1	2	99	66	__ 66 N/A	_____	14

Number of replacement tablets dispensed: ___ on DD/MM/YYYY 66 Not applicable Pharmacist: _____ 10

Number of replacement tablets dispensed: ___ on DD/MM/YYYY 66 Not applicable Pharmacist: _____ 12

Number of tablets returned: ___ 99 Unknown 66 Not applicable Clinic staff: _____ Pharmacist: _____ 13

All blister packs returned? 1 Yes 2 No 18

Reason why study product not returned: _____ 19

[$] ***Successful administration includes doses that were swallowed, but where vomiting occurred afterwards***

[#] ***Please record the number of the doses, NOT the number of tablets***

Hospitalization Log

Staff initials: ___

No	Admission date and time	Discharge date and time	Reason for admission	* Specify
1	DD/MM/YYYY HH:MM	DD/MM/YYYY HH:MM **OR** 1 Ongoing	1 Protocol specified 2 Severe pneumonia 3 Malaria 4 Severe diarrhoea 5 WHO danger sign* 55 Other*	1
2	DD/MM/YYYY HH:MM	DD/MM/YYYY HH:MM **OR** 1 Ongoing	1 Protocol specified 2 Severe pneumonia 3 Malaria 4 Severe diarrhoea 5 WHO danger sign* 55 Other*	2
3	DD/MM/YYYY HH:MM	DD/MM/YYYY HH:MM **OR** 1 Ongoing	1 Protocol specified 2 Severe pneumonia 3 Malaria 4 Severe diarrhoea 5 WHO danger sign* 55 Other*	3
4	DD/MM/YYYY HH:MM	DD/MM/YYYY HH:MM **OR** 1 Ongoing	1 Protocol specified 2 Severe pneumonia 3 Malaria 4 Severe diarrhoea 5 WHO danger sign* 55 Other*	4
5	DD/MM/YYYY HH:MM	DD/MM/YYYY HH:MM **OR** 1 Ongoing	1 Protocol specified 2 Severe pneumonia 3 Malaria 4 Severe diarrhoea 5 WHO danger sign* 55 Other*	5
6	DD/MM/YYYY HH:MM	DD/MM/YYYY HH:MM **OR** 1 Ongoing	1 Protocol specified 2 Severe pneumonia 3 Malaria 4 Severe diarrhoea 5 WHO danger sign* 55 Other*	6
7	DD/MM/YYYY HH:MM	DD/MM/YYYY HH:MM **OR** 1 Ongoing	1 Protocol specified 2 Severe pneumonia 3 Malaria 4 Severe diarrhoea 5 WHO danger sign* 55 Other*	7
8	DD/MM/YYYY HH:MM	DD/MM/YYYY HH:MM **OR** 1 Ongoing	1 Protocol specified 2 Severe pneumonia 3 Malaria 4 Severe diarrhoea 5 WHO danger sign* 55 Other*	8
9	DD/MM/YYYY HH:MM	DD/MM/YYYY HH:MM **OR** 1 Ongoing	1 Protocol specified 2 Severe pneumonia 3 Malaria 4 Severe diarrhoea 5 WHO danger sign* 55 Other*	9
10	DD/MM/YYYY HH:MM	DD/MM/YYYY HH:MM **OR** 1 Ongoing	1 Protocol specified 2 Severe pneumonia 3 Malaria 4 Severe diarrhoea 5 WHO danger sign* 55 Other*	10

Adverse Events

Staff initials: ___

Did the child experience any adverse events during the study? 1 Yes 2 No 1

If "Yes"; please record details of all adverse events below (using one line per event):

No	Adverse event description	Start Date	Stop Date	Outcome[a]	Therapy[b] *(List all that apply)*	Relation-ship[c]	DAIDS Grading[d]	Serious-ness[e]	
1		DD/MM/YYYY	DD/MM/YYYY ***OR*** 1 Ongoing[f]		*Specify:_____				2
2		DD/MM/YYYY	DD/MM/YYYY ***OR*** 1 Ongoing[f]		*Specify:_____				3
3		DD/MM/YYYY	DD/MM/YYYY ***OR*** 1 Ongoing[f]		*Specify:_____				4
4		DD/MM/YYYY	DD/MM/YYYY ***OR*** 1 Ongoing[f]		*Specify:_____				5

[a]Outcome:
1. Resolved
2. Continuing
3. Death
66. Not applicable
99. Unknown

[b]Therapy:
1. None
2 Antibiotics
3. Drug, other than antibiotics
55. Other*
99. Unknown
(All that apply)

[c]Relationship:
1. Certain
2. Probable
3. Possible
4. Probably not
5. Not related
6. Not assessable

[d]DAIDS Grading:
0. Grade 0
1. Grade 1
2. Grade 2
3. Grade 3
4. Grade 4
5. Grade 5

[e]Seriousness:
1. Not serious
2. Life-threatening
3. Persistent disability or incapacity
4. Hospitalization or prolongation of hospitalization
5. Death
6. Congenital anomalies of birth defects

[f] Ongoing at study exit

Is this the last adverse events page? 1 Yes 2 No

Is this the last adverse events page? 1 Yes 2 No

Concomitant Antibiotics

Staff initials: ___

Did the child take any concomitant antibiotics during the study period (from screening to the conclusion of participation)? 1 Yes 2 No 1

If "Yes"; please record details below (using one line per medication):

No	Medication[a]	Formulation[c]	Total daily dose	Route[b]	Start Date	Stop Date	Indication	
1					DD/MM/YYYY	DD/MM/YYYY OR 1 Ongoing		2
2					DD/MM/YYYY	DD/MM/YYYY OR 1 Ongoing		3
3					DD/MM/YYYY	DD/MM/YYYY OR 1 Ongoing		4
4					DD/MM/YYYY	DD/MM/YYYY OR 1 Ongoing		5
5					DD/MM/YYYY	DD/MM/YYYY OR 1 Ongoing		6

[a] Please use generic names for all products with a single active ingredient, and trade names for all combination products.

[b] **Route of Administration:**

1.	Topical	4.	Intramuscular	7.	Intranasal	10.	Into conjunctival sac
2.	Oral	5.	Intravenous	8.	Inhaled	11.	Per vagina
3.	Per rectum.	6.	Subcutaneous	9.	Into auditory meatus	55.	Other

[c] **Formulation:**

1.	Tablet	4.	Injectable	7.	Drops	10.	Suppository
2.	Capsule	5.	Cream	8.	Spray	55.	Other
3.	Suspension/Syrup	6.	Gel	9.	Inhalation		

Is this the last concomitant antibiotics page? 1 Yes 2 No

Prior and Concomitant Medications

Staff initials: ___

Did the child take any medication prior to enrolment (48hrs) or any concomitant medication during the study period (from screening to the conclusion of participation)? 1 Yes 2 No 1

If "Yes"; please record details below (using one line per medication):

No	Medication[a]	Formulation[c]	Total daily dose	Route[b]	Start Date	Stop Date	Indication	
1					DD/MMM/YYYY	DD/MMM/YYYY OR 1 Ongoing		2
2					DD/MMM/YYYY	DD/MMM/YYYY OR 1 Ongoing		3
3					DD/MMM/YYYY	DD/MMM/YYYY OR 1 Ongoing		4
4					DD/MMM/YYYY	DD/MMM/YYYY OR 1 Ongoing		5
5					DD/MMM/YYYY	DD/MMM/YYYY OR 1 Ongoing		6

[a] Please use generic names for all products with a single active ingredient, and trade names for all combination products.

[b] Route of Administration:

1.	Topical	4.	Intramuscular	7.	Intranasal	10.	Into conjunctival sac
2.	Oral	5.	Intravenous	8.	Inhaled	11.	Per vagina
3.	Per rectum.	6.	Subcutaneous	9.	Into auditory meatus	55.	Other

[c] Formulation:

1.	Tablet	4.	Injectable	7.	Drops	10.	Suppository
2.	Capsule	5.	Cream	8.	Spray	55.	Other
3.	Suspension/Syrup	6.	Gel	9.	Inhalation		

Is this the last concomitant medications page? 1 Yes 2 No

Explanatory Notes

66 Not applicable Staff initials: ___ 1

No	Page	Comment	Initials	
1				2
2				3
3				4
4				5
5				6

Missing Data

66 Not applicable Staff initials: ___ 7

No	Page	Missing data	Reason	Initials	
1					8
2					9
3					10
4					11
5					12

Is this the last explanatory notes and missing data page? 1 Yes 2 No

Participant Number

T 2 – ___ – _____

Conclusion of Participation

Staff initials: ___

Date of Conclusion of Participation:	DD/MM/YYYY	1
Child's status upon trial termination:	1 Completed 2 Drop-out	2
If "Drop-out", specify the primary reason for premature discontinuation from trial below (tick only one box):		
	1 Adverse event 2 Protocol non-compliance 3 Lost to follow-up 4 Death 5 Consent withdrawn 6 Sponsor decision 55 Other, specify: _____	3
Was the child referred to continued care?	1 Yes 2 No	4
If Yes; describe referral:	_____	5
Is the participation in the study noted in the child's health passport?	1 Yes 2 No	6
If No; please comment:	_____	7

Checklist

Staff initials: ___

Section		Number of pages/visits	
Unscheduled Visit (prior to Day 6)	66 Not applicable		8
Unscheduled Visit (post Day 6)	66 Not applicable		9
Additional Adverse Events	66 Not applicable		10
Additional Concomitant Antibiotics	66 Not applicable		11
Additional Concomitant Medications	66 Not applicable		12
Additional Explanatory Notes and/or Missing Data	66 Not applicable		13
Non-Compliance	66 Not applicable		14

Clinician Declaration

The information contained on this and the preceding pages, including the results of tests and evaluations performed, accurately reflects the medical records of this child.

Clinician signature: _____ Date: DD/MM/YYYY 15

Staff initials: ___ 16