

Participant ID: _____

Date of Visit: ____/____/____
DD MMM YYYYVisit Day: _____
Initials: _____**Adverse Event Form**

1. Date AE Reported to Site		2. Adverse Event			3. Onset Date	
____/____/____ DD MMM YYYY					____/____/____ DD MMM YYYY	
4. Visit AE Reported (check one box)						
V1.0 Day 1 <input type="checkbox"/>	V2.0 Day 8 <input type="checkbox"/>	V3.0 Day 29 <input type="checkbox"/>	V4.0 Day 181 <input type="checkbox"/>	V5.0 Day 730 <input type="checkbox"/>	Interim Visit <input type="checkbox"/> Interim Code	
5. AE Still Ongoing		Yes <input type="checkbox"/>	No * <input type="checkbox"/>	6. If "No", outcome date		____/____/____ DD MMM YYYY
7. Severity Grade		Grade 1 (mild) <input type="checkbox"/>	Grade 2 (moderate) <input type="checkbox"/>	Grade 3 (severe) <input type="checkbox"/>	Grade 4 (Potentially Life Threatening) <input type="checkbox"/>	Grade 5 (Death) <input type="checkbox"/>
8. Relationship to Study Product			Related <input type="checkbox"/>	Not Related <input type="checkbox"/> <i>(Provide alternate etiology)</i>	9. Alternate Etiology	
			Specify:			
10. Action Taken with Study Product		<input type="checkbox"/> No Change <input type="checkbox"/> Held <input type="checkbox"/> Permanently Discontinued <input type="checkbox"/> Not applicable				
11. Other Actions (mark "none" or all that apply)		<input type="checkbox"/> None <input type="checkbox"/> Medication(s) <input type="checkbox"/> Therapeutic procedure/surgery <input type="checkbox"/> Diagnostic procedure <input type="checkbox"/> Other <i>(specify)</i> _____ _____				
12. Status/Outcome		<input type="checkbox"/> Recovered/Resolved <input type="checkbox"/> Recovering/Resolving <input type="checkbox"/> Recovered/Resolved with Sequelae <input type="checkbox"/> Not Recovered/Not Resolved <input type="checkbox"/> Fatal <input type="checkbox"/> Unknown				

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13. Is This a Serious Adverse Event according to ICH/GCP or Protocol?	<input type="radio"/> Yes <i>(Go to box #14 and "Check all that apply")</i> <input type="radio"/> No <i>(Go to "Has or will AE be reported to DMID as a SAE")</i>	14. Check all that apply	
		Results in death	<input type="radio"/>
		Is life threatening	<input type="radio"/>
		Requires inpatient hospitalization or prolongation of existing hospitalization	<input type="radio"/>
		Results in persistent or significant disability/incapacity	<input type="radio"/>
		Is congenital anomaly/birth defect	<input type="radio"/>
		Is another serious important medical event that may jeopardize the patient require intervention to prevent one of the other outcomes listed above	<input type="radio"/>
13. Has or will this AE be reported to DMID as a SAE	<input type="radio"/> Yes <input type="radio"/> No	14. Date of SAE onset	
		____/____/____ DD MMM YYYY	
15. Does this AE meet criteria for Suspected Unexpected Serious Adverse Reaction (SUSAR)	<input type="radio"/> Yes <input type="radio"/> No	16. Event to be evaluated for halting criteria?	<input type="radio"/> Yes <input type="radio"/> No
17. Was this AE a worsening of a baseline medical condition?	<input type="radio"/> Yes <input type="radio"/> No		

Investigator Signature: _____

Date (dd/mmm/yyyy)

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CONCOMITANT MEDICATIONS

Medication Name	Taken for reported AE?	If "Yes", record AE *
	<input type="radio"/> Yes * <input type="radio"/> No	

Indication	Start Date	Date Stopped	Ongoing
	____/____/____ DD MMM YYYY	____/____/____ DD MMM YYYY	<input type="radio"/> Yes <input type="radio"/> No
Dose Units	Frequency	Route	
<input type="radio"/> Grams	<input type="radio"/> As needed	<input type="radio"/> Oral	
<input type="radio"/> Micrograms	<input type="radio"/> Daily	<input type="radio"/> Intramuscular	
<input type="radio"/> Milligrams	<input type="radio"/> 2 x day	<input type="radio"/> Intravenous	
<input type="radio"/> Milliliters	<input type="radio"/> 3 x day	<input type="radio"/> Topical	
<input type="radio"/> Capsules	<input type="radio"/> 4 x day	<input type="radio"/> Inhalation	
<input type="radio"/> Drops	<input type="radio"/> At hour of wake	<input type="radio"/> Vaginal	
<input type="radio"/> Puffs	<input type="radio"/> At hour of sleep	<input type="radio"/> Rectal	
<input type="radio"/> Sachets	<input type="radio"/> Once	<input type="radio"/> Subcutaneous	
<input type="radio"/> Suppository	<input type="radio"/> Other (Specify): _____	<input type="radio"/> Other (Specify): _____	
<input type="radio"/> Tablets			
<input type="radio"/> Units			
<input type="radio"/> Unknown			
<input type="radio"/> Other (Specify): _____			

Completed by: _____ Date (dd/mmm/yyyy)

Print

Signature

Participant ID:

Date of Visit: ____/____/____
DD MMM YYYYVisit Day:
Initials:**FOLLOW -UP VISIT SUMMARY**

DID THE PARTICIPANT COMPLETE THIS VISIT?	<input type="radio"/> Yes	<input type="radio"/> No (If "No", END FORM)
VISIT DATE	____/____/____ DD MMM YYYY	
DID THE PARTICIPANT EXIT/TERMINATE THE STUDY AT THIS VISIT?	<input type="radio"/> Yes (If "Yes", complete "Study Termination CRF") <input type="radio"/> No	
WERE ANY NEW ADVERSE EVENTS (AE'S) REPORTED AT THIS VISIT?	<input type="radio"/> Yes (If "Yes", update ADVERSE EVENT LOG) <input type="radio"/> No	
IS THE PATICIPANT TAKING ANY CONCOMITANT MEDICATIONS (or are there changes to previously reported medication) THAT HAVE NOT BEEN PREVIOUSLY REPORTED?	<input type="radio"/> Yes (If "Yes", update CONCOMITANT MEDICATION LOG) <input type="radio"/> No	
WERE ANY PROTOCOL DEVIATIONS REPORTED AT THIS VISIT?	<input type="radio"/> Yes (If "Yes", update PROTOCOL DEVIATIONS LOG) <input type="radio"/> No	
We any additional study procedures or forms completed?	SELECT ALL THAT APPLY	
	<input type="radio"/> Physical Examination	<input type="radio"/> Meningococcal Vaccine
	<input type="radio"/> Vital Signs	<input type="radio"/> Measles-Rubella Vaccine
	<input type="radio"/> Specimen Collection-Blood	<input type="radio"/> Yellow Fever Vaccine
	<input type="radio"/> Malaria Test Results	

Completed by: _____ Date (dd/mmm/yyyy)

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Participant ID: _____

Date of Visit: ____/____/____
DD MMM YYYYVisit Day: _____
Initials: _____**INTERIM VISIT SUMMARY**

Visit Date	____/____/____ DD MMM YYYY		INTERIM VISIT CODE:
DID THE PARTICIPANT EXIT/TERMINATE THE STUDY AT THIS VISIT?	<input type="radio"/> Yes	<input type="radio"/> No	
WERE ANY NEW ADVERSE EVENTS (AE'S) REPORTED AT THIS VISIT?	<input type="radio"/> Yes (If "Yes", update ADVERSE EVENT LOG)	<input type="radio"/> No	
IS THE PARTICIPANT TAKING ANY CONCOMITANT MEDICATIONS (<i>or are there changes to previously reported medication</i>) THAT HAVE NOT BEEN PREVIOUSLY REPORTED?	<input type="radio"/> Yes (If "Yes", update CONCOMITANT MEDICATION LOG)	<input type="radio"/> No	
WERE ANY PROTOCOL DEVIATIONS REPORTED AT THIS VISIT?	<input type="radio"/> Yes (If "Yes", update the PROTOCOL DEVIATION LOG)	<input type="radio"/> No	
WHAT WAS THE REASON FOR THIS INTERIM VISIT?	<i>Select all that apply</i>		
	<input type="radio"/> Adverse Event Report or Follow-up <input type="radio"/> Completion of missed visit procedures*(check below) <input type="radio"/> Other (Specify) : _____		
	<i>*If "Completion of missed visit procedures", for which visit are procedures being made up:</i> <input type="radio"/> V1.0 - Day 1 <input type="radio"/> V2.0 - Day 8 <input type="radio"/> V3.0 - Day 29 <input type="radio"/> V4.0 - Day 181 <input type="radio"/> V5.0 - Day 730		
WHAT STUDY PROCEDURES WERE COMPLETED AT THIS VISIT?	SELECT ALL THAT APPLY		
	<input type="radio"/> Physical Examination	<input type="radio"/> Specimen Collection- Blood	
	<input type="radio"/> Vital Signs	<input type="radio"/> Malaria Test Results	
	<input type="radio"/> Reactogenicity-Baseline/Early	<input type="radio"/> Meningococcal Vaccine	
	<input type="radio"/> Reactogenicity-Daily Log	<input type="radio"/> Measles-Rubella Vaccine	
	<input type="radio"/> Reactogenicity-Resolution Symptoms	<input type="radio"/> Yellow Fever Vaccine	

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Initials:

Participant ID:

Date of Visit: ____/____/____
DD MMM YYYY

Visit Day:
Initials:

INCLUSION EXCLUSION CRITERIA

Did the participant meet all eligibility criteria?	<input type="radio"/> Yes <input type="radio"/> No				
Eligibility Status (If "Eligible and Enrolled", or "Incomplete Screening", end of form.)	Eligible and Enrolled <input type="radio"/>	Eligible/Not Enrolled <input type="radio"/>	Ineligible <input type="radio"/>	Incomplete Screening <input type="radio"/>	Ineligible, but Enrolled <input type="radio"/>
Date participant was found "Eligible/Not Enrolled", "Ineligible" or "Incomplete Screening"	____/____/____ DD MMM YYYY				

Select reason(s) why participant is "Eligible/Not Enrolled" or "Ineligible"
<p>INCLUSION</p> <p><input type="checkbox"/> I 1. Male and female children between 9 months and 11 months old inclusive.</p> <p><input type="checkbox"/> I 2. Parent(s) legal guardian(s) have provided written informed consent, after the nature of the study has been explained according to local regulatory requirements.</p> <p><input type="checkbox"/> I 3. The investigator believes that their parent(s)/guardian(s) will be available for all the subjects visits And will comply the requirements of the protocol (e.g., timely reporting of adverse events).</p> <p><input type="checkbox"/> I 4. Individual is in good health as determined by medical history, physical examination, and clinical judgement of the investigator. (Note: the physical examination may have been performed on a separate screening day and will be considered valid if within 14 days of enrollment.</p> <p><input type="checkbox"/> I 5. Individual has completed their local infant EPI vaccines, not including 9-month EPI vaccines (at the 9-month visit) or 15-month EPI vaccines (at the 15-month visit). A birth dose of polio vaccine not required.</p>

Participant ID:

Date of Visit: ____/____/____
DD MMM YYYY

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INCLUSION EXCLUSION CRITERIA

- E 1. History of receipt of any meningococcal vaccine.
- E.2 Has received a measles-containing vaccine.
- E.3. Current or previous, confirm or suspected disease caused by N. meningitidis.
- E 4. Household contact with and/or intimate exposure to an individual with any laboratory' confirmed N. meningitidis infection within 60 days of enrollment or study vaccination (for the 15-month age group).
- E 5. History of severe allergic reactions after previous vaccinations or hypersensitivity to any Study vaccine component including tetanus, diphtheria, and mutant diphtheria toxoid (CRM197)
- E 6. Acute or chronic, clinically significant pulmonary, cardiovascular, metabolic, neurological, hepatic, or renal functional abnormality, as determined by medical history or physical examination.
- E 7. Any confirmed or suspected condition with impaired or altered function of the immune system (e.g., immunodeficiency, autoimmune conditions, malnutrition).
- E 8. Have any bleeding disorder which is considered a contraindication to intramuscular injection or blood draw.
- E 9. Severe acute malnutrition. Note: a weight-for-length Z-score of less than -3 satisfies this Exclusion criteria.
- E 10. History of either hepatitis B or hepatitis C virus infection, human immunodeficiency virus infection, or hereditary immunodeficiency.
- E 11. Presence of major and clinically significant congenital defects.
- E 12. Chronic administration (defined as more than 14 days) of immunosuppressants or other immune-modifying drugs within three months prior to the study vaccination or planned use throughout the study period (for corticosteroids, this means prednisone, or equivalent, ≥ 0.5 mg/kg per day. Inhaled, intranasal, and topical steroids are allowed).
- E 13. Administration of blood, blood products and/or plasma derivatives or any parenteral immunoglobulin preparation in the past 3 months or planned use throughout the study period.
- E 14. Administration of any vaccine within 14 days prior to enrolment in the study or planned administration of any vaccine within 14 days before or after study vaccination.
- E 15. Use of any investigational or non-registered drug or vaccine within 28 days prior to the administration of study vaccine or planned during the study.
- E 16. Malaria infection as confirmed by a Rapid Diagnostic Test. Note: subjects positive at screening may be treated for malaria as per national guidelines outside of the study, and if the subject remains eligible vaccinated no earlier than 5 days after completing treatment.
- E 17. Individuals who are close family member* of individuals conducting this study. *defined as a child with direct genetic relationship to a member of the study team.
- E 18. Have experienced a moderate or severe acute infection and/or fever (defined as temperature $\geq 37.5^{\circ}\text{C}$) within 3 days prior to enrolment or study vaccination.
- E 19. Have received systemic antibiotic treatment within 3 days prior to enrolment or study vaccination.
- E 20. Non-residence in the study area or intent to move out within six months.
- E 21. Any condition which, in the opinion of the investigator, might post additional risk to the subject due to participation in the study.

Participant ID:

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INCLUSION EXCLUSION CRITERIA

If investigator decision, specify (max.200 characters)

Investigator Signature: _____

Date (dd/mmm/yyyy)

Participant ID:

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DD MMM YYYY

Visit Day:
Initials:

INCLUSION EXCLUSION CRITERIA – STEP 2

Did the participant meet all eligibility criteria?	<input type="radio"/> Yes <input type="radio"/> No				
Eligibility Status (If "Eligible and Enrolled", or "Incomplete Screening", end of form.)	Eligible and Enrolled <input type="radio"/>	Eligible/Not Enrolled <input type="radio"/>	Ineligible <input type="radio"/>	Incomplete Screening <input type="radio"/>	Ineligible, but Enrolled <input type="radio"/>
Date participant was found "Eligible/ Not Enrolled", "Ineligible" or "Incomplete Screening"	____/____/____ DD MMM YYYY				

Select reason(s) why participant is "Eligible/Not Enrolled" or "Ineligible"

INCLUSION
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Participant ID:

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INCLUSION EXCLUSION CRITERIA – STEP 2

If investigator decision, specify (max.200 characters)

Investigator Signature: _____

Date (dd/mmm/yyyy)

Participant ID:

Date of Visit: ____/____/____
DD MMM YYYY

Visit Day:
Initials:

MEDICAL HISTORY

Does the participant have any medical history to report?	Yes <input type="radio"/>	No <input type="radio"/>
Date medical history Collected	____/____/____ DD/MMM/YYYY	
Description of medical history condition/event		
Is condition/event gradeable	Yes <input type="radio"/>	No <input type="radio"/>
Severity Grade	Grade 1 (mild) <input type="radio"/> Grade 2 (moderate) <input type="radio"/> Grade 3 (Severe) <input type="radio"/> Grade 4 (Potentially life threatening) <input type="radio"/>	
Start date of pre-existing condition/event	____/____/____ DD/MMM/YYYY	
Is the condition ongoing	Yes <input type="radio"/>	No <input type="radio"/>
Date medical history/condition ended/resolved	____/____/____ DD/MMM/YYYY	
Comment (max. 200 characters)		

Completed by: _____ Date (dd/mmm/yyyy)

Print

Signature

Participant ID:

Date of Visit: ____/____/____
DD MMM YYYY

Visit Day:
Initials:

MISSED VISIT

Target visit date	____/____/____ DD/MMM/YYYY
Reason visit was missed	<input type="radio"/> Unable to contact participant <input type="radio"/> Participant unable to schedule visit within window <input type="radio"/> Participant refused visit <input type="radio"/> Participant withdrew from study <input type="radio"/> Participant deceased <input type="radio"/> Other (Specify) _____
Steps taken to address the missed visit (corrective action plan)	

Completed by: _____ Date (dd/mmm/yyyy)
Print Signature

Participant ID: _____

Date of Visit: ____/____/____
DD MMM YYYY

Visit Day: _____
Initials: _____

Study Termination

Date of Study Exit	____/____/____ DD/MMM/YYYY	Primary Reason for Completion/discontinuation (Check below)
Scheduled exit visit/end of study <input type="checkbox"/>		Adverse event ** <input type="checkbox"/>
Death ** <input type="checkbox"/>		Study terminated by sponsor <input type="checkbox"/>
Participant is unwilling or unable to comply with required study procedures <input type="checkbox"/>		Participant no longer meets eligibility criteria * <input type="checkbox"/>
Lost to follow-up <input type="checkbox"/>		Participant limit has been met for 15-month group <input type="checkbox"/>
Investigator decision <input type="checkbox"/>		Other * <input type="checkbox"/>
Early study closure <input type="checkbox"/>		
Protocol deviation <input type="checkbox"/>		
*If "Other", or "Participant no longer meets eligibility criteria" Specify (max 200 characters):		
**If 'Death', enter date of death		____/____/____ DD/MMM/YYYY
** If "Adverse Event" or "Death" select applicable AE		
Was the participant's termination associated with a safety concern?		No Yes*** <input type="checkbox"/> <input type="checkbox"/>
*** If Yes, Explain		_____ _____ _____

Completed by: _____ Date (dd/mmm/yyyy)

Print

Signature

Participant ID: _____

Date of Visit: ____/____/____
DD MMM YYYY

Visit Day: _____
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PROTOCOL DEVIATIONS

Site Awareness Date	____/____/____ DD/MMM/YYYY	Deviation Date	____/____/____ DD/MMM/YYYY	Has or will this deviation be reported to local IRBEC?	Yes <input type="radio"/>	No <input type="radio"/>
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TYPE OF DEVIATION

<input type="checkbox"/> Inappropriate enrollment <input type="checkbox"/> Failure to follow randomization or blinding procedures <input type="checkbox"/> Study product management deviation <input type="checkbox"/> Study product dispensing error <input type="checkbox"/> Study product use/non-use deviation <input type="checkbox"/> Study product sharing <input type="checkbox"/> Study product not returned <input type="checkbox"/> Conduct of non-protocol procedure <input type="checkbox"/> Improper AE <input type="checkbox"/> Unreported AE <input type="checkbox"/> Breach of confidentiality <input type="checkbox"/> Physical assessment deviation	<input type="checkbox"/> Lab assessment deviation <input type="checkbox"/> Mishandled lab specimen <input type="checkbox"/> Staff performing duties that they are not qualified to perform <input type="checkbox"/> Questionnaire administration deviation <input type="checkbox"/> Counseling deviation <input type="checkbox"/> Use of non-IRB/EC-approved materials <input type="checkbox"/> Use of excluded concomitant medications, devices, or non-study products <input type="checkbox"/> Informed Consent process deviation <input type="checkbox"/> Visit completed outside of window <input type="checkbox"/> Insufficient volume of primary specimen collected <input type="checkbox"/> Minimum number of aliquots not obtained <input type="checkbox"/> Other
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Description of Deviation:	
Plans and/or action taken to address the deviation:	
Plans and/or action taken to prevent future occurrences of the deviation:	

Completed by: _____ Date (dd/mmm/yyyy) _____

Print Signature

Participant ID:

Date of Visit: _____ / _____ / _____
DD MMM YYYY

Visit Day:
Initials:

Deviation Reported By:	
-------------------------------	--

Completed by: _____ **Date (dd/mmm/yyyy)** _____

Print

Signature

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DD MMM YYYY

Visit Day:
Initials:

Physical Exam

Was a Physical Exam performed?	Yes <input type="radio"/>	No <input type="radio"/>	If Yes: Date of Exam ____/____/____ DD/MMM/YYYY
---------------------------------------	------------------------------	-----------------------------	--

Body System	Not Done	Normal	Abnormal	If "Abnormal" specify
HEENT	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Neck	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Lymph Nodes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Heart/Cardiovascular	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Lung/Respiratory	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Liver	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Spleen	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Extremities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Neurological	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Skin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Other System Finding	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
If "Other System", Specify System:				
If "Abnormal", specify				

Comments (max. 200 characters)

Investigator Signature: _____

Date (dd/mmm/yyyy)

Participant ID:

Date of Visit: ____/____/____
DD MMM YYYY

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SPECIMEN COLLECTION - BLOOD

Was Specimen Collected	Yes <input type="radio"/>	* If No, record reason why sample was not collected (<i>max 200 characters</i>)	
	No * <input type="radio"/>		
Specimen Collection Method	<input type="radio"/> Venipuncture <input type="radio"/> Heel Stick		
Specimen Collection Date	____/____/____ DD/MMM/YYYY	Specimen Collection Time	
Was the minimum required volume obtained?	Yes <input type="radio"/>	*If No, record reason why minimum required volume was not obtained (max. 200 characters) and report as a protocol deviation.	
	No * <input type="radio"/>		
Was Sample stored for shipment to Central Lab?	Stored <input type="radio"/>	* If "not stored", record reason why sample was not stored (<i>max 200 characters</i>)	
	Not Stored * <input type="radio"/>		

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Print

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DD MMM YYYY

Visit Day: _____
Initials: _____

MALARIA TEST RESULTS

Was Rapid Malaria Test performed?	Yes <input type="radio"/> No * <input type="radio"/>	* If No, specify reason not done <hr/>	
Collection Date	____/____/____ DD/MMM/YYYY	Collection Time	
Rapid Malaria Test Result	*If "Indeterminate", was a smear sample collected?		
	Positive <input type="radio"/> Negative <input type="radio"/> Indeterminate * <input type="radio"/>	Yes * <input type="radio"/> No <input type="radio"/>	
		* Smear Sample Collection date	____/____/____ DD/MMM/YYYY
		* Smear Sample Collection time	
		*Smear Sample Test Result	Positive <input type="radio"/> Negative <input type="radio"/>

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MENINGOCOCCAL VACCINE

Was a blinded meningococcal vaccination administered at this visit?	Yes <input type="radio"/>	* If No, specify reason not done	
	No * <input type="radio"/>		
Date of Vaccination	____/____/____ DD/MMM/YYYY	Time of injection	
Location of Injection	Right anterolateral aspect of the thigh <input type="radio"/>		
	Left anterolateral aspect of the thigh <input type="radio"/>		
Were there any study product administration errors?	Yes * <input type="radio"/> No <input type="radio"/>	*If "Yes", complete Study Product Administration Error Form	
		Comments (max. 450 characters)	

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MEASLES AND RUBELLA VACCINE

Was a Measles and Rubella Vaccination administered at this visit?	Yes <input type="radio"/>	* If No, specify reason not done	
	No * <input type="radio"/>		
Date of Vaccination	____/____/____ DD/MMM/YYYY	Time of injection	
Location of Injection	Right deltoid <input type="radio"/> Left deltoid <input type="radio"/>		
Were there any study product administration errors?	Yes * <input type="radio"/> No <input type="radio"/>	*If "Yes", complete Study Product Administration Error Form	
		Comments (max. 450 characters)	

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YELLOW FEVER VACCINE

Was a Yellow Fever vaccination administered at this visit?	Yes <input type="radio"/>	* If No, specify reason not done	
	No * <input type="radio"/>		
Date of Vaccination	____/____/____ DD/MMM/YYYY	Time of injection	
Location of Injection	Right deltoid <input type="radio"/> Left deltoid <input type="radio"/>		
Were there any study product administration errors?	Yes * <input type="radio"/> No <input type="radio"/>	*If "Yes", complete Study Product Administration Error Form	
		Comments (max. 450 characters)	

Completed by: _____ Date (dd/mmm/yyyy)

Print

Signature

Participant ID: _____

Date of Visit: ____/____/____
DD MMM YYYYVisit Day: _____
Initials: _____**STUDY PRODUCT ADMINISTRATION ERROR-MENINGOCOCCAL***Reminder to please complete a Protocol Deviation CRF to report the administration error*Date of visit when study
product administration
error(s) occurred____/____/____
DD/MMM/YYYYDescribe administration
error(s)

Mark all that apply

Incorrect administration site

Specify site:

Incorrect product administered

Specify product

Incorrect dose administered

Administered beyond product viability

Administered outside protocol-specified visit window

Other

If "Other", specify (max. 200 characters)

OUTCOMEWhat action was taken as
a result of study product
administration error(s)
described above?Discontinued future study product
administration *

No action taken

Other *

If "Other", specify (max. 200 characters)

** Reminder: If "Discontinued
future study product
administration" complete
Discontinuation of Study
Product Form*

Completed by: _____ Date (dd/mmm/yyyy)

Print

Signature

Participant ID: _____

Date of Visit: ____/____/____
DD MMM YYYYVisit Day: _____
Initials: _____**STUDY PRODUCT ADMINISTRATION ERROR- MEASLES AND RUBELLA***Reminder to please complete a Protocol Deviation CRF to report the administration error*

Date of visit when study product administration error(s) occurred	____/____/____ DD/MMM/YYYY	
Describe administration error(s)	Mark all that apply	
	Incorrect administration site <input type="checkbox"/>	Specify site:
	Incorrect product administered <input type="checkbox"/>	Specify product
	Incorrect dose administered <input type="checkbox"/>	
	Administered beyond product viability <input type="checkbox"/>	
	Administered outside protocol-specified visit window <input type="checkbox"/>	
OUTCOME What action was taken as a result of study product administration error(s) described above? <i>* Reminder: If "Discontinued future study product administration" complete Discontinuation of Study Product Form</i>	Other <input type="checkbox"/>	If "Other", specify (max. 200 characters)
	Discontinued future study product administration * <input type="checkbox"/> No action taken <input type="checkbox"/> Other * <input type="checkbox"/>	If "Other", specify (max. 200 characters)

Completed by: _____ Date (dd/mmm/yyyy)

Print

Signature

Participant ID: _____

Date of Visit: ____/____/____
DD MMM YYYYVisit Day: _____
Initials: _____**STUDY PRODUCT ADMINISTRATION ERROR-YELLOW FEVER***Reminder to please complete a Protocol Deviation CRF to report the administration error*

Date of visit when study product administration error(s) occurred	____/____/____ DD/MMM/YYYY	
Describe administration error(s)	Mark all that apply	
	Incorrect administration site <input type="checkbox"/>	Specify site:
	Incorrect product administered <input type="checkbox"/>	Specify product
	Incorrect dose administered <input type="checkbox"/>	
	Administered beyond product viability <input type="checkbox"/>	
	Administered outside protocol-specified visit window <input type="checkbox"/>	
OUTCOME What action was taken as a result of study product administration error(s) described above? <i>* Reminder: If "Discontinued future study product administration" complete Discontinuation of Study Product Form</i>	Discontinued future study product administration * <input type="checkbox"/> No action taken <input type="checkbox"/> Other * <input type="checkbox"/>	If "Other", specify (max. 200 characters)
		If "Other", specify (max. 200 characters)

Completed by: _____ Date (dd/mmm/yyyy)

Print

Signature

Participant ID:

Date of Visit: ____/____/____
DD MMM YYYY

Visit Day:
Initials:

MISSED STUDY PRODUCT ADMINISTRATION-MENINGOCOCCAL

Reminder to please complete a Protocol Deviation CRF to report the missed study product administration

Visit date of missed study product administration: ____/____/____
DD/MMM/YYYY

What is the primary reason for missing the study product administration at this visit?	Participant unable to schedule visit within window <input type="checkbox"/>	
	Unable to contact participant <input type="checkbox"/>	
	Adverse Event * <input type="checkbox"/>	*Complete Adverse Event Log if AE reporting requirements as specified in the protocol
		*Select AE
	Reactogenicity event * <input type="checkbox"/>	* Specify
Participant refused vaccination <input type="checkbox"/>		
Other * <input type="checkbox"/>	* If "Other", specify	

If "Adverse Event" or "Reactogenicity event", indicate who made the decision to not study product

Mark all that apply

- Clinician
- Participant
- PSRT
- Other (Specify) : _____

Comment (200 max character)

Completed by: _____ Date (dd/mmm/yyyy)

Print

Signature

Participant ID: _____

Date of Visit: ____/____/____
DD MMM YYYY

Visit Day: _____
Initials: _____

MISSED STUDY PRODUCT ADMINISTRATION-MEASLES AND RUBELLA

Reminder to please complete a Protocol Deviation CRF to report the missed study product administration

Visit date of missed study product administration: ____/____/____
DD/MMM/YYYY

What is the primary reason for missing the study product administration at this visit?	Participant unable to schedule visit within window <input type="checkbox"/>	
	Unable to contact participant <input type="checkbox"/>	
	Adverse Event * <input type="checkbox"/>	*Complete Adverse Event Log if AE reporting requirements as specified in the protocol
		*Select AE
	Reactogenicity event * <input type="checkbox"/>	* Specify
Participant refused vaccination <input type="checkbox"/>		
Other * <input type="checkbox"/>	* If "Other", specify	

If "Adverse Event" or "Reactogenicity event", indicate who made the decision to not study product

Mark all that apply

Clinician

Participant

PSRT

Other (Specify) : _____

Comment (200 max character)

Completed by: _____ Date (dd/mmm/yyyy)
Print Signature

Participant ID:

Date of Visit: ____/____/____
DD MMM YYYY

Visit Day:
Initials:

MISSED STUDY PRODUCT ADMINISTRATION- YELLOW FEVER

Reminder to please complete a Protocol Deviation CRF to report the missed study product administration

Visit date of missed study product administration: ____/____/____
DD/MMM/YYYY

What is the primary reason for missing the study product administration at this visit?	Participant unable to schedule visit within window <input type="checkbox"/>	
	Unable to contact participant <input type="checkbox"/>	
	Adverse Event * <input type="checkbox"/>	*Complete Adverse Event Log if AE reporting requirements as specified in the protocol *Select AE
	Reactogenicity event * <input type="checkbox"/>	* Specify
Participant refused vaccination <input type="checkbox"/>		
Other * <input type="checkbox"/>	* If "Other", specify	

If "Adverse Event" or "Reactogenicity event", indicate who made the decision to not study product

Mark all that apply

Clinician
 Participant
 PSRT
 Other (Specify) : _____

Comment (200 max character)

Completed by: _____ Date (dd/mmm/yyyy)
Print Signature

Participant ID: _____

Date of Visit: ____/____/____
DD MMM YYYYVisit Day: _____
Initials: _____**TEMPORARY PRODUCT DELAY**

Does the participant have any temporary product delays?					Yes * <input type="radio"/>	No <input type="radio"/>	(Complete the Temporary Product Delay log below)	
Date when this study product delay was initiated:					____/____/____ DD/MMM/YYYY			
At what visit was this product delay initiated?								
V1.0 (Day 1) <input type="radio"/>	V2.0 (Day 8) <input type="radio"/>	V3.0 (Day 29) <input type="radio"/>	V4.0 (Day 181) <input type="radio"/>	V5.0 (Day 730) <input type="radio"/>	Interim Visit <input type="radio"/> Interim Code			
Why is the vaccine being delayed?								
1. Reported use of prohibited concomitant medications					<input type="radio"/>			
2. Positive Malaria Test					<input type="radio"/>			
3. Adverse Event					<input type="radio"/>			
4. Temperature \geq 37.5C					<input type="radio"/>			
5. Acute infection and/or systemic antibody use within 3 days of vaccination					<input type="radio"/>			
6. Participant unable/unwilling to comply with the required study procedures, or otherwise, might be put at undue risk to their safety and well-being by continuing product use according to the judgment of IoR/designee					<input type="radio"/>			
7. Other (specify if other) _____					<input type="radio"/>			
If product delay was associated with an adverse event, record the applicable AEs:	If product delay was associated with a new or updated concomitant medication, record medication	Will the participant resume study product?			Date participant resumed study product			
		<input type="radio"/>	Yes			____/____/____ DD/MMM/YYYY		
		<input type="radio"/>	No Hold continuing for another reason					
		<input type="radio"/>	No Early Termination					
		<input type="radio"/>	No-Permanently discontinued					

Completed by: _____ Date (dd/mmm/yyyy)

Print

Signature

Participant ID:

Date of Visit: ____/____/____
DD MMM YYYY

Visit Day:
Initials:

PARTICIPANT GROUP

Which group was the participant randomized to?

Group 1 (9 months) Group 2 (15 months)

Completed by: _____ Date (dd/mmm/yyyy)

Print

Signature

Participant ID:

Date of Visit: ____/____/____
DD MMM YYYY

Visit Day:
Initials:

INFORMED CONSENT

Informed Consent Date	____/____/____ DD/MMM/YYYY	Informed Consent Time	
Consent Version		Did participant consent to long term specimen storage and future testing?	Yes <input type="radio"/> No <input type="radio"/>

Completed by: _____ Date (dd/mmm/yyyy)

Print

Signature

Participant ID:

Date of Visit: ____/____/____
DD MMM YYYY

Visit Day:
Initials:

RANDOMIZATION METHOD-STEP 1

<p>Will randomization step 1 be performed online or using an envelope?</p>	<p>Online <input type="radio"/></p> <p>Envelope <input type="radio"/></p> <p>If "Envelope", enter time envelope was opened _____</p> <p>If "Envelope", enter Envelope Number _____</p>
<p>Randomization date</p>	<p>____/____/____ DD/MMM/YYYY</p>

Completed by: _____ Date (dd/mmm/yyyy)

Print

Signature

Participant ID:

Date of Visit: ____/____/____
DD MMM YYYY

Visit Day:
Initials:

RANDOMIZATION METHOD-STEP 2

<p>Will randomization step 2 be performed online or using an envelope?</p>	<p>Online <input type="radio"/></p> <p>Envelope <input type="radio"/></p> <p>If "Envelope", enter time envelope was opened _____</p> <p>If "Envelope", enter Envelope Number _____</p>
<p>Randomization date</p>	<p>____/____/____ DD/MMM/YYYY</p>

Completed by: _____ Date (dd/mmm/yyyy)

Print

Signature

Participant ID: _____

Date of Visit: ____/____/____
DD MMM YYYY

Visit Day: _____
Initials: _____

RANDOMIZATION-STEP 1

<p>Is the participant ready to be randomized to receive the Meningoccal vaccine immediately (9-12 month of age) or delayed (15-18 month of age)</p>	<p>Yes <input type="radio"/></p> <p>No <input type="radio"/></p> <p>Randomization date ____/____/____ DD/MMM/YYYY</p> <p>Randomization time _____</p>
---	---

Completed by: _____ Date (dd/mmm/yyyy) _____
Print Signature

Participant ID:

Date of Visit: ____/____/____
DD MMM YYYY

Visit Day:
Initials:

RANDOMIZATION-STEP 2

<p>Is the participant ready to be randomized to receive the NmCV-5 or MenACWY-TT Meningoccal vaccine</p>	<p>Yes <input type="radio"/></p> <p>No <input type="radio"/></p> <p>Randomization date ____/____/____ DD/MMM/YYYY</p> <p>Randomization time _____</p>
--	---

Completed by: _____ Date (dd/mmm/yyyy)
Print Signature

Participant ID:

Date of Visit: ____/____/____
DD MMM YYYYVisit Day:
Initials:

REACTOGENICITY- Baseline and Early

Was assessment done?	<input type="radio"/> Yes <input type="radio"/> No	If "No" specify reason not done, and end form.	Reason not done:		
Date of Assessment:	____/____/____ dd/mmm/yyyy	Time of assessment:	Assessment Time Point	<input type="radio"/> Baseline	<input type="radio"/> Early Assessment
Body temperature	_____ C	If body temperature ≥ 37.5 C at baseline, DO NOT administer study product. If ANY symptoms are moderate or above: a) at baseline, do not administer study product or b) at early assessment, participant is to be seen by clinician within 48 hours unless symptoms are improving or resolved.			
Severity Grade	None	Mild	Moderate	Severe	Potentially life threatening
Body temperature	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Systemic Symptoms: Irritability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Systemic Symptoms: Drowsiness/Lethargy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Systemic Symptoms: Decrease Eating/Anorexia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Systemic Symptoms: Vomiting	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Local Symptoms: Location of Meningococcal vaccination site only:	Right anterolateral aspect of the thigh <input type="radio"/>	Left anterolateral aspect of the thigh <input type="radio"/>			
Is vaccine-related erythema or induration visible?	<input type="radio"/> Yes <input type="radio"/> No	Erythema and redness largest diameter (record in "xx.x" and "0.0" if none	_____ cm	Erythema /redness % surface area	_____ %
Induration/swelling largest diameter (Record in "xx.x", and if none record "0.0".)	_____ cm	Induration/swelling % surface area	_____ %		
	None	Mild	Moderate	Severe	Potentially life threatening
Local Symptoms: Pain and/or tenderness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Erythema/redness % surface area	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Induration/swelling % surface area	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Participant ID: _____

Date of Visit: ____/____/____
DD MMM YYYYVisit Day: _____
Initials: _____

REACTOGENICITY- RESOLUTION OF SYMPTOMS

Instructions: If no signs or symptoms are continuing at 11:59 p.m. Day 8, do not complete the resolution form. If the participant has any grade 3 symptoms at any point during the reactogenicity period or for any symptoms that are at a higher severity grade than baseline and were reported as continuing at 11:59 p.m. Day 8, report (1) the maximum severity grade experienced since 11:59 p.m. Day 8, and (2) the resolution date or the date the symptom returned to baseline severity grade. Mark "None" for all other signs and symptoms.

Maximum body temperature	_____	Resolution date	____/____/____ dd/mmm/yyyy			
Severity Grade	None	Mild	Moderate	Severe	Potentially life threatening	Resolution date
Body Temperature	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	____/____/____ dd/mmm/yyyy
Systemic Signs/Symptoms: Irritability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	____/____/____ dd/mmm/yyyy
Systemic Symptoms: Drowsiness/Lethargy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	____/____/____ dd/mmm/yyyy
Systemic Symptoms: Decrease Eating/Anorexia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	____/____/____ dd/mmm/yyyy
Systemic Symptoms: Vomiting	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	____/____/____ dd/mmm/yyyy
Local Symptoms: Location of Meningococcal vaccination site only:		Right anterolateral aspect of the thigh		Left anterolateral aspect of the thigh		
		<input type="radio"/>			<input type="radio"/>	
Is vaccine-related erythema or induration visible?	<input type="radio"/> Yes <input type="radio"/> No	Erythema and redness largest diameter (record in "xx.x" and "0.0" if none)	_____ cm	Erythema/redness % surface area	_____ %	
Induration/swelling largest diameter (Record in "xx.x", and if none record "0.0".)	_____ cm	Induration/swelling % surface area	_____ %			
	None	Mild	Moderate	Severe	Potentially life threatening	Resolution Date
Local Symptoms: Pain and/or tenderness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	____/____/____ dd/mmm/yyyy
Erythema/redness % surface area	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	____/____/____ dd/mmm/yyyy
Induration/swelling % surface area	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	____/____/____ dd/mmm/yyyy

Reactogenicity – Resolution of Symptoms

IDCRC DMID 20-0024 Mening-Mali _ Reactogenicity – Resolution of Symptoms_ v1.0_04Mar2022

Participant ID:

Date of Visit: _____/_____/_____
DD MMM YYYY

Visit Day:
Initials:

						dd/mmm/yyyy
Comments (max. 450 characters)						

Completed by: _____ **Date (dd/mmm/yyyy)**

Print

Signature