CRF Completion Guidelines

IDCRC DMID 20-0024

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CRF Completion Guidelines

Protocol Name:	A Phase 3 Trial to Evaluate the Safety, Immunogenicity, and Non-Interference with Concomitant Routine Vaccines, of a Meningococcal Serogroup ACYWX Conjugate Vaccine (NmCV-5) in Comparison with MenACWY-TT Conjugate Vaccine in Healthy Malian Infants
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Version:	2.0

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CRF Completion Guidelines

The following instructions are study-specific data completion guidelines intended to assist site staff when completing electronic case report forms (eCRFs) and paper case report forms (CRFs). Detailed guidance on general data collection, entry, navigation, and general use of Medidata Rave is provided in the Medidata Rave Electronic Data Capture (EDC) Training Manual, which is found on the IDCRC DMID 20-0024 Atlas web page:

https://atlas.scharp.org/cpas/project/IDCRC/DMID%2020-0024/begin.view?

General Guidelines

- The Participant ID is generated by Rave EDC as a 9-digit field, starting with the 3-digit site number followed by a randomly assigned 5-digit participant number, and 1-digit check number.
- All data entered in Rave must match the data on any source documents/paper CRFs.
- Complete all required data fields. Ensure that all entries are in English and are accurate, consistent, complete, and medically logical.
- If “Other” is chosen as a response, further details must be provided by responding to the “If “Other”, specify” field.
- Text box fields have character limits. Text exceeding the limit will not be saved and a “Non-conformant” icon will appear.
- Most date fields require a complete date and must be entered as Day Month Year (dd MMM yyyy) (e.g., 01 NOV 2020). Exceptions are detailed in specific form sections where applicable.
    - Visit dates should be in the order allowed by the protocol.
- Drop-down menus are available for many fields. Use these menus, when available, to select the appropriate response.
- Avoid using abbreviations, symbols or special characters.
- Avoid hitting the return or enter key in text fields, as it may prematurely save the form.
- Log forms allow you to make multiple entries over the course of the study. All entries may be viewed at the same time in “Complete View”. Individual entries may be viewed in “Portrait View” for ease of entry. The following are log forms or have the log format within the form for this study:
    - Adverse Event
    - Medical History
    - Concomitant Medications
    - Protocol Deviations
    - Temporary Product Delay
- To correct/update data fields, click the "pencil" icon next to a field, correct/update the value and give the reason for the change, if applicable. Save the form to capture changes made.
- If an incorrect data entry is made, a system query will fire. Correct the error and save the form.
    - System generated queries with no query response will automatically close with a form correction.

- System generated queries with a query response will need to be closed by the data management team.

- All actions performed on a data field are tracked in the audit trail. All data modifications can be viewed in the field specific audit trail.
- The Investigator of Record (IoR) will electronically sign all forms after the participant's data have been reviewed. After the signature is applied, no further changes or additions to the forms are expected.
  - The SCHARP Clinical Data Manager will provide direction for when the Investigator should perform the final review and sign the forms.
  - Any modifications that are made to forms after the IoR has signed off will remove the signature. Once the data has been reviewed, the signature will need to be applied again.

Add Event

- The Add Event drop-down menu can add select forms and folders to a participant's casebook.
- To add a form or folder to a participant's casebook: navigate to the subject-level page, select the event from the Add Event drop-down menu, then click the "Add" button.
- For IDCRC DMID 20-0024, the drop-down menu will have the following options:
  - **Interim Visit**
    - Select "Interim Visit" from the Add Event drop-down menu to add an Interim Visit folder in the participant's casebook.
    - Open the Interim Visit folder to access the Interim Visit form. On the Interim Visit form, select the forms that are completed at the interim visit. The selected forms will then load within the folder.
  - **Physical Exam – Enrollment**
    - Select "Physical Exam – Enrollment" to add a Physical Exam form to the V1 – Group 1 Day 1 visit folder.
  - **Vital Signs – Enrollment**
    - Select "Vital Signs – Enrollment" to add a Vital Signs form to the V1 – Group 1 Day 1 visit folder.

Loading Forms in Visit Folders

- Forms are added to visit folders in a participant's casebook based on specific form responses. Below are a few key examples.
  - **Example 1**: Follow-up Visit Summary form
    - If the question "Did the participant complete this visit?" is marked "No", the Missed Visit form will be added to the visit folder and the required forms for that visit will not appear in the visit folder.
  - **Example 2**: Follow-up Visit Summary form
    - To add a form to the visit folder (that is not already required at that visit), mark the appropriate check box under the question "Were any additional study procedures or forms completed?"
  - **Example 3**: Interim Visit form

- To add a form to the interim visit folder, mark the appropriate check box under the question “What study procedures were completed at this visit?”.

Loading Folders in Participant Casebook

- Medidata Rave will add folders to a participant’s casebook based on how certain forms are completed. See Table 1 for actions required to add folders to a participant’s casebook.

Table 1. Folder Dynamics

Folder	Action Required to Add Folder
Participant	• Save Participant Identifier form. This will add the **V0.0 – Screening** and **Ongoing Logs** folders.
V0.0 – Screening/Enrollment	• Complete the **Randomization Method – Step 1** form to add the **Randomization – Step 1** form. • Complete the **Randomization – Step 1** form to add the **V1.0 – Day 1** and **Discontinuations** folders.
V1.0 – Day 1	• Complete the **Randomization Method – Step 2** form to add the **Randomization – Step 2** form. • Complete the **Randomization – Step 2** form to add the **V2.0 – Day 1** folder.
V2.0 to V5.0	• Complete the **Follow-up Visit Summary** form and select “No” for “Did the participant exit/terminate the study at this visit?” to add the next visit folder.

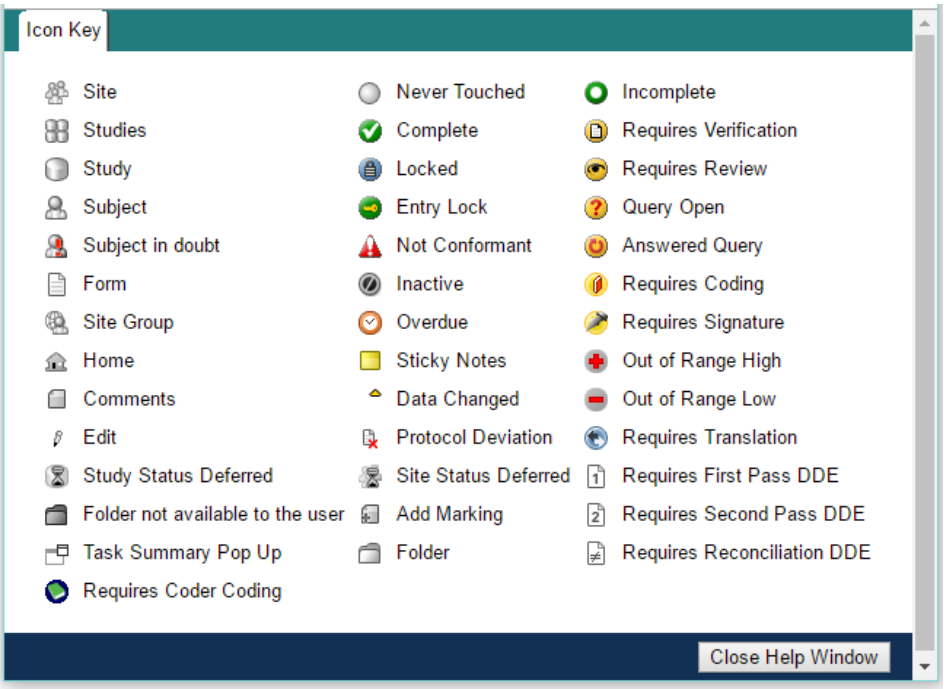
Dynamic Search Lists

- Some forms have data fields with dynamic drop-down lists of available options. Options are populated by corresponding log form entries.
- Dynamic drop-down lists will be blank until entries are made and saved in the corresponding log form.
- Your selection in the dynamic search list can be deleted if entered in error.
- Changing the original log data or inactivating a log form entry that has been selected for a dynamic search list field will make that field non-conformant. To resolve the non-conformant data, make a new selection in the dynamic search list.
- For Example:
  - An AE of ‘*Bruising*’ started on 05 DEC 2021 is reported on the Adverse Events log form.
  - A medication was used for this AE and is entered on the Concomitant Medications form.
  - The applicable AE is linked to this medication by selecting it from the dynamic search list on the Concomitant Medications log entry.
  - The start date for AE *‘Bruising’* is corrected to 06 DEC 2020 on the Adverse Events log form.
  - The selection from the dynamic search list on the Concomitant Medications log entry becomes non-conformant.
  - Re-select the AE ‘*Bruising’* from the dynamic search list with the corrected start date to resolve the non-conformant data.

Icon Key

A link to an Icon Key is available on the subject-level page and at the bottom of each eCRF. The key contains pictures and descriptions of the icons used in Rave. Below is a screen shot of the Icon Key.

Figure 1. Icon Key

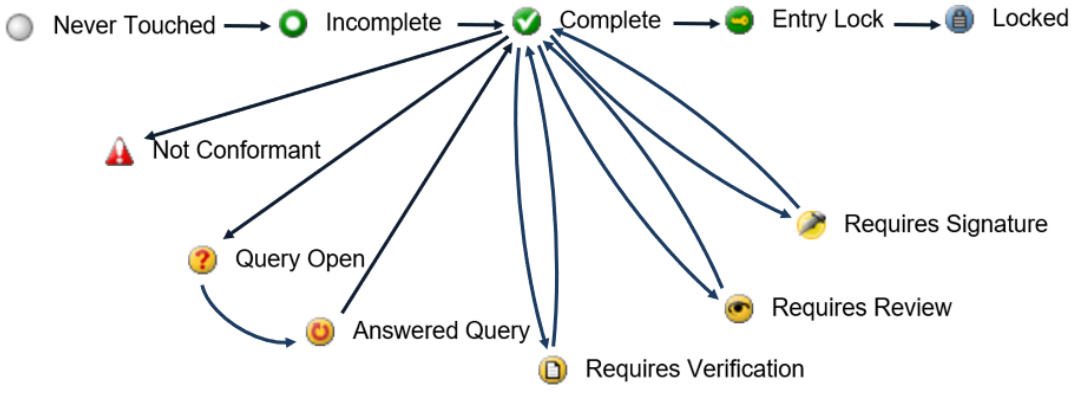


Icon Progression

The life cycle of participants, folders, forms, and fields follows a logical progression starting with “Never Touched” and moving toward “Complete” and “Locked”. Icons are used throughout Rave to show status.

The following figure illustrates the status represented by each icon and the progression of icons through the life cycle.

Figure 2. Icon Progression



Task Summary

The Task Summary displays all pending tasks for a study. At the site level, the Task Summary displays the participants with outstanding tasks that need site review (see Figure 3). For example, click on “Open Queries” to expand the list of participants with open queries (see Figure 4). Click on a PTID to open the participant’s casebook.

Figure 3. Site-Level Task Summary

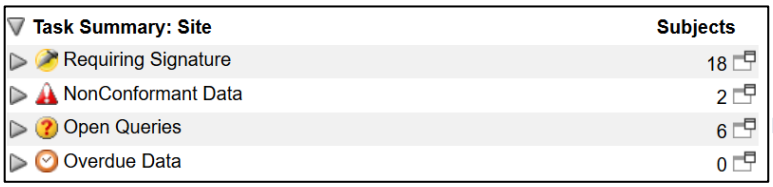
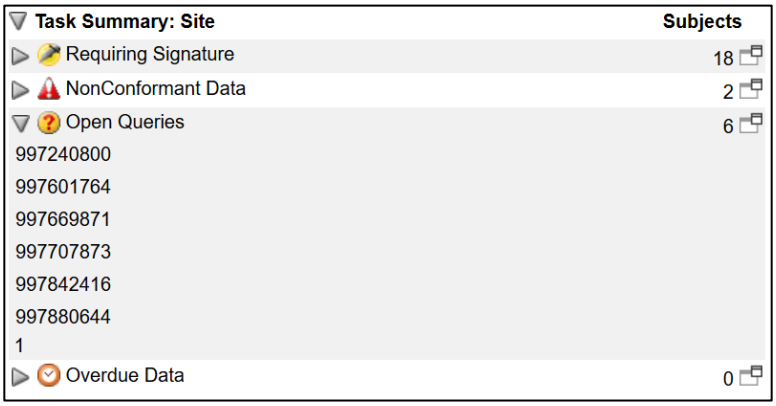
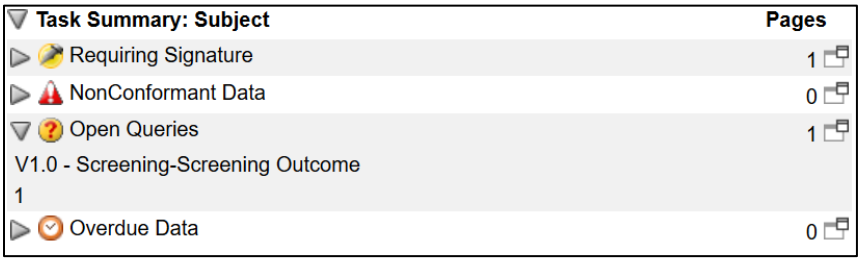


Figure 4. Site-Level Task Summary



At the subject level, the Task Summary displays the forms that need site review. In Figure 5 below, there is one open query for this participant on the Screening Outcome form at V1.0 – Screening. Click on this form in the expanded task summary view to navigate to the open query.

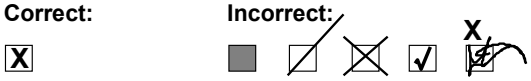
Figure 5. Subject-Level Task Summary



General Guidelines – Paper CRF Completion

CRF PDFs are generated from Rave and posted on the IDCRC DMID 20-0024 Atlas web page. When completing a CRF, refer to form-specific instructions in sections below.

- Based on Good Clinical Practices (GCPs), refer to the following guidelines to complete paper CRFs:
  - Use a black or dark blue medium ballpoint pen. Do not use any other type of writing tool.
  - Print all data and comments legibly by hand. Do not use cursive/script handwriting.
  - Record data on the front side of the paper only.
  - If the spaces/lines provided for a response are not large enough, continue in another blank area of the paper CRF.
  - Mark only one answer unless instructions state to mark or select all that apply.
  - A response is required for every data field unless skip instructions are provided.
  - Do not use correction fluid ("White-Out") or correction tape on paper CRFs.
  - Many items on CRFs have a box or series of boxes for recording a response. Mark the box clearly with an **X**. Do not fill in the box with shading or mark it with a check mark, slash or other character.



Recording Dates – Rave Form and/or Paper CRF

Dates are entered using the "dd MMM yyyy" format, where "dd" represents the two-digit day, "MMM" represents the three-letter abbreviation of the month (in capital letters on paper CRFs), and "yyyy" represents the four digits of the year.

Month abbreviations are shown below. In Rave EDC, these abbreviations are in a drop-down list in the month field.

Month	Abbreviation	Month	Abbreviation
January	JAN	July	JUL
February	FEB	August	AUG
March	MAR	September	SEP
April	APR	October	OCT
May	MAY	November	NOV
June	JUN	December	DEC

For example, record September 20, 2016 as: 20 Sep 2016

Recording Time - Rave Form and/or Paper CRF

Time is recorded using the **24-hour clock** (00:00-23:59), in which hours are designated from 0–23. Midnight is recorded as 00:00, not 24:00.

The following chart shows equivalencies between the 12- and 24-hour clocks:

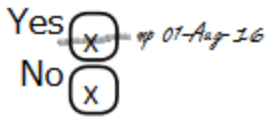
12-hour clock (a.m.)	24-hour clock	12-hour clock (p.m.)	24-hour clock
Midnight	00:00	Noon	12:00
1:00 a.m.	01:00	1:00 p.m.	13:00
2:00 a.m.	02:00	2:00 p.m.	14:00
3:00 a.m.	03:00	3:00 p.m.	15:00
4:00 a.m.	04:00	4:00 p.m.	16:00
5:00 a.m.	05:00	5:00 p.m.	17:00
6:00 a.m.	06:00	6:00 p.m.	18:00
7:00 a.m.	07:00	7:00 p.m.	19:00
8:00 a.m.	08:00	8:00 p.m.	20:00
9:00 a.m.	09:00	9:00 p.m.	21:00
10:00 a.m.	10:00	10:00 p.m.	22:00
11:00 a.m.	11:00	11:00 p.m.	23:00

For example, record 2:25 p.m. as: 14 : 25

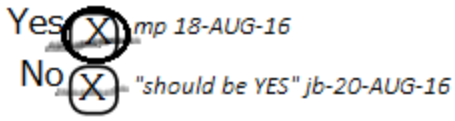
Data Corrections and Additions - Rave Form and/or Paper CRF

- Data fields may need to be updated or corrected, such as in response to a query or after site review.
- If the source document is non-CRF in nature (i.e., lab report), it is sufficient to make data updates in the study database itself. If a paper CRF was completed, make changes to the paper CRF first and then enter the updated data into Rave.
- Use the standards below when changing, clarifying, or amending data on paper CRFs:
    - Draw a single horizontal line through the incorrect entry. Do not obscure the entry or make it unreadable with multiple cross-outs.
    - Place the correct or clarified answer near the previous response.
    - If an **X** is marked in the wrong response box, correct it by doing the following:
        - draw a single horizontal line through the incorrectly marked box
        - mark the correct box

- initial and date the correction as shown below:



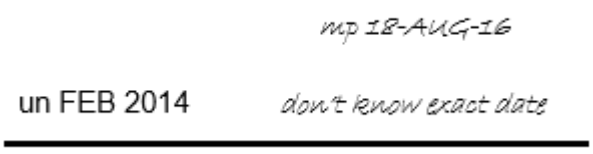
  - If the correct answer has previously been crossed out, do the following:
    - circle the correct response
    - write an explanation in the white space near the response
    - initial and date all corrections as shown below:



- Use the standards below when changing, clarifying, or amending data in Rave:
  - Data previously submitted in an eCRF data field can be updated and resubmitted unless the field is locked.
  - To edit a data field, click on the pencil icon to the right of the field.
  - To edit all data fields on a form, click on the pencil icon at the top right corner of the form. **This is the best method to use if multiple fields need to be edited.**
  - Enter the updated data.
  - Select a reason for the data change from the dropdown menu.
  - Click “Save” at the bottom of the form to save the changes.
  - Otherwise, click “Cancel” to reset the form with the last saved data.
  - Updated data fields will be marked with a delta icon:

Missing and Unknown Data - Rave Form and/or Paper CRF

- Complete dates are required for most date fields unless specified in form-specific instructions below.
- On paper CRFs, if a date is unknown, unavailable, or if the participant refuses to answer, draw a single horizontal line through the applicable question and initial and date. It is helpful to write “don’t know,” “refuses to answer,” “UNK” (unknown), “N/A” (not applicable), or “REF” (refused) near the fields.
  - For example, when recording a date, if the exact day is not known, write “un” to designate the “dd” (or date) and write “don’t know” next to the response, as shown below.



- Initials and date are required for any data that are refused, missing, unknown, or not applicable, regardless of whether they are marked as such during the initial form completion, or as an update to the form.

- In Rave, where the data are missing or unknown, enter “UN” for the day and/or select ‘UNK’ from the drop-down list for the month.

Form-Specific Instructions

Adverse Event Y/N

Purpose:
This form documents if an adverse event was experienced by the participant during the study. This form is used to trigger the Adverse Event log.

General Instructions:
This form is in the "Ongoing Logs" folder and is only completed once, at the time the first adverse event is reported or at the end of the study if no adverse events are reported.

Field-specific Instructions:

Field	Instructions
Has the participant experienced an adverse event during the study?	• If "Yes" is selected, the **Adverse Event** log is added to the Ongoing Logs folder. • At the end of study participation, mark "No" if no adverse events have occurred.

Adverse Event

Purpose:
This form documents Adverse Events (AEs) reported by the participant or clinically observed as defined by the protocol.

General Instructions:

- Complete a separate entry (e.g., a new log line) for each adverse event (AE).
- Add additional log lines by clicking "Add a new Log line".
- Whenever possible, report a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded as separate AE log entries as applicable. If a cluster of symptoms reported on separate AE Log pages is later attributed to a single diagnosis, change/update the earliest reported symptom page to the diagnosis.
- Inactivate log lines by clicking "Inactivate" and selecting the applicable row(s) that should be inactivated.
- Only list conditions that start on or after the enrollment date.
- Record increases in severity/frequency as new events with corresponding start/stop dates.
- Adverse Events should be reassessed and updated as applicable. For example, when an AE resolves, the status/outcome should be updated.

Field-specific Instructions:

Field	Instructions
Date AE reported to site	Record the date the site became aware of the AE. A complete date is required.
Adverse event (AE)	• Describe the AE using medical terminology. • Record a diagnosis and anatomical location if available. • Do not include text on the relationship to study procedure or timing of AE onset with regards to study procedure

Field	Instructions
Onset date	At minimum, month and year are required. Record one of the following, as appropriate: • The date on which the participant reports first experiencing the AE (onset of first symptom if diagnosis has multiple associated symptoms). • If the AE is discovered during a study visit, record the date of the study visit.
At which visit was this adverse event first reported?	Select the appropriate visit (e.g., V1.0 to V5.0) from the dropdown list.
If "Interim visit", specify interim visit code	Record the applicable interim visit code. Refer to the Manual of Procedures for more information on visit codes.
Is the AE still ongoing?	Select “Yes” if the AE is continuing at the time it is first reported. If “Yes”, skip to “Severity grade”.
If "No", outcome date	At minimum, month and year are required. Record one of the following as appropriate: • The date on which the participant reports no longer experiencing the AE or associated symptoms. • The date of the study visit or specimen collection at which the change in status/outcome is first noted.
Severity grade	Record the severity grade using the most current version of the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events* (including relevant appendices/addendums). • Grade 1 (Mild) • Grade 2 (Moderate) • Grade 3 (Severe) • Grade 4 (Potentially life-threatening) • Grade 5 (Death)
Relationship to study product	• Select “Related” if AE is related to study drug. • If "Not related", provide alternate etiology in the text field.
Action taken with study product	Choose the appropriate action taken with the study product using the drop-down list due to the described AE. • No change • Held • Permanently discontinued • Not applicable

Field	Instructions

Other actions	Indicate all treatments administered for this AE, including treatments provided by a health care professional and participant self-treatment.
	• Do not indicate treatments that were clinically indicated or prescribed but not administered.
	
	Select 'None' or check all that apply.
	• ***Medication(s):***
	  ○ Select "Medication(s)" only if the participant reports taking the medication. Report the medication(s) on the Concomitant Medications Log form.
	• ***Therapeutic procedure/surgery:***
	  ○ If "Therapeutic procedure/surgery" is selected, then record applicable details in the "Comments" field at the bottom of the form.
	• ***Diagnostic procedure:***
	  ○ If "Diagnostic procedure" is selected, then record applicable details in the "Comments" field at the bottom of the form.
	• ***Other:***
	  ○ If "Other" is selected, then specify relevant details in the "If "Other", specify" field provided.

Status/Outcome	• ***Recovered/Resolved:*** AE is no longer present or returned to the pre-enrollment severity/frequency. If a participant is taking a medication to control an AE that arose during study participation, it is not considered resolved. • ***Recovering/Resolving:*** Select this option if AE is continuing and has not yet resolved or returned to baseline severity/frequency. • ***Recovered/Resolved with sequelae:*** Participant has recovered from the AE, but with remaining effects or impairment. • ***Not recovered/Not resolved:*** Select this option whenever an AE is continuing at the time of participant termination from the study. • ***Fatal:*** Severity of this AE is Grade 5 (Death). Update any other AEs continuing at the time of death to "Not recovered/Not resolved." • ***Unknown:*** Outcome of AE is unknown (e.g. lost to follow-up).

Is this a serious adverse event according to ICH/GCP or protocol guidelines?	• If "Yes", mark all the SAE criteria that apply.
	  ○ Results in death
	  ○ Is life-threatening
	  ○ Requires inpatient hospitalization or prolongation of existing hospitalization
	  ○ Results in persistent or significant disability/incapacity
	  ○ Is a congenital anomaly/birth defect
	  ○ Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above
	• If "No", go to "Has or will this AE be reported to DMID as an SAE?"

Field	Instructions
Has or will this AE be reported to DMID as a SAE?	Record whether this adverse event will be reported to DMID as a SAE by selecting “Yes” or “No”. If “Yes”, enter the onset date.
SAE onset date	At minimum, month and year are required. Record one of the following, as appropriate: • The date on which the AE first meets seriousness criteria (e.g. the date the participant is hospitalized)
Does this AE meet criteria for a Suspected Unexpected Serious Adverse Reaction (SUSAR)?	Record whether this adverse event meets the criteria for a Suspected Unexpected Serious Adverse Reaction according to protocol guidelines by selecting “Yes” or “No”.
Event to be evaluated for halting criteria?	Record whether this adverse event qualifies as an event to be evaluated for halting criteria according to protocol guidelines by selecting “Yes” or “No”.
Was this AE a worsening of a baseline medical condition?	Record whether this adverse event qualifies as a worsening of a baseline medical condition by selecting “Yes” or “No”. If “Yes” is selected, make sure the baseline condition is recorded on the Medical History eCRF.

Concomitant Medications Y/N

Purpose:
This form documents if any concomitant medications were reported by the participant during the study. This form is used to trigger the Concomitant Medications log.

General Instructions:
This form is in the “Ongoing Logs” folder and is only completed once, at the time the first concomitant medication is reported or at the end of the study if no concomitant medications are reported.

Field-specific Instructions:

Field	Instructions
Were any concomitant medications taken?	• If “Yes” is selected, the **Concomitant Medications** log is added to the Ongoing Logs folder. • At the end of study participation, mark “No” if no concomitant medications were reported.

Concomitant Medications

Purpose:
This form documents all medication(s), other than the meningococcal vaccine, measles and rubella vaccine, and yellow fever vaccine that are used by the participant starting at the screening and enrollment visit.

General Instructions:

- Record all medication(s), other than the meningococcal vaccine, measles and rubella vaccine, and yellow fever vaccine, that are used by the participant starting at the screening and enrollment visit. This includes, but is not limited to: prescription medications, non-prescription (i.e., over-the-counter) medications, medications administered during labor, contraceptive hormonal medications, preventive medications and treatments (e.g., allergy shots, flu shots, and other vaccinations), herbal preparations, vitamin supplements, topical products, naturopathic preparations, and recreational drugs.
- Record any treatment/medication taken for a medical condition/event.
- Record other routine immunizations/vaccinations from pediatric medical records in the infant's casebook.
- Complete a separate entry (e.g., log line) for each reported concomitant medication.
- Add additional log lines by clicking "Add a new Log line".

Field-specific Instructions:

Field	Instructions
Medication name	Record the medication name as reported by the participant. For example, if the participant reports taking a trade name medication, report the trade name. If a trade name is not available or not reportable per national guidelines, record the generic name of the medication. A combination medication can be recorded as one entry using the generic name. If a combination medication does not have a generic name or the generic name is unknown, each active ingredient must be reported as a separate entry.
Indication	• Record the indication for each medication as initially prescribed or self-treated. • For health supplements, such as multivitamins, record "general health". • For preventive medications, record "prevention of [insert condition]" (e.g., for flu shot, record "prevention of influenza"). • For recreational drugs, record "recreation". • If a medication previously recorded for one indication is then taken for another, record this use as a new entry (with the new indication and new date started). • In most instances (excluding health supplements and/or prophylactic treatments), the indication should correspond to an item on the Baseline Medical History, Medical Event, and/or Adverse Event form(s).

Date started	• If the participant is unable to recall the exact date, obtain participant's best estimate. At a minimum, month and year is required.
	  ○ If the exact day is unknown, enter 'UN' for the day field.
	• For injections
	  ○ If it is a one-time injection (including contraception), record each injection as a separate entry, with the same date used for date started and stopped.
	  ○ If it is a series of injections, record the date of the first injection as date started and the date of the last injection as the date stopped.
	• For oral contraceptive birth control pills
	  ○ Record each pill pack confirmed by the participant to have been taken on a new log line. Indicate the start date as the date the first pill of the pack was taken.
	• For implants/devices
	  ○ Record the date the implant/device was inserted as the date started and the date it was removed as the date stopped.

Date stopped
 	
Or
 	
Ongoing
	• If a medication is stopped for a clinically significant period of time, record a stop date. At a minimum, the month and year is required.
	  ○ If the exact day is unknown, enter 'UN' for the day field.
	• If the medication is later restarted, record on a new log line.
	• At the participant's Termination visit, the "Date Stopped" must be recorded for each medication or "Ongoing" must be checked.
	• For injections
	  ○ If it is a one-time injection (including contraception), record each injection as a separate entry, with the same date used for date started and stopped.
	  ○ If it is a series of injections, record the date of the first injection as date started and the date of the last injection as the date stopped.
	• For oral contraceptive birth control pills
	  ○ Record each pill pack confirmed by the participant to have been taken on a new log line. Indicate the start date as the date the first pill of the pack was taken.
	• For implants/devices
	  ○ Record the date the implant/device was inserted as the date started and the date it was removed as the date stopped.

Dose	Record the dose. If the participant does not know the exact dose units (e.g., "250 mg"), record an estimate (e.g., "1 tablet"). For combination drugs, use the '/' or '-' to distinguish the different doses (i.e., hydrocodone/acetaminophen 5/500). For multivitamin tablets or liquids, record the number of tablets or liquid measurement (e.g. "1" pill or "1" tablespoon") if the exact dosage is unknown. • When documenting medical devices with no active medication, such as an IUCD, enter the dose as "1", the dose unit as "Other", and indicate "device" in the text field.

Dose units	Select/record the applicable dose units provided in the drop-down list. If the participant does not know the exact dose units (e.g., “250 mg”), record an estimate (e.g., “1 tablet”). If no information on units is known, select the ‘Unknown’ option. • When documenting medical devices with no active medication, such as an IUCD, mark the dose unit as “Other” and specify “device” in the “If “Other”, specify” text field provided.
Frequency	Select the frequency from options provided in the drop-down list. Below is a list of common frequency abbreviations: • PRN: As needed • QD: Daily • BID: Twice per day • TID: Three times per day • QID: Four times per day • QM: At hour of wake • QH: At hour of sleep • ONCE: ONCE • Other: Alternative dosing schedule or unknown If “Other” is selected, specify in the corresponding “If “Other”, specify” text field provided. For implants/devices • Indicate the frequency as “Other” and specify “continuous” in the text field.
Route	Select the route from options provided in the drop-down list. • PO: Oral • IM: Intramuscular • IV: Intravenous • TOP: Topical • IHL: Inhalation • VAG: Vaginal • REC: Rectal • SC: Subcutaneous • Other: Alternative route or unknown If “Other” is selected, specify in the corresponding “If “Other”, specify” text field provided. For implants/devices • Indicate route as “Other” and specify as appropriate (e.g., “sub-dermal” or “intrauterine”).

Taken for a reported AE?	• If the concomitant medication was administered to treat a reported AE, select "Yes". • If the concomitant medication was not administered to treat an AE, select "No", and end the form.
If "Yes", select adverse event.	Choose the applicable AE log entry from the drop-down list. Note: The applicable AE must first be entered on the AE form in order to be visible in the drop-down list.

Demographics

Purpose:
This form documents a participant's demographic information.

General Instructions:

- Complete and submit this form for participants who have signed a study-specific consent form, regardless if they enroll in the study or not.
- If the participant does not understand the question, read the response options to the participant.
- Responses should reflect the participant's status at screening and should not be changed after screening unless correction is needed.
- If the participant is found to be ineligible prior to the collection of all demographic data, enter all available data and respond to system queries with "Not collected".

Field-specific Instructions:

Field	Instructions
Date of birth	Exact date of birth is required.
Age	The age field (in days) is calculated automatically based on the participant's date of birth and the enrollment date of the study. No data entry is required.
Sex assigned at birth	Record the sex that the participant was assigned at birth.
Ethnicity	Select the ethnicity from options provided in the drop-down list. • Bambara • Mandika/Malinke • Fula/Peuhl • Sarahule/Sarakole • Other • Not reported • Unknown If "Other", specify the ethnicity in the text field.

Field	Instructions
Race	Record the participant's race based on self-definition. Race categories are based on the 1997 Office of Management and Budget (OMB) standards on race and ethnicity. • **American Indian or Alaska Native** – A person having origins in any of the original peoples of North and South America (including Central America) and who maintains tribal affiliation or community attachment. • **Asian** – A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. • **African** – A person having origins in any of the Black racial groups of Africa. • **Native Hawaiian or Other Pacific Islander** – A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands. • **White** – A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

Participant Group

Purpose:
This form is used to document a participant's group (i.e., Randomization – Step 1 assignment).

General Instructions:
Complete this form for each mother and infant participant who is eligible and enrolled into IDCRC DMID 20-0024.

Field-specific Instructions:

Field	Instructions
Which age group was the participant randomized to?	This field is populated automatically once the Randomization – Step 1 form is completed. For participants that do not enroll, this field will remain empty.

Follow-up Visit Summary

Purpose:
These forms are used to summarize information from each participant follow-up study visit.

General Instructions:
This form is completed for each scheduled follow-up visit and is present in each follow-up visit folder, from V2.0 to V5.0 for Groups 1 and 2.

Field-specific Instructions:

Field	Instructions

Did the participant complete this visit? *If "No", end of form.*	If "Yes", continue to fill out the form. If "No", the Missed Visit CRF will populate in the visit folder for completion.
Visit Date	A complete date is required.
Did the participant exit/terminate the study at this visit?	Select "Yes" or "No". If "Yes", then complete the Study Termination CRF within the Discontinuations folder.
Were any new adverse events (AEs) reported at this visit? *If "Yes", update the Adverse Event log.*	Select "Yes" or "No". Select "Yes" if at least one Adverse Event (AE) was newly completed for this visit. Navigate to the Ongoing Logs folder to complete a log line for the applicable AE(s).
Is the participant taking any concomitant medications (or are there changes to a previously reported medication) that have not been previously reported? *If "Yes", update the Concomitant Medications log.*	Select "Yes" or "No" to indicate if participant is taking any concomitant medications that have not been previously reported or if there are any changes to a previously reported medication. If "Yes", navigate to the Ongoing Logs folder to either complete a new log line or to update a log line for the applicable medication(s).
Were any protocol deviations reported at this visit? *If "Yes", update the Protocol Deviations log.*	Select "Yes" or "No". Select 'Yes' if at least one protocol deviation was newly completed for this visit. Navigate to the Ongoing Logs folder to complete a log line for the applicable protocol deviation(s).
Were any additional study procedures or forms completed?	If additional 'as-needed' study procedures were completed at this visit, select "Yes" and mark the applicable CRF(s) to be dynamically added to the visit folder.

Inclusion/Exclusion Criteria

Purpose:
This form documents participant's eligibility and enrollment status at Visit 0.

General Instructions:
Complete this form for each participant who have signed a study-specific consent form, regardless if they enroll in the study.

Field-specific Instructions:

Field	Instructions
Did the participant meet all eligibility criteria?	• Select “Yes” if the participant met all eligibility criteria regardless of whether they enrolled in the study. • Select “No” if the participant did not meet all eligibility criteria or one or more eligibility criteria was not assessed.
Eligibility status	• **Eligible and enrolled**: Participant met all eligibility criteria and enrolled in the study. • If “Eligible and enrolled” is marked, end of form. • **Eligible/Not enrolled**: Participant met all eligibility criteria but did not enroll in the study. • **Ineligible**: One or more eligibility criteria was not met. • **Incomplete screening**: One or more eligibility criteria was not assessed. • **Ineligible, but enrolled**: Participant was enrolled, but later determined to be ineligible
Date participant was found "Eligible/Not Enrolled", "Ineligible", or "Incomplete Screening".	A complete date is required.
Select reason(s) why participant is "Ineligible".	If participant is deemed “Ineligible”, select the reason from the dropdown list.
If "Investigator decision", specify (max. 200 characters):	This field is required if “E2. Any condition, which, in the opinion of the investigators, may pose a health risk or interfere with the evaluation of the study objectives” is selected for the reason why the participant is ineligible.

Inclusion/Exclusion Criteria – Step 2

Purpose:
This form documents participant’s eligibility and enrollment status at Visit 1.

General Instructions:
Complete this form for each mother participant who have signed a study-specific consent form, regardless if they enroll in the study.

Field-specific Instructions:

Field	Instructions
Did the participant meet all eligibility criteria?	• Select “Yes” if the participant met all eligibility criteria regardless of whether they enrolled in the study. • Select “No” if the participant did not meet all eligibility criteria or one or more eligibility criteria was not assessed.

Field	Instructions
Eligibility status	• **Eligible and enrolled**: Participant met all eligibility criteria and enrolled in the study. • If “Eligible and enrolled” is marked, end of form. • **Eligible/Not enrolled**: Participant met all eligibility criteria but did not enroll in the study. • **Ineligible**: One or more eligibility criteria was not met. • **Incomplete screening**: One or more eligibility criteria was not assessed. • **Ineligible, but enrolled**: Participant was enrolled, but later determined to be ineligible
Date participant was found "Eligible/Not Enrolled", "Ineligible", or "Incomplete Screening".	A complete date is required.
Select reason(s) why participant is "Ineligible".	If participant is deemed “Ineligible”, select the reason from the dropdown list.
If "Investigator decision", specify (max. 200 characters):	This field is required if “E2. Any condition, which, in the opinion of the investigators, may pose a health risk or interfere with the evaluation of the study objectives” is selected for the reason why the participant is ineligible.

Informed Consent

Purpose:
This form is used to document a participant’s study consent. This includes consent for specimen storage/use in secondary research and consent for breast milk sample collection.

General Instructions:

- This form is present within the Screening folder.
- Complete this form for each mother participant, and her infant, who screens for IDCRC DMID 20-0024. Record the initial consent information. Use the log to record any additional consents that occur during the study.
- Complete a separate entry (e.g., a new log line) for each additional consent.
- Add additional log lines by clicking “Add a new Log line”.

Field-specific Instructions:

Field	Instructions
Informed consent date	For additional consents, record the date when the additional informed consent is signed. A complete date is required.

Informed consent time	For additional consents, record the time when the additional informed consent is signed.
Consent version	For additional consents, record the version. Only numeric characters are allowed in this field.
Did the participant consent to long-term specimen storage and future testing?	Select “Yes” or “No”.

Interim Visit Summary

Purpose:
This form is used to summarize information at an interim visit and to record all procedures or assessments the participant receives at any interim study visit (e.g., if a clinically indicated physical exam is performed) during the study.

General Instructions:
This form is required for each interim visit completed for a participant.

Field-specific Instructions:

Field	Instructions
Visit date	A complete date is required.
Interim visit code	Record the applicable interim visit code. Refer to the Manual of Procedures for more information on visit codes.
Did the participant exit/terminate the study at this visit?	Select “Yes” or “No”. • If “Yes”, then complete the Study Discontinuation CRF within the Discontinuations folder.
Were any new adverse events (AEs) reported at this visit? *If "Yes", update Adverse Events log.*	Select “Yes” or “No”. • Select “Yes” if at least one Adverse Event (AE) was newly completed for this visit. Navigate to the Ongoing Logs folder to complete a log line for the applicable AE(s).
Is the participant taking any concomitant medications (or are there changes to a previously reported medication) that have not been previously reported? *If "Yes", update the Concomitant Medications log.*	Select “Yes” or “No”. Select “Yes” if at least one concomitant medication was newly completed for this visit. Navigate to the Ongoing Logs folder to complete a log line for the applicable medication(s).
Were any protocol deviations reported at this visit? *If "Yes", update the Protocol Deviations log.*	Select “Yes” or “No”. • Select ‘Yes’ if at least one protocol deviation was newly completed for this visit. Navigate to the Ongoing Logs folder to complete a log line for the applicable protocol deviation(s).

What was the reason for this interim visit? *Select all that apply.*	Select the applicable checkboxes for the reason for interim visit. • If "Completion of missed visit procedures", select the appropriate missed visit from the dropdown list. • If "Other" is selected, specify in the corresponding "If "Other", specify" text field provided.
What study procedures were completed at this visit?	Select the applicable checkboxes for the study procedures that were completed at the interim visit. The applicable form(s) will then be dynamically added to the interim visit folder. • Ensure the correct form is marked based on the specific participant and their procedures. • Procedures that were not completed at this visit should be left blank.

Malaria Test Results

Purpose:
This form documents a participant's malaria testing record.

General Instructions:
Complete this form for each participant in for IDCRC DMID 20-0024.

Field-specific Instructions:

Field	Instructions
Was a rapid malaria test performed?	Select "Yes" or "No".
If "No", specify reason not done	Record the reason the malaria test was not performed in the text field.
Collection date	Enter the date the sample for test was collected. A complete date is required.
Collection time	Enter the time the sample for test was collected. Use a 24-hour clock (00:00-23:59), where hours are designated from 0–23.
Rapid malaria test result	Select "Positive", "Negative", or "Indeterminate".
If "indeterminate", was a smear sample collected?	Select "Yes" or "No". If "Yes," record smear sample collection date and time. A complete date is required.
If "yes", smear sample test result	Select "Positive" or "Negative".

Measles and Rubella Vaccine

Purpose:
This form documents a participant's measles and rubella (MR) vaccination record.

General Instructions:
Complete this form for each participant in for IDCRC DMID 20-0024.

Field-specific Instructions:

Field	Instructions
Was a Measles and Rubella vaccination administered at this visit?	Select "Yes" or "No". If "No" is selected, complete Missed Study Product Administration form populated within the visit folder.
If "No", specify reason not done	If Measles and Rubella vaccine was not administered, record the reason in the text field.
Date of vaccination	Enter the date the participant received the Measles and Rubella vaccination. A complete date is required.
Time of injection	Enter the time the participant received the Measles and Rubella vaccination. Use a 24-hour clock (00:00-23:59), where hours are designated from 0–23.
Location of in injection	Select the location between "Right deltoid" and "Left deltoid".
Were there any study product administration errors? *If "Yes", complete Study Product Administration Error form*.	Select "Yes" or "No". If "Yes, complete Study Product Administration Error form populated within the visit folder and Protocol Deviation form in Ongoing Logs folder.
Comments	Record any comments on the vaccination assessment. Maximum 200 characters.

Medical History Y/N

Purpose:
This form documents if any medical history has been reported. This form is used to trigger the Medical History log.

Do not use this form to document conditions/events that occur after screening and enrollment.
General Instructions:

This form is in the "Ongoing Logs" folder and is only completed once, at the time the baseline medical history is collected or at the end of the study if no medical history is reported.

Field-specific Instructions:

Field	Instructions
Does the participant have any medical history to report?	• If "Yes" is selected, the Medical History log is added to the Ongoing Logs folder. • At the end of study participation, mark "No" if no medical history is reported.

Medical History

Purpose:
This form documents any baseline medical history conditions/events reported at the screening and enrollment visit or recalled by the participant during follow-up.

Do not use this form to document conditions/events that occur after screening and enrollment.
For conditions/events that occur after screening and enrollment, document on the Adverse Event form located in the Ongoing Logs folder.

General Instructions:

- This form is present within the Screening/Enrollment visit folder.
- Report clinically significant conditions/events up to enrollment, including but not limited to: history of hospitalizations, surgeries, allergies, history of conditions related to pregnancy, history of conditions related to respiratory illness, and acute conditions ongoing at enrollment. Also include any history of conditions related to mental illness, alcoholism, drug abuse, and chronic conditions (controlled or not controlled by medication).
- Complete a separate entry (e.g., a new log line) for each medical history condition/event.
- Add additional log lines by clicking "Add a new Log line".
- If a participant recalls additional medical history conditions/events after enrollment, update the Medical History Log by adding a new log line.

Field-specific Instructions:

Field	Instructions
Date medical history collected	Record the date the medical history condition/event was reported by the participant. At least the year is required.
Description of medical history condition/event	Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded as a separate entry on the Medical History Log. Additional information on the frequency and duration of chronic condition outbreaks can also be provided within this description. • If treatment/medication is taken for the condition, record any medication use on the **Concomitant Medications** form located in the Ongoing Logs folder.
Is condition/event gradable?	• Mark "Yes" or "No". • If "Yes", choose the appropriate grade level under Severity grade Field using the drop-down list.

Field	Instructions
Severity grade	Record the severity grade using the most current version of the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events* (including relevant appendices/addendums). • Grade 1 (Mild) • Grade 2 (Moderate) • Grade 3 (Severe) • Grade 4 (Potentially life-threatening)

Start date of pre-existing condition/event	• Record the date the medical condition was first diagnosed or the date the surgery/procedure was performed as applicable.
	• If the participant is unable to recall the exact date, obtain her best estimate. At a minimum, a year is required. If the date is within the same year as study enrollment, the month and year are both required.
	  • If the exact day is unknown, enter "UN" for the day field.
	  • If the exact month is unknown, select "UNK" for the month field.
	• Example: UN-Jan-2020 or UN-UNK-2020.

Is the condition ongoing?	Select 'Yes' for chronic conditions, as well as any other conditions that are ongoing at screening and enrollment. During each follow-up visit, routinely follow-up on any and all ongoing conditions. If the condition resolves during follow-up, this item should not be updated. • If this item is selected 'Yes', then this is the end of form and the "Date medical history condition/event ended/resolved" should be left blank.
Date medical history condition/event ended/resolved	A date is required if "Is the condition ongoing?" is "No". At a minimum, a year is required. • If the exact day is unknown, enter "UN" for the day field. • If the exact month is unknown, select "UNK" for the month field. Record the date the medical condition was considered resolved. For surgeries/procedures, record the date the surgery/procedure was completed. • If the condition resolves during the study, the Baseline Medical History form should not be updated with a resolution or end date for the medical condition.
Comments	Provide any pertinent details in this field, if applicable. A maximum of 200 characters are allowable.

Meningococcal Vaccine

Purpose:
This form documents a participant's Meningococcal vaccination record.

General Instructions:
Complete this form for each participant in for IDCRC DMID 20-0024.

Field-specific Instructions:

Field	Instructions
Was a blinded meningococcal vaccination administered at this visit?	Select “Yes” or “No”. If “No” is selected, complete Missed Study Product Administration – Meningococcal form populated within the visit folder.
If "No", specify reason not done	If Meningococcal vaccine was not administered, record the reason in the text field.
Date of vaccination	Enter the date the participant received the Meningococcal vaccination. A complete date is required.
Time of injection	Enter the time the participant received the Meningococcal vaccination. Use a 24-hour clock (00:00-23:59), where hours are designated from 0–23.
Location of injection	Select the location between “Right anterolateral aspect of the thigh” and “Left anterolateral aspect of the thigh”.
Were there any study product administration errors?	Select “Yes” or “No”. If “Yes”, complete Study Product Administration Error - Meningococcal form populated within the visit folder and Protocol Deviation form in Ongoing Logs folder.
Comments	Record any comments on the vaccination assessment. Maximum 200 characters.

Missed Study Product Administration - Meningococcal

Purpose:
This form documents a meningococcal vaccine that is missed and not administrated.

General Instructions:
Complete this form for each enrolled participant when meningococcal vaccines are missed at a required visit.

Field-specific Instructions:

Field	Instructions
Visit date of missed study product administration	A complete date is required.
What is the primary reason for missing the study product administration at this visit?	Select appropriate reason from the dropdown list. • If "Adverse event", complete Adverse Event log if condition meets AE reporting requirements as specified in the protocol and select AE from the search list provided below. • If “Reactogenicity event”, specify the reason in the text field. • If “Other”, specify the reason in the text field.
If "Adverse event" or "Reactogenicity event", indicate who made the decision to not administer study product. Mark all that apply.	Select all that apply and indicate who made the decision to not administer the study product. • If “Other”, specify the role who made the decision.
Comments	Record any comments on missed study product administration. Maximum 200 characters.

Missed Study Product Administration – Measles and Rubella

Purpose:
This form documents a measles and rubella vaccine that is missed and not administrated.

General Instructions:
Complete this form for each enrolled participant when measles and rubella vaccines are missed at a required visit.

Field-specific Instructions:

Field	Instructions
Visit date of missed study product administration	A complete date is required.
What is the primary reason for missing the study product administration at this visit?	Select appropriate reason from the dropdown list. • If "Adverse event", complete Adverse Event log if condition meets AE reporting requirements as specified in the protocol and select AE from the search list provided below. • If “Reactogenicity event”, specify the reason in the text field. • If “Other”, specify the reason in the text field.

Field	Instructions
If "Adverse event" or "Reactogenicity event", indicate who made the decision to not administer study product. Mark all that apply.	Select all that apply and indicate who made the decision to not administer the study product. • If “Other”, specify the role who made the decision.
Comments	Record any comments on missed study product administration. Maximum 200 characters.

Missed Study Product Administration – Yellow Fever

Purpose:
This form documents a yellow fever vaccine that is missed and not administrated.

General Instructions:
Complete this form for each enrolled participant when yellow fever vaccines are missed at a required visit.

Field-specific Instructions:

Field	Instructions
Visit date of missed study product administration	A complete date is required.
What is the primary reason for missing the study product administration at this visit?	Select appropriate reason from the dropdown list. • If "Adverse event", complete Adverse Event log if condition meets AE reporting requirements as specified in the protocol and select AE from the search list provided below. • If “Reactogenicity event”, specify the reason in the text field. • If “Other”, specify the reason in the text field.
If "Adverse event" or "Reactogenicity event", indicate who made the decision to not administer study product. Mark all that apply.	Select all that apply and indicate who made the decision to not administer the study product. • If “Other”, specify the role who made the decision.
Comments	Record any comments on missed study product administration. Maximum 200 characters.

Missed Visit

Purpose:
Complete this form in the event that an enrolled participant misses a required visit according to the visit window outlined in the protocol or Manual of Procedures (MOP).

General Instructions:
A missed visit form will be dynamically added to a visit folder if the response to "Did the participant complete this visit (or required visit procedures)?" on the Follow-up Visit Summary from is "No, visit missed". Complete the Missed Visit form only for this visit.

Field-specific Instructions:

Field	Instructions
Target visit date	• Record the target date of the visit. A complete date is required.
Reason visit was missed	• Select the reason that the participant missed the visit from the drop-down list. If the reason that the participant missed the visit is not included in this list, select "Other", and specify the reason that the visit was missed in the corresponding "If "Other", specify" text field provided. ○ Unable to contact participant ○ Participant unable to schedule visit within window ○ Participant refused visit ○ Participant withdrew from study ○ Participant deceased ○ Other If "Other" is selected, specify in the corresponding "If "Other", specify" text field provided.
Steps taken to address the missed visit (corrective action plan)	• Record the corrective steps that have been taken or will be taken to address the missed visit and help prevent future missed visits.

Participant Identifier

Purpose:
The Participant Identifier page within Medidata Rave will generate each participant's PTID. This page is the first form completed within Medidata Rave for each participant.

General Instructions:
Complete this form for every IDCRC DMID 20-0024 participant once informed consent is provided for study screening and enrollment.

Field-specific Instructions:

Field	Instructions
Participant ID:	• To add a participant to the study database, select the "Add Subject" link on the site-specific home page for the study. The Participant Identifier form will appear. • No data entry is required on this form. • Click the "Save" button at the bottom of the form. A pop-up box will appear to indicate that a participant has been added to the database and the home page for the participant's file will appear. The link to refer back to the Participant Identifier page is located at the top of each participant's home page. The participant ID will appear on each form generated in Medidata Rave. The participant ID should be written at the top of each paper form completed for a participant. • Refer to the Manual of Procedures for more information on participant IDs.

Physical Exam

Purpose:
This form documents physical exam findings.

General Instructions:
Complete this form when clinically indicated. If abnormal findings are found for any of the assessments, record information on the Baseline Medical History log for mother participants at enrollment or on the Medical Event log for mother and infant participants during follow-up.

Field-specific Instructions

Field	Instructions
Date of exam	A complete date is required.
BODY SYSTEM	For each organ system or body part evaluated, indicate whether the findings were "Normal" or "Abnormal". If "Abnormal", describe the abnormality in the corresponding "If "Abnormal", specify" text field. • If not evaluated, select "Not done".
Other system finding	• If other systems were assessed not covered by the pre-defined assessments, then please specify whether findings were "Normal" or "Abnormal" under the "Other system finding" section. • Specify the body system being referenced in the "If "Other system", specify" text field. • If "Abnormal", describe findings in the corresponding "If "Abnormal", specify" text field. • If no additional body system is evaluated, select "Not done".
Comments (max. 200 characters):	Provide any pertinent details in this field, if applicable. A maximum of 200 characters are allowable.

Temporary Product Delay Y/N

Purpose:
This form documents if a clinician-initiated product hold was applied during the study.

General Instructions:
This form is present within the "Ongoing Logs" folder. Selecting 'Yes' to the "Does the participant have any clinical product holds to be applied?" prompt will add the "Product Hold" log to the "Ongoing Logs" folder.

Temporary Product Delay Log

Purpose:
This form is used to document temporary clinical holds of study product use as instructed by study site staff.

General Instructions:
This form is completed each time a participant is instructed by study staff to temporarily stop (hold) study product use. If, at the same visit, a product hold is initiated for more than one reason, complete one Product Hold log line for each reason. To add an additional Clinical Product Hold log line within Medidata Rave, click "Add a new Log line" to add an additional log line for a new product hold to be completed.

Complete this form for any clinical reason that warrants a product hold regardless of whether participants choose to use study product during the study. Do not complete this form in cases where a participant has decided herself to not use the study product.

Item-specific Instructions:

Field	Instructions
Date when this study product delay was initiated	Record the date when the product was delayed.
At what visit was this product delay initiated?	Select the appropriate visit (e.g., V1.0 to V5.0) from the dropdown list. If "interim visit", specify interim visit code. Refer to the Manual of Procedures for more information on visit codes.
Why is the vaccine being delayed?	Record the reason that study product is being held. If the delay is for any reason not specified, mark "Other" and specify the reason in the If Other", specify. Note that participant decline, or refusal of study product is not documented as a product delay. Do not record this as a reason in 'If, Other, specify".
If product delay was associated with an adverse event, select the applicable AEs:	If study product is being held due to "Adverse Event", select the applicable AE from the drop-down field provided. **Note**: The applicable AE must first be entered on the AE form in order to be visible in the drop-down list.

If product delay was associated with a new or updated concomitant medication, select applicable medication(s):	If study product is being delayed due to "Reported use of prohibited concomitant medication", specify the corresponding concomitant medications log form on which the medication was reported in from the drop-down field provided with Rave. At least one medication must be specified. **Note**: The applicable CM must first be entered on the CM form in order to be visible in the drop-down list.
Date participant resumed study product?	If 'Yes', enter below the date that the participant was instructed to resume study product within the "Date study product resumed" field. Mark, "No – hold continuing for another reason" if the participant would have been instructed to resume study product based on the resolution of the reason indicated on this form. If 'No – hold continuing for another reason', enter below the 'date study product hold continuing for another reason'. Mark, "No – permanently discontinued" if the participant was permanently discontinued from study product due the reason indicated on this form. Mark, "No – early termination" if the product hold was ongoing at the visit at which the participant terminated early from the study. Complete the Study Termination form.
Date participant resumed study product	Record the date that the participant was instructed to resume study product.

Protocol Deviations Y/N

Purpose:
This form documents if a protocol deviation has occurred. This form is used to trigger the Protocol Deviations form.

General Instructions:
This form is in the Ongoing Logs folder and is only completed once, at the time the first protocol deviation is reported or at the end of the study if no protocol deviations are reported.

Field-specific Instructions:

Field	Instructions
Have any protocol deviations been reported?	• Select "Yes" or "No". • Selecting "Yes" will add the Protocol Deviations log to the Ongoing Logs folder.

Protocol Deviations

Purpose:
This form documents and reports protocol deviations for IDCRC DMID 20-0024.

General Information/Instructions:

- Complete one log entry for each protocol deviation.
- Add additional log lines by clicking “Add a new Log line”.
- Refer to the Protocol Deviations section of the Manual of Operations (MOP) for further guidance.

Field-specific Instructions:

Field	Instructions
Site awareness date	Record the date the site became aware of the deviation. (Example: The date the site discovered the deviation, the date the monitor notified the site of a deviation, etc.). A complete date is required.
Deviation date	Record the date the deviation occurred (start date). (Example: The date of procedures conducted outside of the visit window, the date a participant was inappropriately enrolled, etc.). A complete date is required.
Has or will this deviation be reported to local IRB/EC?	Select “Yes” or “No”.
Type of deviation	• Select the applicable deviation from the list of available options. • *Please see table below for the types of deviations.* When entering the type of deviation, the first few letters of the description can be entered within the drop-down list to find the applicable deviation to be entered. • Select “Other” if none of the listed categories match.
Description of deviation	Use the text field to briefly describe the specific details of the deviation.
Plans and/or action taken to address the deviation	Use the text field to provide a brief description of the plans to address the deviation.
Plans and/or action taken to prevent future occurrences of the deviation	Use the text field to provide a brief description of the plans to address future deviations.
Deviation reported by	Record the name of staff member completing the form.

PROTOCOL DEVIATION LIST	
Deviation Type	**Description/Examples**
Inappropriate enrollment	The participant enrolled and not all eligibility requirements were met.
Failure to follow randomization or blinding procedures	The participant failed to be randomized into Group 1 or Group 2.
Study product management deviation	The study product was managed incorrectly.

Study product dispensing error	The study product was dispensed to participant incorrectly.
Study product use/non-use deviation	The study product was missed at required visit.
Study product sharing	The study product was shared with another participant.
Study product not returned	Unused study product was not returned.
Conduct of non-protocol procedure	A clinical or administrative procedure was performed that was not specified in the protocol and was not covered under local standard of care practice.
Improper AE	An AE is not followed per protocol. For example, a clinical finding/lab result is not re-assessed as outlined in the protocol.
Unreported AE	Site staff became aware of an AE but did not report it per protocol requirements.
Breach of confidentiality	Includes potential and actual cases where participant confidentiality was breached. For example, a staff member put a participant's name on a case report form.
Physical assessment deviation	Includes when a protocol-specified exam or assessment was not performed.
Lab assessment deviation	Includes when a protocol-specified safety lab or necessary follow-up laboratory test was not collected or reported to the participant (e.g. HIV testing).
Mishandled lab specimen	Includes errors in labeling, physical handling, processing, testing, storage, or shipment of collected lab specimens.
Staff performing duties that they are not qualified to perform	Includes any instances when any study procedure, including clinical and administrative procedures, was completed by a staff member who is not adequately qualified AND delegated to perform the procedure.
Questionnaire administration deviation	Includes instances when a required questionnaire was not completed according to protocol requirements or where the wrong questionnaire was completed.
Counseling deviation	Protocol-required counseling was not done and/or not documented correctly.

Use of non-IRB/EC-approved materials	Includes use of ANY study-related material that has not received IRB or EC approval for use per site requirements.
Use of excluded concomitant medications, devices, or non-study products	Includes any medications, devices, or non-study products that were excluded per protocol requirements.
Informed consent process deviation	Includes failure to accurately execute and/or document any part of the informed consent process.
Visit completed outside of window	Visit procedures were complete in the wrong visit window or not within a designated visit window. (e.g. visit 3.0 procedures were done in the visit 4.0 window.)
Insufficient volume of primary specimen collected	The site was unable to collect sufficient volume of the blood specimen collection.
Minimum number of aliquots not obtained	The site was unable to collect a sufficient amount of aliquots as required.
Other	Any other deviation not listed above.

Randomization Method – Step 1

Participant Type: Group 1-9 months or Group 2-15 months

Purpose:
This form is used to document the method of randomization for a participant. This form is completed at Visit 0 for participants who have provided informed consent and who are eligible to participate in the study.

General Instructions:
Complete this form for each participant who will enroll in IDCRC DMID 20-0024 indicating whether the method was “Online” or “Envelope”.

Field	Instructions
Will randomization step 1 be performed online or using an envelope?	Select “Online” or “Envelope” • Online: Official randomization occurred within the Medidata Rave database • Envelope: Official randomization occurred offline, with an envelope containing paper documentation.
Randomization Date	A complete date is required. • If randomization occurred “Online”, record the date the Randomization – Step 1 CRF was saved. • If randomization occurred with an envelope, record the date the envelope was opened.

Field	Instructions
If “Envelope”, enter time envelope was opened	Enter the time the envelope was opened. Use a 24-hour clock (00:00-23:59), where hours are designated from 0–23.
If “Envelope”, enter Envelope Number	Enter the envelope number as indicated on the hard copy (paper).

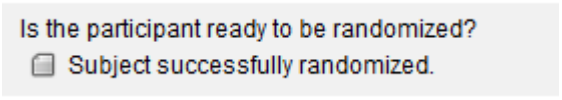
Randomization – Step 1

Participant Type: Group 1-9 months or Group 2-15 months

Purpose:
This form is used to officially randomize a participant for IDCRC DMID 20-0024. This form is completed at Enrollment for participants who have provided informed consent and who are eligible to participate in the study.

General Instructions:
Complete this form for each participant who will enroll in IDCRC DMID 20-0024 indicating the participant is ready to be randomized. The items “Did the participant meet all eligibility criteria?” on the Eligibility Criteria form must be completed before the Randomization form in order for the randomization to be successful.

Item-specific Instructions:

Field	Instructions
Is the participant ready to be randomized to receive the Meningococcal vaccine immediately (9-12 mo of age) or delayed (15-18 mo of age)?	Select ‘Yes’ and Save the form. If the participant is successfully randomized, a note will appear under this item as shown below:  If randomization was not successful, this message will not appear, and the Randomization Date and Time will not automatically populate. If successful, the participant will be assigned to a treatment arm and to participation in IDI in the Medidata Balance module.
Randomization Date and Time	Once “Is the participant ready to be randomized?” is saved as ‘Yes’, then the randomization Date and Time will automatically populate. The Randomization Time will be auto-populated in Coordinated Universal Time (UTC).

Randomization Method – Step 2

Participant Type: Group 1-9 months or Group 2-15 months

Purpose:
This form is used to document the method of randomization for a participant. This form is completed at Visit 1 for participants who have provided informed consent and who are eligible to participate in the study.

General Instructions:
Complete this form for each participant who will enroll in IDCRC DMID 20-0024 indicating whether the method was “Online” or “Envelope”.

Field	Instructions
Will randomization step 2 be performed online or using an envelope?	Select “Online” or “Envelope” • Online: Official randomization occurred within the Medidata Rave database • Envelope: Official randomization occurred offline, with an envelope containing paper documentation.
Randomization Date	A complete date is required. • If randomization occurred “Online”, record the date the Randomization – Step 2 CRF was saved. • If randomization occurred with an envelope, record the date the envelope was opened.
If “Envelope”, enter time envelope was opened	Enter the time the envelope was opened. Use a 24-hour clock (00:00-23:59), where hours are designated from 0–23.
If “Envelope”, enter Envelope Number	Enter the envelope number as indicated on the hard copy (paper).

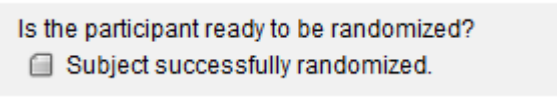
Randomization – Step 2

Participant Type: Group 1-9 months or Group 2-15 months

Purpose:
This form is used to officially randomize a participant for IDCRC DMID 20-0024. This form is completed at Enrollment for participants who have provided informed consent and who are eligible to participate in the study.

General Instructions:
Complete this form for each participant who will enroll in IDCRC DMID 20-0024 indicating the participant is ready to be randomized. The Randomization Date and Time will be auto-populated from Medidata Balance into Medidata Rave. Upon saving this form, the participant’s treatment assignment will be generated in Medidata Balance.

Item-specific Instructions:

Field	Instructions
Is the participant ready to be randomized to receive the NmCV-5 or MenACWY-TT Meningococcal vaccine?	Select 'Yes' and Save the form. If the participant is successfully randomized, a note will appear under this item as shown below:  If randomization was not successful, this message will not appear, and the Randomization Date and Time will not automatically populate. If successful, the participant will be assigned to a treatment arm and to participation in IDI in the Medidata Balance module.
Randomization Date and Time	Once "Is the participant ready to be randomized?" is saved as 'Yes', then the randomization Date and Time will automatically populate. The Randomization Time will be auto-populated in Coordinated Universal Time (UTC).

Reactogenicity – Baseline and Early

Purpose: This form is used to collect reactogenicity assessments for both pre-vaccination and 30 minutes post-vaccination and is only available on study drug vaccination day. Do not use this form to record daily reactogenicity assessments.

General Instructions:

The Reactogenicity – Baseline and Early CRF will auto-populate at Visit 1.

Baseline assessment: The reactogenicity assessment performed immediately prior to vaccination.

Early assessment: The reactogenicity assessment performed 30minute post-vaccination.

At the vaccination visits, where both Baseline and Early assessments are collected, the "Baseline" collection information is displayed initially in portrait format when the CRF is selected. Complete the information and submit.

Once submitted, the "Early assessment" collection information will be available for entry, however it will appear in the log instead of initially presented in portrait mode. Click the "Early assessment" log line to display the early assessment collection information in portrait mode. Enter and submit. You should now have both log lines visible with collection information. See below for an example.

Subject: **999472565**
Page: **Reactogenicity - Baseline and Early - V1 - Enrollment - C1/C2**

#	Reactogenicity Assessment Performed	Reason Not Done	Time Point	Assessment Date	Assessment Time	Body Temperature	Severity grade	Adverse Event	Chills	Adverse Event	Malaise/Fatigue	Adverse Event	Myalgia	Adverse Event	Arthralgia	Adverse Event	Headache	Adverse Event
1	Yes	_	Baseline	02 Jun 2021	08:33	38.5	None	_	None	_	None	_	None	_	None	_	None	_
2	Yes	_	Early assessment	02 Jun 2021	09:45	38.2	None	_	None	_	None	_	None	_	None	_	None	_

Nausea	Adverse Event	Injection Number	Location of Local Assessment	Pain/Tenderness	Adverse Event	Vaccine Related Lesion	Erythema/Redness Diameter	Severity grade	Adverse Event	Induration/Swelling Diameter	Severity grade	Adverse Event	Comments	
None	_	Vaccination 1	Right deltoid	None	_	_	0.0	None	_	0.0	None	_	_	
None	_	Vaccination 1	Right deltoid	None	_	No	0.0	None	_	0.0	None	_	_	

Field-specific Instructions:

Field	Instructions
Was assessment done? *If "No", specify reason not done below and end of form.*	Select "Yes" or "No"
Reason not done	Detail the reason the assessment was not done. Maximum 200 characters.
Assessment time point	This is a non-editable field and will display the assessment collection time point. Information should be entered for the defined time point only.
Date of assessment	Record the date the assessment was performed. A complete date is required.
Time of assessment	Record the time the assessment was performed. Use a 24-hour clock (00:00-23:59), where hours are designated from 0–23.
Body temperature *If body temperature >= 37.5 C at baseline,* ***DO NOT administer study product.***	Record the participant's body temperature in °C. If the participant's body temperature is equal to or exceeds 37.5 °C at **baseline**, the study product should not be administered. If not assessed, leave this field empty.
Severity grade	Record the severity grade of the body temperature reading. If the symptom was assessed, but measurement is less than required for severity grade 1 (mild), put "None". If Body Temperature was NOT assessed, leave the "Body temperature" field blank, and record "Not assessed" in Severity grade, leave the "Adverse event" field blank and record the reason for not assessing the site in the page comments.

Systemic Symptoms *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*. Irritability Drowsiness/Lethargy Decrease Eating/Anorexia Vomiting	Assess the participant for the systemic symptom. If the symptom is present record the severity grade of the specific symptom. In addition, if the assessment meets the criteria for reporting on the AE log, record it on the AE log. If the participant was assessed for a specific symptom, and that symptom is not present, record "None" in Severity.
LOCAL SYMPTOMS **Meningococcal vaccination site only** Location of local assessment	Record the location of the assessment. For Baseline assessments, this location should be for **planned** location where the injection will be administered. For post-injections assessments, it's the actual location of injection.
Local Symptoms Pain and/or tenderness	Assess the injection site. If Pain and/or tenderness is present record the severity grade of the specific symptom. In addition, if the assessment meets the criteria for reporting on the AE log, record it on the AE log. If the injection site was assessed and Pain and/or tenderness is not present, record "None" in Severity grade. If the injection site was NOT assessed, leave the measurement field blank for the assessment that was not measured and record the reason for not assessing the site in the page comments. If the participant's "Pain and/or tenderness" assessment is equal to or exceeds Moderate at **baseline**, the study product should not be administered

Is a vaccine-related erythema or induration visible? *If "No", skip to "Pain and/or tenderness".*	For the baseline assessment: Assess for lesion(s) at the planned injection site. If non-vaccine-related lesions are present, document the information in "Comments". For the early (30-minutes post-dose) assessment: Assess for lesion(s) at the actual injection site. Any AEs/SAEs will be recorded on the appropriate DCF prior to discharge from the clinic.
Local Symptoms Erythema/redness largest diameter Induration/swelling largest diameter	Assess the injection site. If Erythema/redness or Induration/swelling is present, measure and record the diameter in cm. Enter the severity grade of the specific symptom. In addition, if the assessment meets the criteria for reporting on the AE log, record it on the AE log. If the participant was assessed for a specific symptom, and that symptom is not present, record "None" in Severity grade. If there is an alternate etiology, specify in the Comments field provided. **Erythema/redness:** If Induration/swelling is present but Erythema/redness is not present, record 0.0 in the diameter and record "None" in Severity grade. If the injection site was NOT assessed, leave the measurement field blank and record the reason for not assessing the site in the page comments. **Induration/swelling:** If Erythema/redness is present but Induration/swelling is not present, record 0.0 in the diameter and record "None" in Severity grade. If the injection site was NOT assessed, leave the measurement field blank and record the reason for not assessing the site in the page comments.
Comments	Record any comments on the reactogenicity assessment. Maximum 450 characters.

Reactogenicity – Daily Log

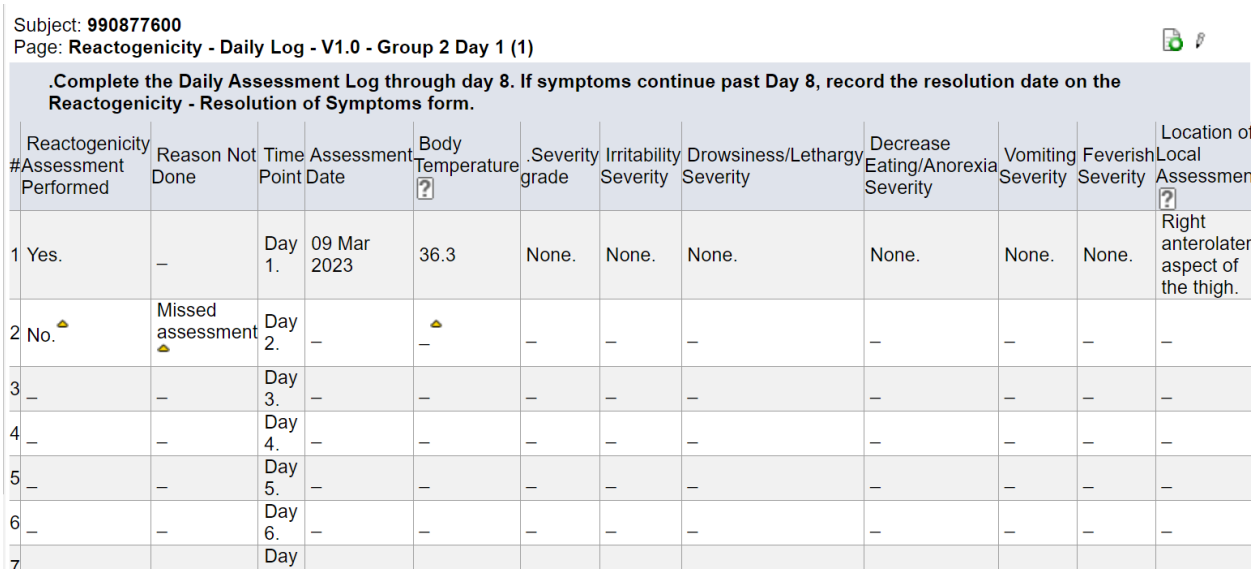
Purpose: This form is used to collect reactogenicity assessments daily, for 7-days post vaccination. Do not use this form to record baseline and early reactogenicity assessments or to log symptoms continued past Day 8.

General Instructions:

The Reactogenicity – Daily Log will auto-populate Visit 1.

At the vaccination visits, where daily reactogenicity assessments are collected, the “Day 1” collection information is displayed initially in portrait format when the CRF is selected. Complete the information and submit. Once submitted, the subsequent time point (Days 2-8) collection information will be available for entry, however each will appear in the log instead of initially presented in portrait mode. Click the “Day 2” log line to display the next assessment collection information in portrait mode, and so on. Enter and submit.

You should now have <u>all</u> log lines visible with collection information as entered. See below for an example.



Subject: **990877600**
Page: **Reactogenicity - Daily Log - V1.0 - Group 2 Day 1 (1)**

.Complete the Daily Assessment Log through day 8. If symptoms continue past Day 8, record the resolution date on the Reactogenicity - Resolution of Symptoms form.

#	Reactogenicity Assessment Performed	Reason Not Done	Time Point	Assessment Date	Body Temperature	.Severity grade	Irritability Severity	Drowsiness/Lethargy Severity	Decrease Eating/Anorexia Severity	Vomiting Severity	Feverish Severity	Location of Local Assessmen
1	Yes.	_	Day 1.	09 Mar 2023	36.3	None.	None.	None.	None.	None.	None.	Right anterolater aspect of the thigh.
2	No.	Missed assessment	Day 2.	_	_	_	_	_	_	_	_	_
3	_	_	Day 3.	_	_	_	_	_	_	_	_	_
4	_	_	Day 4.	_	_	_	_	_	_	_	_	_
5	_	_	Day 5.	_	_	_	_	_	_	_	_	_
6	_	_	Day 6.	_	_	_	_	_	_	_	_	_
7			Day									

Field-specific Instructions:

Field	Instructions
COMPLETE AT DAY 8 ONLY: *Are there any symptoms at a higher severity grade than baseline continuing at the end of Day 8 assessment?* *If “Yes”, complete the Reactogenicity – Resolution of Symptoms form*	Complete at Day 8 only. Select “Yes” or “No”

Was assessment done? *If "No", specify reason not done below and end of form.*	Select “Yes” or “No”
Reason not done	Detail the reason the assessment was not done. Maximum 200 characters.
Assessment time point	This is a non-editable field and will display the assessment collection time point. Information should be entered for the defined time point only.
Date of assessment	Record the date the assessment was performed. A complete date is required.
Body temperature	Record the participant’s body temperature in °C. **If not assessed, leave this field empty.**
Severity grade	Record the severity grade of the body temperature reading. If the symptom was assessed, but measurement is less than required for severity grade 1 (mild) put “None”.
Systemic Symptoms *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*. Irritability Drowsiness/Lethargy Decrease Eating/Anorexia Vomiting Feverish	Assess the participant for the systemic symptom. If the symptom is present record the severity grade of the specific symptom. In addition, if the assessment meets the criteria for reporting on the AE log, record it on the AE log. If the participant was assessed for a specific symptom, and that symptom is not present, record “None” in Severity grade. If there is an alternate etiology, specify in the Comments field provided.
LOCAL SYMPTOMS **Meningococcal vaccination site only** Location of local assessment	Select location of meningococcal vaccination site between “Right anterolateral aspect of the thigh” and “Left anterolateral aspect of the thigh”.

Local Symptoms Pain and/or tenderness	Assess the injection site. If Pain and/or tenderness is present record the severity grade of the specific symptom. In addition, if the assessment meets the criteria for reporting on the AE log, record it on the AE log. If the injection site was assessed and Pain and/or tenderness is not present, record “None” in Severity grade. If the injection site was NOT assessed, leave the measurement field blank for the assessment that was not measured and record the reason for not assessing the site in the page comments.
Is a vaccine-related lesion visible? *If "No", skip to "Pain and/or tenderness".*	Assess for lesion(s) at the injection site. If non-vaccine-related lesions are present, document the information in “Comments”.
Local Symptoms Erythema/redness largest diameter Induration/swelling largest diameter	Assess the injection site. If Erythema/redness or Induration/swelling is present, measure and record the diameter in cm. Enter the severity grade of the specific symptom. In addition, if the assessment meets the criteria for reporting on the AE log, record it on the AE log. If the participant was assessed for a specific symptom, and that symptom is not present, record “None” in Severity grade. If there is an alternate etiology, specify in the Comments field provided. **Erythema/redness:** If Induration/swelling is present but Erythema/redness is not present, record 0.0 in the diameter and record “None” in Severity grade. If the injection site was NOT assessed, leave the measurement field blank and record the reason for not assessing the site in the page comments. **Induration/swelling:** If Erythema/redness is present but Induration/swelling is not present, record 0.0 in the diameter and record “None” in Severity grade. If the injection site was NOT assessed, leave the measurement field blank and record the reason for not assessing the site in the page comments.
Comments	Record any comments on the reactogenicity assessment. Maximum 450 characters.

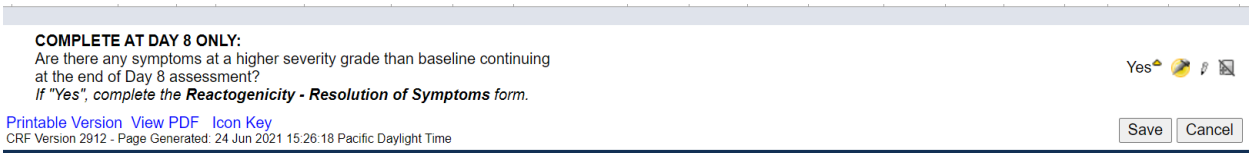
Reactogenicity – Resolution of Symptoms

Purpose: This form is used to collect resolution information for any reactogenicity symptom that persist 7 days post injection.

General Instructions:

The Reactogenicity – Resolution of Symptoms form will auto-populate after the Day 8 assessment has been completed and the question “Are there any symptoms at a higher severity than baseline continuing at the end of Day 8 assessment?” is marked “Yes” on the Reactogenicity Daily Log CRF page. The AE log page must be entered into Rave prior to linking the AE on the Reactogenicity form for the AE to be available to select with the drop-down field.

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 periods 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.



Field-specific Instructions:

Field	Instructions
Maximum body temperature	Record the participant's maximum body temperature in °C. **If not assessed, leave this field empty.**
Severity grade	Record the severity grade of the body temperature reading. If the symptom is not present after Day 8, record "None" in Severity grade and leave the Resolution date and Adverse event fields blank. All symptoms must have an entry in Severity grade. In addition, if the assessment meets the criteria for reporting on the AE log, record it on the AE log. If the participant was assessed for a specific symptom, and that symptom is not present, record "None" in Severity grade. If there is an alternate etiology, specify in the Comments field provided.
Resolution Date	Record the resolution date
Maximum body temperature not applicable	Check this box if the maximum body temperature does not apply to this form.
Systemic Symptoms Irritability Drowsiness/Lethargy Decrease Eating/Anorexia Vomiting	If the systemic symptom is ongoing at the end of the Day 8 assessment, continue to observe for the symptom until it is no longer present. Record the maximum severity of the specific symptom and resolution date for ALL symptoms ongoing at the end of the Day 8 assessment. In addition, if the assessment meets the criteria for reporting on the AE log, link the event to a recorded event by selecting the applicable event from the menu. If the symptom is not present after Day 8, record "None" in Severity grade and leave the Resolution date. All symptoms must have an entry in Severity grade.
LOCAL SYMPTOMS **Meningococcal vaccination site only** Location of local assessment	Select location of meningococcal vaccination site between "Right anterolateral aspect of the thigh" and "Left anterolateral aspect of the thigh".
Local Symptoms	If the local symptom Pain and/or tenderness is ongoing at the end of the Day 8 assessment, continue to observe for the symptom until it is no longer present.

Pain and/or tenderness	Record the maximum severity of the Pain and/or tenderness and resolution date if Pain and/or tenderness is ongoing at the end of the Day 8 assessment. In addition, if the Pain and/or tenderness assessment meets the criteria for reporting on the AE log, record it on the AE log. If the symptom is not present after Day 8, record "None" in Severity grade and leave the Resolution date. All symptoms must have an entry in Severity grade. If there is an alternate etiology, specify in the Comments field provided.
Local Symptoms Erythema/redness largest diameter Induration/swelling largest diameter	Assess the injection site. If Erythema/redness and/or Induration/swelling is ongoing at the end of the Day 8 assessment, measure and record the MAXIMUM diameter in cm. Enter the severity grade of the specific symptom. In addition, if the assessment meets the criteria for reporting on the AE log, record it on the AE log. If there is an alternate etiology, specify in the Comments field provided. **Erythema/redness:** If the injection site was assessed and Erythema/redness is not present, record 0.0 in the diameter, record "None" in Severity grade. If the injection site was NOT assessed, leave the measurement field blank for the assessment that was not measured record the reason for not assessing the site in the page comments. **Induration/swelling:** If the injection site was assessed for induration/swelling but not measured, leave the measurement field blank and record the severity grade. Record the reason for not measuring the site in the page comments.

Specimen Collection – Blood

Purpose:
This form is used to document collection and storage of blood specimens for participants.

General Instructions:
Complete this form to document the participant's blood specimen collection and storage at the visits specified by the protocol.

General Instructions:

- Do not use this form to document any local lab specimens. Use this form only to document the collection of research specimens that will be sent to the site processing lab.
- If a tube type is collected within a visit window but over multiple visits, contact the CDM to add a new Specimen Collection - Blood form to the visit.

Field-specific Instructions:

Field	Instructions
Was specimen collected?	Select “Yes” if any amount of blood specimen was collected.
If "No", record reason why sample was not collected (max. 200 characters).	If specimen was not collected, record the reason why the specimen sample was not collected in the text field. A maximum 200 character is allowable.
Specimen collection method	Select “Venipuncture” or “Heel stick”.
Specimen collection date	Record the date that the specimen was collected, NOT the date the results were reported or recorded on the form for this visit. A complete date is required.
Specimen collection time	Record the time that the specimen was collected.
Was the minimum required volume obtained?	If the amount of specimen collected is less than the requested volume, select “No”.
If "No", record reason why minimum required volume was not obtained (max. 200 characters).	If specimen sample did not meet the requested volume, record the reason in the text field.
Was sample stored for shipment to central lab?	Select “Stored” for specimens that are collected and sent to the lab for processing. If the specimen is required to be stored, but for some reason it is not stored, select “Not stored”.
If "Not stored", record reason why sample was not stored (max. 200 characters).	If specimen sample is not stored, record the reason in the text field.

Study Product Administration Error - Meningococcal

Purpose:
This form documents a meningococcal vaccine is administered with error.

General Instructions:

- Complete this form for each enrolled participant when meningococcal vaccines are administered with error.

Field-specific Instructions:

Field	Instructions
Date of visit when study product administration error(s) occurred *Reminder: please complete a Protocol Deviation CRF to report the administration error*	A complete date is required.
Describe the administration error(s). Mark all that apply.	Select all that apply from the list below. • If “Incorrect administration site” checked, specify the site in the text field. • If “Incorrect product administered” checked, specify the product in the text field • Incorrect dose administered • Administered beyond product viability • Administered outside protocol-specified visit window • For any other reasons, select “Other” and specify the reason in the text field provided.
OUTCOME	Describe the outcome of the administration error.
What action was taken as a result of study product administration error(s) described above?	• If "Discontinued future study product administration", complete Discontinuation of Study Product form. • No action taken. • If “Other” selected, specify the reason in the text field.

Study Product Administration Error – Measles and Rubella

Purpose:
This form documents a measles and rubella vaccine is administered with error.

General Instructions:

- Complete this form for each enrolled participant when measles and rubella vaccines are administered with error.

Field-specific Instructions:

Field	Instructions
Date of visit when study product administration error(s) occurred *Reminder: please complete a Protocol Deviation CRF to report the administration error*	A complete date is required.
Describe the administration error(s). Mark all that apply.	Select all that apply from the list below. • If “Incorrect administration site” checked, specify the site in the text field. • If “Incorrect product administered” checked, specify the product in the text field • Incorrect dose administered • Administered beyond product viability • Administered outside protocol-specified visit window • For any other reasons, select “Other” and specify the reason in the text field provided.
OUTCOME	Describe the outcome of the administration error.
What action was taken as a result of study product administration error(s) described above?	• If "Discontinued future study product administration", complete Discontinuation of Study Product form. • No action taken. • If “Other” selected, specify the reason in the text field.

Study Product Administration Error – Yellow Fever

Purpose:
This form documents a yellow fever vaccine is administered with error.

General Instructions:

- Complete this form for each enrolled participant when yellow fever vaccines are administered with error.

Field-specific Instructions:

Field	Instructions
Date of visit when study product administration error(s) occurred *Reminder: please complete a Protocol Deviation CRF to report the administration error*	A complete date is required.
Describe the administration error(s). Mark all that apply.	Select all that apply from the list below. • If “Incorrect administration site” checked, specify the site in the text field. • If “Incorrect product administered” checked, specify the product in the text field • Incorrect dose administered • Administered beyond product viability • Administered outside protocol-specified visit window • For any other reasons, select “Other” and specify the reason in the text field provided.
OUTCOME	Describe the outcome of the administration error.
What action was taken as a result of study product administration error(s) described above?	• If "Discontinued future study product administration", complete Discontinuation of Study Product form. • No action taken. • If “Other” selected, specify the reason in the text field.

Study Termination

Purpose:
This form documents participant’s exit from the study (i.e. scheduled or early study termination).

General Instructions:

- This form is present within the Discontinuations folder.
- Complete this form for each enrolled participant at either the scheduled exit/end of study visit or when the participant is no longer participating in the study.

Field-specific Instructions:

Field	Instructions
Date of study exit	A complete date is required.

Field	Instructions
Primary reason for completion/discontinuation	• Scheduled exit visit/end of study: Select this reason if the participant completes the final study visit per protocol. If selected, end of form. • Early study closure: Only select this reason when instructed by the CDM. • Participant limit has been met for 15 month group: only select this for the subset of Group 2 participants who are eligible and expressed interest in the study but were not randomized to Step 2 prior to the limit being met. If this option is selected, complete a Termination Vaccination Status form for that participant.
If "Other", specify (max. 200 characters):	• If “Other” selected as primary reason for completion/discontinuation, specify in the “specify” text field.
If "Death", enter date of death.	If the primary reason for study non-completion is “Death”, provide the date of death. A complete date is required.
If "Adverse event" or “Death”, select applicable adverse event.	If “Adverse event” or “Death” is selected as reason for completion/discontinuation, select the applicable Adverse Event from the list of AEs in the drop-down menu. In situations where more than one AE are associated with termination, record the AE that most strongly influenced the decision to terminate. Note: The applicable AE must first be entered on the AE form in order to be visible in the drop-down list.
Was the participant's termination associated with a safety concern?	Select “Yes” if the reason for termination was associated with the participant’s safety concern. If “Yes”, explain the reason in the text field provided.

Termination Vaccination Status

Purpose:
This form documents Nimenrix and Measles-Rubella vaccination status for Group 2 participants who would like to continue in the study but were terminated because the participant limit was met for Group 2 Step 2 randomization
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General Instructions:

- This form will populate within the Discontinuations folder when the response for “Primary reason for completion/discontinuation” field on the Study Termination form is “Participant limit has been met for 15 month group”.
- Complete this form for each enrolled participant at either the scheduled exit/end of study visit or when the participant is no longer participating in the study.

Field-specific Instructions:

Field	Instructions
Date of Study Exit	The date participant terminated from the study. A complete date is required and should match date entered on Study Termination form

Field	Instructions
Did participant receive the **Nimenrix** vaccine as part of the study termination procedures?	If "**No**": record reason why participant did not receive **Nimenrix** vaccine in Comments section If "**Yes**": record date **Nimenrix** vaccine was given to participant, a complete date is required
Did participant receive the **Measles-Rubella** vaccine as part of the study termination procedures?	If "**No**": record reason why participant did not receive **Measles-Rubella** vaccine in Comments section If "**Yes**": record date **Measles-Rubella** vaccine was given to participant, a complete date is required
Comments	Provide any pertinent details in this field, if applicable. A maximum of 200 characters are allowed.

Vital Signs

Purpose:
This form documents the participant's vital signs such as height, weight, temperature, heart rate, and rate of respiration.

Field-specific Instructions:

Field	Instructions
Were vital signs done?	Enter the date the participant's vital signs were measured.
Date of assessment	A complete date is required.
Height	Record the participant's body length in centimeters (cm). **Only complete at Screening and Group 2 V1.0 visits.**
Weight	Record the participant's weight in kilograms (kg). **Only complete at Screening and Group 2 V1.0 visits.**
length-for-weight z-score	Record the participant's z-score for length for weight. **If not assessed, leave this field empty.**
Body temperature	Record the participant's body temperature in Celsius (°C). **If not assessed, leave this field empty.**
Heart Rate (pulse)	Record the participant's heart rate in beats/minute (bpm). **If not assessed, leave this field empty.**

Field	Instructions
Rate of respiration	Record the participant's rate of respiration in breaths/minute. **If not assessed, leave this field empty.**

Yellow Fever Vaccine

Purpose:
This form documents a participant's Yellow Fever (YF) vaccination record.

General Instructions:
Complete this form for each participant in for IDCRC DMID 20-0024.

Field-specific Instructions:

Field	Instructions
Was a Yellow Fever vaccination administered at this visit?	Select "Yes" or "No". If "No", complete Missed Study Product Administration form populated within the visit folder.
If "No", specify reason not done	If yellow fever vaccine was not administered, record the reason in the text field.
Date of vaccination	Enter the date the participant received the yellow fever vaccination. A complete date is required.
Time of injection	Enter the time the participant received the yellow fever vaccination. Use a 24-hour clock (00:00-23:59), where hours are designated from 0–23.
Location of in injection	Select the location between "Right deltoid" and "Left deltoid".
Were there any study product administration errors?	Select "Yes" or "No". If "Yes", complete Study Product Administration Error form populated within the visit folder and Protocol Deviation form in Ongoing Logs folder.
Comments (max. 200 characters)	Record any comments on the vaccination assessment.

Change History

Summary of Changes to CRF Completion Guidelines

Version		Affected Section(s) or Form(s)	Summary of Revisions
Number	**Date**		
1.0	22-FEB-2022	N/A	Initial version
1.1	13-FEB-2023	Entire document reviewed	Reviewed for clarity and to align with form changes since build. Termination Vaccination Status form added.
2.0	27-APR-2023	Entire document	Final version