

DMID 21-0012
Memory Aid

Vaccination Number: 1 2 Boost

PTID _____

Please assess symptoms and fill out the Memory Aid in the evening (after 4:00 pm).

Fill out all the spaces for each day. If you don't have any symptoms, write 0 in all the boxes.

Keep this Memory Aid in a safe place, and bring it to your next phone or clinic visit (approximately 7-14 days after your vaccination).

Post-vaccination day:	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Ongoing after Day 8? [*]	Maximum Severity/ Measurement after Day 8	Stop Date (dd/MMM/yyyy)
Date (dd/MMM/yyyy)											
Maximum Oral Temperature (°F)									<input type="checkbox"/> No <input type="checkbox"/> Yes		

If temperature is less than 97.0°F, wait 10 minutes, and then take temperature again. Only record highest temperature.

General Body Symptoms

Record Intensity Level as 0, 1, 2, or 3

Chills									<input type="checkbox"/> No <input type="checkbox"/> Yes		
Tiredness (fatigue)									<input type="checkbox"/> No <input type="checkbox"/> Yes		
Body Aches/ Muscular Pain (myalgia)									<input type="checkbox"/> No <input type="checkbox"/> Yes		
Joint Pain (arthralgia)									<input type="checkbox"/> No <input type="checkbox"/> Yes		
Headache									<input type="checkbox"/> No <input type="checkbox"/> Yes		
Nausea									<input type="checkbox"/> No <input type="checkbox"/> Yes		

Intensity Grading Scale for General Symptoms

- 0 = None
- 1 = Mild (No interference with daily activity)
- 2 = Moderate (Some interference with daily activity, or OTC medication is used for > 24 hours)
- 3 = Severe (Significant interference, prevents daily activity, or requires intensive therapeutic intervention)
- 4 = Potentially life threatening (Requires ER visit or hospitalization)

HOW TO TAKE TEMPERATURE

- Measure your temperature at approximately the same time each day. If multiple temperatures are measured in one day, record the highest temperature. Do not eat, drink, or smoke for **10 minutes** prior to taking your temperature.
- To use the thermometer, press the button to turn it on, wait for the “Lo” symbol to appear on the screen (Lo °F). Make sure the screen shows °F for Fahrenheit.
- Place the thermometer under your tongue toward the back of your mouth. The tip of the thermometer should rest in the “correct area” as shown in the diagram to the right.
- Keep your mouth closed and the thermometer still until the thermometer beeps rapidly, indicating completion. If you do not hear the beep, leave the thermometer in your mouth for 2 minutes.
- Record the temperature displayed on the screen. Press the button to turn off the thermometer.

√= Correct Area
X=Incorrect areas



* If you have a listed symptom with an intensity level of Grade 1 or greater on Day 8 and you still have that symptom on Day 9 check “Yes” for “Ongoing after Day 8”. Record the **maximum** intensity experienced after Day 8 and the symptom stop date. A temperature is considered Ongoing after Day 8 if it is greater than or equal to 100.4°F. If you have a temperature of 100.4 °F or greater on Day 9, continue to record your temperature every day until it resolves (100.3°F or less).

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Injection Site Reactions

Record Intensity Level as 0, 1, 2, or 3

Post-vaccination day	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Ongoing after Day 8*?	Maximum Severity/ Measurement after Day 8	Stop Date (dd/MMM/yyyy)
Pain -Intensity									<input type="checkbox"/> No <input type="checkbox"/> Yes		
Redness -Intensity									<input type="checkbox"/> No <input type="checkbox"/> Yes		
Swelling/Hardness -Intensity									<input type="checkbox"/> No <input type="checkbox"/> Yes		
Redness -Size (mm)	_____mm	_____mm	_____mm	_____mm	_____mm	_____mm	_____mm	_____mm	<input type="checkbox"/> No <input type="checkbox"/> Yes	_____mm	
Swelling/Hardness -Size (mm)	_____mm	_____mm	_____mm	_____mm	_____mm	_____mm	_____mm	_____mm	<input type="checkbox"/> No <input type="checkbox"/> Yes	_____mm	

Intensity Grading Scale for Pain

Experienced without touching the injection site (spontaneous discomfort)

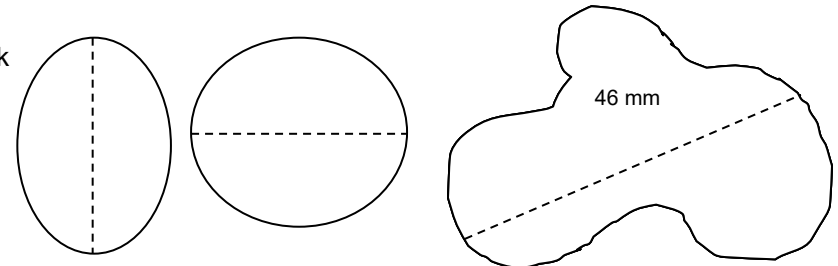
- 0 = None
- 1 = **Mild** (No interference with daily activity)
- 2 = **Moderate** (Repeated use of non-narcotic pain reliever > 24 hours or interferes with activity)
- 3 = **Severe** (Any use of narcotic pain reliever or prevents daily activity)
- 4 = **Potentially life threatening** (Requires ER visit or hospitalization)

Intensity Grading Scale for Itching, Bruising, Redness, Swelling, and Hardness

- 0 = None
- 1 = **Mild** (Does not interfere with daily activity)
- 2 = **Moderate** (Interferes with daily activity)
- 3 = **Severe** (Prevents daily activity)

HOW TO MEASURE SWELLING AND REDNESS AT THE SITE OF THE VACCINATION

- Use the measuring tool the clinic staff gave you. Use the metric (centimeters) ruler.
- Record measurements of swelling and redness in millimeters (mm). Each small hash mark on the centimeter ruler equals one millimeter.
- Follow these instructions to measure the size of the area with swelling or redness.
 1. Determine the widest part (or diameter) of the area.
 2. Measure this distance with the metric ruler on the measuring tool provided.
 3. Measure in millimeters by counting the small hash marks.
 4. Measure the swelling and redness separately and record as individual symptoms.



* If you have a listed symptom with an intensity level of Grade 1 or greater on Day 8 and you still have that symptom on Day 9 check "Yes" for "Ongoing after Day 8". Record the maximum intensity experienced after Day 8 and the symptom stop date.

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Important: If you experience any events of concern, contact the study staff immediately.

Other Symptoms

Other symptoms to report following vaccination: No Yes (Complete chart below)

Intensity Grading Scale for Other Symptoms

- 0 = None
- 1 = Mild (No interference with daily activity)
- 2 = Moderate (Some interference with daily activity, or OTC medication is used for > 24 hours)
- 3 = Severe (Significant interference, prevents daily activity, or requires intensive therapeutic intervention)

<u>Symptom</u>	Intensity: Mild, Moderate or Severe	Start Date (dd/MMM/yyyy)	Stop Date (dd/MMM/yyyy)

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Medications

New medications used following vaccination or changes to previously reported medications: No Yes (Complete chart below)
If you take a new medication, change a medication you were already on, or take something for comfort, please enter this information on the Memory Aid. Do not enter regular medications you have already told us about if there are not any changes.

Medication Name	Dose	Frequency	Start Date (dd/MMM/yyyy)	Stop Date (dd/MMM/yyyy)	Reason

Any visits to the Emergency Room or doctor's office other than for routine check-up? No Yes (explain below)

Comments: _____

Contact the Research Nurse or Doctor...

- If you have **any temperature greater than 102.0°F**.
- If you have **any severe symptoms** (grade 3).
 - Grade 3 symptoms include any chills, tiredness (fatigue), body aches/muscular pain (myalgia), joint pain (arthralgia), headache, nausea, pain at the injection site, hardness (induration)/swelling (edema) at the injection site, or redness (erythema) at the injection site, or any other symptom that **prevents daily activity** or **requires medical care**.
- If you have any other severe symptoms or health complaints, even if they are not the solicited events listed on the Memory Aid.
- If you have any concerns or questions about completing the Memory Aid or about symptoms you are experiencing, please contact the clinic at the number below:

Contact's name: _____ Phone #: _____

Assessment of Solicited Symptom, AE, and Concomitant Medication Data Script for Memory Aid Review

Review of solicited symptoms, adverse events, and concomitant medications is conducted **by telephone 8-9 days post each vaccination**. Site staff should:

- Confirm individual contacted is the subject
- Staff member should identify him/herself by name and association with the study
- Explain the purpose of the call is to collect Memory Aid and safety information

The following questions are asked:

General

- How are you doing?
- Have you experienced anything different or unusual since you got the vaccination?
- Are you having any medical or clinical problems?
 - If so, please tell me about them.
 - *Record illness on Adverse Event form.*
 - *Ask follow-up questions, such as:*
 - What is the problem?
 - When did these symptoms begin and end?
 - How did the symptom/illness affect your daily activities?
 - Were you able to go to work?
 - Did you attend other planned commitments or social activities?
 - Have you taken any medications to alleviate these symptoms?
Record on Concomitant Medication form.

Memory Aid

Memory Aids will be reviewed with the subjects for any AEs (solicited injection site and systemic reactions, as well as unsolicited AEs), SAEs, and concomitant medications **during the telephone or clinic visit approximately 8-14 days post each vaccination**.

Have the subject present his or her Memory Aid when the subject returns at the clinic visit approximately 14 days post each vaccination and **discuss the information recorded together with the subject**.

*If the subject indicates that he/she has experienced symptoms, **ask follow-up questions** to determine the severity of the symptom. Record the appropriate severity level on the Reactogenicity - Daily Log CRF **after discussing the symptom with the subject**.*

- Systemic Symptoms
 - What are the temperatures you have recorded on the Memory Aid?
 - Have you experienced any chills?
 - Have you experienced any tiredness (fatigue)?
 - Have you experienced any body aches/muscular pain (myalgia)?
 - Have you experienced any joint pain (arthralgia)?
 - Have you experienced any headache?
 - Have you experienced any nausea?

Collect information to determine causality or alternate etiology if subject reports any Grade 3 systemic symptoms. (Is the event due to another illness, underlying medical history, or condition?)
- Administration site Symptoms
 - Have you experienced any pain at the injection site?
 - Have you experienced any redness (erythema) at the injection site?
 - Have you experienced any swelling (edema) or hardness (induration) at the injection site?

Assessment of Solicited Symptom, AE, and Concomitant Medication Data Script for Memory Aid Review

- Follow-Up Questions (If Yes to any of the above systemic or local symptoms)
 - How did the symptom affect your daily activities?
 - Were you able to go to work?
 - Did you attend other planned commitments or social activities?
 - Are these symptoms ongoing?
 - Have you taken any medications to alleviate these symptoms?
- Injection Site Measurements
 - What measurements have you recorded for redness?
 - What measurements have you recorded for swelling or hardness?
 - *If subject responds "none" to any of these questions, confirm if there has been no redness or swelling/hardness, or if they have taken no measurements for redness or swelling/hardness.*

Repeat for second injection site if applicable.

Adverse Events (page 3 of Memory Aid)

Complete Adverse Event form, if necessary, **through 28 days post each vaccination.**

- Did you experience any other symptoms or illnesses after vaccination?
 - When did these symptoms begin and end?
 - How did the symptom/illness affect your daily activities?
 - Were you able to go to work?
 - Did you attend other planned commitments or social activities?

Collect information to determine causality or alternate etiology.

 - Have you had close contact with other people with the same symptoms?
 - Have you taken any medications to alleviate these symptoms?

Record on the Concomitant Medication form.
- Have you been seen by a doctor other than for routine check-up?
- Have you been seen in the hospital or emergency room?
 - If yes to either of the above, what was the outcome/diagnosis?
 - If yes to either of the above, what action was taken?

Medications (page 4 of Memory Aid)

Complete Concomitant Medication form, if necessary, **through 28 days post each vaccination.**

- Are you taking any new medications?
- Have there been any changes to previously reported medications?

Record on Concomitant Medication form.

 - Medication name, start and stop dates, indication/reason, dose, and frequency
 - Indication should be recorded as an Adverse Event

Reminders

- Please call us if you experience any events that are unusual or of particular concern.
- Memory Aids information will be collected at the phone or clinic visit approximately 8-14 days after each vaccination.

Other

- Can I answer any other questions?
- Please feel free to contact us at any time. Do you need our phone number again?

Your next scheduled visit is on _____ at _____. We'll see you then.