DIVISION OF MICROBIOLOGY AND INFECTIOUS DISEASES (DMID)

SERIOUS ADVERSE EVENT FORM
CROMS PVG SAE HOTLINE: 1-800-537-9979 (USA) or 301-897-1709 (International)
CROMS PVG SAE FAX LINE: 1-800-275-7619 (USA) or 301-897-1710 (International)
CROMS PVG EMAIL: PVG@dmidcroms.com
Please fill out ALL required fields in bold or marked by an asterisk before submission.

***DMID Protocol #:** _____ ***DMID Participant ID:** _____

Site Name: _____ Site SAE Awareness Date: _____

☐ Initial Report Date: ☐ Follow-up # Date:

1. *PARTICIPANT INFORMATION

* **Sex**: Enter the patient's sex at birth.(the sex the patient has or was assigned to at birth)
☐ Male ☐ Female

***Age**: _____ ☐ Days ☐ Weeks ☐ Months ☐ Years Weight: _____ ☐ lbs ☐ kg

If neonate: Gestational age at birth: _____

Birth weight: _____ ☐ lbs ☐ kg

APGAR scores (1min/5min/10min): _____ / _____ / _____

If SAE occurred in an infant:Participant ID above refers to: ☐ *Mother* OR ☐ *Infant*

***Ethnicity**: ☐ Hispanic/Latino ☐ Not Hispanic/Latino

***Race**:- Check all that apply
☐ American Indian or Alaskan Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White

2. *SAE CATEGORY (CHECK ALL THAT APPLY) (21 CFR 312.32(a))

☐ Death
☐ Life-threatening (immediate risk of death)
☐ Hospitalization/prolongation of existing hospitalization
Admission Date _____ ***Discharge Date*** _____
☐ Important medical event
☐ Required intervention to Prevent Permanent Impairment/Damage
☐ Congenital anomaly/birth defect
☐ Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions

Other Reporting Requirement:

☐ AESI (Adverse Event of Special Interest)
☐ MAAE (Medically Attended Adverse Event)
☐ NOCMC (New Onset Chronic Medical Condition)
☐ PIMMC (Potentially Immune Mediated Medical Condition)
☐ UP (Unanticipated Problem)
☐ Others: _____

3. *SAE INFORMATION (Enter ONE event term per SAE form)

☐ Additional Study Products Attached

*SAE Term (Single medical concept or Final diagnosis)	*Onset Date (DD-MMM-YYYY)	*Severity	*Relationship to Study Product or Intervention	Alternate Etiology (If Not Related to any Study Product, Related to)
		☐ Mild ☐ Moderate ☐ Severe ☐ Life-Threatening ☐ Death	Study Product 1 ☐ Not Related ☐ Related Study Product 2 ☐ Not Related ☐ Related Study Product 3 ☐ Not Related ☐ Related Study Product 4 ☐ Not Related ☐ Related	☐ Study procedure: ☐ Other condition/illness: ☐ Another drug: ☐ Other:

4. *SAE OUTCOME (Check only one)

☐ Recovering/resolving
☐ Not recovered/not resolved
☐ Recovered/resolved Date: (DD-MMM-YYYY)
☐ Recovered/resolved with sequelae Date: (DD-MMM-YYYY) State Sequelae:
☐ Unknown
☐ Fatal (death) Date: (DD-MMM-YYYY)

Autopsy: ☐ Not Performed ☐ Performed (Provide Report) ☐ Planned ☐ Status Unknown
Death Certificate: ☐ Provided ☐ Requested ☐ Not Available ☐ Status Unknown

5. ***STUDY PRODUCT INFORMATION** *(Please include at least one study product; attach more pages if needed)*
☐ Attached

	***Study Product 1**	Study Product 2	Study Product 3	Study Product 4
***Study Product Name**	☐ *Blinded*	☐ *Blinded*	☐ *Blinded*	☐ *Blinded*
***Dosage, Route of Administration, dosing schedule or frequency**				
***Date Started** (DD/MMM/YYYY)				
Date Last Taken Prior to SAE Onset (DD/MMM/YYYY)				
***Action Taken With Study Product**	☐Withdrawn ☐Dose reduced ☐Dose increased ☐Dose not changed ☐Dose interrupted ☐Unknown ☐Not applicable Comments:	☐Withdrawn ☐Dose reduced ☐Dose increased ☐Dose not changed ☐Dose interrupted ☐Unknown ☐Not applicable Comments:	☐Withdrawn ☐Dose reduced ☐Dose increased ☐Dose not changed ☐Dose interrupted ☐Unknown ☐Not applicable Comments:	☐Withdrawn ☐Dose reduced ☐Dose increased ☐Dose not changed ☐Dose interrupted ☐Unknown ☐Not applicable Comments:
Event Abated After Study Product Use Stopped or Dose Reduced? *Add date next to Yes, if Yes is selected	☐Yes ☐No ☐Does not apply Comments:	☐Yes ☐No ☐Does not apply Comments:	☐Yes ☐No ☐Does not apply Comments:	☐Yes ☐No ☐Does not apply Comments:
Event Reappeared After Reintroduction of Study Product? *Add date next to Yes, if Yes is selected	☐Yes ☐No ☐Does not apply Comments:	☐Yes ☐No ☐Does not apply Comments:	☐Yes ☐No ☐Does not apply Comments:	☐Yes ☐No ☐Does not apply Comments:

6. LABORATORY RESULTS *(Please list all relevant laboratory results OR attach copies of the results.)*

☐ Attached

☐ No relevant laboratory tests

Test	**Test Date** (DD-MMM-YYYY)	**Result**	**Baseline Date** (DD-MMM-YYYY)	**Baseline Result**	**Site Normal Range** (including units)
		☐ Pending			
		☐ Pending			
		☐ Pending			
		☐ Pending			

7. DIAGNOSTIC TESTS (e.g. MRI, CT) (Please list relevant test results below OR attach copies of the results.)

☐ Attached

☐ No relevant diagnostic tests

Test	**Test Date** (DD-MMM-YYYY)	**Results/Comments**
		☐ Pending
		☐ Pending
		☐ Pending
		☐ Pending

8. CONCOMITANT MEDICATIONS (Please include prescription and non-prescription medications or supplements.)
☐ Attached

DO NOT include medications used to treat the SAE.

Medication	**Start Date**	**Stop Date**	**Total Daily Dose** (*Include Units*)	**Frequency/Route**	**Indication**	**Suspect?**
		☐ Ongoing				☐ Yes ☐ No
		☐ Ongoing				☐ Yes ☐ No
		☐ Ongoing				☐ Yes ☐ No
		☐ Ongoing				☐ Yes ☐ No
		☐ Ongoing				☐ Yes ☐ No
		☐ Ongoing				☐ Yes ☐ No
		☐ Ongoing				☐ Yes ☐ No

9. *EVENT SUMMARY

Please write a brief summary of the events surrounding the SAE and include the following, if available:

- Chronological order of clinical course surrounding the SAE
- Associated signs and symptoms
- Participant's past relevant medical history, family history, social history and allergies (for newborn and pregnant participant also include maternal history (obstetric and prenatal))
- Reactogenicity records, current and past (FOR VACCINES ONLY)

Attach additional pages and documents as needed.

☐ Attached

10. *REPORTER INFORMATION AND SIGNATURES

(The SAE Form locks after signatures. Please make sure to save this SAE Form before signatures, to be able to reuse for follow up submissions)

Investigator Name:		Investigator Signature:		Date:	
***Reporter Name:**		***Reporter Signature:**		Date:	
Reporter's phone number:		***Reporter's Email Address**			

Submit