ADVERSE EVENT LOG - Instructions for Use:

This log may be modified to capture protocol-specific reporting requirements.
These instructions do not need to be included in the participant binder. Each participant should have their own individual Adverse Event Log included in their binder. Additional copies of the second page may be printed as needed. Ensure page numbers are completed in the footer.

Date Reported:
List the date the study team was initially made aware of the adverse event.

Adverse Event (AE) Description:

- Using accepted medical terminology, enter the diagnosis (if known); otherwise enter a sign or symptom
- Record only one diagnosis, sign or symptom per line *(e.g., nausea and vomiting should be recorded as 2 separate entries)*.
- Death should not be recorded as an event but should be recorded as the outcome of the event. The condition that resulted in the death should be recorded as the AE.

Serious Adverse Event (SAE):
As defined by the FDA, a Serious Adverse Event (SAE) is an event for which the outcome is death, life-threatening, requires hospitalization or a prolongation of hospitalization, results in disability or permanent damage or a congenital anomaly/birth defect, requires intervention to prevent permanent impairment or damage, or is considered an important medical event.

Severity:
Severity grading should be conducted in accordance with the protocol defined rating scale. When the protocol does not define a scale, the following grade descriptions may be used:

1. Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.
2. Moderate; minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADLs (preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.)
3. Severe or medically significant but not immediately life-threatening; hospitalization of prolongation of hospitalization indicated; disabling; limiting self-care ADLs (bathing, dressing and undressing, feeding self, using the toilet, taking medications, and not bedridden)
4. Life Threatening; urgent intervention indicated
5. Death (Fatal)

AE Treatment:
Ensure conmed log is updated if conmeds were administered for an AE. The indication listed on the conmed log should match the AE term precisely.

Outcome:
Adverse events should be followed until resolution. Some events may not resolve and should be followed until stabilization (i.e. until the PI does not expect any further improvement or worsening). In these instances, document the date of stabilization as the 'stop date' and outcome as 'Resolved with sequelae.'

Expected:
Expected AEs will be described in the IB, consent, protocol, etc.

Relation:
Relationship to the study intervention should be determined by the PI

USA HEALTH

ADVERSE EVENT LOG (MUST BE UPDATED AT EACH VISIT)

Principal Investigator:	Study Title:
Subject Initials:	Subject ID:

Did the participant have any Adverse Events (AEs) during the study? ☐ **Yes** ☐ **No** ***(If yes, list each AE below)***

[1]Severity	[2] Action Taken with investigational product	[3]AE Treatment	[4]Outcome	[5]Relation to Study Intervention (Determined by PI)
1 = Mild 2 = Moderate 3 = Severe 4 = Life Threatening 5 = Death (Fatal)	1 = None 2 = Interrupted (temporarily) 3 = Discontinued (permanently) 4 = Dose reduced 5 = Dose increased 6 = Other (list intervention)	1 = None 2 = Medication(s) 3 = Non-medication treatment	1 = Resolved 2 = Resolved with sequelae 3 = Ongoing 4 = Condition worsening 5 = Death 6 = Unknown	1 = Not related 2 = Unlikely related 3 = Possibly related 4 = Probably related 5 = Definitely related

Date Reported	Adverse Event	Start Date (dd/mmm/yyyy)	Stop Date (dd/mmm/yyyy)	SAE (Y or N)	[1]Severity	[2]Action Taken with IP	[3]AE Treatment	[4]Outcome	Expected (Y or N)	[5]Relationship	PI Initials & Date

USA HEALTH

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Principal Investigator:	Study Title:
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Date Reported	Adverse Event	Start Date (dd/mmm/yyyy)	Stop Date (dd/mmm/yyyy)	SAE (Y or N)	[1]Severity	[2]Action Taken with IP	[3]AE Treatment	[4]Outcome	Expected (Y or N)	[5]Relationship	PI Initials & Date