SAE ENTRY FORM

Participant ID

Report Date

PROJECT SETUP

Project ID/Grant #:

Project/Grant Title:

Clinical Trial ID:

Study Title:

Study Agent Name:
(medication trial only)

Trial Phase: ○ Pilot ○ Phase I ○ Phase II ○ Phase III ○ Other

Site/Clinical Trial ID:

GENERAL INFORMATION

Event Onset Date: / /

Event Name:

○ Hospitalization
○ Death of Participant (skip questions 10 through 20 and complete Death section)
○ Other (see questions 18-20)

Description of Event: (symptoms, course, duration, treatment and sequelae)

Age: years

Phase of Treatment: ○ Pre Randomization ○ Active Treatment ○ Follow-Up

Participant ID ____ Report Date ____ / ____ / ____

For what reason(s) was the patient hospitalized?

NO	YES		NO	YES	N/A
○	○	10. Acute psychosis or other serious psychiatric problem			
		a. Did patient have a history of psychiatric illness?	○	○	○
		b. Was patient taking neuroleptic medication?	○	○	○
		c. Was patient taking any other type of medication?	○	○	○
		If so, please describe:_____			
○	○	11. Onset/exacerbation of cognitive impairment (e.g. disorientation, memory loss)			
○	○	12. Deterioration of physical health or onset of medical problem, including accidents			
○	○	13. Extensive or increased drug or alcohol use			
		a. Please indicate days of use in the past 28 ____ ○ unknown			
		b. Please estimate amount used _____			
○	○	14. Recent suicidal ideation, intent or plan			
○	○	15. Recent suicidal gesture			
		a. Any recent history of suicidal ideation/gesture?	○	○	○
○	○	16. Recent homicidal ideation,intent or plan			
○	○	17. Recent homicidal /violent behavior			
		a. Any recent history of homicidal ideation/gesture?	○	○	○
○	○	18. Serious program infraction			
		a. Please describe: _____			
○	○	19. Hospitalization or death of another individual due to direct action of patient			
		a. Please describe: _____			
○	○	20. Other			

Cause of Death (please elaborate in blank space at bottom of page)

NO	YES	
○	○	21. Suicide
○	○	22. Accidental (e.g. car accident, fall)
		a. Was substance use involved? ○ No ○ Yes ○ Unkown ○ N/A
○	○	23. Medical (e.g. chronic condition, liver disease, overdose)
		a. Was substance use involved? ○ No ○ Yes ○ Unkown ○ N/A
○	○	24. Other
○	○	25. Unknown

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IF NON-MEDICATION TRIAL PLEASE STOP HERE

STUDY AGENT

Name: (please indicate if blind broken)

[1] **Route:** *(specify other)*

[2] **Frequency:** *(specify other)*

[3] **Dosage:** *(specify other)*

[4] **Form:** *(specify other)*

Start Date:

Stop Date:

Continuing: ○ No ○ yes

Restart Date:

[1] Route Types: (Select One)
1 Auricular (Otic)
2 Buccal
3 Inhaled
4 Intra-Atricular
5 Intramuscular
6 Intraocular
7 Intravenous (NOS)
8 Nasal
9 Opthalmic
10 Oral
11 Rectal
12 Subcutaneous
13 Sublingual
14 Toppical
15 Transdermal
16 Vaginal
17 Other-Specify

[2] Frequency Types: (Select One)
1 As Needed
2 Four Times A Day
3 Three Times a Day
4 Twice Daily
5 Once Daily
6 Every other Day
7 Single Dose
8 Other-Specify

[3] Dosage Types: (Select One)
1 Grain(s)
2 Gram(s)
3 International Units
4 Microcurie(s)
5 Microgram(s)
6 Microgram(s)/kilogram
7 Microgram(s)/sq. meter
8 Microliter(s)
9 Millicurie(s)
10 Milliequivalent(s)
11 Milligram(s)
12 Milligram(s)/kilogram
13 Milligram(s)/sq. meter
14 Milliliter(s)
15 Other-Specify

[4] Form Types: (Select One)
1 Capsule
2 Drop
3 Gum
4 Lollipop
5 Lotion/Ointment
6 Lozenge
7 Ounce
8 Patch
9 Puff
10 Spray/Squirt
11 Suppository
12 Tablespoon
13 Tablet
14 Teaspoon
15 Wafer
16 Other-Specify

SAE ENTRY FORM

Participant ID

Report Date

CONCOMITANT MEDICATIONS

Name:

[1]Route: **[2]Frequency:** **[3]Dosage:** **[4]Form:**

Start Date: / /

Stop Date: / /

Continuing: ○ No ○ yes

Name:

[1]Route: **[2]Frequency:** **[3]Dosage:** **[4]Form:**

Start Date: / /

Stop Date: / /

Continuing: ○ No ○ yes

Name:

[1]Route: **[2]Frequency:** **[3]Dosage:** **[4]Form:**

Start Date: / /

Stop Date: / /

Continuing: ○ No ○ yes

Name:

[1]Route: **[2]Frequency:** **[3]Dosage:** **[4]Form:**

Start Date: / /

Stop Date: / /

Continuing: ○ No ○ yes

[1] Route Types: (Select One)
1 Auricular (Otic)
2 Buccal
3 Inhaled
4 Intra-Atricular
5 Intramuscular
6 Intraocular
7 Intravenous (NOS)
8 Nasal
9 Opthalmic
10 Oral
11 Rectal
12 Subcutaneous
13 Sublingual
14 Toppical
15 Transdermal
16 Vaginal
17 Other-Specify

[2] Frequency Types: (Select One)
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3 Three Times a Day
4 Twice Daily
5 Once Daily
6 Every other Day
7 Single Dose
8 Other-Specify

[3] Dosage Types: (Select One)
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2 Gram(s)
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5 Microgram(s)
6 Microgram(s)/kilogram
7 Microgram(s)/sq. meter
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11 Suppository
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13 Tablet
14 Teaspoon
15 Wafer
16 Other-Specify