Participant ID

Initials of person entering data

Staff email

CONFIDENTIAL CASE REPORT FORM

Cyclizine for Nausea and Vomiting in Paediatric Palliative and Supportive Care Series 31

IMPACCT Trials Coordination Centre (ITCC)/
Palliative Care Clinical Studies Collaborative (PaCCSC)

RAPID Pharmacovigilance in Palliative Care

The case report form (CRF) is to be completed in compliance with
ITCC/PaCCSC Standard Operating Procedures (SOP)

Reference:
Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0
Published: November 27, 2017, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health, National Cancer Institute

A full copy of the document is available on our RAPID webpage

T0 - Baseline
Demographics

Gender ◯ Male ◯ Female

Ethnicity

◯ European

◯ Maori

◯ Pacific Peoples

◯ Asian

◯ Middle Eastern

◯ Latin American

◯ African

◯ Aboriginal

◯ Torres Strait Islander

◯ Other ethnicity: Please specify_____

Age (0 to <18yrs)

☐ Years_____ ☐ Months_____ ☐ Weeks_____

Weight (kg)

Primary life limiting illness

◯ Cancer

- ☐ Solid tumour
- ☐ CNS tumour
- ☐ Haematological malignancy
-

◯ Neurological disease

- ☐ Neuromuscular disorders
- ☐ Static encephalopathy – GMFCS I-V
- ☐ Progressive encephalopathy or Neurodegenerative disease

◯ Other –please specify: (e.g. cardiac, respiratory failure, hepatic failure, end stage renal failure) _____

Palliative Care Phase?

○ Stable ○ Unstable ○ Deteriorating ○ End of Life

Stable Phase: The person's symptoms are adequately controlled by established management. Further interventions to maintain symptom control and quality of life have been planned.
Unstable: The person experiences the development of a new problem or a rapid increase in the severity of existing problems either of which requires an urgent change in management or emergency treatment.
Deteriorating: The person experiences a gradual worsening of existing symptoms or the development of new but expected problems. These require the application of specific plans of care and regular review but not urgent or emergency treatment.
End of Life Care Phase: Death is likely in a matter of days and no acute intervention is planned or required.

Karnofsky/Lansky Performance Status (please circle appropriate status)

The Karnofsky Scale is designed for recipients aged 16 years and older, and the Lansky Scale is designed for patients less than 16 years old. Use the table below to determine the score (10-100) that best represents the patient's activity status.

Karnofsky/Lansky Scale

Karnofsky Scale (patient's age >/= 16yrs)		**Lansky Scale (recipients age < 16yrs)**	
	Able to carry on normal activity; no special care is needed		**Able to carry on normal activity; no special care is needed**
100	Normal, no complaints, no evidence of disease	100	Fully active
90	Able to carry on normal activity	90	Minor restriction in physically strenuous play
80	Normal activity with effort	80	Restricted in strenuous play, tires more easily, otherwise active
Unable to work, able to live at home cares for most personal needs, a varying amount of assistance needed		**Mild to moderate restriction**	
70	Cares for self, unable to carry on normal activity or to do active work	70	Both greater restrictions of and less time spent in active play
60	Requires occasional assistance but is able to care for most needs	60	Ambulatory up to 50% of the time, limited active play with assistance/supervision
50	Requires considerable assistance and frequent medical care	50	Considerable assistance required for any active play, fully able to engage in quiet play
Unable to care for self, requires equivalent of institutional or hospital care, disease may be progressing rapidly		**Moderate to severe restriction**	
40	Disabled, requires special care and assistance	40	Able to initiate quiet activities
30	Severely disabled, hospitalisation indicated, although death not imminent	30	Needs considerable assistance for quiet activity
20	Very sick, hospitalisation necessary	20	Limited to very passive activity initiated by others (e.g. TV)
10	Moribund, fatal process progressing rapidly	10	Completely disabled, not even passive play

Karnofsky/Lansky Scale Score

Baseline – T0: Medication Commencement

Date of assessment

dd/mm/yyyy	

Indications of interest

Nausea

○ 0 ○ 1 ○ 2 ○ 3

NCI Criteria
0. Nil
1. Loss of appetite without alteration in eating habits
2. Caloric or fluid intake decreased without significant weight loss.
3. Inadequate caloric or fluid intake requiring nutritional intervention or hospitalisation due to nausea

Vomiting

○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5

NCI Criteria
0. Nil
1. 1-2 episodes (separated by > 5 minutes) in 24 hours
2. 3-5 episodes (separated by > 5 minutes) in 24 hours
3. >=6 episodes (separated by > 5 minutes) in 24 hours; new tube feeding, nutritional support or hospitalization indicated
4. Life threatening consequences; urgent intervention indicated
5. Death

Dominant mechanism of nausea/vomiting – please tick only one

Metabolic e.g hypercalcaemia, hyponatraemia, uraemia, hyperglycaemia	☐
Cortical i.e. anxiety, anticipatory nausea or vomiting	☐
Cranial i.e. CNS disease, raised ICP	☐
Vestibular/Movement-related e.g. medication, neuritis	☐
Gastroesophageal reflux	☐
Impaired gastric emptying i.e. gastric stasis, outlet obstruction	☐
Intestinal causes i.e. intestinal obstruction, colitis, constipation	☐
Medication-related	☐
Unclear cause	☐
Other; please specify	☐

Current other anti-emetics – tick all that apply

Anti-histamines:	**Dose: (mg)**	**Frequency:**
□ Diphenhydramine		
□ Meclizine		
Benzodiazepines:	**Dose: (mg)**	**Frequency:**
□ Lorazepam		
□ Diazepam		
Corticosteroids:	**Dose: (mg)**	**Frequency:**
□ Dexamethasone		
□ Prednisone		
□ Prednisolone		
Dopamine antagonist:	**Dose: (mg)**	**Frequency:**
□ Domperidone		
□ Haloperidol		
□ Metoclopramide		
Anticholinergic Agents:	**Dose: (mg)**	**Frequency:**
□ Atropine		
□ Buscopan		
□ Scopolamine		
NK1-receptor antagonist	**Dose: (mg)**	**Frequency:**
□ Aprepitant		
□ Fosaprepitant		
Phenothiazine	**Dose: (mg)**	**Frequency:**
□ Prochlorperazine		
□ chlorpromazine		
□ Levomepromazine		
□ Promethazine		
5HT3-receptor antagonists	**Dose: (mg)**	**Frequency:**
□ Ondansetron		
□ Tropisetron		
□ Granisetron		
□ Dolasetron		
Miscellaneous	**Dose: (mg)**	**Frequency:**
□ Mirtazapine		
□ Olanzapine		
Other: Please specify		
□		
□		

Concurrent Medications (classes of drugs) (tick all that apply)

☐	Alpha 2 agonists - Clonidine
☐	Anti-epileptics
☐	Anti-reflux medications (not being used as anti-emetic)
☐	Anti-secretion drugs (not being used as anti-emetic)
☐	Baclofen
☐	Benzodiazepines (not being used as anti-emetic)
☐	NMDA antagonists – Ketamine, Dextromethorphan
☐	Chemotherapy
☐	Laxatives/aperients
☐	Opioids (including Tramadol)
☐	Radiotherapy
☐	NSAIDS
☐	Other – please specify
☐	Other – please specify

Commencement dose of Cyclizine (mg/kg)

OR

Commencement dose of Cyclizine (mg)

Route of administration

○ Oral ○ IV ○ Both IV & oral ○ Sub cutaneous ○ Both subcutaneous & oral

Frequency of administration:

○ QID (6 hrly) ○ TDS (8 hrly) ○ BD (12 hrly) ○ OD ○ Continuous infusion

○ Other: Please specify (e.g. PRN):_____

Baseline – Symptom/Harms assessment

☐ **Dry Mouth**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Symptomatic (dry or thick saliva) without significant dietary alteration; unstimulated saliva flow >0.2 ml/min
2. Symptomatic and significant oral intake alteration (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods); unstimulated saliva 0.1 to 0.2 ml/min
3. Symptoms leading to inability to adequately aliment orally; IV fluids, tube feedings, or TPN indicated; unstimulated saliva < 0.1 ml/min

☐ **Dizziness**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Mild unsteadiness or sensation of movement
2. Moderate unsteadiness or sensation of movement; limiting instrumental ADL
3. Severe unsteadiness or sensation of movement; limiting self-care ADL

☐ **Blurred vision**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Intervention not indicated
2. Symptomatic; limiting instrumental ADL
3. Limiting self-care ADL

☐ **Palpitations**

○ 1 ○ 2 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Present with associated symptoms (e.g., lightheadedness)
2. Shortness of breath

☐ **Somnolence**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Mild disorientation
2. Moderate disorientation; limiting instrumental ADL
3. Severe disorientation; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Constipation**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema
2. Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Urinary retention**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
2. Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
3. Elective operative or radiologic intervention indicated; substantial loss of affected kidney function or mass
4. Life-threatening consequences; organ failure; urgent operative intervention indicated
5. Death

☐ **Seizures**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Brief partial seizure; no loss of consciousness
2. Brief generalized seizure
3. Multiple seizures despite medical intervention
4. Life-threatening; prolonged repetitive seizures
5. Death

☐ **Respiratory secretions**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Mild or asymptomatic symptoms; clinical or diagnostic observation only; intervention not indicated
2. Moderate, minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL
3. Severe or medically significant but not immediately life-threatening, hospitalisation or prolongation of hospitalisation indicated; disabling, limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Injection site reaction**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)
2. Pain; lipodystrophy; edema; phlebitis
3. Ulceration or necrosis; severe tissue damage; operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Euphoria**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria 1. Mild mood elevation 2. Moderate mood elevation 3. Severe mood elevation (e.g., hypomania)

☐ **Dysphoria**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not recorded

1.Mild negative mood change 2. Moderate mood change 3. Severe mood change

☐ **Other (if exists e.g. extra-pyramidal symptoms, heart failure, precipitation in syringe)**

Please specify other harm here _____

Other harm grade here;
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

☐ **Additional other (if exists)**

Please specify additional other harm here _____

Additional other harm grade here;
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

Which symptom/harm is the most troublesome (Please tick only one)

◯ Dry Mouth
◯ Dizziness
◯ Blurred vision
◯ Palpitations
◯ Somnolence
◯ Confusion
◯ Constipation
◯ Urinary retention
◯ Seizures
◯ Respiratory secretions
◯ Injection site reaction
◯ Euphoria
◯ Dysphoria
◯ Other
◯ Additional Other
◯ Not applicable

T_1 - 24 hours post Baseline

T_1: Assessed/Not assessed (Reason)

◯ Assessed today (continue to complete T_1) OR
◯ Died
◯ Not able to be contacted / located
◯ Too unwell
◯ Other

Date of Death
(dd/mm/yyyy)

End Survey here

Date of Assessment
(dd/mm/yyyy)

Indication of interest

Nausea
◯ 0 ◯ 1 ◯ 2 ◯ 3

NCI Criteria
0. Nil
1. Loss of appetite without alteration in eating habits
2. Oral intake decreased without significant weight loss.
3. Inadequate caloric or fluid intake; requiring nutritional intervention or hospitalisation due to nausea

Vomiting
◯ 0 ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5

NCI Criteria
0. Nil
1. 1-2 episodes (separated by > 5 minutes) in 24 hours
2. 3-5 episodes (separated by > 5 minutes) in 24 hours
3. >=6 episodes (separated by > 5 minutes) in 24 hours; new tube feeding, nutritional support or hospitalization indicated
4. Life threatening consequences; urgent intervention indicated
5. Death

Total dose of Cyclizine given in the last 24 hours (mg/kg)

OR

Total dose of Cyclizine given in the last 24 hours (mg)

Route of administration

○ Oral ○ IV ○ Both IV & oral
○ Sub cutaneous ○ Both subcutaneous & oral

Frequency of administration:

○ QID (6 hrly) ○ TDS (8 hrly) ○ BD (12 hrly) ○ OD ○ Continuous infusion

○ Other: Please specify (e.g. PRN):_____

Current other anti-emetics – tick all that apply
(the options will appear as drop down boxes in REDCap)

Anti-histamines:	**Dose: (mg)**	**Frequency:**
□ Diphenhydramine		
□ Meclizine		
Benzodiazepines:	**Dose: (mg)**	**Frequency:**
□ Lorazepam		
□ Diazepam		
Corticosteroids:	**Dose: (mg)**	**Frequency:**
□ Dexamethasone		
□ Prednisone		
□ Prednisolone		
Dopamine antagonist:	**Dose: (mg)**	**Frequency:**
□ Domperidone		
□ Haloperidol		
□ Metoclopramide		
Anticholinergic Agents:	**Dose: (mg)**	**Frequency:**
□ Atropine		
□ Buscopan		
□ Scopolamine		
NK1-receptor antagonist	**Dose: (mg)**	**Frequency:**
□ Aprepitant		
□ Fosaprepitant		
Phenothiazine	**Dose: (mg)**	**Frequency:**
□ Prochloroperazine		
□ chlorpromazine		
□ Levomepromazine		
□ Promethazine		
5HT3-receptor antagonists	**Dose: (mg)**	**Frequency:**
□ Ondansetron		
□ Tropisetron		
□ Granisetron		
□ Dolasetron		
Miscellaneous	**Dose: (mg)**	**Frequency:**
□ Mirtazapine		
□ Olanzapine		
Other: Please specify		
□		
□		

Were there any other new medications commenced

Yes ◯ Please specify medication, dose, route and frequency No ◯

Harms assessment (T_1)

☐ **Dry Mouth**

◯ 1 ◯ 2 ◯ 3 ◯ Ungradable ◯ No Symptom ◯ Not recorded

NCI Criteria 1.Symptomatic (dry or thick saliva) without significant dietary alteration; unstimulated saliva flow >0.2 ml/min 2. Symptomatic and significant oral intake alteration (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods); unstimulated saliva 0.1 to 0.2 ml/min 3. Symptoms leading to inability to adequately aliment orally; IV fluids, tube feedings, or TPN indicated; unstimulated saliva < 0.1 ml/min

☐ **Dizziness**

◯ 1 ◯ 2 ◯ 3 ◯ Ungradable ◯ No Symptom ◯ Not recorded

NCI Criteria 1. Mild unsteadiness or sensation of movement 2. Moderate unsteadiness or sensation of movement; limiting instrumental ADL 3. Severe unsteadiness or sensation of movement; limiting self-care ADL

☐ **Blurred vision**

◯ 1 ◯ 2 ◯ 3 ◯ Ungradable ◯ No Symptom ◯ Not recorded

NCI Criteria 1.Intervention not indicated 2. Symptomatic; limiting instrumental ADL 3.Limiting self-care ADL

☐ **Palpitations**

◯ 1 ◯ 2 ◯ Ungradable ◯ No Symptom ◯ Not recorded

NCI Criteria 1.Present with associated symptoms (e.g., lightheadedness) 2.Shortness of breath

☐ **Somnolence**

◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ Ungradable ◯ No Symptom ◯ Not recorded

NCI Criteria 1.Mild but more than usual drowsiness or sleepiness 2. Moderate sedation; limiting instrumental ADL 3.Obtundation or stupor 4.Life-threatening consequences; urgent intervention indicated 5.Death

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1.Mild disorientation
2.Moderate disorientation; limiting instrumental ADL
3.Severe disorientation; limiting self-care ADL
4.Life-threatening consequences; urgent intervention indicated
5.Death

☐ **Constipation**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema
2. Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Urinary retention**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1.Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
2.Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
3.Elective operative or radiologic intervention indicated; substantial loss of affected kidney function or mass
4.Life-threatening consequences; organ failure; urgent operative intervention indicated
5.Death

☐ **Seizures**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1.Brief partial seizure; no loss of consciousness
2.Brief generalized seizure
3.Multiple seizures despite medical intervention
4.Life-threatening; prolonged repetitive seizures
5.Death

☐ **Respiratory secretions**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1.Mild or asymptomatic symptoms; clinical or diagnostic observation only; intervention not indicated
2.Moderate, minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL
3.Severe or medically significant but not immediately life-threatening, hospitalisation or prolongation of hospitalisation indicated; disabling, limiting self-care ADL
4.Life-threatening consequences; urgent intervention indicated
5.Death

☐ **Injection site reaction**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1.Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)
2.Pain; lipodystrophy; edema; phlebitis
3.Ulceration or necrosis; severe tissue damage; operative intervention indicated
4.Life-threatening consequences; urgent intervention indicated
5.Death

☐ **Euphoria**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Mild mood elevation
2. Moderate mood elevation
3. Severe mood elevation (e.g., hypomania)

☐ **Dysphoria**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not recorded

1.Mild negative mood change
2. Moderate mood change
3. Severe mood change

☐ **Other (if exists e.g. extra-pyramidal symptoms, heart failure, precipitation in syringe)**

Please specify other harm here _____

Other harm grade here

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

☐ **Additional other (if exists)**

Please specify additional other harm here _____

Additional other harm grade here

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

Which symptom/harm is the most troublesome (Please tick only one)?

◯ Dry Mouth
◯ Dizziness
◯ Blurred vision
◯ Palpitations
◯ Somnolence
◯ Confusion
◯ Constipation
◯ Urinary retention
◯ Seizures
◯ Respiratory secretions
◯ Injection site reaction
◯ Euphoria
◯ Dysphoria
◯ Other
◯ Additional Other
◯ Not applicable

Key questions derived from the Naranjo modified check list-only answer if a harm scored 3 or more

1. Did the adverse reaction appear after the suspected drug was given?
◯ Yes
◯ No
◯ Don't know

2. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was given?
◯ Yes
◯ No
◯ Don't know

3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?
◯ Yes
◯ No
◯ Don't know

4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?
◯ Yes
◯ No
◯ Don't know

5. Was the adverse reaction confirmed by any objective evidence?
◯ Yes
◯ No
◯ Don't know

Based on your assessment today was there any benefit?

Yes ◯ No ◯

What action was taken?

◯ Cyclizine dose unchanged
◯ Cyclizine dose decreased
◯ Cyclizine dose increased – please specify new dose and frequency: _____
◯ Cyclizine ceased
◯ New medication added – please specify: _____
◯ Other - please specify here: _____

T2 – 72 hours post Baseline

T_2: Assessed/Not assessed (Reason)

◯ Assessed today (continue to complete T_2) OR
◯ Died
◯ Not able to be contacted / located
◯ Too unwell
◯ Other

Date of Death
(dd/mm/yyyy)

End Survey here

Date of Assessment
(dd/mm/yyyy)

Indication of interest

Nausea
◯ 0 ◯ 1 ◯ 2 ◯ 3

NCI Criteria
0.Nil
1. Loss of appetite without alteration in eating habits
2. Oral intake decreased without significant weight loss.
3. Inadequate caloric or fluid intake; requiring nutritional intervention or hospitalisation due to nausea

Vomiting
◯ 0 ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5

NCI Criteria
0. Nil
1. 1-2 episodes (separated by > 5 minutes) in 24 hours
2. 3-5 episodes (separated by > 5 minutes) in 24 hour
3. >=6 episodes (separated by > 5 minutes) in 24 hours; new tube feeding, nutritional support or hospitalization indicated
4. Life threatening consequences; urgent intervention indicated
5.Death

Total dose of Cyclizine given in the last 24 hours (mg/kg)

OR

Total dose of Cyclizine given in the last 24 hours (mg)

Route of administration

○ Oral ○ IV ○ Both IV & oral ○ Sub cutaneous ○ Both subcutaneous & oral

Frequency of administration:

○ QID (6 hrly) ○ TDS (8 hrly) ○ BD (12 hrly) ○ OD ○ Continuous infusion

○ Other: Please specify (e.g. PRN):_____

Current other anti-emetics – tick all that apply
(the options will appear as drop down boxes in REDCap)

Anti-histamines:	**Dose: (mg)**	**Frequency:**
□ Diphenhydramine		
□ Meclizine		
Benzodiazepines:	**Dose: (mg)**	**Frequency:**
□ Lorazepam		
□ Diazepam		
Corticosteroids:	**Dose: (mg)**	**Frequency:**
□ Dexamethasone		
□ Prednisone		
□ Prednisolone		
Dopamine antagonist:	**Dose: (mg)**	**Frequency:**
□ Domperidone		
□ Haloperidol		
□ Metoclopramide		
Anticholinergic Agents:	**Dose: (mg)**	**Frequency:**
□ Atropine		
□ Buscopan		
□ Scopolamine		
NK1-receptor antagonist	**Dose: (mg)**	**Frequency:**
□ Aprepitant		
□ Fosaprepitant		
Phenothiazine	**Dose: (mg)**	**Frequency:**
□ Prochloroperazine		
□ chlorpromazine		
□ Levomepromazine		
□ Promethazine		
5HT3-receptor antagonists	**Dose: (mg)**	**Frequency:**
□ Ondansetron		
□ Tropisetron		
□ Granisetron		
□ Dolasetron		
Miscellaneous	**Dose: (mg)**	**Frequency:**
□ Mirtazapine		
□ Olanzapine		
Other: Please specify		
□		
□		

Were any other new medications commenced

Yes ◯ Please specify medication, dose, route and frequency No ◯

Harms assessment (T2)

☐ **Dry Mouth**

◯ 1 ◯ 2 ◯ 3 ◯ Ungradable ◯ No Symptom ◯ Not recorded

NCI Criteria 1.Symptomatic (dry or thick saliva) without significant dietary alteration; unstimulated saliva flow >0.2 ml/min 2. Symptomatic and significant oral intake alteration (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods); unstimulated saliva 0.1 to 0.2 ml/min 3. Symptoms leading to inability to adequately aliment orally; IV fluids, tube feedings, or TPN indicated; unstimulated saliva < 0.1 ml/min

☐ **Dizziness**

◯ 1 ◯ 2 ◯ 3 ◯ Ungradable ◯ No Symptom ◯ Not recorded

NCI Criteria 1. Mild unsteadiness or sensation of movement 2. Moderate unsteadiness or sensation of movement; limiting instrumental ADL 3. Severe unsteadiness or sensation of movement; limiting self-care ADL

☐ **Blurred vision**

◯ 1 ◯ 2 ◯ 3 ◯ Ungradable ◯ No Symptom ◯ Not recorded

NCI Criteria 1. Intervention not indicated 2. Symptomatic; limiting instrumental ADL 3. Limiting self-care ADL

☐ **Palpitations**

◯ 1 ◯ 2 ◯ Ungradable ◯ No Symptom ◯ Not recorded

NCI Criteria 1. Present with associated symptoms (e.g., lightheadedness) 2. Shortness of breath

☐ **Somnolence**

◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ Ungradable ◯ No Symptom ◯ Not recorded

NCI Criteria 1. Mild but more than usual drowsiness or sleepiness 2. Moderate sedation; limiting instrumental ADL 3. Obtundation or stupor 4. Life-threatening consequences; urgent intervention indicated 5. Death

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Mild disorientation
2. Moderate disorientation; limiting instrumental ADL
3. Severe disorientation; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Constipation**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema
2. Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Urinary retention**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
2. Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
3. Elective operative or radiologic intervention indicated; substantial loss of affected kidney function or mass
4. Life-threatening consequences; organ failure; urgent operative intervention indicated
5. Death

☐ **Seizures**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Brief partial seizure; no loss of consciousness
2. Brief generalized seizure
3. Multiple seizures despite medical intervention
4. Life-threatening; prolonged repetitive seizures
5. Death

☐ **Respiratory secretions**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1.Mild or asymptomatic symptoms; clinical or diagnostic observation only; intervention not indicated
2. Moderate, minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL
3. Severe or medically significant but not immediately life-threatening, hospitalisation or prolongation of hospitalisation indicated; disabling, limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Injection site reaction**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1.Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)
2. Pain; lipodystrophy; edema; phlebitis
3.Ulceration or necrosis; severe tissue damage; operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Euphoria**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Mild mood elevation
2. Moderate mood elevation
3. Severe mood elevation (e.g., hypomania)

☐ **Dysphoria**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not recorded

1.Mild negative mood change
2. Moderate mood change
3. Severe mood change

☐ **Other (if exists e.g. extra-pyramidal symptoms, heart failure, precipitation in syringe)**

Please specify other harm here _____

Other harm grade here

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

☐ **Additional other (if exists)**

Please specify additional other harm here _____

Additional other harm grade here

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

Which symptom/harm is the most troublesome (Please tick only one)?

◯ Dry Mouth
◯ Dizziness
◯ Blurred vision
◯ Palpitations
◯ Somnolence
◯ Confusion
◯ Constipation
◯ Urinary retention
◯ Seizures
◯ Respiratory secretions
◯ Injection site reaction
◯ Euphoria
◯ Dysphoria
◯ Other
◯ Additional Other
◯ Not applicable

Key questions derived from the Naranjo modified check list - only answer if a harm scored 3 or more

1. Did the adverse reaction appear after the suspected drug was given?
◯ Yes
◯ No
◯ Don't know

2. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was given?
◯ Yes
◯ No
◯ Don't know

3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?
◯ Yes
◯ No
◯ Don't know

4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?
◯ Yes
◯ No
◯ Don't know

5. Was the adverse reaction confirmed by any objective evidence?
◯ Yes
◯ No
◯ Don't know

Based on your assessment today was there any benefit?

Yes ◯ No ◯

What action was taken?

◯ Cyclizine dose unchanged
◯ Cyclizine dose decreased
◯ Cyclizine dose increased – please specify new dose and frequency: _____
◯ Cyclizine ceased
◯ New medication added – please specify: _____
◯ Other - please specify here: _____

Medication Cessation (complete this page at any time the medication of interest is ceased)

Date of assessment
(dd/mm/yyyy)

Medication was ceased (related to indication of interest):

◯ Symptom continued unchanged
◯ Symptom worsened
◯ Symptom resolved - date of resolution
(dd/mm/yyyy)

◯ Symptom/s worsened - Grade (NCI) - see NCI criteria below

Nausea

◯ 1 ◯ 2 ◯ 3 ◯ Ungradable ◯ No Symptom

NCI Criteria
1. loss of appetite without alteration in eating habits
2. Oral intake decreased without significant weight loss.
3.Inadequate caloric or fluid intake; requiring nutritional intervention or hospitalisation due to nausea

Vomiting

◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ Ungradable ◯ No Symptom

NCI Criteria
1. 1-2 episodes (separated by > 5 minutes) in 24 hours
2. 3-5 episodes (separated by > 5 minutes) in 24 hour
3. >=6 episodes (separated by > 5 minutes) in 24 hours; ; new tube feeding, nutritional support or hospitalization indicated
4. Life threatening consequences; urgent intervention indicated
5. Death

Medication was ceased (related to other reasons):

◯ Adverse event/harm-please complete adhoc adverse event/harm assessment
◯ Patient unable to take medication (Please specify): _____
◯ Other (Please specify): _____

Adhoc Adverse Event/Harms Assessment A - Please complete the survey below.

Were there any adhoc harms?

○ Yes ○ No

Date of assessment

dd/mm/yyyy	

☐ **Dry Mouth**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1.Symptomatic (dry or thick saliva) without significant dietary alteration; unstimulated saliva flow >0.2 ml/min
2. Symptomatic and significant oral intake alteration (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods); unstimulated saliva 0.1 to 0.2 ml/min
3. Symptoms leading to inability to adequately aliment orally; IV fluids, tube feedings, or TPN indicated; unstimulated saliva < 0.1 ml/min

☐ **Dizziness**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Mild unsteadiness or sensation of movement
2. Moderate unsteadiness or sensation of movement; limiting instrumental ADL
3. Severe unsteadiness or sensation of movement; limiting self-care ADL

☐ **Blurred vision**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Intervention not indicated
2. Symptomatic; limiting instrumental ADL
3. Limiting self-care ADL

☐ **Palpitations**

○ 1 ○ 2 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Present with associated symptoms (e.g., lightheadedness)
2. Shortness of breath

☐ **Somnolence**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Mild disorientation
2. Moderate disorientation; limiting instrumental ADL
3. Severe disorientation; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Constipation**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema
2. Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Urinary retention**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
2. Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
3. Elective operative or radiologic intervention indicated; substantial loss of affected kidney function or mass
4. Life-threatening consequences; organ failure; urgent operative intervention indicated
5. Death

☐ **Seizures**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Brief partial seizure; no loss of consciousness
2. Brief generalized seizure
3. Multiple seizures despite medical intervention
4. Life-threatening; prolonged repetitive seizures
5. Death

☐ **Respiratory secretions**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1.Mild or asymptomatic symptoms; clinical or diagnostic observation only; intervention not indicated
2. Moderate, minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL
3. Severe or medically significant but not immediately life-threatening, hospitalisation or prolongation of hospitalisation indicated; disabling, limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Injection site reaction**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria 1.Tenderness with or without associated symptoms (e.g., warmth, erythema, itching) 2. Pain; lipodystrophy; edema; phlebitis 3.Ulceration or necrosis; severe tissue damage; operative intervention indicated 1. Life-threatening consequences; urgent intervention indicated 2. Death

☐ **Euphoria**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria 1. Mild mood elevation 2. Moderate mood elevation 3. Severe mood elevation (e.g., hypomania)

☐ **Dysphoria**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not recorded

1.Mild negative mood change 2. Moderate mood change 3. Severe mood change

Other (if exists e.g. extra-pyramidal symptoms, heart failure, precipitation in syringe)

Please specify other harm here _____

Other harm grade here

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

Additional other (if exists) ☐

Please specify additional other harm here _____

Additional other harm grade here

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

Which symptom/harm is the most troublesome (Please tick only one)?

◯ Dry Mouth
◯ Dizziness
◯ Blurred vision
◯ Palpitations
◯ Somnolence
◯ Confusion
◯ Constipation
◯ Urinary retention
◯ Seizures
◯ Respiratory secretions
◯ Injection site reaction
◯ Euphoria
◯ Dysphoria
◯ Other
◯ Additional Other

Key questions derived from the Naranjo modified check list - only answer if a harm scored 3 or more

1. Did the adverse reaction appear after the suspected drug was given?
◯ Yes
◯ No
◯ Don't know

2. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was given?
◯ Yes
◯ No
◯ Don't know

3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?
◯ Yes
◯ No
◯ Don't know

4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?
◯ Yes
◯ No
◯ Don't know

5. Was the adverse reaction confirmed by any objective evidence?
◯ Yes
◯ No
◯ Don't know

Adhoc Events/Harms Assessment B - Please complete the survey below.

Were there any adhoc harms?

○ Yes ○ No

Date of assessment

dd/mm/yyyy	

☐ **Dry Mouth**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1.Symptomatic (dry or thick saliva) without significant dietary alteration; unstimulated saliva flow >0.2 ml/min
2. Symptomatic and significant oral intake alteration (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods); unstimulated saliva 0.1 to 0.2 ml/min
3. Symptoms leading to inability to adequately aliment orally; IV fluids, tube feedings, or TPN indicated; unstimulated saliva < 0.1 ml/min

☐ **Dizziness**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Mild unsteadiness or sensation of movement
2. Moderate unsteadiness or sensation of movement; limiting instrumental ADL
3. Severe unsteadiness or sensation of movement; limiting self-care ADL

☐ **Blurred vision**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Intervention not indicated
2. Symptomatic; limiting instrumental ADL
3. Limiting self-care ADL

☐ **Palpitations**

○ 1 ○ 2 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Present with associated symptoms (e.g., lightheadedness)
2. Shortness of breath

☐ **Somnolence**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Mild disorientation
2. Moderate disorientation; limiting instrumental ADL
3. Severe disorientation; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Constipation**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema
2. Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Urinary retention**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
2. Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
3. Elective operative or radiologic intervention indicated; substantial loss of affected kidney function or mass
4. Life-threatening consequences; organ failure; urgent operative intervention indicated
5. Death

☐ **Seizures**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Brief partial seizure; no loss of consciousness
2. Brief generalized seizure
3. Multiple seizures despite medical intervention
4. Life-threatening; prolonged repetitive seizures
5. Death

☐ **Respiratory secretions**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1.Mild or asymptomatic symptoms; clinical or diagnostic observation only; intervention not indicated
2. Moderate, minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL
3. Severe or medically significant but not immediately life-threatening, hospitalisation or prolongation of hospitalisation indicated; disabling, limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Injection site reaction**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1.Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)
2. Pain; lipodystrophy; edema; phlebitis
3.Ulceration or necrosis; severe tissue damage; operative intervention indicated
1. Life-threatening consequences; urgent intervention indicated
2. Death

☐ **Euphoria**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Mild mood elevation
2. Moderate mood elevation
3. Severe mood elevation (e.g., hypomania)

☐ **Dysphoria**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not recorded

1.Mild negative mood change
2. Moderate mood change
3. Severe mood change

Other (if exists e.g. extra-pyramidal symptoms, heart failure, precipitation in syringe)

Please specify other harm here _____

Other harm grade here

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

Additional other (if exists) ☐

Please specify additional other harm here _____

Additional other harm grade here

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

Which symptom/harm is the most troublesome (Please tick only one)?

◯ Dry Mouth
◯ Dizziness
◯ Blurred vision
◯ Palpitations
◯ Somnolence
◯ Confusion
◯ Constipation
◯ Urinary retention
◯ Seizures
◯ Respiratory secretions
◯ Injection site reaction
◯ Euphoria
◯ Dysphoria
◯ Other
◯ Additional Other

Key questions derived from the Naranjo modified check list - only answer if a harm scored 3 or more

1. Did the adverse reaction appear after the suspected drug was given?
◯ Yes
◯ No
◯ Don't know

2. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was given?
◯ Yes
◯ No
◯ Don't know

3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?
◯ Yes
◯ No
◯ Don't know

4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?
◯ Yes
◯ No
◯ Don't know

5. Was the adverse reaction confirmed by any objective evidence?
◯ Yes
◯ No
◯ Don't know

Adhoc Adverse Events/Harms C - Please complete the survey below.

Were there any adhoc harms?

○ Yes ○ No

Date of assessment

dd/mm/yyyy	

☐ **Dry Mouth**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1.Symptomatic (dry or thick saliva) without significant dietary alteration; unstimulated saliva flow >0.2 ml/min
2. Symptomatic and significant oral intake alteration (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods); unstimulated saliva 0.1 to 0.2 ml/min
3. Symptoms leading to inability to adequately aliment orally; IV fluids, tube feedings, or TPN indicated; unstimulated saliva < 0.1 ml/min

☐ **Dizziness**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Mild unsteadiness or sensation of movement
2. Moderate unsteadiness or sensation of movement; limiting instrumental ADL
3. Severe unsteadiness or sensation of movement; limiting self-care ADL

☐ **Blurred vision**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Intervention not indicated
2. Symptomatic; limiting instrumental ADL
3. Limiting self-care ADL

☐ **Palpitations**

○ 1 ○ 2 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Present with associated symptoms (e.g., lightheadedness)
2. Shortness of breath

☐ **Somnolence**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Mild disorientation
2. Moderate disorientation; limiting instrumental ADL
3. Severe disorientation; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Constipation**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema
2. Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Urinary retention**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
2. Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
3. Elective operative or radiologic intervention indicated; substantial loss of affected kidney function or mass
4. Life-threatening consequences; organ failure; urgent operative intervention indicated
5. Death

☐ **Seizures**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1. Brief partial seizure; no loss of consciousness
2. Brief generalized seizure
3. Multiple seizures despite medical intervention
4. Life-threatening; prolonged repetitive seizures
5. Death

☐ **Respiratory secretions**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria
1.Mild or asymptomatic symptoms; clinical or diagnostic observation only; intervention not indicated
2. Moderate, minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL
3. Severe or medically significant but not immediately life-threatening, hospitalisation or prolongation of hospitalisation indicated; disabling, limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Injection site reaction**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria 1.Tenderness with or without associated symptoms (e.g., warmth, erythema, itching) 2. Pain; lipodystrophy; edema; phlebitis 3.Ulceration or necrosis; severe tissue damage; operative intervention indicated 1. Life-threatening consequences; urgent intervention indicated 2. Death

☐ **Euphoria**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not recorded

NCI Criteria 1. Mild mood elevation 2. Moderate mood elevation 3. Severe mood elevation (e.g., hypomania)

☐ **Dysphoria**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not recorded

1.Mild negative mood change 2. Moderate mood change 3. Severe mood change

Other (if exists e.g. extra-pyramidal symptoms, heart failure, precipitation in syringe)

Please specify other harm here _____

Other harm grade here

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

Additional other (if exists) ☐

Please specify additional other harm here _____

Additional other harm grade here

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

Which symptom/harm is the most troublesome (Please tick only one)?

◯ Dry Mouth
◯ Dizziness
◯ Blurred vision
◯ Palpitations
◯ Somnolence
◯ Confusion
◯ Constipation
◯ Urinary retention
◯ Seizures
◯ Respiratory secretions
◯ Injection site reaction
◯ Euphoria
◯ Dysphoria
◯ Other
◯ Additional Other

Key questions derived from the Naranjo modified check list - only answer if a harm scored 3 or more

1. Did the adverse reaction appear after the suspected drug was given?
◯ Yes
◯ No
◯ Don't know

2. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was given?
◯ Yes
◯ No
◯ Don't know

3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?
◯ Yes
◯ No
◯ Don't know

4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?
◯ Yes
◯ No
◯ Don't know

5. Was the adverse reaction confirmed by any objective evidence?
◯ Yes
◯ No
◯ Don't know