Participant ID	

Initials of person entering data	

Staff email	

CONFIDENTIAL CASE REPORT FORM

Temazepam for Insomnia

Series 47

IMPACCT Trials Coordination Centre (ITCC)

UTS IMPACCT Rapid Program

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

TABLE OF CONTENTS	**PAGE NO.**

Baseline (T_0)	
Date of Assessment	DD/MM/YYYY

Demographics

Gender *(please tick)* ○ Male ○ Female ○ Other

Age (yrs)		**Weight (kg)**		**Height (cm)**	

Tick ✓	**Primary life limiting illness** *(please choose only one)*
	Advanced cancer – please specify type of caner: _____
	End stage renal failure
	Hepatic failure
	Neurodegenerative disease
	AIDS
	Cardiac failure
	Respiratory failure
	Other - *Please specify:* _____

Tick ✓	**Palliative Care Phase**
	1. 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.
	2. Unstable Phase: 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.
	3. Deteriorating Phase: 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.
	4. Terminal Care Phase: Death is likely in a matter of days and no acute intervention is planned or required.

Tick ✓	**Australian Modified Karnofsky Performance Scale (AKPS)**
	100 - Normal; no complaints; no evidence of disease
	90 - Able to carry on normal activity; minor sign of symptoms of disease
	80 - Normal activity with effort; some signs or symptoms of disease
	70 - Cares for self; unable to carry on normal activity or to do active work
	60 - Requires occasional assistance but is able to care for most needs
	50 - Requires considerable assistance and frequent medical care
	40 - In bed more than 50% of the time
	30 - Almost completely bedfast
	20 - Totally bedfast and requiring extensive nursing care by professionals and/or family
	10 - Comatose or barely rousable
	0 - Dead
	Not able to determine

Charlson Comorbidity Index - Does the patient have any of the following?			
Tick ✓	*(Please tick all that apply)*	**Tick ✓**	*(Please tick all that apply)*
	Myocardial Infarction (history, not ECG changes only)		Hemiplegia
	Congestive Cardiac Failure		Moderate or Severe Renal Disease
	Peripheral Vascular Disease (includes aortic aneurysm ≥ 6 cm)		Diabetes (with end organ damage)
	Cerebrovascular Disease (CVA with mild or no residual or TIA)		Any Tumour
	Dementia		Leukaemia (acute or chronic)
	Chronic Pulmonary Disease		Lymphoma
	Connective Tissue Disease		Moderate or Severe Liver Disease
	Peptic Ulcer Disease		Metastatic Solid Tumour
	Mild Liver Disease (without portal hypertension, includes chronic hepatitis)		AIDS (not just HIV positive)
	Diabetes (without organ damage) (excludes diet-controlled alone)		

Laboratory Tests (only if available within last 14 days)	
Test	**Value**
eGFR (mL/min)	
Bilirubin (mg/dL)	
ALT (U/L)	

Tick ✓		**Is patient currently taking any of these medications to assist with sleep***? (tick 'yes' or 'no' to all)*
Yes	**No**	
		Other benzodiazepines
		Antidepressants
		Melatonin
		Cannabinoids
		'Z-drugs' (Zopiclone, Zaleplon, Zolpidem, Zolpimist)

Baseline T0 - Medication Commencement

Target Symptom Severity - *(Please complete both insomnia symptom assessment scales to give most accurate measure of symptom severity)*

☐ **Insomnia**

○ 1 ○ 2 ○ 3

NCI Criteria
1. Mild difficulty falling asleep, staying asleep or waking up early
2. Moderate difficulty falling asleep, staying asleep or waking up early
3. Severe difficulty in falling asleep, staying asleep

SYMPTOM ASSESSMENT SCALE FOR INSOMNIA *Please circle the appropriate number in box below to indicate* ***patient's level of distress.***

0 = you have no distress caused by the symptom.
10 = means patient is experiencing the worst possible distress caused by the symptom

0	1	2	3	4	5	6	7	8	9	10

No distress **Worst possible distress**

Tick ✓		**Does patient have any pre-existing sleep disorders/disturbances?** *(tick 'yes' or 'no' to all)*
Yes	**No**	
		Obstructive sleep apnoea
		Central sleep apnoea
		Restless legs
		Other; please specify

Temazepam Starting Dose	
	Dose (mgs)

Baseline Symptom/Harm Assessment *(Please grade all harms; indicate that each harm has been assessed by ticking the square box next to each)*

☐ **Daytime Somnolence**

○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable ○ No Symptom

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

☐ **Dizziness**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom

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

☐ **Ataxia**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom

NCI Criteria
1.A symptomatic; clinical or diagnostic observations only; intervention not indicated
2. Moderate symptoms; limiting instrumental ADL
3. Severe symptoms; limiting self care ADL; mechanical assistance indicated

☐ **Headache**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom

NCI Criteria
1. Mild pain
2. Moderate pain; limiting instrumental ADL
3. Severe pain; limiting self-care ADL

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom

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

☐ **Delirium**

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

NCI Criteria
1. Mild acute confusional state
2. Moderate and acute confusional state; limiting instrumental ADL
3. Severe and acute confusional state; limiting self-care ADL; urgent intervention indicated; new onset
4. Life-threatening consequences, threats of harm to self or others; urgent intervention indicated
5. Death

☐ **Other harm** *(only if applicable – can be related or unrelated to the medication)*

Please specify other harm here _____

Other harm NCI criteria harm grade here:
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

☐ **Additional other harm** *(only if applicable – can be related or unrelated to the medication)*
Please specify additional other harm here _____

Additional other harm NCI criteria harm grade here: ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ Ungradable

Tick ✓	**Which symptom/harm is the <u>most</u> troublesome?** *(Tick one only)*
	Somnolence
	Dizziness
	Ataxia
	Headache
	Confusion
	Delirium
	Other
	Additional Other
	Not applicable

T_1 - 3 days post Baseline

Date of Assessment	DD/MM/YYYY
Time of Assessment (24hr clock)	HH:MM

Tick ✓	**T_1: Assessed/Not assessed reason**
	Assessed today *(continue to complete T_1)* OR
	Died *(record date of death below)*
	Not able to be contacted / located
	Too unwell
	Other

Date of Death*	DD/MM/YYYY

End survey here

Please provide reason if today's assessment is not 3 days after baseline. *(e.g., weekend)*

Target Symptom Severity - *(Please complete both insomnia symptom assessment scales to give most accurate measure of symptom severity)*

☐ **Insomnia**

○ 1 ○ 2 ○ 3 ○ No Symptom

NCI Criteria
1. Mild difficulty falling asleep, staying asleep or waking up early
2. Moderate difficulty falling asleep, staying asleep or waking up early
3. Severe difficulty in falling asleep, staying asleep

SYMPTOM ASSESSMENT SCALE FOR INSOMNIA *Please circle the appropriate number in box below to indicate* ***patient's level of distress.***

0 = you have no distress caused by the symptom.
10 = means patient is experiencing the worst possible distress caused by the symptom

0	1	2	3	4	5	6	7	8	9	10

No distress **Worst possible distress**

Current Temazepam Dose	
	Total dose Temazepam given in the last 24 hours *(mg)*
	How long has the patient been on this dose *(days)*

T_1 - Symptom/Harm Assessment *(Please grade all harms; indicate that each harm has been assessed by ticking the square box next to each)*

☐ **Daytime Somnolence**

○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable ○ No Symptom

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

☐ **Dizziness**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom

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

☐ **Ataxia**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom

NCI Criteria
1.A symptomatic; clinical or diagnostic observations only; intervention not indicated
2. Moderate symptoms; limiting instrumental ADL
3. Severe symptoms; limiting self care ADL; mechanical assistance indicated

☐ **Headache**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom

NCI Criteria
1. Mild pain
2. Moderate pain; limiting instrumental ADL
3. Severe pain; limiting self-care ADL

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom

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

☐ **Delirium**

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

NCI Criteria
1. Mild acute confusional state
2. Moderate and acute confusional state; limiting instrumental ADL
3. Severe and acute confusional state; limiting self-care ADL; urgent intervention indicated; new onset
4. Life-threatening consequences, threats of harm to self or others; urgent intervention indicated
5. Death

☐ **Other harm** *(only if applicable – can be related or unrelated to the medication)*

Please specify other harm here _____

Other harm NCI criteria harm grade here:
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

☐ **Additional other harm** *(only if applicable – can be related or unrelated to the medication)*
Please specify additional other harm here _____

Additional other harm NCI criteria harm grade here: ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

Tick ✓	**Which symptom/harm is the <u>most</u> troublesome?** *(Tick one only)*
	Somnolence
	Dizziness
	Ataxia
	Headache
	Confusion
	Delirium
	Other
	Additional Other
	Not applicable

If a harm/toxicity scored 3 or more, please complete this set of questions from the Naranjo modified checklist. *(Tick 'yes', 'no', or 'don't know' for each question below - If the symptom was present at baseline and grading remains unchanged the Naranjo questions are not required to be answered)*

	Yes	**No**	**Don't know**
1. Did the adverse reaction appear after the suspected drug was given?			
2. Did the adverse reaction improve when the drug was discontinued, or a specific antagonist was given?			
3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?			
4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?			
5. Was the adverse event confirmed by any objective evidence?			

What is the intended treatment based on today's assessment?		
Tick ✓	**Medication changes** *(Tick all that apply)*	
	No change to Temazepam/continue current dose	
	Temazepam ceased *(complete medication cessation on page 15)*	
	Temazepam dose reduced - *Please specify new dose in mgs: _____*	
	Temazepam dose increased - *Please specify new dose in mgs:_____*	
Yes	**No**	**Has a medication been added to treat a specific harm?**
		If yes, please specify new medication here: _____

Based on the assessment today has the harm resolved?
○ Yes ○ No ○ Not applicable

T_2 - 7 days post Baseline

Date of Assessment	DD/MM/YYYY
Time of Assessment (24hr clock)	HH:MM

Tick ✓	**T_2: Assessed/Not assessed reason**
	Assessed today *(continue to complete T_2)* OR
	Died *(record date of death below)*
	Not able to be contacted / located
	Too unwell
	Other

Date of Death*	DD/MM/YYYY

End survey here

Please provide reason if today's assessment is not 7 days after baseline. *(e.g., weekend)*

Target Symptom Severity - *(Please complete both insomnia symptom assessment scales to give most accurate measure of symptom severity)*

☐ **Insomnia**

○ 1 ○ 2 ○ 3 ○ No Symptom

NCI Criteria
1. Mild difficulty falling asleep, staying asleep or waking up early
2. Moderate difficulty falling asleep, staying asleep or waking up early
3. Severe difficulty in falling asleep, staying asleep

SYMPTOM ASSESSMENT SCALE FOR INSOMNIA *Please circle the appropriate number in box below to indicate* ***patient's level of distress.***

0 = you have no distress caused by the symptom.
10 = means patient is experiencing the worst possible distress caused by the symptom

0	1	2	3	4	5	6	7	8	9	10

No distress **Worst possible distress**

Current Temazepam Dose	
	Total dose of Temazepam given in the last 24 hours *(mg)*
	How long has the patient been on this dose *(days)*

T_2 - Symptom/Harm Assessment *(Please grade all harms; indicate that each harm has been assessed by ticking the square box next to each)*

☐ **Daytime Somnolence**

○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable ○ No Symptom

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

☐ **Dizziness**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom

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

☐ **Ataxia**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom

NCI Criteria
1.A symptomatic; clinical or diagnostic observations only; intervention not indicated
2. Moderate symptoms; limiting instrumental ADL
3. Severe symptoms; limiting self care ADL; mechanical assistance indicated

☐ **Headache**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom

NCI Criteria
1. Mild pain
2. Moderate pain; limiting instrumental ADL
3. Severe pain; limiting self-care ADL

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom

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

☐ **Delirium**

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

NCI Criteria
1. Mild acute confusional state
2. Moderate and acute confusional state; limiting instrumental ADL
3. Severe and acute confusional state; limiting self-care ADL; urgent intervention indicated; new onset
4. Life-threatening consequences, threats of harm to self or others; urgent intervention indicated
5. Death

☐ **Other harm** *(only if applicable – can be related or unrelated to the medication)*

Please specify other harm here _____

Other harm NCI criteria harm grade here:
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

☐ **Additional other harm** *(only if applicable – can be related or unrelated to the medication)*
Please specify additional other harm here _____

Additional other harm NCI criteria harm grade here: ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

Tick ✓	**Which symptom/harm is the <u>most</u> troublesome?** *(Tick one only)*
	Somnolence
	Dizziness
	Ataxia
	Headache
	Confusion
	Delirium
	Other
	Additional Other
	Not applicable

If a harm/toxicity scored 3 or more, please complete this set of questions from the Naranjo modified checklist. *(Tick 'yes', 'no', or 'don't know' for each question below - If the symptom was present at baseline and grading remains unchanged the Naranjo questions are not required to be answered)*

	Yes	**No**	**Don't know**
1.Did the adverse reaction appear after the suspected drug was given?			
2.Did the adverse reaction improve when the drug was discontinued, or a specific antagonist was given?			
3.Are there alternative causes (other than the drug) that could on their own have caused the reaction?			
4.Did the patient have a similar reaction to the same or similar drug in any previous exposure?			
5. Was the adverse event confirmed by any objective evidence?			

What is the intended treatment based on today's assessment?		
Tick ✓	**Medication changes** *(Tick all that apply)*	
	No change to Temazepam/continue current dose	
	Temazepam ceased *(complete medication cessation on page 15)*	
	Temazepam dose reduced - *Please specify new dose in mgs: _____*	
	Temazepam dose increased - *Please specify new dose in mgs:_____*	
Yes	**No**	**Has a medication been added to treat a specific harm?**
		If yes, please specify new medication here: _____

Based on the assessment today has the harm resolved?
○ Yes ○ No ○ Not applicable

Medication Cessation *(complete this page if the intervention/medication of interest is ceased at any point during the study period)*	
Date of Assessment (medication cessation)	DD/MM/YYYY

Tick ✓	Medication was ceased (related to indication of interest)
	Symptom resolved - *Please indicate date symptom resolved:* DD/MM/YYYY
	Symptom continued unchanged
	Symptom/s worsened - *Please record NCI grade below*

☐ **Insomnia**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom

NCI Criteria
1. Mild difficulty falling asleep, staying asleep or waking up early
2. Moderate difficulty falling asleep, staying asleep or waking up early
3. Severe difficulty in falling asleep, staying asleep

Tick ✓	Intervention/medication was ceased (related to other reasons)
	Harm/toxicity
	Other - *Please specify:*

What treatment did you subsequently initiate following the cessation of the intervention/medication?

Ad hoc A - Unscheduled Harm/Toxicity Assessment

Date of Assessment	DD/MM/YYYY

Harm/toxicity Assessment *(Please grade all harms; indicate that each harm has been assessed by ticking the square box next to each)*

☐ **Daytime Somnolence**

○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable ○ No Symptom

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

☐ **Dizziness**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom

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

☐ **Ataxia**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom

NCI Criteria
1.A symptomatic; clinical or diagnostic observations only; intervention not indicated
2. Moderate symptoms; limiting instrumental ADL
3. Severe symptoms; limiting self care ADL; mechanical assistance indicated

☐ **Headache**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom

NCI Criteria
1. Mild pain
2. Moderate pain; limiting instrumental ADL
3. Severe pain; limiting self-care ADL

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom

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

☐ **Delirium**

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

NCI Criteria
1. Mild acute confusional state
2. Moderate and acute confusional state; limiting instrumental ADL
3. Severe and acute confusional state; limiting self-care ADL; urgent intervention indicated; new onset
4. Life-threatening consequences, threats of harm to self or others; urgent intervention indicated
5. Death

☐ **Other harm** *(only if applicable – can be related or unrelated to the medication)*

Please specify other harm here _____

Other harm NCI criteria harm grade here:
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

☐ **Additional other harm** *(only if applicable – can be related or unrelated to the medication)*
Please specify additional other harm here _____

Additional other harm NCI criteria harm grade here: ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

Tick ✓	**Which symptom/harm is the <u>most</u> troublesome?** *(Tick one only)*
	Somnolence
	Dizziness
	Ataxia
	Headache
	Confusion
	Delirium
	Other
	Additional Other
	Not applicable

If a harm/toxicity scored 3 or more, please complete this set of questions from the Naranjo modified checklist. *(Tick 'yes', 'no', or 'don't know' for each question below - If the symptom was present at baseline and grading remains unchanged the Naranjo questions are not required to be answered)*

	Yes	**No**	**Don't know**
1. Did the adverse reaction appear after the suspected drug was given?			
2. Did the adverse reaction improve when the drug was discontinued, or a specific antagonist was given?			
3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?			
4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?			
5. Was the adverse event confirmed by any objective evidence?			

Ad hoc B - Unscheduled Harm/Toxicity Assessment

Date of Assessment	DD/MM/YYYY

Harm/toxicity Assessment *(Please grade all harms; indicate that each harm has been assessed by ticking the square box next to each)*

☐ **Daytime Somnolence**

○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable ○ No Symptom

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

☐ **Dizziness**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom

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

☐ **Ataxia**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom

NCI Criteria
1.A symptomatic; clinical or diagnostic observations only; intervention not indicated
2. Moderate symptoms; limiting instrumental ADL
3. Severe symptoms; limiting self care ADL; mechanical assistance indicated

☐ **Headache**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom

NCI Criteria
1. Mild pain
2. Moderate pain; limiting instrumental ADL
3. Severe pain; limiting self-care ADL

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom

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

☐ **Delirium**

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

NCI Criteria
1. Mild acute confusional state
2. Moderate and acute confusional state; limiting instrumental ADL
3. Severe and acute confusional state; limiting self-care ADL; urgent intervention indicated; new onset
4. Life-threatening consequences, threats of harm to self or others; urgent intervention indicated
5. Death

☐ **Other harm** *(only if applicable – can be related or unrelated to the medication)*

Please specify other harm here _____

Other harm NCI criteria harm grade here:
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

☐ **Additional other harm** *(only if applicable – can be related or unrelated to the medication)*
Please specify additional other harm here _____

Additional other harm NCI criteria harm grade here: ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ Ungradable

Tick ✓	**Which symptom/harm is the <u>most</u> troublesome?** *(Tick one only)*
	Somnolence
	Dizziness
	Ataxia
	Headache
	Confusion
	Delirium
	Other
	Additional Other
	Not applicable

If a harm/toxicity scored 3 or more, please complete this set of questions from the Naranjo modified checklist. *(Tick 'yes', 'no', or 'don't know' for each question below - If the symptom was present at baseline and grading remains unchanged the Naranjo questions are not required to be answered)*

	Yes	**No**	**Don't know**
1. Did the adverse reaction appear after the suspected drug was given?			
2. Did the adverse reaction improve when the drug was discontinued, or a specific antagonist was given?			
3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?			
4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?			
5. Was the adverse event confirmed by any objective evidence?			

Ad hoc C - Unscheduled Harm/Toxicity Assessment

Date of Assessment	DD/MM/YYYY

Harm/toxicity Assessment *(Please grade all harms; indicate that each harm has been assessed by ticking the square box next to each)*

☐ **Daytime Somnolence**

○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable ○ No Symptom

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

☐ **Dizziness**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom

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

☐ **Ataxia**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom

NCI Criteria
1.A symptomatic; clinical or diagnostic observations only; intervention not indicated
2. Moderate symptoms; limiting instrumental ADL
3. Severe symptoms; limiting self care ADL; mechanical assistance indicated

☐ **Headache**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom

NCI Criteria
1. Mild pain
2. Moderate pain; limiting instrumental ADL
3. Severe pain; limiting self-care ADL

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom

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

☐ **Delirium**

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

NCI Criteria
1. Mild acute confusional state
2. Moderate and acute confusional state; limiting instrumental ADL
3. Severe and acute confusional state; limiting self-care ADL; urgent intervention indicated; new onset
4. Life-threatening consequences, threats of harm to self or others; urgent intervention indicated
5. Death

☐ **Other harm** *(only if applicable – can be related or unrelated to the medication)*

Please specify other harm here _____

Other harm NCI criteria harm grade here:
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

☐ **Additional other harm** *(only if applicable – can be related or unrelated to the medication)*
Please specify additional other harm here _____

Additional other harm NCI criteria harm grade here: ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

Tick ✓	**Which symptom/harm is the <u>most</u> troublesome?** *(Tick one only)*
	Somnolence
	Dizziness
	Ataxia
	Headache
	Confusion
	Delirium
	Other
	Additional Other
	Not applicable

If a harm/toxicity scored 3 or more, please complete this set of questions from the Naranjo modified checklist. *(Tick 'yes', 'no', or 'don't know' for each question below - If the symptom was present at baseline and grading remains unchanged the Naranjo questions are not required to be answered)*

	Yes	**No**	**Don't know**
1. Did the adverse reaction appear after the suspected drug was given?			
2. Did the adverse reaction improve when the drug was discontinued, or a specific antagonist was given?			
3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?			
4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?			
5. Was the adverse event confirmed by any objective evidence?			