

<b>Participant ID</b>	
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<b>Initials of person entering data</b>	
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<b>Staff email</b>	
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CONFIDENTIAL CASE REPORT FORM

**Melatonin Modified Release for Insomnia**

**Series 39**

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)

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## Baseline (T<sub>0</sub>)

Date of Assessment

DD/MM/YYYY

### Demographics

Gender (please tick)  Male  Female  Other

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

Tick ✓	Palliative Care Phase
	<b>1. Stable Phase:</b> The person's symptoms are adequately controlled by established management. Further interventions to maintain symptom control and quality of life have been planned.
	<b>2. Unstable Phase:</b> 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.
	<b>3. Deteriorating Phase:</b> 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.
	<b>4. Terminal Care Phase:</b> 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

<b>Charlson Comorbidity Index - Does the patient have any of the following?</b>			
<b>Tick</b> ✓	<i>(Please tick all that apply)</i>	<b>Tick</b> ✓	<i>(Please tick all that apply)</i>
	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)		

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

<b>Tick</b> ✓		<b>Is patient currently taking any of these medications to assist with sleep?</b> <i>(tick 'yes' or 'no' to all)</i>
<b>Yes</b>	<b>No</b>	
		Benzodiazepines
		Antidepressants
		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	Ungradable
---	---	---	---	---	---	---	---	---	---	----	------------

No distress

Worst possible distress

Tick ✓			Does patient have any pre-existing sleep disorders/disturbances? (tick 'yes', 'no' or 'not reported' to all)
Yes	No	Not reported	
			Obstructive sleep apnoea
			Central sleep apnoea
			Restless legs
			Other; please specify

### Melatonin Modified Release 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

**Irritability**

1  2  3  Ungradable  No Symptom

NCI Criteria

1. Mild; easily consolable
2. Moderate; limiting instrumental ADL; increased attention indicated
3. Severe abnormal or excessive response; limiting self-care ADL; inconsolable; medical or psychiatric intervention indicated

**Anxiety**

1  2  3  4  Ungradable  No Symptom

NCI Criteria

1. Mild symptoms; intervention not indicated
2. Moderate symptoms; limiting instrumental ADL
3. Severe symptoms; limiting self-care ADL; hospitalisation indicated
4. Life-threatening consequences; urgent intervention indicated

**Depression**

1  2  3  4  5  Ungradable  No Symptom

NCI Criteria

1. Mild depressive symptoms
2. Moderate depressive symptoms; limiting instrumental ADL
3. Severe depressive symptoms; limiting self-care ADL; hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

**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

**Other harm** (only if applicable – can be related or unrelated to the medication e.g., nightmares)

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 <b>most</b> troublesome? ( <i>Tick one only</i> )
	Daytime Somnolence
	Dizziness
	Irritability
	Anxiety
	Depression
	Headache
	Other
	Additional Other
	Not applicable

## T<sub>1</sub> - 3 days post Baseline

Date of Assessment

DD/MM/YYYY

Time of Assessment (24hr clock)

HH:MM

Tick ✓	T <sub>1</sub> : Assessed/Not assessed reason
	Assessed today ( <i>continue to complete T<sub>1</sub></i> ) OR
	Died ( <i>record date of death below</i> )
	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	Ungradable
---	---	---	---	---	---	---	---	---	---	----	------------

No distress

Worst possible distress

## Current Melatonin Dose

Total dose Melatonin given in the last 24 hours (*mg*)

How long has the patient been on this dose (*days*)

**T<sub>1</sub> - 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

**Irritability**

1    2    3    Ungradable    No Symptom

NCI Criteria

1. Mild; easily consolable
2. Moderate; limiting instrumental ADL; increased attention indicated
3. Severe abnormal or excessive response; limiting self-care ADL; inconsolable; medical or psychiatric intervention indicated

**Anxiety**

1    2    3    4    Ungradable    No Symptom

NCI Criteria

1. Mild symptoms; intervention not indicated
2. Moderate symptoms; limiting instrumental ADL
3. Severe symptoms; limiting self-care ADL; hospitalization indicated
4. Life-threatening consequences; urgent intervention indicated

**Depression**

1    2    3    4    5    Ungradable    No Symptom

NCI Criteria

1. Mild depressive symptoms
2. Moderate depressive symptoms; limiting instrumental ADL
3. Severe depressive symptoms; limiting self-care ADL; hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

**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

**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: <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> Ungradable
---

Tick ✓	Which symptom/harm is the <b>most</b> troublesome? ( <i>Tick one only</i> )
	Daytime Somnolence
	Dizziness
	Irritability
	Anxiety
	Depression
	Headache
	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?		
<b>Tick ✓</b>	<b>Medication changes</b> ( <i>Tick all that apply</i> )	
	No change to Melatonin/continue current dose	
	Melatonin ceased ( <i>complete medication cessation on page 15</i> )	
	Melatonin dose reduced - <i>Please specify new dose in mgs:</i> _____	
	Melatonin dose increased - <i>Please specify new dose in mgs:</i> _____	
<b>Yes</b>	<b>No</b>	<b>Has a medication been added to treat a specific harm?</b>
		<i>If yes, please specify new medication here:</i> _____
Based on the assessment today has the harm resolved?		
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not applicable		

## T<sub>2</sub> - 7 days post Baseline

Date of Assessment

DD/MM/YYYY

Time of Assessment (24hr clock)

HH:MM

Tick ✓	T <sub>2</sub> : Assessed/Not assessed reason
	Assessed today ( <i>continue to complete T<sub>2</sub></i> ) OR
	Died ( <i>record date of death below</i> )
	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	Ungradable
---	---	---	---	---	---	---	---	---	---	----	------------

No distress

Worst possible distress

### Current Melatonin Dose

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

How long has the patient been on this dose (*days*)

**T<sub>2</sub> - 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

**Irritability**

1    2    3    Ungradable    No Symptom

NCI Criteria

1. Mild; easily consolable
2. Moderate; limiting instrumental ADL; increased attention indicated
3. Severe abnormal or excessive response; limiting self-care ADL; inconsolable; medical or psychiatric intervention indicated

**Anxiety**

1    2    3    4    Ungradable    No Symptom

NCI Criteria

1. Mild symptoms; intervention not indicated
2. Moderate symptoms; limiting instrumental ADL
3. Severe symptoms; limiting self-care ADL; hospitalization indicated
4. Life-threatening consequences; urgent intervention indicated

**Depression**

1    2    3    4    5    Ungradable    No Symptom

NCI Criteria

1. Mild depressive symptoms
2. Moderate depressive symptoms; limiting instrumental ADL
3. Severe depressive symptoms; limiting self-care ADL; hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

**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

**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: <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> Ungradable
---

Tick ✓	Which symptom/harm is the <u>most</u> troublesome? ( <i>Tick one only</i> )
	Somnolence
	Dizziness
	Irritability
	Anxiety
	Depression
	Headache
	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?		
<b>Tick ✓</b>	<b>Medication changes</b> ( <i>Tick all that apply</i> )	
	No change to Melatonin/continue current dose	
	Melatonin ceased ( <i>complete medication cessation on page 15</i> )	
	Melatonin dose reduced - <i>Please specify new dose in mgs:</i> _____	
	Melatonin dose increased - <i>Please specify new dose in mgs:</i> _____	
<b>Yes</b>	<b>No</b>	<b>Has a medication been added to treat a specific harm?</b>
		<i>If yes, please specify new medication here:</i> _____
Based on the assessment today has the harm resolved?		
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> 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 - <i>Please indicate date symptom resolved: DD/MM/YYYY</i>
	Symptom continued unchanged
	Symptom/s worsened - <i>Please record NCI grade below</i>

**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 - <i>Please specify:</i>

**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

**Irritability**

1    2    3    Ungradable    No Symptom

NCI Criteria

1. Mild; easily consolable
2. Moderate; limiting instrumental ADL; increased attention indicated
3. Severe abnormal or excessive response; limiting self-care ADL; inconsolable; medical or psychiatric intervention indicated

**Anxiety**

1    2    3    4    Ungradable    No Symptom

NCI Criteria

1. Mild symptoms; intervention not indicated
2. Moderate symptoms; limiting instrumental ADL
3. Severe symptoms; limiting self-care ADL; hospitalization indicated
4. Life-threatening consequences; urgent intervention indicated

**Depression**

1    2    3    4    5    Ungradable    No Symptom

NCI Criteria

1. Mild depressive symptoms
2. Moderate depressive symptoms; limiting instrumental ADL
3. Severe depressive symptoms; limiting self-care ADL; hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

**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



**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
	Irritability
	Anxiety
	Depression
	Headache
	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

**Irritability**

1  2  3  Ungradable  No Symptom

NCI Criteria

1. Mild; easily consolable
2. Moderate; limiting instrumental ADL; increased attention indicated
3. Severe abnormal or excessive response; limiting self-care ADL; inconsolable; medical or psychiatric intervention indicated

**Anxiety**

1  2  3  4  Ungradable  No Symptom

NCI Criteria

1. Mild symptoms; intervention not indicated
2. Moderate symptoms; limiting instrumental ADL
3. Severe symptoms; limiting self-care ADL; hospitalization indicated
4. Life-threatening consequences; urgent intervention indicated

**Depression**

1  2  3  4  5  Ungradable  No Symptom

NCI Criteria

1. Mild depressive symptoms
2. Moderate depressive symptoms; limiting instrumental ADL
3. Severe depressive symptoms; limiting self-care ADL; hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

**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

**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 <b>most</b> troublesome? ( <i>Tick one only</i> )
	Somnolence
	Dizziness
	Irritability
	Anxiety
	Depression
	Headache
	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)

**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

**Irritability**

1    2    3    Ungradable    No Symptom

NCI Criteria

1. Mild; easily consolable
2. Moderate; limiting instrumental ADL; increased attention indicated
3. Severe abnormal or excessive response; limiting self-care ADL; inconsolable; medical or psychiatric intervention indicated

**Anxiety**

1    2    3    4    Ungradable    No Symptom

NCI Criteria

1. Mild symptoms; intervention not indicated
2. Moderate symptoms; limiting instrumental ADL
3. Severe symptoms; limiting self-care ADL; hospitalization indicated
4. Life-threatening consequences; urgent intervention indicated

**Depression**

1    2    3    4    5    Ungradable    No Symptom

NCI Criteria

1. Mild depressive symptoms
2. Moderate depressive symptoms; limiting instrumental ADL
3. Severe depressive symptoms; limiting self-care ADL; hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

**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

**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
	Irritability
	Anxiety
	Depression
	Headache
	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
6. Did the adverse reaction appear after the suspected drug was given?			
7. Did the adverse reaction improve when the drug was discontinued, or a specific antagonist was given?			
8. Are there alternative causes (other than the drug) that could on their own have caused the reaction?			
9. Did the patient have a similar reaction to the same or similar drug in any previous exposure?			
10. Was the adverse event confirmed by any objective evidence?			