

Participant ID	
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Initials of person entering data	
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Staff email	
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CONFIDENTIAL CASE REPORT FORM

Corticosteroids for Mesothelioma Night Sweats

Series 44

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 (T₀)

Date of Assessment

DD/MM/YYYY

Demographics

Gender (please tick) Male Female Other

Age (yrs)		Weight (kg)		Height (cm)	
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Yes	No	Is a diagnosis of Mesothelioma confirmed?

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 ✓	<i>(Please tick all that apply)</i>	Tick ✓	<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)		

Laboratory Tests (only if available)	
Test	Value
Haemoglobin (Hb)	
Platelets (mCL)	
CRP (mg/L)	
eGFR (mL/min)	
INR	
BSL (mmol/L)	
ALT (U/L)	

Yes Tick ✓	No Tick ✓	Is patient currently on any systemic therapy? <i>(Tick yes or no to all)</i>
		Chemotherapy
		Immunotherapy
		Bevacizumab

Baseline T₀ - Medication Commencement

Target Symptom Severity - (Please grade symptom; indicate that the symptom has been assessed by ticking the square box next to the symptom)

Night Sweats

0 1 2 3

NCI Criteria

- 0. Asymptomatic
- 1. Mild
- 2. Moderate night sweats (e.g., need to change pyjamas through the night)
- 3. Severe (e.g., needing to change bed clothes through the night)

Yes	No	Are the night sweats interfering with the patients sleep?
<input type="checkbox"/>	<input type="checkbox"/>	

Which corticosteroid is patient being commenced on for night sweats?

Dexamethasone **OR** **Prednisolone**

CORTICOSTEROID STARTING DOSE

	Dose (mgs)
	Frequency - <i>e.g., Daily (mane), BD, TDS, QID</i>
	Route - <i>oral, subcutaneous</i>

Yes	No	Is patient taking any other medications for the night sweats? <i>If yes, please specify below.</i>
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="radio"/> Paracetamol <input type="radio"/> NSAIDS <input type="radio"/> Other: please specify here: _____		

Yes	No	Will patient continue to take these medications for the night sweats as well as the corticosteroid?
<input type="checkbox"/>	<input type="checkbox"/>	

Tick ✓	Other non-pharmacological measures being used (<i>tick all that apply</i>)
<input type="checkbox"/>	Keeping the temperature low in the house at night
<input type="checkbox"/>	Sleeping with just a sheet
<input type="checkbox"/>	Using a cold compress
<input type="checkbox"/>	Using a fan or air conditioning
<input type="checkbox"/>	Staying hydrated with cold drinks
<input type="checkbox"/>	Using ice packs
<input type="checkbox"/>	Avoiding caffeine, alcohol, and spicy foods
<input type="checkbox"/>	Using relaxation strategies

Yes	No	Is patient currently on or being commenced on gastric protection (<i>e.g., ranitidine or esomeprazole?</i>)
<input type="checkbox"/>	<input type="checkbox"/>	

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

Hyperglycaemia

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Fasting glucose value >ULN - 160 mg/dL; Fasting glucose value >ULN - 8.9 mmol/L
2. Fasting glucose value >160 - 250 mg/dL; Fasting glucose value >8.9 - 13.9 mmol/L
3. >250 - 500 mg/dL; >13.9 - 27.8 mmol/L; hospitalisation indicated
4. >500 mg/dL; >27.8 mmol/L; life-threatening consequences
5. Death

Mania

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild manic symptoms (e.g., elevated mood, rapid thoughts, rapid speech, decreased need for sleep)
2. Moderate manic symptoms (e.g., relationship and work difficulties; poor hygiene)
3. Severe manic symptoms (e.g., hypomania; major sexual or financial indiscretions); hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

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

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

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; hospitalisation indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

Agitation

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild mood alteration
2. Moderate mood alteration
3. Severe agitation; hospitalisation not indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

Dyspepsia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Dyspepsia Mild symptoms; intervention not indicated
2. Moderate symptoms; medical intervention indicated
3. Severe symptoms; surgical intervention indicated

Increased Appetite/Weight gain

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild increase in appetite; 5-<10% increase in weight from baseline
2. Moderate increase in appetite; 10-<20% increase in weight from baseline
3. Extreme increase in appetite; >20% increase in weight from baseline

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 most troublesome? (<i>Tick one only</i>)
	Hyperglycaemia
	Mania
	Depression
	Insomnia
	Delirium
	Agitation
	Dyspepsia
	Increased Appetite/Weight Gain
	Other
	Additional Other
	Not applicable

T₁ 5 – 7 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 (<i>continue to complete T₁</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 grade symptom; indicate that the symptom has been assessed by ticking the square box next to the symptom)

Night Sweats

0 1 2 3

NCI Criteria

0. Asymptomatic

1. Mild

2. Moderate night sweats (e.g., need to change pyjamas through the night)

3. Severe (e.g., needing to change bed clothes through the night)

Yes

No

Are the night sweats interfering with the patients sleep?

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

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

Tick ✓

Has patient been commenced on any new medications since baseline? (If yes please specify name of medication, dose, and frequency.)

Yes

No

Medication Name

Dose

Frequency

T₁ - Symptom/Harm Assessment (Please grade all harms; indicate that each harm has been assessed by ticking the square box next to each)

Hyperglycaemia

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Fasting glucose value >ULN - 160 mg/dL; Fasting glucose value >ULN - 8.9 mmol/L
2. Fasting glucose value >160 - 250 mg/dL; Fasting glucose value >8.9 - 13.9 mmol/L
3. >250 - 500 mg/dL; >13.9 - 27.8 mmol/L; hospitalisation indicated
4. >500 mg/dL; >27.8 mmol/L; life-threatening consequences
5. Death

Mania

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild manic symptoms (e.g., elevated mood, rapid thoughts, rapid speech, decreased need for sleep)
2. Moderate manic symptoms (e.g., relationship and work difficulties; poor hygiene)
3. Severe manic symptoms (e.g., hypomania; major sexual or financial indiscretions); hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

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

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

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; hospitalisation indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

Agitation

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild mood alteration
2. Moderate mood alteration
3. Severe agitation; hospitalisation not indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

Dyspepsia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Dyspepsia Mild symptoms; intervention not indicated
2. Moderate symptoms; medical intervention indicated
3. Severe symptoms; surgical intervention indicated

Increased Appetite/Weight gain

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild increase in appetite; 5-<10% increase in weight from baseline
2. Moderate increase in appetite; 10-<20% increase in weight from baseline
3. Extreme increase in appetite; >20% increase in weight from baseline

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 most troublesome? (<i>Tick one only</i>)
	Hyperglycaemia
	Mania
	Depression
	Insomnia
	Delirium
	Agitation
	Dyspepsia
	Increased Appetite/Weight Gain
	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 corticosteroid /continue current dose
	Corticosteroid ceased (complete medication cessation on page 15)
	Corticosteroid dose reduced - Please specify new dose in mgs: _____ If reduced, please tick all the reasons that apply: <input type="radio"/> Weaning off corticosteroid <input type="radio"/> Routine practice <input type="radio"/> Side effects <input type="radio"/> Other – please specify: _____
	Corticosteroid dose increased - Please specify new dose in mgs: _____
	New medication being commenced for night sweats. Please specify which medication below. <input type="radio"/> Paracetamol <input type="radio"/> NSAIDS <input type="radio"/> Other: Please specify: _____

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

T₂ 14 - 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 (<i>continue to complete T₂</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 14 days after baseline.
(*e.g., weekend*)

Target Symptom Severity - (*Please grade symptom; indicate that each symptom has been assessed by ticking the square box next to each*)

Night Sweats

0 1 2 3

NCI Criteria

0. Asymptomatic

1. Mild

2. Moderate night sweats (*e.g., need to change pyjamas through the night*)

3. Severe (*e.g., needing to change bed clothes through the night*)

Yes No Are the night sweats interfering with the patients sleep?

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

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

Tick ✓		Has patient been commenced on any new medications since T ₁ ? (<i>If yes please specify name of medication, dose, and frequency.</i>)		
Yes	No	Medication Name	Dose	Frequency

T₂ - Symptom/Harm Assessment (Please grade all harms; indicate that each harm has been assessed by ticking the square box next to each)

Hyperglycaemia

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Fasting glucose value >ULN - 160 mg/dL; Fasting glucose value >ULN - 8.9 mmol/L
2. Fasting glucose value >160 - 250 mg/dL; Fasting glucose value >8.9 - 13.9 mmol/L
3. >250 - 500 mg/dL; >13.9 - 27.8 mmol/L; hospitalisation indicated
4. >500 mg/dL; >27.8 mmol/L; life-threatening consequences
5. Death

Mania

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild manic symptoms (e.g., elevated mood, rapid thoughts, rapid speech, decreased need for sleep)
2. Moderate manic symptoms (e.g., relationship and work difficulties; poor hygiene)
3. Severe manic symptoms (e.g., hypomania; major sexual or financial indiscretions); hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

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

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

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; hospitalisation indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

Agitation

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild mood alteration
2. Moderate mood alteration
3. Severe agitation; hospitalisation not indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

Dyspepsia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Dyspepsia Mild symptoms; intervention not indicated
2. Moderate symptoms; medical intervention indicated
3. Severe symptoms; surgical intervention indicated

Increased Appetite/Weight gain

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild increase in appetite; 5-<10% increase in weight from baseline
2. Moderate increase in appetite; 10-<20% increase in weight from baseline
3. Extreme increase in appetite; >20% increase in weight from baseline

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 most troublesome? (<i>Tick one only</i>)
	Hyperglycaemia
	Mania
	Depression
	Insomnia
	Delirium
	Agitation
	Dyspepsia
	Increased Appetite/Weight Gain
	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 corticosteroid /continue current dose
	Corticosteroid ceased (complete medication cessation on page 15)
	Corticosteroid dose reduced - Please specify new dose in mgs: _____ If reduced, please tick all the reasons that apply: <input type="radio"/> Weaning off corticosteroid <input type="radio"/> Routine practice <input type="radio"/> Side effects <input type="radio"/> Other – please specify: _____
	Corticosteroid dose increased - Please specify new dose in mgs: _____
	New medication being commenced for night sweats. Please specify which medication below. <input type="radio"/> Paracetamol <input type="radio"/> NSAIDS <input type="radio"/> Other: Please specify: _____

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 - <i>Please indicate date symptom resolved: DD/MM/YYYY</i>
	Symptom continued unchanged
	Symptom/s worsened - <i>Please record NCI grade below</i>

Night Sweats

0 1 2 3

NCI Criteria

0. Asymptomatic

1. Mild

2. Moderate night sweats (e.g., need to change pyjamas through the night)

3. Severe (e.g., needing to change bed clothes through the night)

Tick ✓	Intervention/medication was ceased (related to other reasons)
	Harm/toxicity
	Patient unable to take medication
	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)

Hyperglycaemia

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Fasting glucose value >ULN - 160 mg/dL; Fasting glucose value >ULN - 8.9 mmol/L
2. Fasting glucose value >160 - 250 mg/dL; Fasting glucose value >8.9 - 13.9 mmol/L
3. >250 - 500 mg/dL; >13.9 - 27.8 mmol/L; hospitalisation indicated
4. >500 mg/dL; >27.8 mmol/L; life-threatening consequences
5. Death

Mania

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild manic symptoms (e.g., elevated mood, rapid thoughts, rapid speech, decreased need for sleep)
2. Moderate manic symptoms (e.g., relationship and work difficulties; poor hygiene)
3. Severe manic symptoms (e.g., hypomania; major sexual or financial indiscretions); hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

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

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

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; hospitalisation indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

Agitation

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild mood alteration
2. Moderate mood alteration
3. Severe agitation; hospitalisation not indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

Dyspepsia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Dyspepsia Mild symptoms; intervention not indicated
2. Moderate symptoms; medical intervention indicated
3. Severe symptoms; surgical intervention indicated

Increased Appetite/Weight gain

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild increase in appetite; 5-<10% increase in weight from baseline
2. Moderate increase in appetite; 10-<20% increase in weight from baseline
3. Extreme increase in appetite; >20% increase in weight from baseline

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 most troublesome? (<i>Tick one only</i>)
	Hyperglycaemia
	Mania
	Depression
	Insomnia
	Delirium
	Agitation
	Dyspepsia
	Increased Appetite/Weight Gain
	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)

Hyperglycaemia

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Fasting glucose value >ULN - 160 mg/dL; Fasting glucose value >ULN - 8.9 mmol/L
2. Fasting glucose value >160 - 250 mg/dL; Fasting glucose value >8.9 - 13.9 mmol/L
3. >250 - 500 mg/dL; >13.9 - 27.8 mmol/L; hospitalisation indicated
4. >500 mg/dL; >27.8 mmol/L; life-threatening consequences
5. Death

Mania

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild manic symptoms (e.g., elevated mood, rapid thoughts, rapid speech, decreased need for sleep)
2. Moderate manic symptoms (e.g., relationship and work difficulties; poor hygiene)
3. Severe manic symptoms (e.g., hypomania; major sexual or financial indiscretions); hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

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

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

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; hospitalisation indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

Agitation

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild mood alteration
2. Moderate mood alteration
3. Severe agitation; hospitalisation not indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

Dyspepsia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Dyspepsia Mild symptoms; intervention not indicated
2. Moderate symptoms; medical intervention indicated
3. Severe symptoms; surgical intervention indicated

Increased Appetite/Weight gain

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild increase in appetite; 5-<10% increase in weight from baseline
2. Moderate increase in appetite; 10-<20% increase in weight from baseline
3. Extreme increase in appetite; >20% increase in weight from baseline

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 most troublesome? (<i>Tick one only</i>)
	Hyperglycaemia
	Mania
	Depression
	Insomnia
	Delirium
	Agitation
	Dyspepsia
	Increased Appetite/Weight Gain
	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)

Hyperglycaemia

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Fasting glucose value >ULN - 160 mg/dL; Fasting glucose value >ULN - 8.9 mmol/L
2. Fasting glucose value >160 - 250 mg/dL; Fasting glucose value >8.9 - 13.9 mmol/L
3. >250 - 500 mg/dL; >13.9 - 27.8 mmol/L; hospitalisation indicated
4. >500 mg/dL; >27.8 mmol/L; life-threatening consequences
5. Death

Mania

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild manic symptoms (e.g., elevated mood, rapid thoughts, rapid speech, decreased need for sleep)
2. Moderate manic symptoms (e.g., relationship and work difficulties; poor hygiene)
3. Severe manic symptoms (e.g., hypomania; major sexual or financial indiscretions); hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

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

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

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; hospitalisation indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

Agitation

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild mood alteration
2. Moderate mood alteration
3. Severe agitation; hospitalisation not indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

Dyspepsia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Dyspepsia Mild symptoms; intervention not indicated
2. Moderate symptoms; medical intervention indicated
3. Severe symptoms; surgical intervention indicated

Increased Appetite/Weight gain

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild increase in appetite; 5-<10% increase in weight from baseline
2. Moderate increase in appetite; 10-<20% increase in weight from baseline
3. Extreme increase in appetite; >20% increase in weight from baseline

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 most troublesome? (<i>Tick one only</i>)
	Hyperglycaemia
	Mania
	Depression
	Insomnia
	Delirium
	Agitation
	Dyspepsia
	Increased Appetite/Weight Gain
	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?			
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