

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

Antidepressant agents in palliative care

(Mirtazapine, Duloxetine, Citalopram and Escitalopram)

Series 49

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

Yes	No	Does this patient have a diagnosis of depression documented in the medical record? (Tick 'yes', 'no')

Demographics

Gender (please tick) Male Female Other

Language spoken at home

Age (yrs)

Weight (kg)

Height (cm)

Tick ✓	Place of Care (tick whichever applies)
	Inpatient
	Outpatient Clinic
	Community/Home
	Residential Aged Care Facility
	Other; Please specify here. _____
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
	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 non-metastatic 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 4 weeks)	
Test	Value
eGFR (mL/min)	

Baseline T ₀ – Medication Commencement	
Tick ✓	Which antidepressant agent is patient being commenced on?
	Citalopram
	Escitalopram
	Duloxetine
	Mirtazapine

Starting Dose of antidepressant medication	
	Dose (mgs)
	Frequency - <i>e.g., Daily mane, daily nocte, BD, TDS</i>

Tick ✓		Is patient commencing the antidepressant today as first line treatment? <i>(If no, please specify what was first line treatment below)</i>
Yes	No	

Tick ✓		Is patient currently taking any other antidepressant or medication below for any indication? <i>(tick 'yes' or 'no' to all)</i>
Yes	No	
		Selective Serotonin Reuptake Inhibitors If yes please specify which SSRI is being taken. <input type="checkbox"/> Fluoxetine <input type="checkbox"/> Sertraline <input type="checkbox"/> Paroxetine <input type="checkbox"/> Mirtazapine <input type="checkbox"/> Citalopram <input type="checkbox"/> Escitalopram <input type="checkbox"/> Other SSRI; _____ Will patient continue to take this medication <input type="radio"/> Yes <input type="radio"/> No
		Serotonin and Norepinephrine Reuptake Inhibitors If yes please specify which SNRI is being taken. <input type="checkbox"/> Desvenlafaxine <input type="checkbox"/> Venlafaxine <input type="checkbox"/> Duloxetine <input type="checkbox"/> Levomilnacipran <input type="checkbox"/> Other SNRI; _____ Will patient continue to take this medication <input type="radio"/> Yes <input type="radio"/> No
		Antipsychotic: If yes please specify which antipsychotic is being taken. <input type="checkbox"/> Haloperidol <input type="checkbox"/> Olanzapine <input type="checkbox"/> Risperidone <input type="checkbox"/> Levomepromazine <input type="checkbox"/> Quetiapine <input type="checkbox"/> Other: please specify. _____ Will patient continue to take this medication <input type="radio"/> Yes <input type="radio"/> No
		Tricyclic antidepressant: If yes please specify which antidepressant is being taken. <input type="checkbox"/> Amitriptyline <input type="checkbox"/> Nortriptyline <input type="checkbox"/> Doxepin <input type="checkbox"/> Other: please specify _____ Will patient continue to take this medication <input type="radio"/> Yes <input type="radio"/> No
		Psychostimulants: If yes please specify which psychostimulant is being taken. <input type="checkbox"/> Methylphenidate <input type="checkbox"/> Modafinil <input type="checkbox"/> Other: please specify. _____ Will patient continue to take this medication <input type="radio"/> Yes <input type="radio"/> No
		Benzodiazepine: If yes please specify which medication is being taken. <input type="checkbox"/> Lorazepam <input type="checkbox"/> Diazepam <input type="checkbox"/> Midazolam <input type="checkbox"/> Clonazepam <input type="checkbox"/> Temazepam <input type="checkbox"/> Alprazolam <input type="checkbox"/> Other: please specify. _____ Will patient continue to take this medication <input type="radio"/> Yes <input type="radio"/> No
		Other anti-depressant drugs: Please specify name of drug. _____ Will patient continue to take this medication <input type="radio"/> Yes <input type="radio"/> No

Tick ✓		Other non – pharmacological interventions <i>(Please tick yes or no to all interventions)</i>
Yes	No	
		Social work
		Pastoral care
		Psychiatrist review
		Psychologist review
		Psychotherapy
		Cognitive/Behavioural Therapy
		Counselling
		Other
		Exercise/Gym
		Meditation/ Mindfulness
		Relaxation
		Music Therapy
		Other: please specify. _____

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

Depression

0 1 2 3 4

NCI Criteria

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

Other symptom of interest:

Anxiety

0 1 2 3 4

NCI Criteria

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

Baseline Symptom Assessment - As these symptoms can be associated with several causes, including depression and the underlying condition, you will be asked to attribute causation for each symptom.

(Please grade all symptoms; indicate that each has been assessed by ticking the square box next to each. Please also select 1 option of causation for each symptom)

Somnolence

1 2 3 4 5 Ungradable No Symptom

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

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Increased appetite

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild increase in appetite
2. Moderate increase in appetite
3. Extreme increase in appetite

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

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 or waking up early

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Suicidal Ideation

1 2 3 4 Ungradable No Symptom

NCI Criteria

1. Increased thoughts of death but no wish to kill oneself
2. Suicidal ideation with no specific plan or intent
3. Specific plan to commit suicide without serious intent to die which may not require hospitalisation
4. Specific plan to commit suicide with serious intent to die which requires hospitalisation

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Falls

1 2 3 Ungradable No Symptom

NCI Criteria

1. Minor with no resultant injuries; intervention not indicated
2. Symptomatic, non-invasive intervention indicated
3. Hospitalisation indicated; invasive intervention indicated

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Dry Mouth

1 2 3 Ungradable No Symptom

NCI Criteria

- 1: Symptomatic (e.g., dry or thick saliva) without significant dietary alteration
- 2: Moderate symptoms; oral intake alterations (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods)
- 3: Inability to adequately ailment orally; tube feeding or TPN indicated

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Motor retardation

1 2 3 Ungradable No Symptom

DRS-R-98 Criteria

- 0. No slowness of voluntary movement
- 1. Mildly reduced frequency, spontaneity or speed of motor movements
- 2. Moderately reduced frequency, spontaneity, or speed of motor movements
- 3. Severe motor retardation with few spontaneous movements

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

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, dehydration, or malnutrition
- 3. Inadequate oral caloric or fluid intake; tube feeding, TPN or hospitalisation indicated

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Anorexia

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

- 1. Loss of appetite without alteration in eating habits
- 2. Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated
- 3. Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated
- 4. Life-threatening consequences; urgent intervention indicated
- 5. Death

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

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

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Constipation

1 2 3 Ungradable No Symptom

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

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Other symptom (e.g. sedation, increased sweating, tremor, vomiting etc.) only if applicable – can be related or unrelated to the medication)

Please specify other symptom here _____

Other harm NCI criteria symptom grade here:

1 2 3 4 5 Ungradable

Is this symptom **primarily** attributable to?

depression underlying illness antidepressant medication other medication
 none of these

Additional other symptom (only if applicable – can be related or unrelated to the medication)

Please specify additional other symptom here _____

Additional other harm NCI criteria symptom grade here:

1 2 3 4 5 Ungradable

Is this symptom **primarily** attributable to? depression underlying illness

antidepressant medication other medication none of these

Tick ✓	Which symptom/harm is the most troublesome? (Tick one only)
	Somnolence
	Increased Appetite
	Insomnia
	Suicidal Ideation
	Falls
	Dry Mouth
	Motor Retardation
	Nausea
	Anorexia
	Headache
	Constipation
	Additional Other
	Not applicable

T₁ - 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 symptoms; indicate that the symptom has been assessed by ticking the square box next to the symptom)

 Depression 0 1 2 3 4*NCI Criteria*

1. Mild depressive symptoms
2. Moderate depressive symptoms; the depression is limiting instrumental ADL
3. Severe depressive symptoms; the depression is limiting self-care ADL
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated

Other symptom of interest: **Anxiety** 0 1 2 3 4*NCI Criteria*

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

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

T₁ - Symptom/Harm Assessment (Please grade all symptoms; indicate that each has been assessed by ticking the square box next to each. Please also select 1 option of causation for each symptom)

Somnolence

1 2 3 4 5 Ungradable No Symptom

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

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Increased appetite

1 2 3 Ungradable No Symptom

NCI Criteria

4. Mild increase in appetite
5. Moderate increase in appetite
6. Extreme increase in appetite

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

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 or waking up early

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Suicidal Ideation

1 2 3 4 Ungradable No Symptom

NCI Criteria

1. Increased thoughts of death but no wish to kill oneself
2. Suicidal ideation with no specific plan or intent
3. Specific plan to commit suicide without serious intent to die which may not require hospitalisation
4. Specific plan to commit suicide with serious intent to die which requires hospitalisation

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Falls

1 2 3 Ungradable No Symptom

NCI Criteria

1. Minor with no resultant injuries; intervention not indicated
2. Symptomatic, non-invasive intervention indicated
3. Hospitalisation indicated; invasive intervention indicated

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Dry Mouth

1 2 3 Ungradable No Symptom

NCI Criteria

- 1: Symptomatic (e.g., dry or thick saliva) without significant dietary alteration
- 2: Moderate symptoms; oral intake alterations (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods)
- 3: Inability to adequately ailment orally; tube feeding or TPN indicated

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Motor retardation

1 2 3 Ungradable No Symptom

DRS-R-98 Criteria

- 0. No slowness of voluntary movement
- 1. Mildly reduced frequency, spontaneity or speed of motor movements
- 2. Moderately reduced frequency, spontaneity, or speed of motor movements
- 3. Severe motor retardation with few spontaneous movements

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

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, dehydration, or malnutrition
- 3. Inadequate oral caloric or fluid intake; tube feeding, TPN or hospitalisation indicated

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Anorexia

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

- 1. Loss of appetite without alteration in eating habits
- 2. Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated
- 3. Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated
- 4. Life-threatening consequences; urgent intervention indicated
- 5. Death

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

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

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Constipation

1 2 3 Ungradable No Symptom

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

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Other symptom (e.g. sedation, increased sweating, tremor, vomiting etc.) only if applicable – can be related or unrelated to the medication)

Please specify other symptom here _____

Other harm NCI criteria symptom grade here:

1 2 3 4 5 Ungradable

Is this symptom **primarily** attributable to?

depression underlying illness antidepressant medication other medication
 none of these

Additional other symptom (only if applicable – can be related or unrelated to the medication)

Please specify additional other symptom here _____

Additional other harm NCI criteria symptom grade here:

1 2 3 4 5 Ungradable

Is this symptom **primarily** attributable to? depression underlying illness

antidepressant medication other medication none of these

Tick ✓	Which symptom/harm is the most troublesome? (Tick one only)
	Somnolence
	Increased Appetite
	Insomnia
	Suicidal Ideation
	Falls
	Dry Mouth
	Motor Retardation
	Nausea
	Anorexia
	Headache
	Constipation
	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 antidepressant medication, continue current dose
	Antidepressant medication ceased (complete medication cessation on page 27)
	Antidepressant medication dose reduced - Please specify new dose in mgs: _____
	Antidepressant medication 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

Benefit Assessment

Yes Tick ✓	No Tick ✓	Has there been an improvement in depression since the antidepressant was commenced?
		If yes, please answer the two questions below.
		Yes No Don't know
		1. Did the improvement in depressive symptom score appear after the drug was given?
		2. Are there alternative causes (other than the drug) that could on their own have caused the beneficial effect on depressive symptoms?

Yes Tick ✓	No Tick ✓	Were there any other benefits noted at today's assessment?
		<i>If yes, please describe benefits in a few words. E.g., patient reported that they had gone out and visited grandchildren or improvement in pain</i>

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 7 days after baseline. (e.g., weekend)

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

Depression

0 1 2 3 4

NCI Criteria

1. Mild depressive symptoms
2. Moderate depressive symptoms; the depression is limiting instrumental ADL
3. Severe depressive symptoms; the depression is limiting self-care ADL
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated

Other symptom of interest:

Anxiety

0 1 2 3 4

NCI Criteria

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

Current antidepressant dose

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

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

T₂ - Symptom/Harm Assessment (Please grade all symptoms; indicate that each has been assessed by ticking the square box next to each. Please also select 1 option of causation for each symptom)

Somnolence

1 2 3 4 5 Ungradable No Symptom

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

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Increased appetite

1 2 3 Ungradable No Symptom

NCI Criteria

7. Mild increase in appetite
8. Moderate increase in appetite
9. Extreme increase in appetite

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

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 or waking up early

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Suicidal Ideation

1 2 3 4 Ungradable No Symptom

NCI Criteria

1. Increased thoughts of death but no wish to kill oneself
2. Suicidal ideation with no specific plan or intent
3. Specific plan to commit suicide without serious intent to die which may not require hospitalisation
4. Specific plan to commit suicide with serious intent to die which requires hospitalisation

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Falls

1 2 3 Ungradable No Symptom

NCI Criteria

1. Minor with no resultant injuries; intervention not indicated
2. Symptomatic, non-invasive intervention indicated
3. Hospitalisation indicated; invasive intervention indicated

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Dry Mouth

1 2 3 Ungradable No Symptom

NCI Criteria

- 1: Symptomatic (e.g., dry or thick saliva) without significant dietary alteration
- 2: Moderate symptoms; oral intake alterations (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods)
- 3: Inability to adequately ailment orally; tube feeding or TPN indicated

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Motor retardation

1 2 3 Ungradable No Symptom

DRS-R-98 Criteria

- 0. No slowness of voluntary movement
- 1. Mildly reduced frequency, spontaneity or speed of motor movements
- 2. Moderately reduced frequency, spontaneity, or speed of motor movements
- 3. Severe motor retardation with few spontaneous movements

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

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, dehydration, or malnutrition
- 3. Inadequate oral caloric or fluid intake; tube feeding, TPN or hospitalisation indicated

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Anorexia

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

- 1. Loss of appetite without alteration in eating habits
- 2. Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated
- 3. Associated with significant weight loss or malnutrition (e.g, inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated
- 4. Life-threatening consequences; urgent intervention indicated
- 5. Death

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

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

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Constipation

1 2 3 Ungradable No Symptom

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

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Other symptom (e.g. sedation, increased sweating, tremor, vomiting etc.) only if applicable – can be related or unrelated to the medication)

Please specify other symptom here _____

Other harm NCI criteria symptom grade here:

1 2 3 4 5 Ungradable

Is this symptom **primarily** attributable to?

depression underlying illness antidepressant medication other medication
 none of these

Additional other symptom (only if applicable – can be related or unrelated to the medication)

Please specify additional other symptom here _____

Additional other harm NCI criteria symptom grade here:

1 2 3 4 5 Ungradable

Is this symptom **primarily** attributable to? depression underlying illness

antidepressant medication other medication none of these

Tick ✓	Which symptom/harm is the most troublesome? (Tick one only)
	Somnolence
	Increased Appetite
	Insomnia
	Suicidal Ideation
	Falls
	Dry Mouth
	Motor Retardation
	Nausea
	Anorexia
	Headache
	Constipation
	Additional Other
	Not applicable

Yes Tick ✓	No Tick ✓	Were there any other benefits noted at today's assessment?
		<i>If yes, please describe benefits in a few words. E.g., patient reported that they had gone out and visited grandchildren or improvement in pain</i>

T₃ - 28 days post Baseline

Date of Assessment

DD/MM/YYYY

Time of Assessment (24hr clock)

HH:MM

Tick ✓	T ₃ : Assessed/Not assessed reason
	Assessed today (<i>continue to complete T₃</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 symptoms; indicate that the symptom has been assessed by ticking the square box next to the symptom)

Depression

0 1 2 3 4

NCI Criteria

1. Mild depressive symptoms
2. Moderate depressive symptoms; the depression is limiting instrumental ADL
3. Severe depressive symptoms; the depression is limiting self-care ADL
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated

Other symptom of interest:

Anxiety

0 1 2 3 4

NCI Criteria

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

Current antidepressant dose

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

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

T₃ - Symptom/Harm Assessment (Please grade all symptoms; indicate that each has been assessed by ticking the square box next to each. Please also select 1 option of causation for each symptom)

Somnolence

1 2 3 4 5 Ungradable No Symptom

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

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Increased appetite

1 2 3 Ungradable No Symptom

NCI Criteria

10. Mild increase in appetite
11. Moderate increase in appetite
12. Extreme increase in appetite

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

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 or waking up early

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Suicidal Ideation

1 2 3 4 Ungradable No Symptom

NCI Criteria

1. Increased thoughts of death but no wish to kill oneself
2. Suicidal ideation with no specific plan or intent
3. Specific plan to commit suicide without serious intent to die which may not require hospitalisation
4. Specific plan to commit suicide with serious intent to die which requires hospitalisation

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Falls

1 2 3 Ungradable No Symptom

NCI Criteria

1. Minor with no resultant injuries; intervention not indicated
2. Symptomatic, non-invasive intervention indicated
3. Hospitalisation indicated; invasive intervention indicated

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Dry Mouth

1 2 3 Ungradable No Symptom

NCI Criteria

- 1: Symptomatic (e.g., dry or thick saliva) without significant dietary alteration
- 2: Moderate symptoms; oral intake alterations (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods)
- 3: Inability to adequately ailment orally; tube feeding or TPN indicated

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Motor retardation

1 2 3 Ungradable No Symptom

DRS-R-98 Criteria

- 0. No slowness of voluntary movement
- 1. Mildly reduced frequency, spontaneity or speed of motor movements
- 2. Moderately reduced frequency, spontaneity, or speed of motor movements
- 3. Severe motor retardation with few spontaneous movements

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

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, dehydration, or malnutrition
- 3. Inadequate oral caloric or fluid intake; tube feeding, TPN or hospitalisation indicated

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Anorexia

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

- 1. Loss of appetite without alteration in eating habits
- 2. Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated
- 3. Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated
- 4. Life-threatening consequences; urgent intervention indicated
- 5. Death

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

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

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Constipation

1 2 3 Ungradable No Symptom

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

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Other symptom (*e.g. sedation, increased sweating, tremor, vomiting etc.*) *only if applicable – can be related or unrelated to the medication*

Please specify other symptom here _____

Other harm NCI criteria symptom grade here:

1 2 3 4 5 Ungradable

Is this symptom **primarily** attributable to?

depression underlying illness antidepressant medication other medication
 none of these

Additional other symptom (*only if applicable – can be related or unrelated to the medication*)

Please specify additional other symptom here _____

Additional other harm NCI criteria symptom grade here:

1 2 3 4 5 Ungradable

Is this symptom **primarily** attributable to? depression underlying illness

antidepressant medication other medication none of these

Tick ✓	Which symptom/harm is the most troublesome? (<i>Tick one only</i>)
	Somnolence
	Increased Appetite
	Insomnia
	Suicidal Ideation
	Falls
	Dry Mouth
	Motor Retardation
	Nausea
	Anorexia
	Headache
	Constipation
	Additional Other
	Not applicable

Yes Tick ✓	No Tick ✓	Were there any other benefits noted at today's assessment?
		<i>If yes, please describe benefits in a few words. E.g., patient reported that they had gone out and visited grandchildren or improvement in pain</i>

Medication Cessation (complete this page if the antidepressant was ceased at any point during the study period)

Date of Assessment (medication cessation) DD/MM/YYYY

Tick ✓	Antidepressant 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

Depression

0 1 2 3 4

NCI Criteria

1. Mild depressive symptoms
2. Moderate depressive symptoms; the depression is limiting instrumental ADL
3. Severe depressive symptoms; the depression is limiting self-care ADL
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated

Anxiety

0 1 2 3 4

NCI Criteria

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

Tick ✓	Antidepressant medication was ceased (related to other reasons)
	Harm/toxicity
	Patient unable to take medication
	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 symptoms; indicate that each has been assessed by ticking the square box next to each. Please also select 1 option of causation for each symptom)

Somnolence

1 2 3 4 5 Ungradable No Symptom

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

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Increased appetite

1 2 3 Ungradable No Symptom

NCI Criteria

13. Mild increase in appetite
14. Moderate increase in appetite
15. Extreme increase in appetite

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

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 or waking up early

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Suicidal Ideation

1 2 3 4 Ungradable No Symptom

NCI Criteria

1. Increased thoughts of death but no wish to kill oneself
2. Suicidal ideation with no specific plan or intent
3. Specific plan to commit suicide without serious intent to die which may not require hospitalisation
4. Specific plan to commit suicide with serious intent to die which requires hospitalisation

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Falls

1 2 3 Ungradable No Symptom

NCI Criteria

1. Minor with no resultant injuries; intervention not indicated
2. Symptomatic, non-invasive intervention indicated
3. Hospitalisation indicated; invasive intervention indicated

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Dry Mouth

1 2 3 Ungradable No Symptom

NCI Criteria

- 1: Symptomatic (e.g., dry or thick saliva) without significant dietary alteration
- 2: Moderate symptoms; oral intake alterations (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods)
- 3: Inability to adequately ailment orally; tube feeding or TPN indicated

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Motor retardation

1 2 3 Ungradable No Symptom

DRS-R-98 Criteria

- 0. No slowness of voluntary movement
- 1. Mildly reduced frequency, spontaneity or speed of motor movements
- 2. Moderately reduced frequency, spontaneity, or speed of motor movements
- 3. Severe motor retardation with few spontaneous movements

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

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, dehydration, or malnutrition
- 3. Inadequate oral caloric or fluid intake; tube feeding, TPN or hospitalisation indicated

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Anorexia

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

- 1. Loss of appetite without alteration in eating habits
- 2. Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated
- 3. Associated with significant weight loss or malnutrition (e.g, inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated
- 4. Life-threatening consequences; urgent intervention indicated
- 5. Death

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

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

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Constipation

1 2 3 Ungradable No Symptom

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

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Other symptom (*e.g. sedation, increased sweating, tremor, vomiting etc.*) only if applicable – can be related or unrelated to the medication)

Please specify other symptom here _____

Other harm NCI criteria symptom grade here:

1 2 3 4 5 Ungradable

Is this symptom **primarily** attributable to?

depression underlying illness antidepressant medication other medication
 none of these

Additional other symptom (*only if applicable – can be related or unrelated to the medication*)

Please specify additional other symptom here _____

Additional other harm NCI criteria symptom grade here:

1 2 3 4 5 Ungradable

Is this symptom **primarily** attributable to? depression underlying illness

antidepressant medication other medication none of these

Tick ✓	Which symptom/harm is the most troublesome? (<i>Tick one only</i>)
	Somnolence
	Increased Appetite
	Insomnia
	Suicidal Ideation
	Falls
	Dry Mouth
	Motor Retardation
	Nausea
	Anorexia
	Headache
	Constipation
	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 symptoms; indicate that each has been assessed by ticking the square box next to each. Please also select 1 option of causation for each symptom)

Somnolence

1 2 3 4 5 Ungradable No Symptom

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

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Increased appetite

1 2 3 Ungradable No Symptom

NCI Criteria

16. Mild increase in appetite
17. Moderate increase in appetite
18. Extreme increase in appetite

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

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 or waking up early

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Suicidal Ideation

1 2 3 4 Ungradable No Symptom

NCI Criteria

1. Increased thoughts of death but no wish to kill oneself
2. Suicidal ideation with no specific plan or intent
3. Specific plan to commit suicide without serious intent to die which may not require hospitalisation
4. Specific plan to commit suicide with serious intent to die which requires hospitalisation

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Falls

1 2 3 Ungradable No Symptom

NCI Criteria

1. Minor with no resultant injuries; intervention not indicated
2. Symptomatic, non-invasive intervention indicated
3. Hospitalisation indicated; invasive intervention indicated

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Dry Mouth

1 2 3 Ungradable No Symptom

NCI Criteria

- 1: Symptomatic (e.g., dry or thick saliva) without significant dietary alteration
- 2: Moderate symptoms; oral intake alterations (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods)
- 3: Inability to adequately ailment orally; tube feeding or TPN indicated

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Motor retardation

1 2 3 Ungradable No Symptom

DRS-R-98 Criteria

- 0. No slowness of voluntary movement
- 1. Mildly reduced frequency, spontaneity or speed of motor movements
- 2. Moderately reduced frequency, spontaneity, or speed of motor movements
- 3. Severe motor retardation with few spontaneous movements

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

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, dehydration, or malnutrition
- 3. Inadequate oral caloric or fluid intake; tube feeding, TPN or hospitalisation indicated

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Anorexia

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

- 1. Loss of appetite without alteration in eating habits
- 2. Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated
- 3. Associated with significant weight loss or malnutrition (e.g, inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated
- 4. Life-threatening consequences; urgent intervention indicated
- 5. Death

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

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

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Constipation

1 2 3 Ungradable No Symptom

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

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Other symptom (e.g. sedation, increased sweating, tremor, vomiting etc.) only if applicable – can be related or unrelated to the medication)

Please specify other symptom here _____

Other harm NCI criteria symptom grade here:

1 2 3 4 5 Ungradable

Is this symptom **primarily** attributable to?

depression underlying illness antidepressant medication other medication
 none of these

Additional other symptom (only if applicable – can be related or unrelated to the medication)

Please specify additional other symptom here _____

Additional other harm NCI criteria symptom grade here:

1 2 3 4 5 Ungradable

Is this symptom **primarily** attributable to? depression underlying illness

antidepressant medication other medication none of these

Tick ✓	Which symptom/harm is the most troublesome? (Tick one only)
	Somnolence
	Increased Appetite
	Insomnia
	Suicidal Ideation
	Falls
	Dry Mouth
	Motor Retardation
	Nausea
	Anorexia
	Headache
	Constipation
	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 symptoms; indicate that each has been assessed by ticking the square box next to each. Please also select 1 option of causation for each symptom)

Somnolence

1 2 3 4 5 Ungradable No Symptom

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

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Increased appetite

1 2 3 Ungradable No Symptom

NCI Criteria

19. Mild increase in appetite
20. Moderate increase in appetite
21. Extreme increase in appetite

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

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 or waking up early

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Suicidal Ideation

1 2 3 4 Ungradable No Symptom

NCI Criteria

1. Increased thoughts of death but no wish to kill oneself
2. Suicidal ideation with no specific plan or intent
3. Specific plan to commit suicide without serious intent to die which may not require hospitalisation
4. Specific plan to commit suicide with serious intent to die which requires hospitalisation

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Falls

1 2 3 Ungradable No Symptom

NCI Criteria

1. Minor with no resultant injuries; intervention not indicated
2. Symptomatic, non-invasive intervention indicated
3. Hospitalisation indicated; invasive intervention indicated

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Dry Mouth

1 2 3 Ungradable No Symptom

NCI Criteria

- 1: Symptomatic (e.g., dry or thick saliva) without significant dietary alteration
- 2: Moderate symptoms; oral intake alterations (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods)
- 3: Inability to adequately ailment orally; tube feeding or TPN indicated

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Motor retardation

1 2 3 Ungradable No Symptom

DRS-R-98 Criteria

- 0. No slowness of voluntary movement
- 1. Mildly reduced frequency, spontaneity or speed of motor movements
- 2. Moderately reduced frequency, spontaneity, or speed of motor movements
- 3. Severe motor retardation with few spontaneous movements

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

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, dehydration, or malnutrition
- 3. Inadequate oral caloric or fluid intake; tube feeding, TPN or hospitalisation indicated

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Anorexia

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

- 1. Loss of appetite without alteration in eating habits
- 2. Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated
- 3. Associated with significant weight loss or malnutrition (e.g, inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated
- 4. Life-threatening consequences; urgent intervention indicated
- 5. Death

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

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

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Constipation

1 2 3 Ungradable No Symptom

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

Is this symptom **primarily** attributable to? depression underlying illness
 antidepressant medication other medication none of these

Other symptom (e.g. sedation, increased sweating, tremor, vomiting etc.) only if applicable – can be related or unrelated to the medication)

Please specify other symptom here _____

Other harm NCI criteria symptom grade here:

1 2 3 4 5 Ungradable

Is this symptom **primarily** attributable to?

depression underlying illness antidepressant medication other medication
 none of these

Additional other symptom (only if applicable – can be related or unrelated to the medication)

Please specify additional other symptom here _____

Additional other harm NCI criteria symptom grade here:

1 2 3 4 5 Ungradable

Is this symptom **primarily** attributable to? depression underlying illness

antidepressant medication other medication none of these

Tick ✓	Which symptom/harm is the most troublesome? (Tick one only)
	Somnolence
	Increased Appetite
	Insomnia
	Suicidal Ideation
	Falls
	Dry Mouth
	Motor Retardation
	Nausea
	Anorexia
	Headache
	Constipation
	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?			