

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

Benzodiazepines for Breathlessness

Series 10

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 (please tick)

Gender Male Female Other

Age (yrs)		Weight (kg)		Height (cm)	
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Tick ✓	Primary life limiting illness (please choose only one)
	Advanced metastatic cancer
	End stage renal failure
	Hepatic failure
	Neurodegenerative disease
	Cardiac failure
	Respiratory failure
	AIDS
	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? <i>(Please tick ✓ all that apply)</i>			
Tick ✓		Tick ✓	
	Myocardial Infarction (history, not ECG changes only)		Hemiplegia
	Congestive Cardiac Failure		Moderate or Severe Renal Disease
	Peripheral Vascular Disease (includes aortic aneurysm \geq 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
Blood sugar level (mmol/L or mg/dL)	
INR (International Normalised Ratio)	
Calculated Creatinine Clearance (CCr) (mL/min)	
Albumin (g/dL)	

Baseline T₀ - Medication Commencement

Tick ✓	Describe this episode of breathlessness in this patient. <i>(Tick one)</i>
	A de novo (new) episode of acute breathlessness
	A progression of chronic breathlessness
	An acute exacerbation on a background of chronic breathlessness
	Other

Symptom Severity Scores

Breathlessness (*0 = nil criteria observed*)

0 1 2 3 4 5

NCI Criteria:

- 1: Shortness of breath with moderate exertion
- 2: Shortness of breath with minimal exertion; limiting instrumental ADL
- 3: Shortness of breath at rest limiting self-care ADL
- 4: Life-threatening consequences; urgent intervention indicated
- 5: Death

Anxiety (*0 = nil criteria observed*)

0 1 2 3 4 5

NCI Criteria:

- 1: Mild symptoms; intervention not indicated
- 2: Moderate symptoms; limiting instrumental ADL
- 3: Severe symptoms; limiting self-care ADL; hospitalisation not indicated
- 4: Life-threatening; hospitalisation indicated
- 5: Death

Is the patient currently on Benzodiazepines for breathlessness? *(Tick all that apply then indicate dose and route of administration)*

Tick ✓	Name	Total dose in 24hrs (mgs)	Route of Administration		
			Oral	Injectable	Rectal
	Diazepam				
	Clonazepam				
	Nitrazepam				
	Flurazepam				
	Lorazepam				
	Midazolam				
	Alprazolam				
	Other 1-please specify:				
	Other 2-please specify:				
	Other 3-please specify:				

Tick ✓	What other treatments (if any) is this person on for breathlessness? <i>(Tick all that apply)</i>
	Opioid
	Oxygen therapy
	None
	Other; please specify:

Tick ✓	Is the patient on benzodiazepines for another reason other than breathlessness? <i>(If yes, please specify reason in the table below)</i> <input type="radio"/> Yes <input type="radio"/> No
	Anxiety
	Sleep
	Nausea
	Pain
	Other; please specify:

Please record Benzodiazepines the patient is currently taking that are NOT for breathlessness? <i>(Tick all that apply then indicate dose and route of administration)</i>					
Tick ✓	Name	Total dose in 24hrs (mgs)	Route of Administration		
			Oral	Injectable	Rectal
	Diazepam				
	Clonazepam				
	Nitrazepam				
	Flurazepam				
	Lorazepam				
	Midazolam				
	Alprazolam				
	Other 1-please specify:				
	Other 2-please specify:				
	Other 3-please specify:				

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

Dizziness

1 2 3 Ungradable No Symptom

NCI Criteria

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

Amnesia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild; transient memory loss
2. Moderate; short term memory loss; limiting instrumental ADL
3. Severe; long term memory loss; limiting self-care ADL

Blurred vision

1 2 3 Ungradable No Symptom

NCI Criteria

1. Intervention not indicated
2. Symptomatic; moderate decrease in visual acuity (best corrected visual acuity 20/40 and better or 3 lines or less decreased vision from known baseline); limiting instrumental ADL
3. Symptomatic with marked decrease in visual acuity (best corrected visual acuity worse than 20/40 or more than 3 lines of decreased vision from known baseline, up to 20/200); limiting self-care ADL

Slurred speech

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild slurred speech
2. Moderate impairment of articulation or slurred speech
3. Severe impairment of articulation or slurred speech

Ataxia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Asymptomatic; clinical or diagnostic observations only; intervention not indicated
2. Moderate symptoms; limiting instrumental ADL
3. Severe symptoms; limiting self-care ADL; mechanical assistance indicated

Fall

1 2 3 Ungradable No Symptom

NCI Criteria

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

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

Confusion

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

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

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

Other harm 1 (only if applicable e.g., dyspepsia, personality change, psychosis, muscle weakness, acne etc.). *Please specify other harm:* _____

1 2 3 4 5 Ungradable

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

Additional other harm 2 (only if applicable-can be related or unrelated to intervention)

Please specify additional other harm: _____

1 2 3 4 5 Ungradable

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

Additional other harm 3 (only if applicable-can be related or unrelated to intervention)

Please specify additional other harm: _____

1 2 3 4 5 Ungradable

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

Tick ✓	Which symptom/harm is the most troublesome? <i>(Tick one only)</i>
	Dizziness
	Amnesia
	Blurred vision
	Slurred speech
	Ataxia
	Fall
	Somnolence
	Confusion
	Agitation
	Other harm 1
	Additional other harm 2
	Additional other harm 3
	Not applicable

**T₁ – 24 hours post Baseline
Clinical benefit and Toxicity Assessment**

Date of Assessment

dd/mm/yyyy

Tick ✓	T ₁ : Assessed/Not assessed reason
	Assessed today (continue to complete T ₁) OR
	Died – record date of death below
	Not able to be contacted / located
	Too unwell
	Other

Date of Death*

dd/mm/yyyy

***End survey here**

Was there any benefit? Yes No

Tick ✓	Medication changes (<i>Tick all that apply</i>)
	No change to medication of interest/continue current dose
	Medication of interest ceased (complete medication cessation on page 17)
	Medication of interest dose reduced; please specify new dose:
	Medication of interest increased; please specify new dose:

Symptom Severity Score

Breathlessness (*0 = nil criteria observed*)

0 1 2 3 4 5

NCI Criteria:

- 1: Shortness of breath with moderate exertion
- 2: Shortness of breath with minimal exertion; limiting instrumental ADL
- 3: Shortness of breath at rest limiting self-care ADL
- 4: Life-threatening consequences; urgent intervention indicated
- 5: Death

Anxiety (*0 = nil criteria observed*)

0 1 2 3 4 5

NCI Criteria:

- 1: Mild symptoms; intervention not indicated
- 2: Moderate symptoms; limiting instrumental ADL
- 3: Severe symptoms; limiting self-care ADL; hospitalisation not indicated
- 4: Life-threatening; hospitalisation indicated
- 5: Death

T1 – Symptomatic Adverse Event Assessment

(Please grade all harms/toxicities regardless of whether they are attributable to the medication of interest or not; indicate that each harm has been assessed by ticking the square box next to each)

 Dizziness

1 2 3 Ungradable No Symptom

NCI Criteria

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

 Amnesia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild; transient memory loss
2. Moderate; short term memory loss; limiting instrumental ADL
3. Severe; long term memory loss; limiting self-care ADL

 Blurred vision

1 2 3 Ungradable No Symptom

NCI Criteria

1. Intervention not indicated
2. Symptomatic; moderate decrease in visual acuity (best corrected visual acuity 20/40 and better or 3 lines or less decreased vision from known baseline); limiting instrumental ADL
3. Symptomatic with marked decrease in visual acuity (best corrected visual acuity worse than 20/40 or more than 3 lines of decreased vision from known baseline, up to 20/200); limiting self-care ADL

 Slurred speech

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild slurred speech
2. Moderate impairment of articulation or slurred speech
3. Severe impairment of articulation or slurred speech

 Ataxia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Asymptomatic; clinical or diagnostic observations only; intervention not indicated
2. Moderate symptoms; limiting instrumental ADL
3. Severe symptoms; limiting self-care ADL; mechanical assistance indicated

 Fall

1 2 3 Ungradable No Symptom

NCI Criteria

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

 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

Confusion

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

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

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

Other harm 1 (only if applicable e.g., dyspepsia, personality change, psychosis, muscle weakness, acne etc.). *Please specify other harm:* _____

1 2 3 4 5 Ungradable

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

Additional other harm 2 (only if applicable-can be related or unrelated to intervention)

Please specify additional other harm: _____

1 2 3 4 5 Ungradable

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

Additional other harm 3 (only if applicable-can be related or unrelated to intervention)

Please specify additional other harm: _____

1 2 3 4 5 Ungradable

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

Tick ✓	Which symptom/harm is the most troublesome? <i>(Tick one only)</i>
	Dizziness
	Amnesia
	Blurred vision
	Slurred speech
	Ataxia
	Fall
	Somnolence
	Confusion
	Agitation
	Other harm 1
	Additional other harm 2
	Additional other harm 3
	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?			

Tick ✓	What is the intended treatment based on today's assessment? <i>(Tick all that apply)</i>
	No change to medication of interest/continue current dose
	Medication of interest ceased
	Medication of interest dose reduced; please specify new dose:
	Medication of interest increased; please specify new dose:
Yes	Has an intervention/medication been added to treat a specific harm/toxicity? If yes, please specify:
No	

Based on the assessment today has the harm/toxicity resolved?

Yes No N/A

T₂ – 72 hours post Baseline

Date of Assessment

dd/mm/yyyy

Tick ✓	T ₂ : Assessed/Not assessed reason
	Assessed today (continue to complete T ₂) OR
	Died – record date of death below
	Not able to be contacted / located
	Too unwell
	Other

Date of Death*

dd/mm/yyyy

***End survey here**

Was there any benefit?

Yes

No

Tick ✓	Medication changes since T ₁ (Tick all that apply)
	No change to medication of interest/continue current dose
	Medication of interest ceased
	Medication of interest dose reduced; please specify new dose:
	Medication of interest increased; please specify new dose:

Target Symptom Severity

Breathlessness (0 = nil criteria observed)

0 1 2 3 4 5

NCI Criteria:

- 1: Shortness of breath with moderate exertion
- 2: Shortness of breath with minimal exertion; limiting instrumental ADL
- 3: Shortness of breath at rest limiting self-care ADL
- 4: Life-threatening consequences; urgent intervention indicated
- 5: Death

Anxiety (0 = nil criteria observed)

0 1 2 3 4 5

NCI Criteria:

- 1: Mild symptoms; intervention not indicated
- 2: Moderate symptoms; limiting instrumental ADL
- 3: Severe symptoms; limiting self-care ADL; hospitalisation not indicated
- 4: Life-threatening; hospitalisation indicated
- 5: Death

T₂ - Symptomatic Adverse Event Assessment (Please grade all harms/toxicities regardless of whether they are attributable to the medication of interest or not; indicate that each harm has been assessed by ticking the square box next to each)

Dizziness

1 2 3 Ungradable No Symptom

NCI Criteria

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

Amnesia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild; transient memory loss
2. Moderate; short term memory loss; limiting instrumental ADL
3. Severe; long term memory loss; limiting self-care ADL

Blurred vision

1 2 3 Ungradable No Symptom

NCI Criteria

1. Intervention not indicated
2. Symptomatic; moderate decrease in visual acuity (best corrected visual acuity 20/40 and better or 3 lines or less decreased vision from known baseline); limiting instrumental ADL
3. Symptomatic with marked decrease in visual acuity (best corrected visual acuity worse than 20/40 or more than 3 lines of decreased vision from known baseline, up to 20/200); limiting self-care ADL

Slurred speech

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild slurred speech
2. Moderate impairment of articulation or slurred speech
3. Severe impairment of articulation or slurred speech

Ataxia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Asymptomatic; clinical or diagnostic observations only; intervention not indicated
2. Moderate symptoms; limiting instrumental ADL
3. Severe symptoms; limiting self-care ADL; mechanical assistance indicated

Fall

1 2 3 Ungradable No Symptom

NCI Criteria

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

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

Confusion

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

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

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

Other harm 1 (only if applicable e.g., dyspepsia, personality change, psychosis, muscle weakness, acne etc.). *Please specify other harm:* _____

1 2 3 4 5 Ungradable

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

Additional other harm 2 (only if applicable-can be related or unrelated to intervention)

Please specify additional other harm: _____

1 2 3 4 5 Ungradable

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

Additional other harm 3 (only if applicable-can be related or unrelated to intervention)

Please specify additional other harm: _____

1 2 3 4 5 Ungradable

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

Tick ✓	Which symptom/harm is the most troublesome? <i>(Tick one only)</i>
	Dizziness
	Amnesia
	Blurred vision
	Slurred speech
	Ataxia
	Fall
	Somnolence
	Confusion
	Agitation
	Other harm 1
	Additional other harm 2
	Additional other harm 3
	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?			

Tick ✓	What is the intended treatment based on today's assessment? <i>(Tick all that apply)</i>
	No change to medication of interest/continue current dose
	Medication of interest ceased
	Medication of interest dose reduced; please specify new dose:
	Medication of interest increased; please specify new dose:
Yes	Has an intervention/medication been added to treat a specific harm/toxicity? If yes, please specify:
No	

Based on the assessment today has the harm/toxicity resolved?

- Yes
 No
 N/A

Medication Cessation (complete this page if the intervention/medication of interest is ceased at any point during the study period)

Date of Assessment (medication cessation) dd/mm/yyyy

Tick ✓	Medication was ceased (related to indication of interest)
	Symptom resolved; please indicate date symptom resolved:
	Symptom continued unchanged
	Symptom/s worsened; please grade below:

Breathlessness (0 = nil criteria observed)

0 1 2 3 4 5

NCI Criteria:

- 1: Shortness of breath with moderate exertion
- 2: Shortness of breath with minimal exertion; limiting instrumental ADL
- 3: Shortness of breath at rest limiting self-care ADL
- 4: Life-threatening consequences; urgent intervention indicated
- 5: Death

Anxiety (0 = nil criteria observed)

0 1 2 3 4 5

NCI Criteria:

- 1: Mild symptoms; intervention not indicated
- 2: Moderate symptoms; limiting instrumental ADL
- 3: Severe symptoms; limiting self-care ADL; hospitalisation not indicated
- 4: Life-threatening; hospitalisation indicated
- 5: Death

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

Was there any benefit?

Yes No

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

Dizziness

1 2 3 Ungradable No Symptom

NCI Criteria

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

Amnesia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild; transient memory loss
2. Moderate; short term memory loss; limiting instrumental ADL
3. Severe; long term memory loss; limiting self-care ADL

Blurred vision

1 2 3 Ungradable No Symptom

NCI Criteria

1. Intervention not indicated
2. Symptomatic; moderate decrease in visual acuity (best corrected visual acuity 20/40 and better or 3 lines or less decreased vision from known baseline); limiting instrumental ADL
3. Symptomatic with marked decrease in visual acuity (best corrected visual acuity worse than 20/40 or more than 3 lines of decreased vision from known baseline, up to 20/200); limiting self-care ADL

Slurred speech

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild slurred speech
2. Moderate impairment of articulation or slurred speech
3. Severe impairment of articulation or slurred speech

Ataxia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Asymptomatic; clinical or diagnostic observations only; intervention not indicated
2. Moderate symptoms; limiting instrumental ADL
3. Severe symptoms; limiting self-care ADL; mechanical assistance indicated

Fall

1 2 3 Ungradable No Symptom

NCI Criteria

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

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

Confusion

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

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

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

Other harm 1 (only if applicable - e.g., dyspepsia, personality change, psychosis, muscle weakness, acne etc.). *Please specify other harm:* _____

1 2 3 4 5 Ungradable

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

Additional other harm 2 (only if applicable-can be related or unrelated to intervention)

Please specify additional other harm: _____

1 2 3 4 5 Ungradable

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

Additional other harm 3 (only if applicable-can be related or unrelated to intervention)

Please specify additional other harm: _____

1 2 3 4 5 Ungradable

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

Tick ✓	Which symptom/harm is the most troublesome? (Tick one only)
	Dizziness
	Amnesia
	Blurred vision
	Slurred speech
	Ataxia
	Fall
	Somnolence
	Confusion
	Agitation
	Other harm 1
	Additional other harm 2
	Additional other harm 3
	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 all that apply)

Tick ✓		
		No change to medication of interest/continue current dose
		Medication of interest ceased
		Medication of interest dose reduced; please specify new dose:
		Medication of interest increased; please specify new dose:
Yes	No	Has an intervention/medication been added to treat a specific harm/toxicity? If yes, please specify:

Ad hoc B - Unscheduled Harm/Toxicity Assessment

Date of Assessment

dd/mm/yyyy

Was there any benefit? Yes No

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

Dizziness

1 2 3 Ungradable No Symptom

NCI Criteria

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

Amnesia

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild; transient memory loss
2. Moderate; short term memory loss; limiting instrumental ADL
3. Severe; long term memory loss; limiting self-care ADL

Blurred vision

1 2 3 Ungradable No Symptom

NCI Criteria

1. Intervention not indicated
2. Symptomatic; moderate decrease in visual acuity (best corrected visual acuity 20/40 and better or 3 lines or less decreased vision from known baseline); limiting instrumental ADL
3. Symptomatic with marked decrease in visual acuity (best corrected visual acuity worse than 20/40 or more than 3 lines of decreased vision from known baseline, up to 20/200); limiting self-care ADL

Slurred speech

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild slurred speech
2. Moderate impairment of articulation or slurred speech
3. Severe impairment of articulation or slurred speech

Ataxia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Asymptomatic; clinical or diagnostic observations only; intervention not indicated
2. Moderate symptoms; limiting instrumental ADL
3. Severe symptoms; limiting self-care ADL; mechanical assistance indicated

Fall

1 2 3 Ungradable No Symptom

NCI Criteria

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

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

Confusion

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

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

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

Other harm 1 (only if applicable - e.g., dyspepsia, personality change, psychosis, muscle weakness, acne etc.). *Please specify other harm:* _____

1 2 3 4 5 Ungradable

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

Additional other harm 2 (only if applicable-can be related or unrelated to intervention)

Please specify additional other harm: _____

1 2 3 4 5 Ungradable

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

Additional other harm 3 (only if applicable-can be related or unrelated to intervention)

Please specify additional other harm: _____

1 2 3 4 5 Ungradable

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

Tick ✓	Which symptom/harm is the most troublesome? (Tick one only)
	Dizziness
	Amnesia
	Blurred vision
	Slurred speech
	Ataxia
	Fall
	Somnolence
	Confusion
	Agitation
	Other harm 1
	Additional other harm 2
	Additional other harm 3
	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 all that apply)

Tick ✓		
		No change to medication of interest/continue current dose
		Medication of interest ceased
		Medication of interest dose reduced; please specify new dose:
		Medication of interest increased; please specify new dose:
Yes	No	Has an intervention/medication been added to treat a specific harm/toxicity? If yes, please specify:

Ad hoc C - Unscheduled Harm/Toxicity Assessment

Date of Assessment

dd/mm/yyyy

Was there any benefit? Yes No

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

Dizziness

1 2 3 Ungradable No Symptom

NCI Criteria

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

Amnesia

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild; transient memory loss
2. Moderate; short term memory loss; limiting instrumental ADL
3. Severe; long term memory loss; limiting self-care ADL

Blurred vision

1 2 3 Ungradable No Symptom

NCI Criteria

1. Intervention not indicated
2. Symptomatic; moderate decrease in visual acuity (best corrected visual acuity 20/40 and better or 3 lines or less decreased vision from known baseline); limiting instrumental ADL
3. Symptomatic with marked decrease in visual acuity (best corrected visual acuity worse than 20/40 or more than 3 lines of decreased vision from known baseline, up to 20/200); limiting self-care ADL

Slurred speech

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild slurred speech
2. Moderate impairment of articulation or slurred speech
3. Severe impairment of articulation or slurred speech

Ataxia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Asymptomatic; clinical or diagnostic observations only; intervention not indicated
2. Moderate symptoms; limiting instrumental ADL
3. Severe symptoms; limiting self-care ADL; mechanical assistance indicated

Fall

1 2 3 Ungradable No Symptom

NCI Criteria

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

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

Confusion

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

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

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

Other harm 1 (only if applicable e.g., dyspepsia, personality change, psychosis, muscle weakness, acne etc.). Please specify other harm: _____

1 2 3 4 5 Ungradable

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

Additional other harm 2 (only if applicable-can be related or unrelated to intervention)

Please specify additional other harm: _____

1 2 3 4 5 Ungradable

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

Additional other harm 3 (only if applicable-can be related or unrelated to intervention)

Please specify additional other harm: _____

1 2 3 4 5 Ungradable

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

Tick ✓	Which symptom/harm is the most troublesome? (Tick one only)
	Dizziness
	Amnesia
	Blurred vision
	Slurred speech
	Ataxia
	Fall
	Somnolence
	Confusion
	Agitation
	Other harm 1
	Additional other harm 2
	Additional other harm 3
	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 all that apply)

Tick ✓		
		No change to medication of interest/continue current dose
		Medication of interest ceased
		Medication of interest dose reduced; please specify new dose:
		Medication of interest increased; please specify new dose:
Yes	No	Has an intervention/medication been added to treat a specific harm/toxicity? If yes, please specify: