

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

**Opioids for symptomatic breathlessness  
Rapid Program Series No: 21**

IMPACCT Trials Coordination Centre (ITCC)  
UTS Rapid Program

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

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**Baseline (T<sub>0</sub>)****Date of Assessment**

DD/MM/YYYY

**Is the patient already on opioids for a reason other than breathlessness?** **Yes** - patient is excluded from this series  **No** - continue completing the CRF**Demographics** (*please tick*)**Gender**  Male  Female  Other**Age (yrs.)****Weight (kg)****Height (cm)**

<b>Tick ✓</b>	<b>Primary life-limiting illness</b> <i>Please tick only one</i>
	Advanced metastatic cancer
	End stage renal failure
	Hepatic failure
	Neurodegenerative disease
	Cardiac failure
	Respiratory failure
	AIDS
	Other; Please specify: _____

<b>Tick ✓</b>	<b>Palliative Care Phase</b>
	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.

**Laboratory Tests** (only if available)

<b>Test</b>	<b>Value</b>
Haemoglobin (Hb) g/L	
Calculated Creatinine Clearance (CCr) (mL/min)	

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

<b>Tick</b> ✓	<b>Australian Modified Karnofsky Performance Scale (AKPS)</b>
	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

## Baseline T<sub>0</sub> - Medication Commencement

Tick ✓	Describe this episode of breathlessness in this patient. <i>Tick one</i>
	Treating established chronic breathlessness
	An acute exacerbation on a background of chronic breathlessness
	A new ( <i>de novo</i> ) episode of acute breathlessness
	Other: Please specify here: _____

**Symptom Severity Scores** *Please grade both symptoms; indicate that each harm has been assessed by ticking the square box above each.*

**Breathlessness**

1    2    3    4    no symptom    ungradable

*modified Medical Research Council (mMRC) breathlessness scale*

0. Breathlessness only with strenuous exercise  
 1. Breathlessness when hurrying or walking up a slight hill  
 2. Walks slower than people of the same age because of breathlessness or has to stop for breath when walking at own pace  
 3. Stops for breath after walking 100 yards or after a few minutes  
 4. Too breathless to leave house or breathless when dressing or undressing

**Anxiety**

1    2    3    4    5    no symptom    ungradable

*NCI Criteria*

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

Tick ✓	What other treatments (if any) is this person on for breathlessness? <i>Tick all that apply</i>
	Benzodiazepine
	Oxygen therapy
	None
	Other;(e.g., fan) please specify: _____

**Baseline Symptom/Harm Assessment**

Please grade all harms; indicate that each harm has been assessed by ticking the square box above 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

**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 hospitalization 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 threats of harm to self or others; hospitalization indicated
- 5. Death

**Constipation**

1    2    3    4    5    ungradable    no symptom

*NCI Criteria*

- 1. Mild; asymptomatic or mild symptoms
- 2. Moderate; minimal; local or non-invasive intervention indicated
- 3. Severe or medically significant but not immediately life threatening
- 4. Life threatening consequences; urgent intervention indicated
- 5. Death

**What is the patient's respiratory rate (breaths/min)**

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

Please specify other harm here \_\_\_\_\_

Other harms grade here.

1    2    3    4    5    Ungradable

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

*Please specify additional other harm here* \_\_\_\_\_

Additional other harm grade here

1    2    3    4    5    Ungradable

<b>Tick ✓</b>	<b>Which symptom/harm is the most troublesome?</b> ( <i>excluding the target symptoms of breathlessness and anxiety</i> ) ( <i>Tick one only</i> )
	Dizziness
	Nausea
	Somnolence
	Confusion
	Respiratory Depression
	Constipation
	Other harm
	Additional other harm
	Not applicable

## Baseline – T<sub>0</sub> – Medication Commencement

### Date and Time of first dose of opioid administered for breathlessness

<b>Date</b>	DD/MM/YYYY	<b>Time (24-hr clock)</b>	HH:MM
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Indicate which opioid(s) are being commenced for breathlessness. (If you are prescribing a regular opioid as well as PRN doses for breathlessness, please record in the separate tables provided:

### Has a **REGULAR** opioid been commenced for breathlessness?

Yes - please complete table below     No – proceed to PRN Opioid section

### REGULAR OPIOID COMMENCEMENT

Tick ✓	Name of regular opioid commenced for breathlessness
	Morphine
	Oxycodone
	Fentanyl
	Buprenorphine
	Tramadol
	Tapentadol
	Codeine
	Hydromorphone
	Other(s); please specify:

Tick ✓	Route of administration/formulation
	Oral immediate release solution
	Oral immediate release tablet
	Oral extended-release tablet
	Subcutaneous
	Intravenous
	Transdermal
	Transmucosal
	Other; please specify:

**Total dose of REGULAR opioid prescribed in 24 hours for breathlessness**

**Unit of Measure:** Tick whichever applies

mg     mcg

**AS NEEDED (PRN) OPIOID COMMENCEMENT**

Has a PRN opioid been commenced for breathlessness?

 Yes - please complete table below     No – no further questions at this timepoint.

Tick ✓	Indicate which PRN ( <i>Pro re nata</i> / as needed) opioid commenced for breathlessness.
	Morphine
	Oxycodone
	Fentanyl
	Buprenorphine
	Tramadol
	Tapentadol
	Codeine
	Hydromorphone
	Other(s); please specify:

Tick ✓	Route of administration/formulation
	Oral immediate release solution
	Oral immediate release tablet
	Oral extended-release tablet
	Subcutaneous
	Intravenous
	Transdermal
	Transmucosal
	Other; please specify:

<b>PRN dose prescribed by doctor.</b>		
<b>Unit of Measure:</b> <i>Tick whichever applies</i>		<input type="radio"/> mg <input type="radio"/> mcg
<b>Frequency of PRN dose prescribed</b> ( <i>Please circle frequency, or indicate other</i> )		
Q1h	Q2h	Q3h
Q4h	Q6h	Q8h
Q12	Other: Please specify here:	
<b>Maximum number of doses of PRN allowed in 24-hour period:</b>		



## T<sub>1</sub> – 2 days post baseline

Tick ✓	T <sub>1</sub> : Assessed/Not assessed reason
	Assessed today (continue to complete T <sub>1</sub> ) 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**

**Date of T<sub>1</sub> Assessment**

DD/MM/YYYY

**Time of Assessment** (24-hr clock)

HH:MM

**If T<sub>1</sub> assessment is not within the timeframe above, please provide the reason**  
*e.g. weekend*

## Symptom Severity Scores

*Please grade both symptoms; indicate that each harm has been assessed by ticking the square box above each.*

### **Breathlessness**

1    2    3    4    ungradable    no symptom

*modified Medical Research Council (mMRC) breathlessness scale*

0. Breathlessness only with strenuous exercise
1. Breathlessness when hurrying or walking up a slight hill
2. Walks slower than people of the same age because of breathlessness or has to stop for breath when walking at own pace
3. Stops for breath after walking 100 yards or after a few minutes
4. Too breathless to leave house or breathless when dressing or undressing

### **Anxiety**

1    2    3    4    5    ungradable    no symptom

*NCI Criteria*

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

**T1 - REGULAR OPIOID DOSING DETAILS****Total dose of REGULAR opioid given in the last 24 hours for breathlessness?****Unit of Measure:** *(tick whichever applies)* mg     mcg**How long has the patient been on this REGULAR dose (days)****T1- PRN/AS NEEDED OPIOID DOSING DETAILS****Total Dose of PRN/as needed opioid administered in the last 24 hours for breathlessness?****Unit of Measure:** *(tick whichever applies)* mg     mcg**How long has the patient been on this PRN dose (days)****Based on your assessment at this time, was there any benefit?** Yes     No**T1 – Symptom/Harm 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 above 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

 **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 hospitalization 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

<p><i>NCI Criteria</i></p> <ol style="list-style-type: none"> <li>1. Mild disorientation</li> <li>2. Moderate disorientation; limiting instrumental ADL</li> <li>3. Severe disorientation; limiting self-care ADL</li> <li>4. Life-threatening consequences threats of harm to self or others; hospitalization indicated</li> <li>5. Death</li> </ol>
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**Constipation**

1    2    3    4    5    ungradable    no symptom

<p><i>NCI Criteria</i></p> <ol style="list-style-type: none"> <li>1. Mild; asymptomatic or mild symptoms</li> <li>2. Moderate; minimal; local or non-invasive intervention indicated</li> <li>3. Severe or medically significant but not immediately life threatening</li> <li>4. Life threatening consequences; urgent intervention indicated</li> <li>5. Death</li> </ol>
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<b>What is the patient's respiratory rate (breaths/min)</b>	
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**Other harm** (*only if applicable – can be related or unrelated to the medication*)

Please specify other harm here \_\_\_\_\_

<p>Other harms grade:</p> <p><input type="radio"/> 1   <input type="radio"/> 2   <input type="radio"/> 3   <input type="radio"/> 4   <input type="radio"/> 5   <input type="radio"/> Ungradable</p>
---

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

Please specify additional other harm here \_\_\_\_\_

<p>Additional other harm grade:</p> <p><input type="radio"/> 1   <input type="radio"/> 2   <input type="radio"/> 3   <input type="radio"/> 4   <input type="radio"/> 5   <input type="radio"/> Ungradable</p>
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Tick ✓	Which symptom/harm is the most troublesome? ( <i>excluding the target symptoms of breathlessness and anxiety</i> ) (Tick one only)
	Dizziness
	Nausea
	Somnolence
	Confusion
	Respiratory Depression
	Constipation
	Other harm
	Additional other harm
	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, answering the Naranjo questions is not required.*

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?

## HARM ASSESSMENT FOLLOW-UP

**What is the intended treatment based on the T<sub>1</sub> assessment?**

*Tick yes or no to all*

Yes	No	Changes to opioid for breathlessness
		No change to opioid/continue current dose
		Opioid for breathlessness ceased ( <i>complete cessation form pg. 21</i> )
		Opioid dose decreased/reduced
		Opioid dose increased
		Current opioid ceased and new opioid started. Please specify new opioid, the reason for the change, and the dose & frequency:
		Has a non-opioid medication been added to treat a specific harm? If yes, please specify medication and dose:

<b>What is the new Day 2 total 24hr dose of REGULAR opioid after harm assessment?</b>		
<b>Unit of Measure:</b> <i>(Tick whichever applies)</i>		<input type="radio"/> mg <input type="radio"/> mcg
<b>What is the new Day 2 PRN/as needed dose after harm assessment?</b>		
<b>Unit of Measure:</b> <i>(Tick whichever applies)</i>		<input type="radio"/> mg <input type="radio"/> mcg
<b>Frequency of PRN dose prescribed</b> <i>(Please circle frequency, or indicate other)</i>		
Q1h	Q2h	Q3h
Q4h	Q6h	Q8h
Q12	Other: Please specify here:	
<b>Maximum number of PRN doses allowed in 24-hour period:</b>		

<b>Based on the assessment today, has the harm resolved?</b>
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A

## T<sub>2</sub> 7-14 days after baseline

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

<b>Date of Death*</b>	DD/MM/YYYY
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**\*End survey here**

<b>Date of T<sub>2</sub> Assessment</b>	DD/MM/YYYY
<b>Time of Assessment</b> (24 hr. clock)	HH:MM

If today's assessment is not 7-14 days after baseline, please give reason below e.g., standard practice is different.

--

### T<sub>2</sub> - REGULAR OPIOID DOSING DETAILS

**Has the *REGULAR* opioid been changed to a different opioid since T<sub>1</sub>?**

**Yes** - please complete *REGULAR* opioid changes below       **No**

**Total dose of *regular* opioid given in the last 24 hours for breathlessness?**

**Unit of Measure:** (tick whichever applies)

mg       mcg

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

### T<sub>2</sub>- PRN/AS NEEDED OPIOID DOSING DETAILS

**Has the *PRN* opioid been changed to a different opioid since T<sub>1</sub>?**

**Yes** - please complete *PRN* opioid changes below       **No**

**Total Dose of *PRN/as needed* opioid administered in the last 24 hours for breathlessness?**

**Unit of Measure:**

*Tick whichever applies*

mg       mcg

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

**REGULAR OPIOID CHANGES***Only complete if different to T<sub>1</sub>*

<b>Tick ✓</b>	<b>Name of regular opioid for breathlessness</b>	
	Morphine	
	Oxycodone	
	Fentanyl	
	Buprenorphine	
	Tramadol	
	Tapentadol	
	Codeine	
	Hydromorphone	
	Other(s); please specify:	
<b>Tick ✓</b>	<b>Route of administration/formulation</b>	
	Oral immediate release solution	
	Oral immediate release tablet	
	Oral extended-release tablet	
	Subcutaneous	
	Intravenous	
	Transdermal	
	Transmucosal	
	Other; please specify:	
<b>Total dose of REGULAR opioid given in the last 24 hours for breathlessness</b>		
<b>Unit of Measure:</b> <i>Tick whichever applies</i>		<input type="radio"/> mg <input type="radio"/> mcg

**AS NEEDED (PRN) OPIOID CHANGES***Only complete if different to T<sub>1</sub>)*

<b>Tick ✓</b>	<b>Indicate which PRN opioid commenced for breathlessness.</b>				
	Morphine				
	Oxycodone				
	Fentanyl				
	Buprenorphine				
	Tramadol				
	Tapentadol				
	Codeine				
	Hydromorphone				
	Other(s); please specify:				
<b>Tick ✓</b>	<b>Route of administration/formulation</b>				
	Oral immediate release solution				
	Oral immediate release tablet				
	Oral extended-release tablet				
	Subcutaneous				
	Intravenous				
	Transdermal				
	Transmucosal				
	Other; please specify:				
<b>PRN dose prescribed by doctor</b>					
<b>Unit of Measure:</b> <i>Tick whichever applies</i>					<input type="radio"/> mg <input type="radio"/> mcg
<b>Frequency of PRN dose prescribed</b> <i>(Please circle frequency, or indicate other)</i>					
Q1h	Q2h	Q3h	Q4h	Q6h	Q8h
Q12	Other: Please specify here:				
<b>Maximum number of PRN doses allowed in 24-hour period:</b>					



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

### Symptom Severity Scores

Please grade both symptoms; indicate that each harm has been assessed by ticking the square box above each.

**Breathlessness**

1    2    3    4    ungradable    no symptom

*modified Medical Research Council (mMRC) breathlessness scale*

- 0. Breathlessness only with strenuous exercise
- 1. Breathlessness when hurrying or walking up a slight hill
- 2. Walks slower than people of the same age because of breathlessness or has to stop for breath when walking at own pace
- 3. Stops for breath after walking 100 yards or after a few minutes
- 4. Too breathless to leave house or breathless when dressing or undressing

**Anxiety**

1    2    3    4    5    ungradable    no symptom

*NCI Criteria*

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

**Based on your assessment at this time was there any benefit?**

Yes    No

**T<sub>2</sub> – Symptom/Harm 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

**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 hospitalization 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 threats of harm to self or others; hospitalization indicated
5. Death

**Constipation**

1    2    3    4    5    ungradable    no symptom

*NCI Criteria*

1. Mild; asymptomatic or mild symptoms
2. Moderate; minimal; local or non-invasive intervention indicated
3. Severe or medically significant but not immediately life threatening
4. Life threatening consequences; urgent intervention indicated
5. Death

**What is the patient's respiratory rate (breaths/min)**

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

Please specify other harm here \_\_\_\_\_

Other harms grade:

1    2    3    4    5    Ungradable

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

Please specify additional other harm here \_\_\_\_\_

Additional other harm grade:

1    2    3    4    5    Ungradable

<b>Tick ✓</b>	<b>Which symptom/harm is the most troublesome?</b> <i>(excluding the target symptoms of breathlessness and anxiety) (Tick one only)</i>
	Dizziness
	Nausea
	Somnolence
	Confusion
	Respiratory Depression
	Constipation
	Other harm
	Additional other harm
	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, answering the Naranjo questions is not required.*

<b>Yes</b>	<b>No</b>	<b>Don't know</b>	
			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?

## **HARM ASSESSMENT FOLLOW-UP**

**What is the intended treatment based on today's T<sub>2</sub> assessment?**

*Tick yes or no to all*

<b>Yes</b>	<b>No</b>	<b>Changes to opioid for breathlessness</b>
		No change to opioid/continue current dose
		Opioid for breathlessness ceased <i>(complete cessation form pg. 21)</i>
		Opioid dose decreased/reduced
		Opioid dose increased
		Current opioid ceased and new opioid started. Please specify new opioid, the reason for the change, and the dose & frequency:
		Has a non-opioid medication been added to treat a specific harm? If yes, please specify medication and dose:

<b>What is the new T<sub>2</sub> total 24hr dose prescribed of REGULAR opioid after harm assessment?</b>	
<b>Unit of Measure:</b> <i>Tick whichever applies</i>	<input type="radio"/> mg <input type="radio"/> mcg

<b>What is the new T<sub>2</sub> PRN/as needed prescribed dose after harm assessment?</b>	
<b>Unit of Measure:</b> <i>Tick whichever applies</i>	<input type="radio"/> mg <input type="radio"/> mcg

<b>Frequency of PRN dose prescribed</b> <i>Circle frequency or indicate other</i>					
Q1h	Q2h	Q3h	Q4h	Q6h	Q8h
Q12	Other: Please specify here:				
<b>Maximum number of PRN doses allowed in 24-hour period</b>					

<b>Based on the assessment today, has the harm resolved?</b>
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> 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/s resolved; please indicate date symptom resolved:
	Symptom/s 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

### Harm/toxicity Assessment

#### Symptom Severity Scores

Please grade all harms; indicate that each harm has been assessed by ticking the square box above each

**Breathlessness**

1    2    3    4    ungradable    no symptom

*modified Medical Research Council (mMRC) breathlessness scale*

0. Breathlessness only with strenuous exercise
1. Breathlessness when hurrying or walking up a slight hill
2. Walks slower than people of the same age because of breathlessness or has to stop for breath when walking at own pace
3. Stops for breath after walking 100 yards or after a few minutes
4. Too breathless to leave house or breathless when dressing or undressing

**Anxiety**

1    2    3    4    5    ungradable    no symptom

*NCI Criteria*

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

**Symptom/Harm 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

**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 hospitalization 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 threats of harm to self or others; hospitalization indicated
5. Death

**Constipation**

1    2    3    4    5    ungradable    no symptom

*NCI Criteria*

1. Mild; asymptomatic or mild symptoms
2. Moderate; minimal; local or non-invasive intervention indicated
3. Severe or medically significant but not immediately life threatening
4. Life threatening consequences; urgent intervention indicated
5. Death

**What is the patient's respiratory rate (breaths/min)**

**Other harms (if they have been experienced)**

*Please specify other harm:* \_\_\_\_\_

Other harms grade:

1    2    3    4    5    Ungradable

**Additional other harms (if they have been experienced)**

*Please specify additional other harm:* \_\_\_\_\_

Additional other harm grade:

1    2    3    4    5    Ungradable

Tick ✓	Which symptom/harm is the most troublesome? (excluding the target symptoms of breathlessness and anxiety) (Tick one only)
	Dizziness
	Nausea
	Somnolence
	Confusion
	Respiratory Depression
	Constipation
	Other harm
	Additional other harm
	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, answering the Naranjo questions is not required.*

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

#### Symptom Severity Scores

Please grade all harms; indicate that each harm has been assessed by ticking the square box above each.

**Breathlessness**

1    2    3    4    ungradable    no symptom

*modified Medical Research Council (mMRC) breathlessness scale*

0. Breathlessness only with strenuous exercise
1. Breathlessness when hurrying or walking up a slight hill
2. Walks slower than people of the same age because of breathlessness or has to stop for breath when walking at own pace
3. Stops for breath after walking 100 yards or after a few minutes
4. Too breathless to leave house or breathless when dressing or undressing

**Anxiety**

1    2    3    4    5    ungradable    no symptom

*NCI Criteria*

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

#### Symptom/Harm 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 above 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

**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 hospitalization 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 threats of harm to self or others; hospitalization indicated
5. Death

**Constipation**

1    2    3    4    5    ungradable    no symptom

*NCI Criteria*

1. Mild; asymptomatic or mild symptoms
2. Moderate; minimal; local or non-invasive intervention indicated
3. Severe or medically significant but not immediately life threatening
4. Life threatening consequences; urgent intervention indicated
5. Death

**What is the patient's respiratory rate (breaths/min)**

**Other harms (if they have been experienced)**

*Please specify other harm here* \_\_\_\_\_

Other harms grade:

1    2    3    4    5    Ungradable

**Additional other harms (if they have been experienced)**

*Please specify additional other harm here* \_\_\_\_\_

Additional other harm grade:

1    2    3    4    5    Ungradable

Tick ✓	Which symptom/harm is the most troublesome? (excluding the target symptoms of breathlessness and anxiety) (Tick one only)
	Dizziness
	Nausea
	Somnolence
	Confusion
	Respiratory Depression
	Constipation
	Other harm
	Additional other harm
	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, answering the Naranjo questions is not required.*

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

## Ad hoc C - Unscheduled Harm/Toxicity Assessment

Date of Assessment

DD/MM/YYYY

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

### Symptom Severity Scores

Please grade all harms; indicate that each harm has been assessed by ticking the square box above each

**Breathlessness**

1    2    3    4    ungradable    no symptom

*modified Medical Research Council (mMRC) breathlessness scale*

0. Breathlessness only with strenuous exercise
1. Breathlessness when hurrying or walking up a slight hill
2. Walks slower than people of the same age because of breathlessness or has to stop for breath when walking at own pace
3. Stops for breath after walking 100 yards or after a few minutes
4. Too breathless to leave house or breathless when dressing or undressing

**Anxiety**

1    2    3    4    5    ungradable    no symptom

*NCI Criteria*

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

### Symptom/Harm 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

**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 hospitalization 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 threats of harm to self or others; hospitalization indicated
5. Death

**Constipation**

1    2    3    4    5    ungradable    no symptom

*NCI Criteria*

1. Mild; asymptomatic or mild symptoms
2. Moderate; minimal; local or non-invasive intervention indicated
3. Severe or medically significant but not immediately life threatening
4. Life threatening consequences; urgent intervention indicated
5. Death

**What is the patient's respiratory rate (breaths/min)**

**Other harms (if they have been experienced)**

*Please specify other harm here* \_\_\_\_\_

Other harms grade:

1    2    3    4    5    Ungradable

**Additional other harms (if they have been experienced)**

*Please specify additional other harm here* \_\_\_\_\_

Additional other harm grade:

1    2    3    4    5    Ungradable

<b>Tick ✓</b>	<b>Which symptom/harm is the most troublesome?</b> <i>(excluding the target symptoms of breathlessness and anxiety) (Tick one only)</i>
	Dizziness
	Nausea
	Somnolence
	Confusion
	Respiratory Depression
	Constipation
	Other harm
	Additional other harm
	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, answering the Naranjo questions is not required.*

<b>Yes</b>	<b>No</b>	<b>Don't know</b>	
			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?