***Patient ID**

Site identifier / Medication number / Patient number

Name of person entering data

CONFIDENTIAL

CASE REPORT FORM

BENZODIAZEPINES FOR BREATHLESSNESS

Palliative Care Clinical Studies Collaborative

The case report form is to be completed in compliance with PaCCSC Standard Operating Procedures

Version 1.4 May 2017

Your participation in the RAPID program might be considered one element of your organisations locally adopted continuous quality improvement strategy and assist your local accreditation program. In Australia this participation may provide evidence to demonstrate meeting of the National Safety and Quality Health Service (NSQHS) Standards.

If you wish to stop email reminders being sent to you for a patient who has died, follow this link and enter the patient ID in the space provided. Remember to come back to this page, click next at the bottom of the screen to save the death date (otherwise it wont be recorded) it, then you can close the page using the X at top right.

NOTE: During data entry, you must navigate all the way to the end of the survey by clicking on Next at the bottom of each page and click Finish otherwise the data will not be saved.

Time Periods and forms:

T0 - Baseline (pages 2-6)
T1 - 24hrs after baseline (pages 7-11)
T2 - 24 - 72 hrs after baseline (pages 13-15)
Medication cessation (page 17)
Symptom resolution (page 18)
Unscheduled & Adhoc Adverse Events (page 19-26)
Notification of date of death (page 27)

Demographics

***Gender** ◯ Male ◯ Female

Age
Years

	Estimated	Unit
Weight	◯	Select:
Height	◯	Select:

*Primary life limiting illness

Tick one

- ◯ Advanced metastatic cancer
- ◯ AIDS
- ◯ End stage renal failure
- ◯ Cardiac failure
- ◯ Hepatic failure
- ◯ Respiratory failure
- ◯ Neurodegenerative disease
- ◯ Other (please specify)

What palliative care phase would you place the Patient in?

◯ Stable phase ◯ Unstable phase ◯ Deteriorating phase ◯ Terminal phase

Click here to download the Palliative Care Phase definitions listed above.

Laboratory tests[1]

Only if available

		Not available
Serum albumin		☐
International normalised ratio (INR)		☐
Calculated creatinine clearance (CCr)*		☐
Blood sugar level (mmol/L or mg/dL)		☐

Charlson Comorbidity Index

Conditions

- ☐ Myocardial infarct
- ☐ Congestive cardiac failure
- ☐ Peripheral vascular disease
- ☐ Cerebrovascular disease
- ☐ Dementia
- ☐ Chronic pulmonary disease
- ☐ Connective tissue disease
- ☐ Ulcer disease
- ☐ Mild liver disease
- ☐ Diabetes
- ☐ Hemiplegia
- ☐ Moderate or severe renal disease
- ☐ Diabetes with end organ damage
- ☐ Any tumour
- ☐ Leukaemia
- ☐ Lymphoma
- ☐ Moderate or severe liver disease
- ☐ Metastatic solid tumour
- ☐ AIDS

* Australian Modified Karnofsky Performance Scale (AKPS)[2]

- ○ 100 = Normal; no complaints; no evidence of disease.
- ○ 90 = Able to carry on normal activity; minor signs or symptoms.
- ○ 80 = Normal activity with effort; some signs of symptoms or 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 of his 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

DATA POINTS

*

Date of Medication Commencement (Baseline)

dd/mm/yyyy (please use date-picker)

*

Day 1 Assessment

24 hours after baseline - (dd/mm/yyyy - please use date-picker)

*

Day 3 Assessment

72 hours after baseline (dd/mm/yyyy - please use date-picker)

Reminders will be sent to this email address 24 and 72 hours after baseline

Please take care to type your email address correctly otherwise the reminders cannot be sent to you.

@@Email

Reminders will be sent to this email address 24 and 72 hours after baseline

This second email is optional

*

Cease *ad hoc* Toxicity reporting 1 week after baseline

1 week after baseline (dd/mm/yyyy - please use date-picker)

Email Reminder content

This email is to remind you to record Benzodiazepines data for patient [PID]
To complete the next section of the survey, go to the RDMS in CareSearch and search for the date you started entering data

Baseline - Medication Commencement

How would you describe this episode of breathlessness in this patient?

- ○ 1. A de novo episode of acute breathlessness
- ○ 2. A progression of chronic breathlessness
- ○ 3. An acute exacerbation on a background of chronic breathlessness
- ○ Other:

*Symptom Severity Score

Grade @@530633 according to NCI criteria

	1	2	3	4	5
Breathlessness	○	○	○	○	○
Anxiety	○	○	○	○	○

NCI Criteria:

Anxiety

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

Breathlessness

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

Benzodiazepines the patient is currently on for breathlessness?

	Tick all that apply	Dose over 24 hours	Route of Administration: Oral	Injectable	Rectal
Diazepam	☐		○	○	○
Clonazepam	☐		○	○	○
Nitrazepam	☐		○	○	○
Flurazepam	☐		○	○	○
Lorazepam	☐		○	○	○
Midazolam	☐		○	○	○
Alprazolam	☐		○	○	○
Other(s) (please specify below)	☐		○	○	○

If Other(s) for breathlessness please specify here:

	Drug Name	Dose over 24 hours	Route of Administration: Oral	Injectable	Rectal
Other Benzodiazepine			○	○	○
Other Benzodiazepine			○	○	○
Other Benzodiazepine			○	○	○

What other treatments is this person on for breathlessness *(if any)* ?

- ☐ Opioid
- ☐ Oxygen therapy
- ☐ None
- ☐ Other:

Is the patient on Benzodiazepines for another reason other than breathlessness?

- ☐ Yes

- [ ] No

If Yes, please indicate why.

- [ ] Anxiety
- [ ] Sleep
- [ ] Nausea
- [ ] Pain
- [ ] Other

Benzodiazepines the patient is currently taking that are NOT for breathlessness?

	Tick all that apply	Dose over 24 hours	Route of Administration		
			Oral	Injectable	Rectal
Diazepam	☐		○	○	○
Clonazepam	☐		○	○	○
Nitrazepam	☐		○	○	○
Flurazepam	☐		○	○	○
Lorazepam	☐		○	○	○
Midazolam	☐		○	○	○
Alprazolam	☐		○	○	○
Other(s) (please specify below)	☐		○	○	○

If Other(s) NOT for breathlessness please specify here:

	Drug Name	Dose over 24 hours	Route of Administration		
			Oral	Injectable	Rectal
Other Benzodiazepine			○	○	○
Other Benzodiazepine			○	○	○
Other Benzodiazepine			○	○	○

NCI Criteria (summary list of expected toxicities) - click here to download a pdf version
NCI Criteria V 4.03 (full list for all other toxicities) - click here to download a pdf version

* Toxicities

Specify any adverse drug event and grade it according to NCI criteria.

	1	2	3	Un-gradable	No symptom
Dizziness	○	○	○	○	○
Amnesia	○	○	○	○	○
Blurred vision	○	○	○	○	○
Slurred speech	○	○	○	○	○
Ataxia	○	○	○	○	○
Fall	○	○	○	○	○

*

	1	2	3	4	5	Un-gradable	No symptom
Somnolence	○	○	○	○	○	○	○
Confusion	○	○	○	○	○	○	○
Agitation	○	○	○	○	○	○	○
Other - please specify below	○	○	○	○	○	○	○
Other - please specify below	○	○	○	○	○	○	○
Other - please specify below	○	○	○	○	○	○	○

***Which toxicity is the most troublesome?**

Select: ▾

If "Other", please specify here

(e.g , dyspepsia, personality change, psychosis, muscle weakness, acne etc)

If "Other", please specify here

(e.g , dyspepsia, personality change, psychosis, muscle weakness, acne etc)

If "Other", please specify here

(e.g , dyspepsia, personality change, psychosis, muscle weakness, acne etc)

***Do you have data for the next timepoint to be entered at this time?**

○ Yes (continue to next timepoint)

○ No (Finish & close survey for now)

Toxicity assessment - Benzodiazepines for breathlessness

Dizziness

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

Amnesia

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

Blurred vision

Intervention not indicated	1
Symptomatic; limiting instrumental ADL	2
Limiting self-care ADL	3

Slurred speech

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

Ataxia

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

Fall

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

Somnolence

Mild but more than usual drowsiness or sleepiness	1
Moderate sedation; limiting instrumental ADL	2
Obtundation or stupor	3
Life-threatening consequences; urgent intervention indicated	4
Death	5

Confusion

Mild disorientation	1
Moderate disorientation; limiting instrumental ADL	2
Severe disorientation; limiting self-care ADL	3
Life-threatening consequences threats of harm to self or others; hospitalization indicated	4
Death	5

Agitation

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

Other

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

Clinical Benefit & Toxicity Assessment - *(24 hours after baseline)*

Please score the symptom of interest and also list any toxicities that occur (regardless of whether they are attributable to the medication of interest or not).

*Assessed / Not assessed reason

- Assessed today (continue)
- Died (date of death required on final page)
- Not able to be contacted / located
- Too unwell
- Other

***Date of Day 1 assessment (benefit & toxicity time point)**

(dd/mm/yyyy - please use date-picker)

***Was there any benefit?**

- Yes
- No

***Medication changes**

- No change to medication of interest/continue current dose
- Medication of interest ceased
- Medication of interest dose reduced
- Medication of interest dose increased (please specify new dose):

***Symptom Severity Score**

Grade @@530633 according to NCI criteria

	1	2	3	4	5
Breathlessness	○	○	○	○	○
Anxiety	○	○	○	○	○

NCI Criteria:

Anxiety

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

Breathlessness

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

Symptomatic Adverse Event Assessment (0-24 hours)

Please list any symptomatic adverse events that occur (regardless of whether they are attributable to the medication of interest or not)

*Was there any toxicity?

- Yes
- No

NCI Criteria (summary list of expected toxicities) - click here to download a pdf version
NCI Criteria V 4.03 (full list for all other toxicities) - click here to download a pdf version

* Toxicities

Specify any adverse drug event and grade it according to NCI criteria.

	1	2	3	Un-gradable	No symptom
Dizziness					
Amnesia					
Blurred vision					
Slurred speech					
Ataxia					
Fall					

*

	1	2	3	4	5	Un-gradable	No symptom
Somnolence							
Confusion							
Agitation							
Other - please specify below							
Other - please specify below							
Other - please specify below							

If "Other", please specify here
(e.g , dyspepsia, personality change, psychosis, muscle weakness, acne etc)

If "Other", please specify here
(e.g , dyspepsia, personality change, psychosis, muscle weakness, acne etc)

If "Other", please specify here
(e.g , dyspepsia, personality change, psychosis, muscle weakness, acne etc)

*Which toxicity is the most troublesome?

Select:

*If there were toxicities, were any given a grade of 3 or more?

- Yes
- No
- Not applicable

***What is the intended treatment based on the assessment today?**

- No change to medication of interest / continue current dose
- Medication of interest ceased
- Medication of interest dose reduced
- Medication to treat a specific toxicity added (please specify below)
- Medication of interest dose increased (please specify new dose)

If a medication to treat a specific toxicity has been added, please specify here

Based on the assessment today has toxicity resolved? Yes No

***Do you have data for the next timepoint to be entered at this time?**

- Yes (continue to next timepoint)
- No (Finish & close survey for now)

Key questions derived from the Naranjo check list.
(only complete this section if any toxicity on the previous page is 3 or greater)

***1. Did the adverse reaction appear after the suspected drug was given?**

- Yes
- No
- Don't know

***2. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was given?**

- Yes
- No
- Don't know

***3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?**

- Yes
- No
- Don't know

***4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?**

- Yes
- No
- Don't know

***5. Was the adverse event confirmed by any objective evidence?**

- Yes
- No
- Don't know

Clinical Benefit & Toxicity Assessment - *(72 hours after baseline)*

Please score the symptom of interest and also list any toxicities that occur (regardless of whether they are attributable to the medication of interest or not).

*Assessed / Not assessed reason

- Assessed today (continue)
- Died (date of death required on final page)
- Not able to be contacted / located
- Too unwell
- Other

***Date of Day 3 assessment (benefit & toxicity time point)**
(dd/mm/yyyy - please use date-picker)

***Was there any benefit?**

- Yes
- No

***Medication changes**

- No change to medication of interest/continue current dose
- Medication of interest ceased (go to page 17)
- Medication of interest dose reduced
- Medication of interest dose increased (please specify new dose):

***Symptom Severity Score**
Grade @@530633 according to NCI criteria

	1	2	3	4	5
Breathlessness	○	○	○	○	○
Anxiety	○	○	○	○	○

NCI Criteria:

Anxiety

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

Breathlessness

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

Symptomatic Adverse Event Assessment (24-72 hours)

Please list any symptomatic adverse events that occur (regardless of whether they are attributable to the medication of interest or not)

*Was there any toxicity?

- Yes
- No

NCI Criteria (summary list of expected toxicities) - click here to download a pdf version
NCI Criteria V 4.03 (full list for all other toxicities) - click here to download a pdf version

* Toxicities

Specify any adverse drug event and grade it according to NCI criteria.

	1	2	3	Un-gradable	No symptom
Dizziness					
Amnesia					
Blurred vision					
Slurred speech					
Ataxia					
Fall					

*

	1	2	3	4	5	Un-gradable	No symptom
Somnolence							
Confusion							
Agitation							
Other - please specify below							
Other - please specify below							
Other - please specify below							

If "Other", please specify here

(e.g , dyspepsia, personality change, psychosis, muscle weakness, acne etc)

If "Other", please specify here

(e.g , dyspepsia, personality change, psychosis, muscle weakness, acne etc)

If "Other", please specify here

(e.g , dyspepsia, personality change, psychosis, muscle weakness, acne etc)

*Which toxicity is the most troublesome?

Select:

*If there were toxicities, were any given a grade of 3 or more?

- Yes
- No
- Not applicable

***What is the intended treatment based on the assessment today?**

- No change to medication of interest / continue current dose
- Medication of interest ceased
- Medication of interest dose reduced
- Medication to treat a specific toxicity added (please specify below)
- Medication of interest dose increased (please specify new dose)

If a medication to treat a specific toxicity has been added, please specify here

Based on the assessment today has toxicity resolved? Yes No

Key questions derived from the Naranjo check list.
(only complete this section if any toxicity on the previous page is 3 or greater)

***1. Did the adverse reaction appear after the suspected drug was given?**

- Yes
- No
- Don't know

***2. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was given?**

- Yes
- No
- Don't know

***3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?**

- Yes
- No
- Don't know

***4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?**

- Yes
- No
- Don't know

***5. Was the adverse event confirmed by any objective evidence?**

- Yes
- No
- Don't know

Medication Cessation

(complete this page at any time the medication of interest is ceased)

Date of assessment (medication cessation)

(dd/mm/yyyy - please use date-picker)

Medication was ceased (related to indication of interest):

- ○ Symptom resolved (provide date on next page, question a)
- ○ Symptom continued unchanged
- ○ Symptom worsened - (please specify on next page, question b)

Medication was ceased (related to other reasons):

- ☐ Toxicity (Refer to unscheduled toxicity assessment pg 11, Q3)
- ☐ Patient unable to take medication due to swallowing difficulty
- ☐ Patient refused to take medication
- ☐ Other - please specify

What treatment did you subsequently initiate following cessation of the medication of interest?

a) Symptom resolved - date of resolution

(dd/mm/yyyy - please use date-picker)

b) Symptom worsened - Grade (NCI)

c) Patient unable to take medication please specify

***Were there any ad hoc toxicities?**

Yes No

Unscheduled Toxicity Assessment (a)

Please list any toxicities that occur at any time regardless of whether they are attributable to the medication of interest or not.

***Date of assessment (ad hoc a)**

(dd/mm/yyyy - please use date-picker)

Was there any toxicity

Yes No

Was there any benefit?

Yes No

*** Toxicities**

Specify any adverse drug event and grade it according to NCI criteria.

	1	2	3	Un-gradable	No symptom
Dizziness					
Amnesia					
Blurred vision					
Slurred speech					
Ataxia					
Fall					

*

	1	2	3	4	5	Un-gradable	No symptom
Somnolence							
Confusion							
Agitation							
Other - please specify below							
Other - please specify below							
Other - please specify below							

If "Other", please specify here

If "Other", please specify here

If "Other", please specify here

***Which toxicity is the most troublesome?**

Select:

***If there were toxicities, were any given a grade of 3 or more?**

Yes No Not applicable

What is the intended treatment based on the assessment today?

- No change to medication of interest / continue current dose
- Medication to treat a specific toxicity added (please specify below)
- Medication of interest ceased
- Medication of interest dose increased (please specify new dose)
- Medication of interest dose reduced

If a medication to treat a specific toxicity has been added, please specify here

Key questions derived from the Naranjo check list (a).
(only complete this section if any toxicity on the previous page is 3 or greater)

***1. Did the adverse reaction appear after the suspected drug was given?**

- Yes
- No
- Don't know

***2. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was given?**

- Yes
- No
- Don't know

***3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?**

- Yes
- No
- Don't know

***4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?**

- Yes
- No
- Don't know

***5. Was the adverse event confirmed by any objective evidence?**

- Yes
- No
- Don't know

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***Were there any further ad hoc toxicities?**

- Yes
- No

Unscheduled Toxicity Assessment (b)

Please list any toxicities that occur at any time regardless of whether they are attributable to the medication of interest or not.

***Date of assessment (ad hoc b)**

(dd/mm/yyyy - please use date-picker)

Was there any toxicity

○ Yes ○ No

Was there any benefit?

○ Yes ○ No

* Toxicities

Specify any adverse drug event and grade it according to NCI criteria.

	1	2	3	Un-gradable	No symptom
Dizziness	○	○	○	○	○
Amnesia	○	○	○	○	○
Blurred vision	○	○	○	○	○
Slurred speech	○	○	○	○	○
Ataxia	○	○	○	○	○
Fall	○	○	○	○	○

*

	1	2	3	4	5	Un-gradable	No symptom
Somnolence	○	○	○	○	○	○	○
Confusion	○	○	○	○	○	○	○
Agitation	○	○	○	○	○	○	○
Other - please specify below	○	○	○	○	○	○	○
Other - please specify below	○	○	○	○	○	○	○
Other - please specify below	○	○	○	○	○	○	○

If "Other", please specify here	
If "Other", please specify here	
If "Other", please specify here	

*Which toxicity is the most troublesome?

Select: ▾

*If there were toxicities, were any given a grade of 3 or more?

○ Yes ○ No ○ Not applicable

What is the intended treatment based on the assessment today?

○ No change to medication of interest / continue current dose

○ Medication to treat a specific toxicity added (please specify below)

○ Medication of interest ceased

○ Medication of interest dose increased (please specify new dose)

○ Medication of interest dose reduced

If a medication to treat a specific toxicity has been added, please specify here

Key questions derived from the Naranjo check list (b).
(only complete this section if any toxicity on the previous page is 3 or greater)

***1. Did the adverse reaction appear after the suspected drug was given?**

- Yes
- No
- Don't know

***2. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was given?**

- Yes
- No
- Don't know

***3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?**

- Yes
- No
- Don't know

***4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?**

- Yes
- No
- Don't know

***5. Was the adverse event confirmed by any objective evidence?**

- Yes
- No
- Don't know

***Were there any further ad hoc toxicities?**

- Yes
- No

Unscheduled Toxicity Assessment (c)

Please list any toxicities that occur at any time regardless of whether they are attributable to the medication of interest or not.

***Date of assessment (ad hoc c)**
(dd/mm/yyyy - please use date-picker)

Was there any toxicity

○ Yes ○ No

Was there any benefit?

○ Yes ○ No

*** Toxicities**

Specify any adverse drug event and grade it according to NCI criteria.

	1	2	3	Un-gradable	No symptom
Dizziness	○	○	○	○	○
Amnesia	○	○	○	○	○
Blurred vision	○	○	○	○	○
Slurred speech	○	○	○	○	○
Ataxia	○	○	○	○	○
Fall	○	○	○	○	○

*

	1	2	3	4	5	Un-gradable	No symptom
Somnolence	○	○	○	○	○	○	○
Confusion	○	○	○	○	○	○	○
Agitation	○	○	○	○	○	○	○
Other - please specify below	○	○	○	○	○	○	○
Other - please specify below	○	○	○	○	○	○	○
Other - please specify below	○	○	○	○	○	○	○

If "Other", please specify here	
If "Other", please specify here	
If "Other", please specify here	

***Which toxicity is the most troublesome?**

Select: ▾

***If there were toxicities, were any given a grade of 3 or more?**

○ Yes ○ No ○ Not applicable

What is the intended treatment based on the assessment today?

○ No change to medication of interest / continue current dose

○ Medication to treat a specific toxicity added (please specify below)

○ Medication of interest ceased

○ Medication of interest dose increased (please specify new dose)

○ Medication of interest dose reduced

If a medication to treat a specific toxicity has been added, please specify here

Key questions derived from the Naranjo check list (c).
(only complete this section if any toxicity on the previous page is 3 or greater)

***1. Did the adverse reaction appear after the suspected drug was given?**

- Yes
- No
- Don't know

***2. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was given?**

- Yes
- No
- Don't know

***3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?**

- Yes
- No
- Don't know

***4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?**

- Yes
- No
- Don't know

***5. Was the adverse event confirmed by any objective evidence?**

- Yes
- No
- Don't know

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*Date of death

Please use date-picker