#### \*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:

TO - 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)

age 2			
Demographics			
*Gender   Male   Female			
Age			
Years			
	Estimated	Unit	
Weight		Select: ▼	
Height	0	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 specif	6v)	
-			
What palliative care phase would	-		
<ul> <li>Stable phase</li> <li>Unstable phase</li> </ul>	e Oeteriorating	phase O Termin	al phase
Click here to download the Palliative Care	Phase definitions list	ted above.	
Laboratory tests¹ Only if available			
		Not	available
Serum albumin			
International normalised ratio (INF	R)		
Calculated creatinine clearance (C	CCr)*		
Blood sugar level (mmol/L or mg/o	JI X		

Page 3	
	rlson Comorbidity Index
Cond	Myocardial infarct
	Congestive cardiac failure
	Peripheral vascular disease
	Cerebrovascular disease
	Dementia
	Chronic pulmonary disease
	Connective tissue disease
	Ulcer disease
	Mild liver disease
	Diabetes
	Hemiplegia  M. Landan and M. L
	Moderate or severe renal disease
	Diabetes with end organ damage
	Any tumour
	Leukaemia
	Lymphoma
	Moderate or severe liver disease
	Metastatic solid tumour
	AIDS
* A	ustralian Modified Karnofsky Performance Scale (AKPS)²
$\circ$	100 = Normal; no complaints; no evidence of disease.
0	90 = Able to carry on normal activity; minor signs or symptoms.
	80 = Normal activity with effort; some signs of symptoms or disease.
$\circ$	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.
0	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

e 4	
DATA POINTS	
Date of Medication Commencement	
(Baseline)	
ld/mm/yyyy (please use date-picker)	
Day 1 Assessment	
4 hours after baseline - (dd/mm/yyyy - please use date-picker)	
Day 3 Assessment	
'2 hours after baseline (dd/mm/yyyy - please use date-picker)	
<b>##</b>	
Please take care to type your email address correctly otherwise the reminder  @@Email  Reminders will be sent to this email address 24 and 72 I  This second email is optional	
Cease <i>ad hoc</i> Toxicity reporting 1 week after	
baseline	
week after baseline (dd/mm/yyyy - please use date-picker)	
Email Reminder content	
	A
This email is to remind you to record Benzodiazepines data for	

5						
Baseline - Medication	Commencement					
low would you desc	cribe this episo	de of breat	hlessness in this patient	?		
<ul><li>1. A de novo episo</li></ul>	de of acute breath	lessness				
<ul><li>2. A progression of</li></ul>	f chronic breathles	sness				
<ul> <li>3. An acute exacer</li> </ul>	bation on a backg	round of chro	onic breathlessness			
Other:						
Symptom Severity Strade @@530633 according						
1	2 3 4 5	;				
Breathlessness	0 0 0 0					
Anxiety	0 0 0 0					
ICI Criteria:						
Anxiety			Breathlessness			
L: Mild symptoms; interve	ntion not indicated		1: Shortness of brea	ath with mo	derate exertion	
2: Moderate symptoms; lir		ADL	2: Shortness of brea	ath with mir	nimal exertion; li	miting instrume
				ath at roct li	miting colf care /	VDI
3: Severe symptoms; limiti	ng self care ADL; hos	spitalization n	ot indicated 3: Shortness of brea	atii at iCst ii	illitilig sell care F	ADL
3: Severe symptoms; limiti 1: Life-threatening; hospita		spitalization n	ot indicated 3: Shortness of brea 4: Life-threatening			
l: Life-threatening; hospita		spitalization n				
		spitalization n	4: Life-threatening			
l: Life-threatening; hospita i: Death	alization indicated		4: Life-threatening 5: Death			
e: Life-threatening; hospita i: Death	alization indicated		4: Life-threatening 5: Death	consequenc	es; urgent interv	ention indicated
e: Life-threatening; hospita i: Death	elization indicated		4: Life-threatening 5: Death  r breathlessness?  Dose over 24 hours	consequenc		ention indicated
e: Life-threatening; hospita i: Death Benzodiazepines the	elization indicated	ently on fo	4: Life-threatening 5: Death  r breathlessness?  Dose over 24 hours	Rout	es; urgent interv	ention indicated
a: Life-threatening; hospita i: Death Benzodiazepines the	elization indicated	ently on fo	4: Life-threatening 5: Death  r breathlessness?  Dose over 24 hours	Rout Oral	es; urgent interv  e of Adminis Injectable	tration Rectal
E: Life-threatening; hospitals: Death  Benzodiazepines the  Diazepam	elization indicated	ently on fo	4: Life-threatening 5: Death  r breathlessness?  Dose over 24 hours	Rout Oral	es; urgent interv	tration Rectal
e: Life-threatening; hospitals: Death  Benzodiazepines the  Diazepam  Clonazepam  Nitrazepam	elization indicated	ently on fo	4: Life-threatening 5: Death  r breathlessness?  Dose over 24 hours	Rout Oral	es; urgent interv	tration Rectal
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E: Life-threatening; hospitals: Death  Benzodiazepines the  Diazepam  Clonazepam  Nitrazepam  Flurazepam  Lorazepam  Midazolam	e patient is curr	ently on fo	4: Life-threatening 5: Death  r breathlessness?  Dose over 24 hours	Route	es; urgent interv	tration Rectal
E: Life-threatening; hospitals: Death  Benzodiazepines the  Diazepam  Clonazepam  Nitrazepam  Flurazepam  Lorazepam  Midazolam  Alprazolam  Other(s) (please spe	e patient is curr Tick	ently on fo	4: Life-threatening 5: Death  r breathlessness?  Dose over 24 hours	Route	e of Adminis Injectable	tration Rectal
E: Life-threatening; hospitals: Death  Benzodiazepines the  Diazepam  Clonazepam  Nitrazepam  Flurazepam  Lorazepam  Midazolam  Alprazolam	e patient is curr Tick	ently on fo	4: Life-threatening 5: Death  r breathlessness?  Dose over 24 hours	Route	e of Adminis Injectable	tration Rectal
E: Life-threatening; hospitals: Death  Benzodiazepines the  Diazepam  Clonazepam  Nitrazepam  Flurazepam  Lorazepam  Midazolam  Alprazolam  Other(s) (please spe	e patient is curre  Tick  cify below)	ently on fo	4: Life-threatening 5: Death  r breathlessness?  Dose over 24 hours	Route	e of Adminis Injectable	tration Rectal
E: Life-threatening; hospitals: Death  Benzodiazepines the  Diazepam  Clonazepam  Nitrazepam  Flurazepam  Lorazepam  Midazolam  Alprazolam  Other(s) (please spe	cify below)  lessness pleas  Drug N	ently on fo	4: Life-threatening 5: Death  r breathlessness?  Dose over 24 hours	Route	e of Adminis Injectable	tration Rectal
E: Life-threatening; hospitals: Death  Benzodiazepines the  Diazepam  Clonazepam  Nitrazepam  Flurazepam  Lorazepam  Midazolam  Alprazolam  Other(s) (please spe	cify below)  lessness pleas  Drug N	ently on fo	4: Life-threatening 5: Death  r breathlessness?  Dose over 24 hours	Route	e of Administ Injectable  of Administ Injectable Injectable	tration Rectal

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

Opioid

NoneOther:

Oxygen therapy

f Yes, please indicate wh	ıy.				
Anxiety					
Sleep					
Nausea					
Pain					
Other					
Panzadiazaninas the noti	iont io ourrontly toking	that are NOT for breathl		2	
enzodiazepines the pati	ent is currently taking	that are <u>NOT</u> for breathl  Dose over 24 hours		r e of Adminis	tration
	Tick all that apply		Oral	Injectable	Recta
Diazepam					
Clonazepam					
Nitrazepam					
Flurazepam					
Lorazepam					
Midazolam			0		
Alprazolam			0		
Other(s) (please specify b	elow)				
Other(s) <u>NOT</u> for breath	alosenose nloaso enoc	ify horo:			
Other(3) ItO1 breat	Drug Name	Dose over 24 hours	Route	of Administ	ration
	· ·		Oral	Injectable	Rectal
Other Benzodiazepine					
Other Benzodiazepine				0	
•					

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.

				Un-	No
	1	2	3	gradable	symptom
Dizziness	0		$\circ$		0
Amnesia			$\circ$		$\circ$
Blurred vision	0		$\circ$		
Slurred speech	0		$\circ$		
Ataxia	0				
Fall		0		0	0

	1	2	3	4	5	Un- gradable	No symptom
Somnolence							0
Confusion							0
Agitation	$\circ$	0				0	0
Other - please specify below	$\circ$						0
Other - please specify below	$\circ$				$\circ$		0
Other - please specify below	$\circ$						0

*Which	toxicity	is the	most	troub	lesome?	•
--------	----------	--------	------	-------	---------	---

which toxicity is the most troublesome:	
Select:   V	
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	t this time?
<ul><li>Yes (continue to next timepoint)</li></ul>	

- 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

1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	1
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

Dogo	7
Page	1

### 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	
<ul><li>No</li></ul>	
Medication changes	
No change to medication of interest/continue current dose	
Medication of interest ceased	
Madication of interest days radiused	
Medication of interest dose reduced	
<ul> <li>Medication of interest dose reduced</li> <li>Medication of interest dose increased (please specify new do</li> </ul>	se):
<ul> <li>Medication of interest dose increased (please specify new do</li> </ul>	se):
Medication of interest dose increased (please specify new do  Symptom Severity Score	se):
Medication of interest dose increased (please specify new do  Symptom Severity Score  Grade @@530633 according to NCI criteria	se):
Medication of interest dose increased (please specify new do  Symptom Severity Score  Grade @@530633 according to NCI criteria  1 2 3 4 5	se):
Medication of interest dose increased (please specify new dose Symptom Severity Score Grade @@530633 according to NCI criteria  1 2 3 4 5  Breathlessness	se):
Medication of interest dose increased (please specify new do  Symptom Severity Score  Grade @@530633 according to NCI criteria  1 2 3 4 5	se):
Medication of interest dose increased (please specify new dose Symptom Severity Score Grade @@530633 according to NCI criteria  1 2 3 4 5  Breathlessness	se):
Medication of interest dose increased (please specify new dose Symptom Severity Score Grade @@530633 according to NCI criteria  1 2 3 4 5  Breathlessness	se): Breathlessness
Medication of interest dose increased (please specify new do  Symptom Severity Score  Grade @@530633 according to NCI criteria  1 2 3 4 5  Breathlessness  Anxiety  NCI Criteria:	
Medication of interest dose increased (please specify new dose Symptom Severity Score Grade @@530633 according to NCI criteria  1 2 3 4 5  Breathlessness	Breathlessness
Medication of interest dose increased (please specify new do  Symptom Severity Score  Grade @@530633 according to NCI criteria  1 2 3 4 5  Breathlessness	Breathlessness 1: Shortness of breath with moderate exertion 2: Shortness of breath with minimal exertion; limiting instrumental ADI 3: Shortness of breath at rest limiting self care ADL
Medication of interest dose increased (please specify new dose increased)  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	Breathlessness  1: Shortness of breath with moderate exertion  2: Shortness of breath with minimal exertion; limiting instrumental ADI

No    Yes	Was there any toxicity	y?						
Contrain (aummary list of expected toxicities) - click here to download a pdf version  Cotietria v 4.83 (hit list for all other toxicities) - click here to download a pdf version  Toxicities  seelly any adverse drug event and grade it according to NCI criteria.  Un- No Dizziness  Un- No Dizziness  Amnesia  Blurred vision  Surred speech  Ataxia  I 2 3 4 5 gradable symptom  Somnolence  Confusion  Agitation  Other - please specify below  Other - please specify below  Other - please specify below  Other - please specify here  g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)	Yes							
Citteria V 4.03. (full list for all other toxicities) - click here to download a pdf version.  Toxicities  city any adverse drug event and grade it according to NCI criteria.  1 2 3 gradable symptom  Dizziness  Including the symptom of the sympto	No							
Toxicities  city any adverse drug event and grade it according to NCI criteria.  Un- No 1 2 3 gradable symptom  Dizziness  Amnesia  Burred vision  Surred speech  Ataxia  1 2 3 4 5 gradable symptom  Ataxia  Fall  Un- No  Dizziness  Amnesia  Burred vision  Surred speech  Ataxia  1 2 3 4 5 gradable symptom  Somnolence  Confusion  Qither - please specify below  Dither - please specify below  Tother", please specify below  Tother", please specify here  g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  Tother", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  Tother", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  Tother", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  Tother", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  Which toxicity is the most troublesome?  Select: T	I Criteria (summary list of e	xpected tox	icities) - d	click here to	download a	pdf version		
1 2 3 gradable symptom								
Un- No 1 2 3 gradable symptom  Dizziness  Annesia Blurred vision Slurred speech Ataxia								
Dizziness Amnesia Blurred vision Slurred speech Ataxia 1 2 3 4 5 gradable symptom Somnolence Confusion Agitation Other - please specify below Other - please specify here 1.g., dyspepsia, personality change, psychosis, muscle weakness, acne etc) Other - please specify here 2.g., dyspepsia, personality change, psychosis, muscle weakness, acne etc) Other - please specify here 2.g., dyspepsia, personality change, psychosis, muscle weakness, acne etc) Other - please specify here 3.g., dyspepsia, personality change, psychosis, muscle weakness, acne etc) Other - please specify here 3.g., dyspepsia, personality change, psychosis, muscle weakness, acne etc) Other - please specify here 3.g., dyspepsia, personality change, psychosis, muscle weakness, acne etc) Other - please specify here 3.g., dyspepsia, personality change, psychosis, muscle weakness, acne etc) Other - please specify here 3.g., dyspepsia, personality change, psychosis, muscle weakness, acne etc) Other - please specify here 3.g., dyspepsia, personality change, psychosis, muscle weakness, acne etc) Other - please specify here 3.g., dyspepsia, personality change, psychosis, muscle weakness, acne etc) Other - please specify here 3.g., dyspepsia, personality change, psychosis, muscle weakness, acne etc) Other - please specify here 3.g., dyspepsia, personality change, psychosis, muscle weakness, acne etc) Other - please specify here 3.g., dyspepsia, personality change, psychosis, muscle weakness, acne etc) Other - please specify here 3.g., dyspepsia, personality change, psychosis, muscle weakness, acne etc) Other - please specify here 3.g., dyspepsia, personality change, psychosis, muscle weakness, acne etc) Other - please specify here 3.g., dyspepsia, personality change, psychosis, muscle weakness, acne etc)	ecity any adverse drug event and	grade it acco	rding to NC	oriteria.	Un-	No		
Amnesia Blurred vision Slurred speech Ataxia 1 2 3 4 5 gradable symptom Somnolence Confusion Agitation Other - please specify below Other - please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other other oth	1		2	3	gradable	symptom		
Blurred vision Slurred speech Ataxia Fall  1 2 3 4 5 gradable symptom Somnolence Confusion Agitation Other - please specify below Other - please specify bere g. dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here g. dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here g. dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other blease specify here g. dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other blease specify here g. dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other blease specify here g. dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other blease specify here g. dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other blease specify here g. dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other blease specify here g. dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other blease specify here g. dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other blease specify here g. dyspepsia, personality change, psychosis, muscle weakness, acne etc)	Dizziness		0		0			
Slurred speech  Ataxia  Tall  1 2 3 4 5 gradable symptom  Somnolence  Confusion  Agitation  Other - please specify below  Tother", please specify here  g. dyspepsia, personality change, psychosis, muscle weakness, acne etc)  Tother", please specify here  g. dyspepsia, personality change, psychosis, muscle weakness, acne etc)  Tother", please specify here  g. dyspepsia, personality change, psychosis, muscle weakness, acne etc)  Tother blease specify here  g. dyspepsia, personality change, psychosis, muscle weakness, acne etc)  Which toxicity is the most troublesome?  Select:  There were toxicities, were any given a grade of 3 or more?  Yes	Amnesia		0		$\circ$			
Ataxia  Fall  1 2 3 4 5 gradable symptom  Somnolence  Confusion  Agitation  Other - please specify below  Other - please specify here  g.g. dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here  g.g. dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here  g.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	Blurred vision				$\circ$			
Fall  1 2 3 4 5 gradable symptom  Somnolence  Confusion  Agitation  Other - please specify below  Other - please specify here  g. dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here  g. dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here  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	Slurred speech				$\circ$			
Somnolence  Confusion  Agitation  Other - please specify below  T'Other", please specify here  ag , dyspepsia, personality change, psychosis, muscle weakness, acne etc)  T'Other", please specify here  ag , dyspepsia, personality change, psychosis, muscle weakness, acne etc)  Which toxicity is the most troublesome?  Select:  There were toxicities, were any given a grade of 3 or more?  Yes	Ataxia				$\circ$			
Somnolence Confusion Agitation Other - please specify below Other - please specify below Other - please specify below Other - please specify here e.g., dyspepsia, personality change, psychosis, muscle weakness, acne etc) "Other", please specify here e.g., dyspepsia, personality change, psychosis, muscle weakness, acne etc) "Other", please specify here e.g., dyspepsia, personality change, psychosis, muscle weakness, acne etc) "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	Fall		0			0		
Somnolence Confusion Agitation Other - please specify below Other - please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here  g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  Which toxicity is the most troublesome? Select:  T there were toxicities, were any given a grade of 3 or more?  Yes								
Somnolence Confusion Agitation Other - please specify below Other", please specify here .g., dyspepsia, personality change, psychosis, muscle weakness, acne etc) "Other", please specify here .g., dyspepsia, personality change, psychosis, muscle weakness, acne etc) "Other", please specify here .g., dyspepsia, personality change, psychosis, muscle weakness, acne etc)  Which toxicity is the most troublesome? Select:  f there were toxicities, were any given a grade of 3 or more?  Yes								
Confusion  Agitation  Other - please specify below  Other - please specify below  Other - please specify below  "Other", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  Which toxicity is the most troublesome?  Gelect:  I there were toxicities, were any given a grade of 3 or more?  Yes			1	2	3	4	5	No symptom
Agitation Other - please specify below Other - please specify below Other - please specify below  "Other", please specify here .g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here .g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here .g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  Which toxicity is the most troublesome? Select:  There were toxicities, were any given a grade of 3 or more?  Yes	Somnolence					$\circ$		
Other - please specify below Other - please specify below Other - please specify below  "Other", please specify here .g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here .g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here .g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  Which toxicity is the most troublesome? Select:  There were toxicities, were any given a grade of 3 or more?  Yes	Confusion					$\circ$		
Other - please specify below  "Other", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  Which toxicity is the most troublesome?  Select:  There were toxicities, were any given a grade of 3 or more?  Yes	Agitation		$\circ$			0		
Other - please specify below  "Other", please specify here .g , dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here .g , dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here .g , dyspepsia, personality change, psychosis, muscle weakness, acne etc)  Which toxicity is the most troublesome? Select:  There were toxicities, were any given a grade of 3 or more?  Yes	Other - please specify l	below	$\circ$	$\circ$		0		0
"Other", please specify here .g , dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here .g , dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here .g , dyspepsia, personality change, psychosis, muscle weakness, acne etc)  Which toxicity is the most troublesome?  Select:  There were toxicities, were any given a grade of 3 or more?  Yes	Other - please specify l	below	$\circ$	$\circ$		0		0
"Other", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  "Other", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  Which toxicity is the most troublesome?  Select:  There were toxicities, were any given a grade of 3 or more?  Yes	Other - please specify l	below	0	0	0	0		0
e.g , dyspepsia, personality change, psychosis, muscle weakness, acne etc)  i "Other", please specify here e.g , dyspepsia, personality change, psychosis, muscle weakness, acne etc)  i "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	"Other", please spec	ify here						
"Other", please specify here g, dyspepsia, personality change, psychosis, muscle weakness, acne etc)  Which toxicity is the most troublesome?  Select:  f there were toxicities, were any given a grade of 3 or more?  Yes	• •	-	nosis, mus	scle weakne	ess, acne etc)			
## Other", please specify here  ## of "Other", please specify here  ## deg , dyspepsia, personality change, psychosis, muscle weakness, acne etc)  ## Which toxicity is the most troublesome?  ## Select:  ## of there were toxicities, were any given a grade of 3 or more?  ## Yes	"Other", please spec	ify here						
Which toxicity is the most troublesome? Select:  f there were toxicities, were any given a grade of 3 or more?  Yes	.g , dyspepsia, personality ch	nange, psych	nosis, mus	scle weakne	ess, acne etc)			
Which toxicity is the most troublesome?  Select:  If there were toxicities, were any given a grade of 3 or more?  Yes	"Other", please spec	ify here						
f there were toxicities, were any given a grade of 3 or more?  Yes	.g , dyspepsia, personality ch	nange, psych	nosis, mus	scle weakne	ess, acne etc)			
If there were toxicities, were any given a grade of 3 or more?  Yes	Which toxicity is the r	most troເ	ıblesor	ne?				
<ul><li>Yes</li></ul>	Select: ▼							
	f there were toxicities	s, were a	ny give	n a grad	e of 3 or n	nore?		
No	Yes							
	No							

Page 11
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?
<ul><li>Yes</li></ul>
<ul><li>No</li></ul>
Don't know
*2. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was given?
<ul><li>Yes</li></ul>
<ul><li>No</li></ul>
<ul><li>Don't know</li></ul>
*3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?
<ul><li>Yes</li></ul>
<ul><li>No</li></ul>
<ul><li>Don't know</li></ul>
*4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?
<ul><li>Yes</li></ul>
<ul><li>No</li></ul>
<ul> <li>Don't know</li> </ul>
*5. Was the adverse event confirmed by any objective evidence?
<ul><li>Yes</li></ul>
<ul><li>No</li></ul>
<ul> <li>Don't know</li> </ul>

D	4	2
⊦ade	- 1	2

### 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	
O No	
Medication changes	
No change to medication of interest/continue current dose	
<ul> <li>Medication of interest ceased (go to page 17)</li> </ul>	
Medication of interest dose reduced	
Medication of interest dose reduced  Medication of interest dose increased (please specify new do	co):
<ul> <li>Medication of interest dose reduced</li> <li>Medication of interest dose increased (please specify new do</li> </ul>	se):
<ul> <li>Medication of interest dose increased (please specify new do</li> </ul>	se):
Medication of interest dose increased (please specify new do     Symptom Severity Score	se):
Medication of interest dose increased (please specify new do     Symptom Severity Score     Grade @@530633 according to NCI criteria	se):
Medication of interest dose increased (please specify new do  Symptom Severity Score  Grade @@530633 according to NCI criteria  1 2 3 4 5	se):
Medication of interest dose increased (please specify new do     Symptom Severity Score     Grade @@530633 according to NCI criteria	se):
Medication of interest dose increased (please specify new do  Symptom Severity Score  Grade @@530633 according to NCI criteria  1 2 3 4 5	se):
Medication of interest dose increased (please specify new do  Symptom Severity Score  Grade @@530633 according to NCI criteria  1 2 3 4 5  Breathlessness	se):
Medication of interest dose increased (please specify new do  Symptom Severity Score  Grade @@530633 according to NCI criteria  1 2 3 4 5  Breathlessness  Anxiety  NCI Criteria:	se): Breathlessness
Medication of interest dose increased (please specify new do  Symptom Severity Score  Grade @@530633 according to NCI criteria  1 2 3 4 5  Breathlessness	
Medication of interest dose increased (please specify new dose increased)  Symptom Severity Score  Grade @@530633 according to NCI criteria  1 2 3 4 5  Breathlessness	Breathlessness 1: Shortness of breath with moderate exertion 2: Shortness of breath with minimal exertion; limiting instrumental AD
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  L: Mild symptoms; intervention not indicated 2: Moderate symptoms; limiting instrumental ADL 3: Severe symptoms; limiting self care ADL; hospitalization not indicated	Breathlessness 1: Shortness of breath with moderate exertion 2: Shortness of breath with minimal exertion; limiting instrumental AD 3: Shortness of breath at rest limiting self care ADL
Medication of interest dose increased (please specify new do  Symptom Severity Score  Grade @@530633 according to NCI criteria  1 2 3 4 5  Breathlessness  Anxiety  MCI Criteria:  Anxiety  L: Mild symptoms; intervention not indicated  2: Moderate symptoms; limiting instrumental ADL	Breathlessness 1: Shortness of breath with moderate exertion 2: Shortness of breath with minimal exertion; limiting instrumental AD

Was there any toxicity	y?							
Yes								
No								
Cl Criteria (summary list of e	xpected tox	icities) - (	click here to	o download a	pdf version			
CI Criteria V 4.03 (full list for all								
Toxicities								
pecify any adverse drug event and	grade it accor	ding to NC	CI criteria.	Un-	No			
1		2	3	gradable	symptom			
Dizziness		0	0					
Amnesia		0		$\circ$				
Blurred vision								
Slurred speech								
Ataxia		0	0					
Fall		0	0					
		1	2	3	4	5	Un- gradable	No symptom
Somnolence								0
Confusion			0					
Agitation								
Other - please specify l	below							0
Other - please specify l	below	$\bigcirc$	$\circ$					0
Other - please specify l	below			0	0		0	0
"Other", please spec	ifv here							
g , dyspepsia, personality ch	-	osis, mu	scle weakne	ess, acne etc)				
"Other", please spec	ify here							
g , dyspepsia, personality ch	nange, psych	iosis, mu	scle weakne	ess, acne etc)				
"Other", please spec	ify here							
.g , dyspepsia, personality ch	nange, psych	osis, mu	scle weakne	ess, acne etc)				
Which toxicity is the r	most trou	blesor	ne?					
Select: ▼								
f there were toxicities	s, were ar	ny give	n a grad	e of 3 or n	nore?			
Yes								
○ No								
0 110								

Page 15	
*What is the intended treatment based on the assessment today?	
<ul> <li>No change to medication of interest / continue current dose</li> </ul>	
<ul> <li>Medication of interest ceased</li> </ul>	
<ul> <li>Medication of interest dose reduced</li> </ul>	
<ul> <li>Medication to treat a specific toxicity added (please specify below)</li> </ul>	
<ul> <li>Medication of interest dose increased (please specify new dose)</li> </ul>	
If a medication to treat a specific toxicity has been added, please specify here	
Based on the assessment today has toxicity resolved?   Yes No	

Page 16
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?
<ul><li>Yes</li></ul>
<ul><li>No</li></ul>
<ul> <li>Don't know</li> </ul>
*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
<ul><li>Don't know</li></ul>

Page 17
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):
<ul> <li>Symptom resolved (provide date on next page, question a)</li> </ul>
<ul> <li>Symptom continued unchanged</li> </ul>
<ul> <li>Symptom worsened - (please specify on next page, question b)</li> </ul>
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?

Page 18			
a) Symptom resolved - d (dd/mm/yyyy - please use date-pid			
b) Symptom worsened -	Grade (NCI)		
c) Patient unable to take	medication please specify		
*Were there any ad hoc t	oxicities?		
○ Yes ○ No			

as there any toxicity  Yes No as there any benefit?  Yes No  Toxicities  It 2 3 gradable symptom  Dizziness  It 2 3 4 5 gradable symptom  Somnolence	Was there any toxicity  Ves No  Vas there any benefit?  Ves No  Toxicities  and grade is according to NCI criteria.  Un No Dizziness  Arnnesia  Blurred vision  Slurred speech  Ataxia  Fall  1 2 3 4 5 gradable symptom  Somnolence  Confusion  Agitation  Other - please specify below  Other - please specify below  Ofter - please specify below  Ofter - 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?  Ves No No Not applicable  What is the intended treatment based on the assessment today?  No change to medication of interest / continue current dose	ease list any toxicities that occur	at any time re	gardless of v	whether they are	e attributable i	to the medication of	interest or not		
as there any toxicity  Yes No as there any benefit?  Yes No  Toxicities  It 2 3 gradable symptom  Dizziness  It 2 3 4 5 gradable symptom  Somnolence	As there any toxicity  Yes No  As there any benefit?  Yes No  Toxicities  at a 2 3 gradable symptom  Dizziness  Amnesia	Date of assessment (	ad hoc a	)						
as there any benefit?  Yes No  Toxicities  It 2 3 gradable symptom  Dizziness	As there any benefit?  Yes No  Toxicities  Ledity any adverse drug event and grade it according to NCI criteria.  1 2 3 gradable symptom  Dizziness  Amnesia	•	-	,						
as there any benefit?  Yes No  No  No  No  gradable symptom  Sizziness  In 2 3 gradable symptom  Sizured vision  In 2 3 4 5 gradable symptom  Sizured speech  In 2 3 4 5 gradable symptom  Sizured speech  In 2 3 4 5 gradable symptom  Sizured speech  In 2 3 4 5 gradable symptom  Sizured speech  In 3 4 5 gradable symptom  Sizured speech  In 4 5 gradable symptom  Sizured speech  In 5 gradable symptom  Sizured speech  In 6 gradable symptom  Sizured speech  In 7 gradable symptom  Sizured speech  In 8 gradable symptom  Sizured speech  In 9 gradable symptom  In 1 2 3 4 5 gradable symptom  Sizured speech  In 9 gradable symptom  In 1 2 3 4 5 gradable sympto	As there any benefit?  Yes No  Toxicities  ecrity any adverse drug event and grade it according to NCI criteria.  I 2 3 gradable symptom  Dizziness  Annesia  Burred vision  Siurred speech  Ataxia  All Vin No  gradable symptom  Somnolence  Confusion  Agitation  Other - please specify below  Other - please specify below  Other - please specify here  I **Other**, please specify he	as there any toxicity	1							
Toxicities  Softy any adverse drug event and grade it according to NCI criteria.  1 2 3 gradable symptom  Dizziness  Incomplete the symptom of the symptom o	Toxicities  actify any adverse drug event and grade it according to NCI oriteria.    1	○ Yes ○ No								
Toxicities  Softy any adverse drug event and grade it according to NCI criteria.  1 2 3 gradable symptom  Dizziness  Incomplete the symptom of the symptom o	Toxicities    Comparison of the Comparison of th	las there any henefit	2							
terify any adverse drug event and grade it according to NCI criteria.  1 2 3 gradable symptom  Dizziness  In	the control of the control of the continue current and grade it according to NCI criteria.  I 2 3 gradable symptom  Dizziness  Annesia  Blurred vision  Slurred speech  Ataxia  I 2 3 4 5 gradable symptom  Somnolence  Confusion  Agitation  Other - please specify below  Other - please specify below  Other - please specify below  Other - please specify here  f "Other", please specify here  Mich toxicity is the most troublesome?  Select:  Ves No Not applicable  What is the intended treatment based on the assessment today?  No change to medication of interest / continue current dose	_	•							
Un- No gradable symptom  Dizziness  Inmesia  Idurred vision  Idurred speech  I	Un- No gradable symptom  Dizziness Armesia Blurred vision Blurred vision Ataxia  1 2 3 4 5 gradable symptom  Ataxia  1 2 3 4 5 gradable symptom  Confusion Agitation Confusion C									
Dizziness Jurned vision  Siturred speech  Ataxia  1 2 3 4 5 gradable symptom  Somnolence  Confusion  Other - please specify below  Other - please specify below  Therefore the specify below	Dizziness Amnesia Blurred vision Situred speech Ataxia Fall  1 2 3 4 5 gradable symptom Somnolence Confusion Agitation Other - please specify below Other - please specify below Other - please specify below Other - please specify here f "Other", please specify here Mhich toxicity is the most troublesome? Select:  f 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)	ecify any adverse drug event an	d grade it acco	ording to NC	I criteria.	Un-	No			
Amnesia  Blurred vision  Blurred speech  Ataxia  The state of the stat	Amnesia Silurred vision Silurred speech Ataxia  Tall  1 2 3 4 5 gradable symptom Somnolence Confusion Agitation Other - please specify below Other - please specify here  If "Other", please specify here  If "Other 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 specific specific specific toxicity added (please specific specific specific toxicity added (please specific		1	2	3	gradable	symptom			
Sturred vision  staxia  all  1 2 3 4 5 gradable symptom  somnolence  confusion  digitation  other - please specify below	Blurred vision  Solured speech  Ataxia  1 2 3 4 5 gradable symptom  Somnolence  Confusion  Agitation  Other - please specify below  Other - please specify here  If "Other", please specify here  If "Other which toxicity is the most troublesome?  Select:  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 specific toxicity added (	Dizziness	$\circ$			0				
Sturred speech  staxia  all  1 2 3 4 5 gradable symptom  Somnolence  Confusion  Other - please specify below	Sturred speech Ataxia  Tall  The specific toxicity is the most troublesome?  Select:  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 specific dose)	Amnesia (		$\circ$		0				
staxia  iall  1 2 3 4 5 gradable symptom  comnolence  confusion  gitation  Other - please specify below  Other - please specify here  Tother", please specify here	Ataxia    Fall	3lurred vision		$\circ$		0				
In the specify below	The first street of the continue current of the continue current of the content o	Slurred speech				$\circ$				
Un- No 1 2 3 4 5 gradable symptom  Somnolence Confusion Other - please specify below Other - please specify here	Somnolence Confusion Agitation Other - please specify below Other - please specify here If "Other", please specify here If "Other 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)	Ataxia				0	0			
1 2 3 4 5 gradable symptom commolence confusion confusio	Somnolence Confusion Agitation Other - please specify below Other - please specify below Other - please specify below If "Other", please specify here If "Other toxicity is the most troublesome? Select: v  Which toxicity is the most troublesome? Select: v  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 specific dose)	Fall	$\supset$			$\circ$	0			
ogitation Other - please specify below Other", please specify here	Agitation Other - please specify below Other - please specify here  f "Other", please specify here f "Other", please specify here  Which toxicity is the most troublesome? Select:  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)	Somnolence		•					_	
ogitation Other - please specify below Other", please specify here	Agitation Other - please specify below Off "Other", please specify here If there were toxicities, were any given a grade of 3 or more?  Yes No Not applicable  No change to medication of interest / continue current dose  Medication to treat a specific toxicity added (please specify here)  Medication to treat a specific toxicity added (please specify here)  Medication to treat a specific toxicity added (please specify here)									
Other - please specify below Other", please specify here	Other - please specify below  If "Other", please specify here If "Other									
Other - please specify below  "Other", please specify here "Other", please specify here	Other - please specify below  f "Other", please specify here f "Other", please specify here f "Other", please specify here  Which toxicity is the most troublesome? Select:  f 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 specific toxicity added (please specific toxicity added)	Other - please specify	below			0			0	0
"Other", please specify here "Other", please specify here	f "Other", please specify here f "Other", please specify here f "Other", please specify here  Which toxicity is the most troublesome? Select:  f 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 specific dose)	Other - please specify	below			0			0	0
"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 specific dose)	Other - please specify	below	0	0	0	0	0	0	0
	Mhich toxicity is the most troublesome?  Select:  f 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 specific toxicity added (please specific toxicity added)	If "Other", please spec	ify here							]
"Other" places energify 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 spe	If "Other", please spec	ify here							
Other, please specify here	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 specific toxicity added (please specific toxicity added)	If "Other", please spec	ify here							
MIICH LUXICHV 13 HIE HIUSL HUUDIESUHE!	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 specific toxicity added)									
	Yes No Not applicable  No change to medication of interest / continue current dose  No change to medication of interest / continue current below)  No change to medication of interest / continue current below)	f there were toxicitie	s wara s	ny aivo	n a grade	of 3 or n	nore?			
Select:	/hat 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 specific tox				u graue	J. J J. II				
there were toxicities, were any given a grade of 3 or more?	No change to medication of interest / continue current dose  Medication to treat a specific toxicity added (please specific to									
there were toxicities, were any given a grade of 3 or more?  Yes No Not applicable	dose below)						•			
there were toxicities, were any given a grade of 3 or more?  Yes No Not applicable  hat is the intended treatment based on the assessment today?	<ul> <li>Medication of interest ceased</li> <li>Medication of interest dose increased (please specify remainder of interest dose)</li> </ul>		ation of int	erest / co	ntinue curre	ent		treat a sp	ecific toxicity	added (please s <sub>l</sub>
there were toxicities, were any given a grade of 3 or more?  Yes No Not applicable  hat is the intended treatment based on the assessment today?  No change to medication of interest / continue current  Medication to treat a specific toxicity added (please s							Medication o	f interest de	ose increased	I (please specify

Page 20
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?
<ul><li>Yes</li></ul>
<ul><li>No</li></ul>
<ul> <li>Don't know</li> </ul>
*2. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was given?
<ul><li>Yes</li></ul>
No
Don't know
*3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?
<ul><li>Yes</li></ul>
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

Page 21				
*Were there	any further ad hoc toxicitie	s?		
○ Yes				
○ No				

	•			• • • • • • • • • • • • • • • • • •	to the medication o	i interest or not	•	
Date of assessme	-	b)						
d/mm/yyyy - please use	e date-picker)							
as there any tox	icity							
as there any ber	nefit?							
Yes ○ No								
Toxicities								
ecify any adverse drug eve	ent and grade it ac	cording to NC	I criteria.					
	1	2	3	Un- gradable	No symptom			
Dizziness				$\circ$				
Amnesia	0	$\bigcirc$						
Blurred vision	0	$\bigcirc$						
Slurred speech		$\bigcirc$	$\circ$					
Ataxia		$\bigcirc$	$\circ$	$\circ$				
Fall								
							Un-	No
		1	2	3	4	5	gradable	symptom
Somnolence		$\circ$	0				0	
Confusion					$\circ$			
Agitation					$\circ$			
Other - please spe	cify below	$\circ$	0					
Other - please spe	cify below	$\circ$	0					
Other - please spe	cify below	0	0	0	0	0	0	
f "Other", please s	specify here							]
f "Other", please s								
f "Other", please s								
			_					
Which toxicity is Select:	tne most tro	oubleson	ne?					
f there were toxic			n a grad	e of 3 or n	nore?			
○ Yes ○ No ○	Not applical	ble						
hat is the intend	ed treatmer	nt based	on the a	ssessmen	t today?			
No change to m	edication of in	terest / co	ntinue curi	rent	Medication to	o treat a sp	ecific toxicity	added (please spe
<ul><li>Medication of in</li></ul>	terest ceased				,	of interest de	ose increased	l (please specify ne
				_				

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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
<ul><li>No</li></ul>
<ul> <li>Don't know</li> </ul>
*2. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was given?
<ul><li>Yes</li></ul>
No
Don't know
*3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?
<ul><li>Yes</li></ul>
<ul><li>No</li></ul>
<ul> <li>Don't know</li> </ul>
*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
<ul> <li>Don't know</li> </ul>

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*We	re there any further ad hoc toxicities?
0	Yes
0	No

Date of assessment (ad hoc c)  Idimm/yyyy- please use date-picker)  Was there any toxicity  Yes No  Was there any benefit?  Yes No  Toxicities  1 2 3 gradable symptom  Dizziness  Amnesia  Blurred vision  Slurred speech  Ataxia  1 2 3 4 5 gradable symptom  Somnolence  Confusion  Agitation  Other - please specify below  Other - please specify below  If "Other", please specify bere  If "Other", please specify here  Which toxicity is the most troublesome?	lease list any toxicities that occur	sessmen at any time re		whether they are	e attributable i	o the medication of	interest or not		
As there any toxicity  Yes No  Vas there any benefit?  Yes No  Toxicities  ecity any adverse drug event and grade it according to NCI criteria.  Un- No gradable symptom  Dizziness			_	-	,0000004				
As there any benefit?  Yes No  Toxicities  1 2 3 gradable symptom  Dizziness  Amnesia	·		'/						
As there any benefit?  Yes No  Toxicities  1 2 3 gradable symptom  Dizziness  Amnesia  Blurred vision  I 2 3 4 5 gradable symptom  Slurred speech  Ataxia  I 2 3 4 5 gradable symptom  Confusion  Ataxia  I 2 3 4 5 gradable symptom  Dizziness  Attaxia  I 2 3 4 5 gradable symptom  Confusion  I 2 3 4 5 gradable symptom  Confusion  I 2 3 4 5 gradable symptom  Confusion  Agitation  Confusion  Agitation  I I I I I I I I I I I I I I I I I I I	las there any toxicity	,							
Tas there any benefit?  Yes No  Toxicities  edity any adverse drug event and grade it according to Not criteria.  Un No gradable symptom  Dizziness									
Toxicities  Dizziness  Annesia  I  I  I  I  I  I  I  I  I  I  I  I  I		_							
Toxicities exify any adverse drug event and grade it according to NCI criteria.  1 2 3 gradable symptom Dizziness Amnesia Blurred vision Slurred speech Ataxia 1 2 3 4 5 gradable symptom Somnolence Confusion Agitation Dither - please specify below Dither - please specify below Tother", please specify here  f "Other", please specify here	-	?							
Lecify any adverse drug event and grade it according to NCI criteria.  1 2 3 gradable symptom  Dizziness  Amnesia Blurred vision Slurred speech Ataxia 1 2 3 4 5 gradable symptom  Somnolence Confusion Agitation Other - please specify below Other - please specify below  The Tother", please specify here  f "Other", please specify here	Yes No								
Un- No Dizziness Amnesia Blurred vision Slurred speech Ataxia  1 2 3 4 5 gradable symptom Somnolence Confusion Agitation Other - please specify below Other - please specify below Other - please specify here f "Other", please specify here f "Other", please specify here f "Other", please specify here									
1 2 3 gradable symptom  Dizziness Amnesia Blurred vision Slurred speech Ataxia I 2 3 4 5 gradable symptom  Somnolence Confusion Agitation Other - please specify below Other - please specify here If "Other", please specify here	ecify any adverse drug event and	d grade it acc	ording to NC	I criteria.	Un-	No			
Amnesia Blurred vision Slurred speech Ataxia  1 2 3 4 5 gradable symptom Somnolence Confusion Agitation Other - please specify below Other - please specify here f "Other", please specify here f "Other", please specify here f "Other", please specify here	1	1	2	3	_				
Blurred vision Slurred speech Ataxia Fall  1 2 3 4 5 gradable symptom Somnolence Confusion Agitation Other - please specify below Other - please specify here If "Other", please specify here	Dizziness				0				
Slurred speech Ataxia  Fall  1 2 3 4 5 gradable symptom  Somnolence Confusion Agitation Other - please specify below Other - please specify here If "Other", please specify here If "Other", please specify here If "Other", please specify here	Amnesia				0				
Ataxia Fall  1 2 3 4 5 gradable symptom  Somnolence Confusion Agitation Other - please specify below Other - please specify here If "Other", please specify here	Blurred vision				0				
Fall  1 2 3 4 5 gradable symptom  Somnolence Confusion Agitation Other - please specify below Other - please specify here If "Other", please specify here	Slurred speech				0				
Somnolence Confusion Agitation Other - please specify below Other - please specify here If "Other", please specify here If "Other", please specify here	Ataxia				0				
Somnolence Confusion Agitation Other - please specify below Other - please specify here If "Other", please specify here If "Other", please specify here	Fall								
Somnolence Confusion Agitation Other - please specify below Other - please specify here If "Other", please specify here If "Other", please specify here If "Other", please specify here									
Somnolence Confusion Agitation Other - please specify below Other - please specify below Other - please specify below Other - please specify here f "Other", please specify here f "Other", please specify here f "Other", please specify here									
Somnolence Confusion Agitation Other - please specify below of "Other", please specify here of "Other", please specify here of "Other", please specify here									
Confusion Agitation Other - please specify below Other - please specify below Other - please specify below of "Other", please specify here If "Other", please specify here If "Other", please specify here If "Other", please specify here	_		1	2	3	4	5	gradable	symptom
Agitation  Other - please specify below  Other - please specify below  Other - please specify below  of "Other", please specify here  f "Other", please specify here  f "Other", please specify here									
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Other - please specify below  If "Other", please specify here  If "Other", please specify here  If "Other", please specify here									
If "Other", please specify here  If "Other", please specify here  If "Other", please specify here									
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If "Other", please specify here	If "Other", please spec	ify here							
	If "Other", please spec	ify here							
	f "Other", please spec	ify here							
		-						<u> </u>	J
	Select:								
Select: v	f there were toxicities	s, were a	ny give	n a grade	of 3 or n	nore?			
	Yes No No	ot applicab	le						
f there were toxicities, were any given a grade of 3 or more?	/hat is the intended t	reatmen	t hased	on the as	sessmen	t today?			
f there were toxicities, were any given a grade of 3 or more?  Yes No Not applicable						-	treat a sp	ecific toxicity a	added (please s
f there were toxicities, were any given a grade of 3 or more?  Yes No Not applicable  /hat is the intended treatment based on the assessment today?	dose					below)	a. a op	_ se toxioity (	(p.0000 0
f 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  Medication to treat a specific toxicity added (please specific toxicity added)	Medication of interest ceased					Medication of	f interest de	ose increased	l (please specify
f there were toxicities, were any given a grade of 3 or more?  Yes No Not applicable  Yhat 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 specific toxicity added)	<ul> <li>Medication of interes</li> </ul>	st ceased				Wicaloution of	intoroot at		(1 )

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

