Participant ID	

Initials of person entering data	

Staff email	

CONFIDENTIAL CASE REPORT FORM

<u>NSAIDS</u> - Mesothelioma Night Sweats

Rapid Program Series No: 44

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)

Baseline (T_0)	
Date of Assessment	DD/MM/YYYY
Time of Assessment (24 hr time)	HH:MM

Demographics

Gender ○ Male ○ Female ○ Other

Age (yrs)		**Weight (kg)**		**Height (cm)**	

Yes	**No**	**Is a diagnosis of Mesothelioma confirmed?**

Tick ✓	**Palliative Care Phase**
	1. Stable Phase: The person's symptoms are adequately controlled by established management. Further interventions to maintain symptom control and quality of life have been planned.
	2. Unstable Phase: The person experiences the development of a new problem or a rapid increase in the severity of existing problems either of which requires an urgent change in management or emergency treatment.
	3. Deteriorating Phase: The person experiences a gradual worsening of existing symptoms or the development of new but expected problems. These require the application of specific plans of care and regular review but not urgent or emergency treatment.
	4. Terminal Care Phase: Death is likely in a matter of days and no acute intervention is planned or required.

Tick ✓	**Australian Modified Karnofsky Performance Scale (AKPS)**
	100 - Normal; no complaints; no evidence of disease
	90 - Able to carry on normal activity; minor sign of symptoms of disease
	80 - Normal activity with effort; some signs or symptoms of disease
	70 - Cares for self; unable to carry on normal activity or to do active work
	60 - Requires occasional assistance but is able to care for most needs
	50 - Requires considerable assistance and frequent medical care
	40 - In bed more than 50% of the time
	30 - Almost completely bedfast
	20 - Totally bedfast and requiring extensive nursing care by professionals and/or family
	10 - Comatose or barely rousable
	0 - Dead
	Not able to determine

Charlson Comorbidity Index - Does the patient have any of the following? *(Please tick ✓ all that apply)*			
Tick ✓		**Tick ✓**	
	Myocardial Infarction (history, not ECG changes only)		Hemiplegia
	Congestive Cardiac Failure		Moderate Or Severe Renal Disease
	Peripheral Vascular Disease (includes aortic aneurysm >= 6 cm)		Diabetes with End Organ Damage
	Cerebrovascular Disease (CVA with mild or no residual or TIA)		Any Tumour
	Dementia		Leukaemia (acute or chronic)
	Chronic Pulmonary Disease		Lymphoma
	Connective Tissue Disease		Moderate or Severe Liver Disease
	Peptic Ulcer Disease		Metastatic Solid Tumour
	Mild Liver Disease (without portal hypertension, includes chronic hepatitis)		AIDS (not just HIV positive)
	Diabetes (without organ damage) (excludes diet-controlled alone)		

Laboratory Tests (only if available)	
Test	**Value**
Haemoglobin (Hb)	
Platelets (mcL)	
CRP (mg/L)	
eGFR (mL/min)	
INR	
BSL (mmol/L)	
ALT (U/L)	

Yes	**No**	**Is patient currently on any systemic therapy?** *(Tick yes or no to all)*
Tick ✓	**Tick ✓**	
		Chemotherapy
		Immunotherapy
		Bevacizumab

Baseline T_0 - Medication Commencement

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

☐ **Night Sweats**

○ 0 ○ 1 ○ 2 ○ 3

NCI Criteria
0. Asymptomatic
1. Mild
2. Moderate night sweats (e.g., need to change pyjamas through the night)
3. Severe (e.g., needing to change bed clothes through the night)

Yes	No	Are the night sweats interfering with the patients sleep?

Which NSAID is patient being commence on for night sweats?	
Tick ✓	**Name**
	Ibuprofen
	Naproxen
	Diclofenac
	Celecoxib
	Meloxicam
	Aspirin
	Other: Please specify here: _____

NSAID STARTING DOSE	
	Dose (mgs)
	Frequency - *e.g., Daily (mane), BD, TDS, QID*
	Route - *oral, rectal*

Yes	No	Is patient taking any other medications for the night sweats? *If yes, please specify below.*
○ Paracetamol ○ Corticosteroids ○ Other: please specify here: _____		

Yes	No	Will patient continue to take these medications for the night sweats as well as the NSAID?

Yes	No	Is patient currently on or being commenced on gastric protection *(e.g., ranitidine or esomeprazole?)*

Tick ✓	**Other non-pharmacological measures being used** *(tick all that apply)*
	Keeping the temperature low in the house at night
	Sleeping with just a sheet
	Using a cold compress
	Using a fan or air conditioning
	Staying hydrated with cold drinks
	Using ice packs
	Avoiding caffeine, alcohol, and spicy foods
	Using relaxation strategies
	No non – pharmacological measures being used

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

☐ **Dyspepsia**

○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

NCI Critera
1.Mild symptoms; intervention not indicated
2.Moderate symptoms; medical intervention indicated
3. Severe symptoms; surgical intervention indicated

☐ **Gastroesophageal reflux disease**

○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

NCI Criteria
1.Mild symptoms; intervention not indicated
2.Moderate symptoms; medical intervention indicated
3.Severe symptoms; surgical intervention indicated

☐ **Gastrointestinal ulceration**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ No Symptom ○ Ungradable

NCI Criteria
1.Asymptomatic; clinical or intervention not indicated
2.Symptomatic; altered GI function; medical intervention indicated; limiting instrumental ADL
3.Severely altered GI function; TPN indicated; elective operative or endoscopic intervention indicated; limiting self-care ADL; disabling.
4.Life-threatening consequences; urgent operative intervention indicated
5.Death

☐ **Gastrointestinal haemorrhage**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ No Symptom ○ Ungradable

NCI Criteria
1.Mild; intervention not indicated
2. Moderate symptoms; medical intervention or minor cauterization indicated
3.Transfusion, radiologic, endoscopic, or elective operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5.Death

☐ **Bleeding non gastrointestinal**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ No Symptom ○ Ungradable

NCI Criteria
1.Mild: intervention not indicated
2.Moderate symptom: medical intervention or minor cauterization indicated
3.Transfusion, radiologic, endoscopic or elective operative intervention indicated
4.Life-threatening consequences: urgent intervention indicated
5.Death

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

NCI Criteria
1. Loss of appetite without alteration in eating habits
2. Oral intake decreased without significant weight loss.
3. Inadequate caloric or fluid intake; tube feeding, TPN or hospitalisation indicated.

☐ **Vomiting**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ no symptom ○ ungradable

NCI Criteria
1. 1 - 2 episodes (separated by 5 minutes) in 24 hrs
2. 3 - 5 episodes (separated by 5 minutes) in 24 hrs
3. >=6 episodes (separated by 5 minutes) in 24 hrs; tube feeding, TPN or hospitalization indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Acute kidney injury**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ no Symptom ○ ungradable

NCI Criteria
1.Creatinine level increase of >0.3 mg/dL; creatinine 1.5 -2.0 x above baseline
2.Creatinine 2 - 3 x above baseline
3.Creatinine >3 x baseline or >4.0 mg/dL; hospitalization indicated
4.Life-threatening consequences; dialysis indicated
5. Death

☐ **Oedema**

○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

NCI Criteria
1. 5-10% inter-limb discrepancy in volume or circumference at point of greatest visible difference; swelling or obscuration of anatomic architecture on close inspection
2. >10-30% inter-limb discrepancy in volume or circumference at point of greatest visible difference; readily apparent obscuration of anatomic architecture: obliteration of skin folds: readily apparent deviation from normal anatomic contour: limiting instrumental ADL
3. >30% inter-limb discrepancy in volume; gross deviation from normal anatomical contour; limiting self-care ADL

☐ **Allergic reaction**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ no symptom ○ ungradable

NCI Criteria
1.Transient flushing or rash, drug fever <38 degrees C (<100.4 degrees F); intervention not indicated
2.Intervention or infusion interruption indicated; responds promptly to symptomatic treatment (e.g., antihistamines, NSAIDS, narcotics); prophylactic medications indicated for <=24 hrs
3.Prolonged (e.g., not rapidly responsive to symptomatic medication and/or brief interruption of infusion); recurrence of symptoms following initial improvement; hospitalization indicated for clinical sequelae (e.g., renal impairment, pulmonary infiltrates)
4.Life-threatening consequences; urgent intervention indicated
5.Death

☐ **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

Tick ✓	**Which symptom is the most troublesome?**
	Dyspepsia
	Gastroesophageal reflux disease
	Gastrointestinal ulceration
	Gastrointestinal haemorrhage
	Bleeding non gastrointestinal
	Nausea
	Vomiting
	Acute kidney injury
	Oedema
	Allergic Reaction
	Other
	Additional Other

T_1 – 7 days post Baseline Assessment	
Date of Assessment	DD/MM/YYYY
Time of Assessment (24 hr time)	HH:MM

Tick ✓	T_1: Assessed/Not assessed reason
	Assessed today (continue to complete T_1) OR
	Died – record date of death below
	Not able to be contacted / located
	Too unwell
	Other

Date of Death*	DD:MM: YYYY

End survey here

Please provide reason if today's assessment is not 7 days after baseline. *(e.g., weekend)*

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

☐ **Night Sweats**

○ 0 ○ 1 ○ 2 ○ 3

NCI Criteria
0. Asymptomatic
1. Mild
2. Moderate night sweats (e.g., need to change pyjamas through the night)
3. Severe (e.g., needing to change bed clothes through the night)

Yes	No	Are the night sweats interfering with the patients sleep?

Total dose of NSAID given in the last 24 hours (mg)	
How long has the patient been on this dose (days)	

Tick ✓		Has patient been commenced on any new medications since baseline? (*If yes please specify name of medication, dose, and frequency.*		
Yes	No	**Medication Name**	**Dose**	**Frequency**

Tick ✓	**Other non-pharmacological measures being used** *(tick all that apply)*
	Keeping the temperature low in the house at night
	Sleeping with just a sheet
	Using a cold compress
	Using a fan or air conditioning
	Staying hydrated with cold drinks
	Using ice packs
	Avoiding caffeine, alcohol, and spicy foods
	Using relaxation strategies
	No non – pharmacological measures being used

T_1 –Harm/Toxicity 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)

☐ **Dyspepsia**
○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

NCI Critera
1.Mild symptoms; intervention not indicated
2.Moderate symptoms; medical intervention indicated
3. Severe symptoms; surgical intervention indicated

☐ **Gastroesophageal reflux disease**
○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

NCI Criteria
1.Mild symptoms; intervention not indicated
2.Moderate symptoms; medical intervention indicated
3.Severe symptoms; surgical intervention indicated

☐ **Gastrointestinal ulceration**
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ No Symptom ○ Ungradable

NCI Criteria
1.Asymptomatic; clinical or intervention not indicated
2.Symptomatic; altered GI function; medical intervention indicated; limiting instrumental ADL
3.Severely altered GI function; TPN indicated; elective operative or endoscopic intervention indicated; limiting self-care ADL; disabling.
4.Life-threatening consequences; urgent operative intervention indicated
5.Death

☐ **Gastrointestinal haemorrhage**
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ No Symptom ○ Ungradable

NCI Criteria
1.Mild; intervention not indicated
2. Moderate symptoms; medical intervention or minor cauterization indicated
3.Transfusion, radiologic, endoscopic, or elective operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5.Death

☐ **Bleeding non gastrointestinal**
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ No Symptom ○ Ungradable

NCI Criteria
1.Mild: intervention not indicated
2.Moderate symptom: medical intervention or minor cauterization indicated
3.Transfusion, radiologic, endoscopic or elective operative intervention indicated
4.Life-threatening consequences: urgent intervention indicated
5.Death

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

NCI Criteria
1. Loss of appetite without alteration in eating habits
2. Oral intake decreased without significant weight loss.
3. Inadequate caloric or fluid intake; tube feeding, TPN or hospitalisation indicated.

☐ **Vomiting**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ no symptom ○ ungradable

NCI Criteria
1. 1 - 2 episodes (separated by 5 minutes) in 24 hrs
2. 3 - 5 episodes (separated by 5 minutes) in 24 hrs
3. >=6 episodes (separated by 5 minutes) in 24 hrs; tube feeding, TPN or hospitalization indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Acute kidney injury**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ no Symptom ○ ungradable

NCI Criteria
1.Creatinine level increase of >0.3 mg/dL; creatinine 1.5 -2.0 x above baseline
2.Creatinine 2 - 3 x above baseline
3.Creatinine >3 x baseline or >4.0 mg/dL; hospitalization indicated
4.Life-threatening consequences; dialysis indicated
5. Death

☐ **Oedema**

○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

NCI Criteria
1. 5-10% inter-limb discrepancy in volume or circumference at point of greatest visible difference; swelling or obscuration of anatomic architecture on close inspection
2. >10-30% inter-limb discrepancy in volume or circumference at point of greatest visible difference; readily apparent obscuration of anatomic architecture: obliteration of skin folds: readily apparent deviation from normal anatomic contour: limiting instrumental ADL
3. >30% inter-limb discrepancy in volume; gross deviation from normal anatomical contour; limiting self-care ADL

☐ **Allergic reaction**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ no symptom ○ ungradable

NCI Criteria
1.Transient flushing or rash, drug fever <38 degrees C (<100.4 degrees F); intervention not indicated
2.Intervention or infusion interruption indicated; responds promptly to symptomatic treatment (e.g., antihistamines, NSAIDS, narcotics); prophylactic medications indicated for <=24 hrs
3.Prolonged (e.g., not rapidly responsive to symptomatic medication and/or brief interruption of infusion); recurrence of symptoms following initial improvement; hospitalization indicated for clinical sequelae (e.g., renal impairment, pulmonary infiltrates)
4.Life-threatening consequences; urgent intervention indicated
5.Death

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

Please specify other harm here _____

Other harm NCI criteria harm 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 NCI criteria harm grade here: ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

Tick ✓	Which symptom is the most troublesome?
	Dyspepsia
	Gastroesophageal reflux disease
	Gastrointestinal ulceration
	Gastrointestinal haemorrhage
	Bleeding non gastrointestinal
	Nausea
	Vomiting
	Acute kidney injury
	Oedema
	Allergic Reaction
	Other
	Additional Other

If a harm/toxicity scored 3 or more, please complete this set of questions from the Naranjo modified checklist. *(Tick 'yes', 'no', or 'don't know' for each question below) (If the symptom was present at baseline and grading remains unchanged the Naranjo questions are not required to be answered.)*

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

What is the intended treatment based on today's assessment?

Tick ✓	**Medication Changes** *(Tick all that apply)*
	No change to medication of interest/continue current dose
	Medication of interest ceased (complete medication cessation on page 19)
	Medication of interest dose reduced; please specify new dose in mgs:
	Medication of interest increased; please specify new dose in mgs:
	New medication being commenced for night sweats. *Please specify which medication below.* ◯ Paracetamol ◯ Corticosteroids ◯ Other: Please specify: _____

Yes	**No**	**Has a medication been added to treat a specific harm?**
		If yes, please specify new medication here: _____

Based on the assessment today has the toxicity resolved?
◯ Yes ◯ No ◯ N/A

T_2 – 14 days post Baseline Assessment	
Date of Assessment	DD:MM: YYYY
Time of Assessment (24 hr time)	HH:MM

Tick ✓	T_2: Assessed/Not assessed reason
	Assessed today (continue to complete T_2) OR
	Died – record date of death below
	Not able to be contacted / located
	Too unwell
	Other

Date of Death*	DD:MM: YYYY

End survey here

Please provide reason if today's assessment is not 14 days after baseline. *(e.g., weekend)*

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

☐ **Night Sweats**

○ 0 ○ 1 ○ 2 ○ 3

NCI Criteria
0. Asymptomatic
1. Mild
2. Moderate night sweats (e.g., need to change pyjamas through the night)
3. Severe (e.g., needing to change bed clothes through the night)

Yes	No	Are the night sweats interfering with the patients sleep?

Total dose of NSAID given in the last 24 hours (mg)	
How long has the patient been on this dose (days)	

Tick ✓		**Has patient been commenced on any new medications since T_1?** (*If yes please specify name of medication, dose, and frequency.*		
Yes	No	**Medication Name**	**Dose**	**Frequency**

Tick ✓	**Other non-pharmacological measures being used** *(tick all that apply)*
	Keeping the temperature low in the house at night
	Sleeping with just a sheet
	Using a cold compress
	Using a fan or air conditioning
	Staying hydrated with cold drinks
	Using ice packs
	Avoiding caffeine, alcohol, and spicy foods
	Using relaxation strategies
	No non – pharmacological measures being used

T_2 –Harm/Toxicity 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)

☐ **Dyspepsia**
○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

NCI Critera
1.Mild symptoms; intervention not indicated
2.Moderate symptoms; medical intervention indicated
3. Severe symptoms; surgical intervention indicated

☐ **Gastroesophageal reflux disease**
○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

NCI Criteria
1.Mild symptoms; intervention not indicated
2.Moderate symptoms; medical intervention indicated
3.Severe symptoms; surgical intervention indicated

☐ **Gastrointestinal ulceration**
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ No Symptom ○ Ungradable

NCI Criteria
1.Asymptomatic; clinical or intervention not indicated
2.Symptomatic; altered GI function; medical intervention indicated; limiting instrumental ADL
3.Severely altered GI function; TPN indicated; elective operative or endoscopic intervention indicated; limiting self-care ADL; disabling
4.Life-threatening consequences; urgent operative intervention indicated
5.Death

☐ **Gastrointestinal haemorrhage**
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ No Symptom ○ Ungradable

NCI Criteria
1.Mild; intervention not indicated
2. Moderate symptoms; medical intervention or minor cauterization indicated
3.Transfusion, radiologic, endoscopic, or elective operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5.Death

☐ **Bleeding non gastrointestinal**
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ No Symptom ○ Ungradable

NCI Criteria
1.Mild: intervention not indicated
2.Moderate symptom: medical intervention or minor cauterization indicated
3.Transfusion, radiologic, endoscopic or elective operative intervention indicated
4.Life-threatening consequences: urgent intervention indicated
5.Death

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

NCI Criteria
1. Loss of appetite without alteration in eating habits
2. Oral intake decreased without significant weight loss.
3. Inadequate caloric or fluid intake; tube feeding, TPN or hospitalisation indicated.

☐ **Vomiting**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ no symptom ○ ungradable

NCI Criteria
1. 1 - 2 episodes (separated by 5 minutes) in 24 hrs
2. 3 - 5 episodes (separated by 5 minutes) in 24 hrs
3. >=6 episodes (separated by 5 minutes) in 24 hrs; tube feeding, TPN or hospitalization indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Acute kidney injury**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ no Symptom ○ ungradable

NCI Criteria
1.Creatinine level increase of >0.3 mg/dL; creatinine 1.5 -2.0 x above baseline
2.Creatinine 2 - 3 x above baseline
3.Creatinine >3 x baseline or >4.0 mg/dL; hospitalization indicated
4.Life-threatening consequences; dialysis indicated
5. Death

☐ **Oedema**

○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

NCI Criteria
1. 5-10% inter-limb discrepancy in volume or circumference at point of greatest visible difference; swelling or obscuration of anatomic architecture on close inspection
2. >10-30% inter-limb discrepancy in volume or circumference at point of greatest visible difference; readily apparent obscuration of anatomic architecture: obliteration of skin folds: readily apparent deviation from normal anatomic contour: limiting instrumental ADL
3. >30% inter-limb discrepancy in volume; gross deviation from normal anatomical contour; limiting self-care ADL

☐ **Allergic reaction**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ no symptom ○ ungradable

NCI Criteria
1.Transient flushing or rash, drug fever <38 degrees C (<100.4 degrees F); intervention not indicated
2.Intervention or infusion interruption indicated; responds promptly to symptomatic treatment (e.g., antihistamines, NSAIDS, narcotics); prophylactic medications indicated for <=24 hrs
3.Prolonged (e.g., not rapidly responsive to symptomatic medication and/or brief interruption of infusion); recurrence of symptoms following initial improvement; hospitalization indicated for clinical sequelae (e.g., renal impairment, pulmonary infiltrates)
4.Life-threatening consequences; urgent intervention indicated
5.Death

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

Please specify other harm here _____

Other harm NCI criteria harm 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 NCI criteria harm grade here: ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

Tick ✓	**Which symptom is the most troublesome?**
	Dyspepsia
	Gastroesophageal reflux disease
	Gastrointestinal ulceration
	Gastrointestinal haemorrhage
	Bleeding non gastrointestinal
	Nausea
	Vomiting
	Acute kidney injury
	Oedema
	Allergic Reaction
	Other
	Additional Other

If a harm/toxicity scored 3 or more, please complete this set of questions from the Naranjo modified checklist. *(Tick 'yes', 'no', or 'don't know' for each question below) (If the symptom was present at baseline and grading remains unchanged the Naranjo questions are not required to be answered.)*

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

What is the intended treatment based on today's assessment?

Tick ✓	**Medication Changes** *(Tick all that apply)*
	No change to medication of interest/continue current dose
	Medication of interest ceased (complete medication cessation on page 19)
	Medication of interest dose reduced; please specify new dose in mgs:
	Medication of interest increased; please specify new dose in mgs:
	New medication being commenced for night sweats. *Please specify which medication below.* ◯ Paracetamol ◯ Corticosteroids ◯ Other: Please specify: _____

Yes	**No**	**Has a medication been added to treat a specific harm?**
		If yes, please specify new medication here: _____

Based on the assessment today has the toxicity resolved?
◯ Yes ◯ No ◯ N/A

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

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

Tick ✓	**Medication was ceased (related to indication of interest)**
	Symptom resolved; please indicate date symptom resolved: DD:MM: YYYY
	Symptom continued unchanged.
	Symptom/s worsened; please grade below: ☐ **Night Sweats** ○ 0 ○ 1 ○ 2 ○ 3 *NCI Criteria* 0. Asymptomatic 1. Mild 2. Moderate night sweats (e.g., need to change pyjamas through the night) 3. Severe (e.g., needing to change bed clothes through the night)

Tick ✓	**Intervention/medication was ceased (related to other reasons)**
	Harm/toxicity
	Patient unable to take medication; please specify reason: _____
	Other: please specify: _____

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

Adhoc A - 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)*

☐ **Dyspepsia**

○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

NCI Critera
1.Mild symptoms; intervention not indicated
2.Moderate symptoms; medical intervention indicated
3. Severe symptoms; surgical intervention indicated

☐ **Gastroesophageal reflux disease**

○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

NCI Criteria
1.Mild symptoms; intervention not indicated
2.Moderate symptoms; medical intervention indicated
3.Severe symptoms; surgical intervention indicated

☐ **Gastrointestinal ulceration**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ No Symptom ○ Ungradable

NCI Criteria
1.Asymptomatic; clinical or intervention not indicated
2.Symptomatic; altered GI function; medical intervention indicated; limiting instrumental ADL
3.Severely altered GI function; TPN indicated; elective operative or endoscopic intervention indicated; limiting self-care ADL; disabling
4.Life-threatening consequences; urgent operative intervention indicated
5.Death

☐ **Gastrointestinal haemorrhage**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ No Symptom ○ Ungradable

NCI Criteria
1.Mild; intervention not indicated
2. Moderate symptoms; medical intervention or minor cauterization indicated
3.Transfusion, radiologic, endoscopic, or elective operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5.Death

☐ **Bleeding non gastrointestinal**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ No Symptom ○ Ungradable

NCI Criteria
1.Mild: intervention not indicated
2.Moderate symptom: medical intervention or minor cauterization indicated
3.Transfusion, radiologic, endoscopic or elective operative intervention indicated
4.Life-threatening consequences: urgent intervention indicated
5.Death

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

NCI Criteria
1. Loss of appetite without alteration in eating habits
2. Oral intake decreased without significant weight loss.
3. Inadequate caloric or fluid intake; tube feeding, TPN or hospitalisation indicated.

☐ **Vomiting**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ no symptom ○ ungradable

NCI Criteria
1. 1 - 2 episodes (separated by 5 minutes) in 24 hrs
2. 3 - 5 episodes (separated by 5 minutes) in 24 hrs
3. >=6 episodes (separated by 5 minutes) in 24 hrs; tube feeding, TPN or hospitalization indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Acute kidney injury**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ no Symptom ○ ungradable

NCI Criteria
1.Creatinine level increase of >0.3 mg/dL; creatinine 1.5 -2.0 x above baseline
2.Creatinine 2 - 3 x above baseline
3.Creatinine >3 x baseline or >4.0 mg/dL; hospitalization indicated
4.Life-threatening consequences; dialysis indicated
5. Death

☐ **Oedema**

○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

NCI Criteria
1. 5-10% inter-limb discrepancy in volume or circumference at point of greatest visible difference; swelling or obscuration of anatomic architecture on close inspection
2. >10-30% inter-limb discrepancy in volume or circumference at point of greatest visible difference; readily apparent obscuration of anatomic architecture: obliteration of skin folds: readily apparent deviation from normal anatomic contour: limiting instrumental ADL
3. >30% inter-limb discrepancy in volume; gross deviation from normal anatomical contour; limiting self-care ADL

☐ **Allergic reaction**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ no symptom ○ ungradable

NCI Criteria
1.Transient flushing or rash, drug fever <38 degrees C (<100.4 degrees F); intervention not indicated
2.Intervention or infusion interruption indicated; responds promptly to symptomatic treatment (e.g., antihistamines, NSAIDS, narcotics); prophylactic medications indicated for <=24 hrs
3.Prolonged (e.g., not rapidly responsive to symptomatic medication and/or brief interruption of infusion); recurrence of symptoms following initial improvement; hospitalization indicated for clinical sequelae (e.g., renal impairment, pulmonary infiltrates)
4.Life-threatening consequences; urgent intervention indicated
5.Death

☐ **Other harm (if exists) –** e.g., bronchospasm

Please specify other harm here _____

Other harm NCI criteria harm grade here:
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

☐ **Additional other harm (if exists)**

Please specify additional other harm here _____

Additional other harm NCI criteria harm grade here:
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

Tick ✓	Which symptom is the most troublesome?
	Dyspepsia
	Gastroesophageal reflux disease
	Gastrointestinal ulceration
	Gastrointestinal haemorrhage
	Bleeding non gastrointestinal
	Nausea
	Vomiting
	Acute kidney injury
	Oedema
	Allergic Reaction
	Other
	Additional Other

If a harm/toxicity scored 3 or more, please complete this set of questions from the Naranjo modified checklist. *(Tick 'yes', 'no', or 'don't know' for each question below) (If the symptom was present at baseline and grading remains unchanged the Naranjo questions are not required to be answered.)*

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

Adhoc B - 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)*

☐ **Dyspepsia**

○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

NCI Critera
1.Mild symptoms; intervention not indicated
2.Moderate symptoms; medical intervention indicated
3. Severe symptoms; surgical intervention indicated

☐ **Gastroesophageal reflux disease**

○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

NCI Criteria
1.Mild symptoms; intervention not indicated
2.Moderate symptoms; medical intervention indicated
3.Severe symptoms; surgical intervention indicated

☐ **Colitis**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ No Symptom ○ Ungradable

NCI Criteria
1.Asymptomatic; clinical or diagnostic observations only; intervention not indicated
2.Abdominal pain; mucus or blood in stool
3.Severe abdominal pain; change in bowel habits; medical intervention indicated; peritoneal signs
4.Life-threatening consequences; urgent intervention indicated
5.Death

☐ **Gastrointestinal ulceration**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ No Symptom ○ Ungradable

NCI Criteria
1.Asymptomatic; clinical or intervention not indicated
2.Symptomatic; altered GI function; medical intervention indicated; limiting instrumental ADL
3.Severely altered GI function; TPN indicated; elective operative or endoscopic intervention indicated; limiting self-care ADL; disabling
4.Life-threatening consequences; urgent operative intervention indicated
5.Death

☐ **Gastrointestinal haemorrhage**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ No Symptom ○ Ungradable

NCI Criteria
1.Mild; intervention not indicated
2. Moderate symptoms; medical intervention or minor cauterization indicated
3.Transfusion, radiologic, endoscopic, or elective operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5.Death

☐ **Bleeding non gastrointestinal**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ No Symptom ○ Ungradable

NCI Criteria
1.Mild: intervention not indicated
2.Moderate symptom: medical intervention or minor cauterization indicated
3.Transfusion, radiologic, endoscopic or elective operative intervention indicated
4.Life-threatening consequences: urgent intervention indicated
5.Death

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

NCI Criteria
1. Loss of appetite without alteration in eating habits
2. Oral intake decreased without significant weight loss.
3. Inadequate caloric or fluid intake; tube feeding, TPN or hospitalisation indicated.

☐ **Vomiting**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ no symptom ○ ungradable

NCI Criteria
1. 1 - 2 episodes (separated by 5 minutes) in 24 hrs
2. 3 - 5 episodes (separated by 5 minutes) in 24 hrs
3. >=6 episodes (separated by 5 minutes) in 24 hrs; tube feeding, TPN or hospitalization indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Tinnitus**

○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

NCI Criteria
1.Mild symptoms; intervention not indicated
2.Moderate symptoms; limiting instrumental ADL
3. Severe symptoms; limiting self-care ADL

☐ **Dizziness**

○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

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

☐ **Acute kidney injury**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ no Symptom ○ ungradable

NCI Criteria
1.Creatinine level increase of >0.3 mg/dL; creatinine 1.5 -2.0 x above baseline
2.Creatinine 2 - 3 x above baseline
3.Creatinine >3 x baseline or >4.0 mg/dL; hospitalization indicated
4.Life-threatening consequences; dialysis indicated
5. Death

☐ **Oedema**

○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

NCI Criteria
1. 5-10% inter-limb discrepancy in volume or circumference at point of greatest visible difference; swelling or obscuration of anatomic architecture on close inspection
2. >10-30% inter-limb discrepancy in volume or circumference at point of greatest visible difference; readily apparent obscuration of anatomic architecture: obliteration of skin folds: readily apparent deviation from normal anatomic contour: limiting instrumental ADL
3. >30% inter-limb discrepancy in volume; gross deviation from normal anatomical contour; limiting self-care ADL

☐ **Bronchospasm**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ no symptom ○ ungradable

NCI Criteria
1. Mild symptoms; intervention not indicated
2.Symptomatic; medical intervention indicated; limiting instrumental ADL
3.Limiting self-care ADL; oxygen saturation decreased
4.Life-threatening respiratory or haemodynamic compromise; intubation or urgent intervention indicated
5.Death

☐ **Allergic reaction**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ no symptom ○ ungradable

NCI Criteria

1.Transient flushing or rash, drug fever <38 degrees C (<100.4 degrees F); intervention not indicated
2.Intervention or infusion interruption indicated; responds promptly to symptomatic treatment (e.g., antihistamines, NSAIDS, narcotics); prophylactic medications indicated for <=24 hrs
3.Prolonged (e.g., not rapidly responsive to symptomatic medication and/or brief interruption of infusion); recurrence of symptoms following initial improvement; hospitalization indicated for clinical sequelae (e.g., renal impairment, pulmonary infiltrates)
4.Life-threatening consequences; urgent intervention indicated
5.Death

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

Please specify other toxicity here _____

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

Please specify additional other toxicity here _____

Tick ✓	**Which symptom is the most troublesome?**
	Dyspepsia
	Gastroesophageal reflux disease
	Gastrointestinal ulceration
	Gastrointestinal haemorrhage
	Bleeding non gastrointestinal
	Nausea
	Vomiting
	Acute kidney injury
	Oedema
	Allergic Reaction
	Other
	Additional Other

If a harm/toxicity scored 3 or more, please complete this set of questions from the Naranjo modified checklist. *(Tick 'yes', 'no', or 'don't know' for each question below) (If the symptom was present at baseline and grading remains unchanged the Naranjo questions are not required to be answered.)*

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

Adhoc 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)*

☐ **Dyspepsia**

○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

NCI Critera
1.Mild symptoms; intervention not indicated
2.Moderate symptoms; medical intervention indicated
3. Severe symptoms; surgical intervention indicated

☐ **Gastroesophageal reflux disease**

○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

NCI Criteria
1.Mild symptoms; intervention not indicated
2.Moderate symptoms; medical intervention indicated
3.Severe symptoms; surgical intervention indicated

☐ **Gastrointestinal ulceration**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ No Symptom ○ Ungradable

NCI Criteria
1.Asymptomatic; clinical or intervention not indicated
2.Symptomatic; altered GI function; medical intervention indicated; limiting instrumental ADL
3.Severely altered GI function; TPN indicated; elective operative or endoscopic intervention indicated; limiting self-care ADL; disabling
4.Life-threatening consequences; urgent operative intervention indicated
5.Death

☐ **Gastrointestinal haemorrhage**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ No Symptom ○ Ungradable

NCI Criteria
1.Mild; intervention not indicated
2. Moderate symptoms; medical intervention or minor cauterization indicated
3.Transfusion, radiologic, endoscopic, or elective operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5.Death

☐ **Bleeding non gastrointestinal**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ No Symptom ○ Ungradable

NCI Criteria
1.Mild: intervention not indicated
2.Moderate symptom: medical intervention or minor cauterization indicated
3.Transfusion, radiologic, endoscopic or elective operative intervention indicated
4.Life-threatening consequences: urgent intervention indicated
5.Death

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

NCI Criteria
1. Loss of appetite without alteration in eating habits
2. Oral intake decreased without significant weight loss.
3. Inadequate caloric or fluid intake; tube feeding, TPN or hospitalisation indicated.

☐ **Vomiting**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ no symptom ○ ungradable

NCI Criteria
1. 1 - 2 episodes (separated by 5 minutes) in 24 hrs
2. 3 - 5 episodes (separated by 5 minutes) in 24 hrs
3. >=6 episodes (separated by 5 minutes) in 24 hrs; tube feeding, TPN or hospitalization indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Acute kidney injury**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ no Symptom ○ ungradable

NCI Criteria
1.Creatinine level increase of >0.3 mg/dL; creatinine 1.5 -2.0 x above baseline
2.Creatinine 2 - 3 x above baseline
3.Creatinine >3 x baseline or >4.0 mg/dL; hospitalization indicated
4.Life-threatening consequences; dialysis indicated
5. Death

☐ **Oedema**

○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

NCI Criteria
1. 5-10% inter-limb discrepancy in volume or circumference at point of greatest visible difference; swelling or obscuration of anatomic architecture on close inspection
2. >10-30% inter-limb discrepancy in volume or circumference at point of greatest visible difference; readily apparent obscuration of anatomic architecture: obliteration of skin folds: readily apparent deviation from normal anatomic contour: limiting instrumental ADL
3. >30% inter-limb discrepancy in volume; gross deviation from normal anatomical contour; limiting self-care ADL

☐ **Allergic reaction**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ no symptom ○ ungradable

NCI Criteria
1.Transient flushing or rash, drug fever <38 degrees C (<100.4 degrees F); intervention not indicated
2.Intervention or infusion interruption indicated; responds promptly to symptomatic treatment (e.g., antihistamines, NSAIDS, narcotics); prophylactic medications indicated for <=24 hrs
3.Prolonged (e.g., not rapidly responsive to symptomatic medication and/or brief interruption of infusion); recurrence of symptoms following initial improvement; hospitalization indicated for clinical sequelae (e.g., renal impairment, pulmonary infiltrates)
4.Life-threatening consequences; urgent intervention indicated
5.Death

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

Please specify other toxicity here _____

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

Please specify additional other toxicity here _____

Tick ✓	Which symptom is the most troublesome?
	Dyspepsia
	Gastroesophageal reflux disease
	Gastrointestinal ulceration
	Gastrointestinal haemorrhage
	Bleeding non gastrointestinal
	Nausea
	Vomiting
	Acute kidney injury
	Oedema
	Allergic Reaction
	Other
	Additional Other

If a harm/toxicity scored 3 or more, please complete this set of questions from the Naranjo modified checklist. *(Tick 'yes', 'no', or 'don't know' for each question below) (If the symptom was present at baseline and grading remains unchanged the Naranjo questions are not required to be answered.)*

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