

Participant ID (PID)

Initials of person entering data

Staff email

CONFIDENTIAL CASE REPORT FORM

NSAIDS (PAIN) Series No: 16

Palliative Care Clinical Studies Collaborative (PaCCSC)

RAPID Pharmacovigilance in Palliative Care

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

NSAIDS for pain - Baseline

Demographics

Gender ☐ Male
☐ Female

Age _____

Weight (kg)
Height (cm)

Primary life limiting illness

- ☐ Advanced metastatic cancer
- ☐ End stage renal failure
- ☐ Hepatic failure
- ☐ Neurodegenerative disease
- ☐ AIDS
- ☐ Cardiac failure
- ☐ Respiratory failure
- ☐ Other

Please specify Other Life limiting Illness _____

Palliative Care Phase?

☐ Stable ☐ Unstable ☐ Deteriorating ☐ Terminal

Stable: The person's symptoms are adequately controlled by established management. Further interventions to maintain symptom control and quality of life have been planned.

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.

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.

Terminal Care Phase: Death is likely in a matter of days and no acute intervention is planned or required.

Laboratory Tests (only if available)

Test	Value
Haemoglobin (Hb)	
Platelets	
International Normalised Ratio (INR)	
Creatinine	
eGFR	

Charlson Comorbidity Index

- ☐ Myocardial infarction
- ☐ Congestive cardiac failure
- ☐ Peripheral vascular disease
- ☐ Cerebrovascular disease
- ☐ Dementia
- ☐ Chronic pulmonary disease
- ☐ Connective tissue disease
- ☐ Ulcer disease
- ☐ Mild liver disease
- ☐ Diabetes (without organ damage)
- ☐ Hemiplegia
- ☐ Moderate or severe renal disease
- ☐ Diabetes with end organ damage
- ☐ Any tumour
- ☐ Leukaemia
- ☐ Lymphoma
- ☐ Moderate or severe liver disease
- ☐ Metastatic solid tumour
- ☐ AIDS

Australian Modified Karnofsky Performance Scale (AKPS)

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

Baseline – T₀-Medication Commencement

NSAID of interest

- ☐ Ibuprofen
- ☐ Naproxen
- ☐ Diclofenac
- ☐ Celecoxib
- ☐ Aspirin (only analgesic doses, at least 600mg per day)
- ☐ Other

Please specify other NSAID here

Date of Baseline

dd/mm/yyyy

Initial dose regimen – (dose in mg, frequency and route)

Time of initial dose (in 24hr clock e.g. 2200)

Other medications – (tick all that are appropriate)

- ☐ Proton pump inhibitor (e.g. omeprazole)
- ☐ H₂ antagonist (e.g. ranitidine)
- ☐ Glucocorticoid (e.g. prednisone)
- ☐ Antiplatelet drug (e.g. Aspirin < 150 mg per day or clopidogrel)
- ☐ Anticoagulant therapeutic doses (e.g. Warfarin)
- ☐ Anticoagulant at prophylactic doses (e.g. low molecular weight Heparin)
- ☐ ACE inhibitor (e.g. enalapril)
- ☐ Angiotensin receptor blocker (e.g. candesartan)
- ☐ Thiazide diuretic (e.g. bendrofluazide)
- ☐ Loop diuretic (e.g. frusemide)
- ☐ Paracetamol
- ☐ Opioids (please specify below)

Symptom Severity Score – Pain

- ☐ 1 ☐ 2 ☐ 3

NCI Criteria

- 1. Mild pain
- 2. Moderate pain; limiting instrumental ADL

3. Severe pain; limiting self-care ADL

What is the main aetiology of the pain?

- ☐ Cancer related bone pain
☐ Neuropathic pain
☐ Chemotherapy related pain
☐ Post-operative pain
☐ Tissue invasion of tumour
☐ Non oncological musculoskeletal pain
☐ Radiotherapy related pain
☐ Other

Please specify other:

Baseline Symptoms of interest (prior to commencement of medication)

Dyspepsia ☐

- ☐ 0 ☐ 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

Gastroesophageal reflux disease ☐

- ☐ 0 ☐ 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 ☐ Ungradable ☐ No Symptom

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 ☐ Ungradable ☐ No Symptom

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 ☐ Ungradable ☐ No Symptom

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 ☐ Ungradable ☐ No Symptom

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 ☐

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ no symptom ☐ ungradable

NCI Criteria

0. Nil
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 ☐ Ungradable ☐ No Symptom

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 ☐

☐ 0 ☐ 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 ☐

☐ 0 ☐ 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 ☐ Ungradable ☐ No Symptom

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 ☐

☐ 0 ☐ 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 ☐ Ungradable ☐ No Symptom

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 ☐ Ungradable ☐ No Symptom

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 (if exists) ☐

Please specify other toxicity here _____

Additional other (if exists) ☐

Please specify additional other toxicity here _____

Which toxicity is the most troublesome?

- ☐ Dyspepsia
- ☐ Gastroesophageal reflux disease
- ☐ Nausea
- ☐ Tinnitus
- ☐ Dizziness
- ☐ Oedema
- ☐ Colitis
- ☐ Gastrointestinal ulceration
- ☐ Gastrointestinal haemorrhage
- ☐ Bleeding non gastrointestinal
- ☐ Acute kidney injury
- ☐ Vomiting
- ☐ Bronchospasm
- ☐ Allergic Reaction
- ☐ Other 1
- ☐ Other 2

T₁ – 2 days post Baseline

T₁: Assessed/Not assessed reason

- ☐ Assessed today (continue to complete T₁) OR
- ☐ Died
- ☐ Not able to be contacted / located
- ☐ Too unwell
- ☐ Other

Date of Death

dd/mm/yyyy

End Survey here

Date and Time of Assessment Today

dd/mm/yyyy

00:00 24hr time

Symptom Severity Score – Pain

- ☐ 1 ☐ 2 ☐ 3

NCI Criteria

1. Mild pain

2. Moderate pain; limiting instrumental ADL

3. Severe pain; limiting self-care ADL

Total dose of NSAID of interest given in the last 24 hours (mg) _____

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

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

Yes ☐. No ☐

Symptoms of interest day 2 after baseline

Dyspepsia ☐

☐ 0 ☐ 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

Gastroesophageal reflux disease ☐

☐ 0 ☐ 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 ☐ Ungradable ☐ No Symptom

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 ☐ Ungradable ☐ No Symptom

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 ☐ Ungradable ☐ No Symptom

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 ☐ Ungradable ☐ No Symptom

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 ☐

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ no symptom ☐ ungradable

NCI Criteria

0. Nil
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 ☐ Ungradable ☐ No Symptom

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 ☐

☐ 0 ☐ 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 ☐

☐ 0 ☐ 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 ☐ Ungradable ☐ No Symptom

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 ☐

☐ 0 ☐ 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 ☐ Ungradable ☐ No Symptom

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 ☐ Ungradable ☐ No Symptom

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 (if exists) ☐

Please specify other toxicity here _____

Additional other (if exists) ☐

Please specify additional other toxicity here _____

Which toxicity is the most troublesome?

- ☐ Dyspepsia
- ☐ Gastroesophageal reflux disease
- ☐ Nausea
- ☐ Tinnitus
- ☐ Dizziness
- ☐ Oedema
- ☐ Colitis
- ☐ Gastrointestinal ulceration
- ☐ Gastrointestinal haemorrhage
- ☐ Bleeding non gastrointestinal
- ☐ Acute kidney injury
- ☐ Vomiting
- ☐ Bronchospasm
- ☐ Allergic Reaction
- ☐ Other 1
- ☐ Other 2

Key questions derived from the Naranjo modified check list

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

- ☐ Yes
- ☐ No
- ☐ Don't know

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

- ☐ Yes
- ☐ No
- ☐ Don't know

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

- ☐ Yes
- ☐ No
- ☐ Don't know

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

- ☐ Yes
- ☐ No
- ☐ Don't know

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

- ☐ Yes
- ☐ No
- ☐ Don't know

Post toxicity assessment

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

- ☐ No change to medication of interest/continue current dose
- ☐ Medication of interest ceased
- ☐ Medication of interest reduced
- ☐ Medication of interest increased – please specify dose

What is the Day 2 increased dose after assessment?

mgs

Has a medication been added to treat a specific toxicity?

Yes ☐ No ☐

If yes please specify medication.

Based on the assessment today has the toxicity resolved?

Yes ☐ No ☐ N/A ☐

T₂ – Day 2 – Day 14

T₂: Assessed/Not assessed reason

- ☐ Assessed today (continue to complete T₁) OR
- ☐ Died
- ☐ Not able to be contacted / located
- ☐ Too unwell
- ☐ Other

Date of Death

dd/mm/yyyy

End Survey here

Date of and Time of Assessment Today

dd/mm/yyyy

00:00 24hr time

If today's date of assessment is not three days after the Baseline date of assessment please provide the reason below

Symptom Severity Score – Pain

- ☐ 1 ☐ 2 ☐ 3

NCI Criteria

1. Mild pain

2. Moderate pain; limiting instrumental ADL

3. Severe pain; limiting self-care ADL

Total dose of NSAID of interest given in the last 24 hours (mg) _____

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

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

Yes ☐. No ☐

Symptoms of interest Day 2 – Day 14

Dyspepsia ☐

☐ 0 ☐ 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

Gastroesophageal reflux disease ☐

☐ 0 ☐ 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 ☐ Ungradable ☐ No Symptom

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 ☐ Ungradable ☐ No Symptom

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 ☐ Ungradable ☐ No Symptom

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 ☐ Ungradable ☐ No Symptom

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 ☐

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ no symptom ☐ ungradable

NCI Criteria

0. Nil
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 ☐ Ungradable ☐ No Symptom

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 ☐

☐ 0 ☐ 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 ☐

☐ 0 ☐ 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 ☐ Ungradable ☐ No Symptom

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 ☐

☐ 0 ☐ 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 ☐ Ungradable ☐ No Symptom

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 ☐ Ungradable ☐ No Symptom

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 (if exists) ☐

Please specify other toxicity here _____

Additional other (if exists) ☐

Please specify additional other toxicity here _____

Which toxicity is the most troublesome?

- ☐ Dyspepsia
- ☐ Gastroesophageal reflux disease
- ☐ Nausea
- ☐ Tinnitus
- ☐ Dizziness
- ☐ Oedema
- ☐ Colitis
- ☐ Gastrointestinal ulceration
- ☐ Gastrointestinal haemorrhage
- ☐ Bleeding non gastrointestinal
- ☐ Acute kidney injury
- ☐ Vomiting
- ☐ Bronchospasm
- ☐ Allergic Reaction
- ☐ Other 1
- ☐ Other 2

Key questions derived from the Naranjo modified check list

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

- ☐ Yes
- ☐ No
- ☐ Don't know

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

- ☐ Yes
- ☐ No
- ☐ Don't know

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

- ☐ Yes
- ☐ No
- ☐ Don't know

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

- ☐ Yes
- ☐ No
- ☐ Don't know

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

- ☐ Yes
- ☐ No
- ☐ Don't know

Please specify new medication here

Please specify new dose here

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

Date of assessment

dd/mm/yyyy

Medication was ceased (related to indication of interest):

- ☐ Symptom resolved
☐ Symptom worsened
☐ Symptom continued unchanged

Medication was ceased (related to other reasons):

- ☐ Toxicity
☐ Patient unable to take medication
☐ Other

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

Symptom resolved – date of resolution

dd/mm/yyyy

Symptom worsened (NCI grade)

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

Please specify the 'other' reason medication was ceased

Please specify the patient's inability to take medication

Adhoc Toxicities A - Please complete the survey below.

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

Were there any unscheduled adverse events/toxicities?

☐ Yes ☐ No

Date of assessment

dd/mm/yyyy

Symptom Severity Score – Pain

☐ 1 ☐ 2 ☐ 3

NCI Criteria

1. Mild pain
2. Moderate pain; limiting instrumental ADL
3. Severe pain; limiting self-care ADL

Symptoms of interest

Dyspepsia ☐

☐ 0 ☐ 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

Gastroesophageal reflux disease ☐

☐ 0 ☐ 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 ☐ Ungradable ☐ No Symptom

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 ☐ Ungradable ☐ No Symptom

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 ☐ Ungradable ☐ No Symptom

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 ☐ Ungradable ☐ No Symptom

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 ☐

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ no symptom ☐ ungradable

NCI Criteria

0. Nil
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 ☐ Ungradable ☐ No Symptom

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 ☐

☐ 0 ☐ 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 ☐

☐ 0 ☐ 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 ☐ Ungradable ☐ No Symptom

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 ☐

☐ 0 ☐ 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 ☐ Ungradable ☐ No Symptom

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 ☐ Ungradable ☐ No Symptom

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 (if exists) ☐

Please specify other toxicity here _____

Additional other (if exists) ☐

Please specify additional other toxicity here _____

Which toxicity is the most troublesome?

- ☐ Dyspepsia
- ☐ Gastroesophageal reflux disease
- ☐ Nausea
- ☐ Tinnitus
- ☐ Dizziness
- ☐ Oedema
- ☐ Colitis
- ☐ Gastrointestinal ulceration
- ☐ Gastrointestinal haemorrhage
- ☐ Bleeding non gastrointestinal
- ☐ Acute kidney injury
- ☐ Vomiting
- ☐ Bronchospasm
- ☐ Allergic Reaction
- ☐ Other 1
- ☐ Other 2

Adhoc Toxicities B - Please complete the survey below.

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

Were there any unscheduled adverse events/toxicities?

☐ Yes ☐ No

Date of assessment

dd/mm/yyyy

Symptom Severity Score – Pain

☐ 1 ☐ 2 ☐ 3

NCI Criteria

- 1.Mild pain
- 2.Moderate pain; limiting instrumental ADL
3. Severe pain; limiting self-care ADL

Symptoms of interest

Dyspepsia ☐

☐ 0 ☐ 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

Gastroesophageal reflux disease ☐

☐ 0 ☐ 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 ☐ Ungradable ☐ No Symptom

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 ☐ Ungradable ☐ No Symptom

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 ☐ Ungradable ☐ No Symptom

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 ☐ Ungradable ☐ No Symptom

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 ☐

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ no symptom ☐ ungradable

NCI Criteria

0. Nil
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 ☐ Ungradable ☐ No Symptom

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 ☐

☐ 0 ☐ 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 ☐

☐ 0 ☐ 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 ☐ Ungradable ☐ No Symptom

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 ☐

☐ 0 ☐ 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 ☐ Ungradable ☐ No Symptom

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 ☐ Ungradable ☐ No Symptom

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 (if exists) ☐

Please specify other toxicity here _____

Additional other (if exists) ☐

Please specify additional other toxicity here _____

Which toxicity is the most troublesome?

- ☐ Dyspepsia
- ☐ Gastroesophageal reflux disease
- ☐ Nausea
- ☐ Tinnitus
- ☐ Dizziness
- ☐ Oedema
- ☐ Colitis
- ☐ Gastrointestinal ulceration
- ☐ Gastrointestinal haemorrhage
- ☐ Bleeding non gastrointestinal
- ☐ Acute kidney injury
- ☐ Vomiting
- ☐ Bronchospasm
- ☐ Allergic Reaction
- ☐ Other 1
- ☐ Other 2

Adhoc Toxicities C - Please complete the survey below.

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

Were there any unscheduled adverse events/toxicities?

☐ Yes ☐ No

Date of assessment

dd/mm/yyyy

Symptom Severity Score – Pain

☐ 1 ☐ 2 ☐ 3

NCI Criteria

1. Mild pain
2. Moderate pain; limiting instrumental ADL
3. Severe pain; limiting self-care ADL

Symptoms of interest

Dyspepsia ☐

☐ 0 ☐ 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

Gastroesophageal reflux disease ☐

☐ 0 ☐ 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 ☐ Ungradable ☐ No Symptom

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 ☐ Ungradable ☐ No Symptom

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 ☐ Ungradable ☐ No Symptom

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 ☐ Ungradable ☐ No Symptom

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 ☐

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ no symptom ☐ ungradable

NCI Criteria

0. Nil
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 ☐ Ungradable ☐ No Symptom

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 ☐

☐ 0 ☐ 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 ☐

☐ 0 ☐ 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 ☐ Ungradable ☐ No Symptom

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 ☐

☐ 0 ☐ 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 ☐ Ungradable ☐ No Symptom

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 ☐ Ungradable ☐ No Symptom

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 (if exists) ☐

Please specify other toxicity here _____

Additional other (if exists) ☐

Please specify additional other toxicity here _____

Which toxicity is the most troublesome?

- ☐ Dyspepsia
- ☐ Gastroesophageal reflux disease
- ☐ Nausea
- ☐ Tinnitus
- ☐ Dizziness
- ☐ Oedema
- ☐ Colitis
- ☐ Gastrointestinal ulceration
- ☐ Gastrointestinal haemorrhage
- ☐ Bleeding non gastrointestinal
- ☐ Acute kidney injury
- ☐ Vomiting
- ☐ Bronchospasm
- ☐ Allergic Reaction
- ☐ Other 1
- ☐ Other 2