Participant ID	

Initials of person entering data	

Staff email	

CONFIDENTIAL CASE REPORT FORM

Ranitidine or Famotidine for Bowel Obstruction

Series 56

IMPACCT Trials Coordination Centre (ITCC)

UTS IMPACCT Rapid Program

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

References:
Common Terminology Criteria for Adverse Events (CTCAE). Version 5.0. Published: November 27, 2017. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES National Institutes of Health, National Cancer Institute

(T_0) - Baseline Assessment	
Date of Assessment	DD/MM/YYYY
Time of Assessment *(24-hour clock)*	HH:MM

Demographics					
Gender *(please tick)* ○ Male ○ Female ○ Non-binary					
Age (yrs)		**Weight (kg)**		**Height (cm)**	

Tick ✓	**Primary malignancy** *(please choose only one)*
	Breast
	Colorectal
	Lung
	Mesothelioma
	Ovarian
	Pancreatic
	Primary peritoneal
	Stomach
	Other - *Please specify:* _____

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?			
Tick ✓	*(Please tick all that apply)*	**Tick ✓**	*(Please tick all that apply)*
	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)		

Tick ✓	**Place of Care** *(please tick)*
	Inpatient Acute Hospital
	Inpatient Hospice/Palliative Care Unit
	Outpatient
	Residential Aged Care Facility/Nursing Home
	Other; *Please specify here:*

Tick ✓	**Mechanism of bowel obstruction** *(tick all that apply)*
	Adhesions
	Peritoneal disease
	Gastric outlet
	Small bowel
	Large bowel
	Multi-level
	Other - *Please specify:* _____
	Unknown

Medication Commencement

Tick ✓	**Which medication is the patient being commenced on?**
	Ranitidine
	Famotidine

Dosing plan at time of commencement	
Total daily dose (mg)	
Tick ✓	**Frequency**
	Daily
	BD
	TDS
	QID
	Continuous infusion
	Other; please specify:
Tick ✓	**Route of administration**
	Oral
	Intravenous
	Subcutaneous
	Other; please specify:

Concurrent Medications	
Tick ✓	**What other medications for nausea and vomiting is this participant using?** *Tick all that apply*
	Cyclizine
	Dexamethasone
	Haloperidol
	Metoclopramide
	Octreotide
	Parenteral fluids
	Hyoscine butyl bromide
	Other. Please specify:
	Not applicable

Target Symptom Assessment - Vomiting

Vomiting

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

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

Vomiting output	
Use of nasogastric (NG) tube	○ Yes, *answer 'estimated volume' only* ○ No, *answer both questions below*
Number of vomits (Last 24 hrs)	
Estimated volume	

Tick ✓	**Description of vomit** *(Tick all that apply)*
	Blood
	Bilious
	Coffee ground
	Fecal
	Undigested food
	Other; Please specify here. _____

Baseline Symptom/Harm Assessment *(Please grade all harms)*

Abdominal pain

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

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

Constipation

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

NCI Criteria
1.Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema
2. Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

Dizziness

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

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

Dry Mouth

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

NCI Criteria
1. Symptomatic (e.g., dry or thick saliva) without significant dietary alteration; unstimulated saliva flow >0.2 ml/min

2. Moderate symptoms; oral intake alterations (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods); unstimulated saliva 0.1 to 0.2 ml/min 3. Inability to adequately aliment orally; tube feeding or TPN indicated; unstimulated saliva

Headache

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

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

Hypersensitivity (Allergic Reaction)

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

NCI Criteria 1.Systemic intervention not indicated 2.Oral intervention indicated 3.Bronchospasm; hospitalization indicated for clinical sequelae; intravenous intervention indicated 4.Life-threatening consequences; urgent intervention indicated 5.Death

Nausea

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

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

Rash

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

Criteria 1. Mild 2. Moderate 3. Severe

Reflux

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

NCI Criteria 1. Mild symptoms 2. Moderate symptoms 3. Severe symptoms

Site reaction

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

NCI Criteria 1. Tenderness with or without associated symptoms (e.g., warmth, erythema, itching) 2. Pain; lipodystrophy; edema; phlebitis 3. Ulceration or necrosis; severe tissue damage; operative intervention indicated 4. Life-threatening consequences; urgent intervention indicated 5. Death
If applicable, please specify what else was in the infusion with Ranitidine/Famotidine:

Other *(only if applicable – can be related or unrelated to the medication)*
Please specify other symptom here_____
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate
3. Severe
4. Life threatening
5. Death

Additional other *(only if applicable – can be related or unrelated to the medication)*
Please specify additional other symptom here_____
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate
3. Severe
4. Life threatening
5. Death

Tick ✓	**Which symptom/harm is the <u>most</u> troublesome?** *(Tick one only)*
	Abdominal pain
	Constipation
	Dizziness
	Dry Mouth
	Headache
	Hypersensitivity – Allergic Reaction
	Nausea
	Rash
	Reflux
	Site reaction
	Vomiting
	Other
	Additional Other
	Not applicable

T_1 – 24 hours post Baseline

Date of Assessment	DD/MM/YYYY
Time of Assessment (24hr clock)	HH:MM

Tick ✓	**T_1: Assessed/Not assessed reason**
	Assessed today *(continue to complete T_1)* OR
	Symptom resolved *(complete medication cessation form)*
	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 24 hours after baseline. *(e.g., weekend)*

Target Symptom Assessment - Vomiting

Vomiting

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

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

Vomiting output	
Use of nasogastric (NG) tube	○ Yes, *answer 'estimated volume' only* ○ No, *answer both questions below*
Number of vomits (Last 24 hrs)	
Estimated volume	

Tick ✓	**Description of vomit** *(Tick all that apply)*
	Blood
	Bilious
	Coffee ground

	Fecal
	Undigested food
	Other; Please specify here. _____

T_1 Symptom/Harm Assessment *(Please grade all harms)*

Abdominal pain

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

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

Dizziness

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

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

Dry Mouth

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

NCI Criteria
1. Symptomatic (e.g., dry or thick saliva) without significant dietary alteration; unstimulated saliva flow >0.2 ml/min
2. Moderate symptoms; oral intake alterations (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods); unstimulated saliva 0.1 to 0.2 ml/min
3. Inability to adequately aliment orally; tube feeding or TPN indicated; unstimulated saliva

Headache

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

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

Hypersensitivity (Allergic Reaction)

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

NCI Criteria
1.Systemic intervention not indicated
2.Oral intervention indicated
3.Bronchospasm; hospitalization indicated for clinical sequelae; intravenous intervention indicated
4.Life-threatening consequences; urgent intervention indicated
5.Death

Nausea

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

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

Rash

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

Criteria
1. Mild
2. Moderate
3. Severe

Reflux

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

NCI Criteria
1. Mild symptoms
2. Moderate symptoms
3. Severe symptoms

Site reaction

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

NCI Criteria
1. Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)
2. Pain; lipodystrophy; edema; phlebitis
3. Ulceration or necrosis; severe tissue damage; operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death
If applicable, please specify what else was in the infusion with Ranitidine/Famotidine:

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

Please specify other symptom here_____

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate
3. Severe
4. Life threatening
5. Death

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

Please specify additional other symptom here_____

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate
3. Severe
4. Life threatening
5. Death

Tick ✓	**Which symptom/harm is the <u>most</u> troublesome?** *(Tick one only)*
	Abdominal pain
	Dizziness
	Dry Mouth
	Headache

	Hypersensitivity – Allergic Reaction
	Nausea
	Rash
	Reflux
	Site reaction
	Vomiting
	Other
	Additional Other
	Not applicable

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

Impression of change

Based on your assessment at T_1, rate any change <u>compared to Baseline</u>.

Symptom	Impression of change
Vomiting	Improved / No Change / Worse
Abdominal pain	Improved / No Change / Worse
Constipation	Improved / No Change / Worse
Nausea	Improved / No Change / Worse
Reflux	Improved / No Change / Worse

What is the intended treatment based on today's assessment?	
Tick ✓	**Medication changes** *(Tick all that apply)*
	No change to medication or treatment regimen/continue current dose
	Dose decreased
	Dose increased
	Medication ceased *(Complete medication cessation form)*
	New medication commenced: Please specify here: _____ _____

Based on the assessment today has the bowel obstruction/function resolved?
◯ Yes ◯ No ◯ Partial resolution ◯ Not applicable

T_2 – 72 hours post Baseline

Date of Assessment	DD/MM/YYYY
Time of Assessment (24hr clock)	HH:MM

Tick ✓	T_2: Assessed/Not assessed reason
	Assessed today *(continue to complete T_1)* OR
	Symptom resolved *(complete medication cessation form)*
	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 72 hours after baseline. *(e.g., weekend)*

Target Symptom Assessment - Vomiting

Vomiting

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

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

Vomiting output	
Use of nasogastric (NG) tube	○ Yes, *answer 'estimated volume' only* ○ No, *answer both questions below*
Number of vomits (Last 24 hrs)	
Estimated volume	

Tick ✓	**Description of vomit** *(Tick all that apply)*
	Blood
	Bilious
	Coffee ground
	Fecal
	Undigested food
	Other; Please specify here. _____

T_2 Symptom/Harm Assessment *(Please grade all harms)*

Abdominal pain

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

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

Dizziness

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

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

Dry Mouth

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

NCI Criteria
1. Symptomatic (e.g., dry or thick saliva) without significant dietary alteration; unstimulated saliva flow >0.2 ml/min
2. Moderate symptoms; oral intake alterations (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods); unstimulated saliva 0.1 to 0.2 ml/min
3. Inability to adequately aliment orally; tube feeding or TPN indicated; unstimulated saliva

Headache

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

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

Hypersensitivity (Allergic Reaction)

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

NCI Criteria
1.Systemic intervention not indicated
2.Oral intervention indicated
3.Bronchospasm; hospitalization indicated for clinical sequelae; intravenous intervention indicated
4.Life-threatening consequences; urgent intervention indicated
5.Death

Nausea

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

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

Rash

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

Criteria
1. Mild
2. Moderate
3. Severe

Reflux

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

NCI Criteria
1. Mild symptoms
2. Moderate symptoms
3. Severe symptoms

Site reaction

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

NCI Criteria
1. Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)
2. Pain; lipodystrophy; edema; phlebitis
3. Ulceration or necrosis; severe tissue damage; operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death
If applicable, please specify what else was in the infusion with Ranitidine/Famotidine:

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

Please specify other symptom here_____

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate
3. Severe
4. Life threatening
5. Death

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

Please specify additional other symptom here_____

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate
3. Severe
4. Life threatening
5. Death

Tick ✓	**Which symptom/harm is the <u>most</u> troublesome?** *(Tick one only)*
	Abdominal pain
	Dizziness
	Dry Mouth
	Headache
	Hypersensitivity – Allergic Reaction
	Nausea
	Rash
	Reflux
	Site reaction
	Vomiting
	Other
	Additional Other
	Not applicable

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

Impression of change

Based on your assessment at T_2, rate any change <u>compared to Baseline</u>.	
Symptom	**Impression of change**
Vomiting	Improved / No Change / Worse
Abdominal pain	Improved / No Change / Worse
Constipation	Improved / No Change / Worse
Nausea	Improved / No Change / Worse
Reflux	Improved / No Change / Worse

What is the intended treatment based on today's assessment?	
Tick ✓	**Medication changes** *(Tick all that apply)*
	No change to medication or treatment regimen/continue current dose
	Dose decreased
	Dose increased
	Medication ceased *(Complete medication cessation form)*
	New medication commenced: Please specify here: _____ _____

Based on the assessment today has the bowel obstruction/function resolved?
◯ Yes ◯ No ◯ Partial resolution ◯ Not applicable

Medication Cessation *(complete this page if Ranitidine or Famotidine was 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 record NCI grade below*

Specify symptom here: _____

○ 1 ○ 2 ○ 3 ○ 4 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate
3. Severe
4. Life-threatening

Tick ✓	**Medication was ceased (related to other reasons)**
	Harm/toxicity
	Patient unable to take medication
	Availability/access to medication
	Practical issues e.g. packaging, breakage of vials
	Other - *Please specify:*

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

Ad hoc A - Unscheduled Harm/Toxicity Assessment

Date of Assessment	dd/mm/yyyy

Vomiting

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

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

Abdominal pain

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

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

Constipation

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

NCI Criteria
1.Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema
2. Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

Dizziness

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

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

Dry Mouth

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

NCI Criteria
1. Symptomatic (e.g., dry or thick saliva) without significant dietary alteration; unstimulated saliva flow >0.2 ml/min
2. Moderate symptoms; oral intake alterations (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods); unstimulated saliva 0.1 to 0.2 ml/min
3. Inability to adequately aliment orally; tube feeding or TPN indicated; unstimulated saliva

Headache

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

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

Hypersensitivity (Allergic Reaction)

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

NCI Criteria
1.Systemic intervention not indicated
2.Oral intervention indicated
3.Bronchospasm; hospitalization indicated for clinical sequelae; intravenous intervention indicated
4.Life-threatening consequences; urgent intervention indicated
5.Death

Nausea

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

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

Rash

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

Criteria
1. Mild
2. Moderate
3. Severe

Reflux

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

NCI Criteria
1. Mild symptoms
2. Moderate symptoms
3. Severe symptoms

Site reaction

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

NCI Criteria
1. Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)
2. Pain; lipodystrophy; edema; phlebitis
3. Ulceration or necrosis; severe tissue damage; operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death
If applicable, please specify what else was in the infusion with Ranitidine/Famotidine:

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

Please specify other symptom here_____

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate
3. Severe
4. Life threatening
5. Death

Additional other *(only if applicable – can be related or unrelated to the medication)*
Please specify additional other symptom here_____
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate
3. Severe
4. Life threatening
5. Death

Ad hoc B - Unscheduled Harm/Toxicity Assessment

Date of Assessment	dd/mm/yyyy

Vomiting

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

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

Abdominal pain

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

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

Constipation

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

NCI Criteria
1.Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema
2. Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

Dizziness

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

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

Dry Mouth

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

NCI Criteria
1. Symptomatic (e.g., dry or thick saliva) without significant dietary alteration; unstimulated saliva flow >0.2 ml/min
2. Moderate symptoms; oral intake alterations (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods); unstimulated saliva 0.1 to 0.2 ml/min
3. Inability to adequately aliment orally; tube feeding or TPN indicated; unstimulated saliva

Headache

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

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

Hypersensitivity (Allergic Reaction)

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

NCI Criteria
1.Systemic intervention not indicated
2.Oral intervention indicated
3.Bronchospasm; hospitalization indicated for clinical sequelae; intravenous intervention indicated
4.Life-threatening consequences; urgent intervention indicated
5.Death

Nausea

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

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

Rash

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

Criteria
1. Mild
2. Moderate
3. Severe

Reflux

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

NCI Criteria
1. Mild symptoms
2. Moderate symptoms
3. Severe symptoms

Site reaction

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

NCI Criteria
1. Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)
2. Pain; lipodystrophy; edema; phlebitis
3. Ulceration or necrosis; severe tissue damage; operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death
If applicable, please specify what else was in the infusion with Ranitidine/Famotidine:

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

Please specify other symptom here_____

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate
3. Severe
4. Life threatening
5. Death

Additional other *(only if applicable – can be related or unrelated to the medication)*
Please specify additional other symptom here_____
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate
3. Severe
4. Life threatening
5. Death

Ad hoc C - Unscheduled Harm/Toxicity Assessment

Date of Assessment	dd/mm/yyyy

Vomiting

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

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

Abdominal pain

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

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

Constipation

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

NCI Criteria
1.Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema
2. Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

Dizziness

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

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

Dry Mouth

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

NCI Criteria
1. Symptomatic (e.g., dry or thick saliva) without significant dietary alteration; unstimulated saliva flow >0.2 ml/min
2. Moderate symptoms; oral intake alterations (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods); unstimulated saliva 0.1 to 0.2 ml/min
3. Inability to adequately aliment orally; tube feeding or TPN indicated; unstimulated saliva

Headache

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

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

Hypersensitivity (Allergic Reaction)

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

NCI Criteria
1.Systemic intervention not indicated
2.Oral intervention indicated
3.Bronchospasm; hospitalization indicated for clinical sequelae; intravenous intervention indicated
4.Life-threatening consequences; urgent intervention indicated
5.Death

Nausea

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

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

Rash

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

Criteria
1. Mild
2. Moderate
3. Severe

Reflux

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

NCI Criteria
1. Mild symptoms
2. Moderate symptoms
3. Severe symptoms

Site reaction

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

NCI Criteria
1. Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)
2. Pain; lipodystrophy; edema; phlebitis
3. Ulceration or necrosis; severe tissue damage; operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death
If applicable, please specify what else was in the infusion with Ranitidine/Famotidine:

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

Please specify other symptom here_____

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate
3. Severe
4. Life threatening
5. Death

Additional other *(only if applicable – can be related or unrelated to the medication)*
Please specify additional other symptom here_____
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate
3. Severe
4. Life threatening
5. Death