Participant ID	
Initials of person entering da	ta
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)

TABLE OF CONTENTS	PAGE NO.	
T ₀ -Baseline	2	
T ₁ – 24 hours post baseline	8	
T ₂ – 72 hours post baseline	13	
Medication Cessation (only complete if medication is ceased	18	
during the study period. Otherwise leave blank).		
The Adhoc pages only need to be completed if an unexpected harm occurs outside of the		
assessment timepoints.		
Adhoc A	19	
Adhoc B	22	
Adhoc C	25	

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

Tick ✓	Primary malignancy (please choose only one)		
	Breast		
	Colorectal		
	Lung		
Mesothelioma	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

Cha	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:			

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

	m		

○1 ○2 ○3 ○4 ○5○Ungradable ○No symptom

- 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

Vomiti	ng output	
Use of r	nasogastric (NG) tube	O Yes, answer 'estimated volume' only
		O No, answer both questions below
	of vomits (Last 24 hrs) ed volume	
EStillat	eu voiume	
Tick ✓	Description of vomit (Tick	all that apply)
	Blood	
	Bilious	
	Coffee ground	
	Fecal	
	Undigested food	
	Other; Please specify here	
		_
Basell	ne Symptom/Harm A	ssessment (Please grade all harms)
	a	но зутрент
Constipa		Jngradable ○ No symptom
NCI Criterion		nal use of stool softeners, laxatives, dietary modification, or
enema		
	nt symptoms with regular use of laxat iion with manual evacuation indicated	ives or enemas; limiting instrumental ADL
	eatening consequences; urgent interve	
5. Death		
Dizzines	5	
	2 O 3 O Ungradable O No	symptom
NCI Criteri	a teadiness or sensation of movement	
	e unsteadiness or sensation of movement	nent; limiting instrumental ADL
	unsteadiness or sensation of movemen	
Dry Mout	th	
$0.1 \bigcirc$		symptom
NCI Criteri		-

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
	Moderate pain; limiting instrumental ADL
	3. Severe pain; limiting self care ADL
	o. oo. o. o pa,
	Hypersensitivity (Allergic Reaction)
	\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc Ungradable \bigcirc 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
	Nausaa
	Nausea ○ 1
	2 1 2 2 3 3 6 originatable 3 110 symptom
	NCI Criteria
	Loss of appetite without alteration in eating habits Oral intake decreased without significant weight loss.
	Inadequate caloric or fluid intake; tube feeding, TPN or hospitalisation indicated.
	5. Inducquate calone of hala make, tube recaing, 1114 of hospitalisation indicated.
	Rash
,	\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc Ungradable \bigcirc No symptom
1	Criteria
	1. Mild
	2. Moderate
	3. Severe
	Reflux
	\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc Ungradable \bigcirc No symptom
	NCI Criteria
	1. Mild symptoms
	2. Moderate symptoms
	3. Severe symptoms
	Cita was ation
	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
	Ulceration or necrosis; severe tissue damage; operative intervention indicated Life-threatening consequences; urgent intervention indicated
	5. Death
	If applicable, please specify what else was in the infusion with Ranitidine/Famotidine:
	applicable, please speelly titlat cloc tras in the infasion trun Ramballine, i amoutamen

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						
O 1 O 2 O 3 O 4 O 5 O Ungradable						
NCI Criteria						
1. Mild						
2. Moderate						
3. Severe						
3. Severe4. Life threatening5. Death						

Tick ✓	Which symptom/harm is the most 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					

^{*}End survey here

Please provide reason if today's assessment is not 24 hours after baseline. (e.g., weekend)					

Target Symptom Assessment - Vomiting

Vomiting

\bigcirc 1	\cup 2	\cup 3	\bigcirc 4	\bigcirc 5	\cup	Ungradable	\bigcirc	No s	vmptom
--------------	----------	----------	--------------	--------------	--------	------------	------------	------	--------

- 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 Sym	ptom/Harm Assessment (Please grade all harms)
Abdomina	I pain ○ 3 ○ Ungradable ○ No symptom
NCI Criteria 1. Mild pain	
	pain; limiting instrumental ADL
3. Severe pa	in; limiting self-care ADL
Dizziness	
$\bigcirc 1 \bigcirc 2$	○ 3 ○ Ungradable ○ No symptom
NCI Criteria	adinace as conception of mayore ont
	adiness or sensation of movement unsteadiness or sensation of movement; limiting instrumental ADL
	steadiness or sensation of movement; limiting self care ADL
ml/min 2. Moderate and/or soft,	symptoms; oral intake alterations (e.g., copious water, other lubricants, diet limited to purees moist foods); unstimulated saliva 0.1 to 0.2 ml/min adequately aliment orally; tube feeding or TPN indicated; unstimulated saliva
Headache 1 2 NCI Criteria 1. Mild pain 2. Moderate	○ 3 ○ Ungradable ○ No symptom pain; limiting instrumental ADL
	in; limiting self care ADL
Hypersens 1 0 2 NCI Criteria	sitivity (Allergic Reaction) 3 04 05 0 Ungradable 0 No symptom
2.Oral interve 3.Bronchospa	ntervention not indicated ention indicated asm; hospitalization indicated for clinical sequelae; intravenous intervention indicated ening consequences; urgent intervention indicated
Nausea 1 2 NCI Criteria	○ 3 ○ Ungradable ○ No symptom

9

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

Rasn ○1 ○2	2 O 3 O Ungradable O No symptom
Criteria	
1. Mild	
2. Moderate	
3. Severe	
Reflux	
$\bigcirc 1 \bigcirc \bigcirc$	
NCI Criteria	
1. Mild sym	
2. Moderate	
3. Severe s	mptoms
Site react	ion
$\bigcirc 1 \bigcirc 2$	2 03 04 05 0 Ungradable 0 No symptom
NCI Criteria	<u> </u>
	ess with or without associated symptoms (e.g., warmth, erythema, itching)
	dystrophy; edema; phlebitis
	n or necrosis; severe tissue damage; operative intervention indicated
5. Death	atening consequences; urgent intervention indicated
	ole, please specify what else was in the infusion with Ranitidine/Famotidine:
ii applicat	ne, please specify what else was in the infusion with Kamtume, I amoutume.
Other (on	ly if applicable – can be related or unrelated to the medication)
Please spe	cify other symptom here
_ :	2 03 04 05 Oungradable
NCI Criteria	
1. Mild	
2. Moderate	!
3. Severe	
4. Life threa	itening
5. Death	
Additions	l other (only if applicable – can be related or unrelated to the medication)
	cify additional other symptom here
~ ·	
<u> </u>	- c c c c c c c c c c c c c c c c c c c
NCI Criteria	
1. Mild 2. Moderate	
3. Severe	
4. Life threa	atenina
5. Death	
3. 2 3441	
Tick ✓	Which symptom/harm is the <u>most</u> troublesome? (Tick one only)

Tick ✓	Which symptom/harm is the most 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	assessmo	ent today has the bo	owel obstruction/function resolved?
○ Yes	○ No	O 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		

^{*}End survey here

Please provide reason if today's assessment is not 72 hours after baseline.	
(e.g., weekend)	

Target Symptom Assessment - Vomiting

`\'	_	199	iti	-	~
v					

\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc Ungradable \bigcirc No sym
--

- 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.

12 Symptom/ narm Assessment (Please grade all narms)
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
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)

 \bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc Ungradable \bigcirc No symptom

- 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
Oral intake decreased without significant weight loss. Inadequate caloric or fluid intake; tube feeding, TPN or hospitalisation indicated.
3. Inducquate calone of hala intake, tabe recalling, 11 N of 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)
Pain; lipodystrophy; edema; phlebitis 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 (and "Grand" and a second and an annual attention and "ast" and
Other (only if applicable – can be related or unrelated to the medication)
Please specify other symptom here
01 02 03 04 05 Oungradable
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
O1 O2 O3 O4 O5 O Ungradable
NCI Criteria 1. Mild
2. Moderate
2. Moderate 3. Severe

Tick ✓	Which symptom/harm is the most 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	assessm	ent 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)

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			

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 0 1 0 2 0 3 0 4 0 5	i ○ 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 ○ Ungrada	ble O No symptom	
NCI Criteria1. Mild pain2. Moderate pain; limiting instrumental3. Severe pain; limiting self-care ADL	ADL	
Constipation ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	○ Ungradable ○ No symptom	
enema		
Dizziness ○ 1 ○ 2 ○ 3 ○ Ungradable NCI Criteria	e ○ No symptom	
Mild unsteadiness or sensation of mo Moderate unsteadiness or sensation of Severe unsteadiness or sensation of	of movement; limiting instrumental ADL	
Dry Mouth ○ 1 ○ 2 ○ 3 ○ Ungradable	e ○ 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	e ○ No symptom	
NCI Criteria 1. Mild pain 2. Moderate pain; limiting instrumental 3. Severe pain; limiting self care ADL		

\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc Ungradable \bigcirc 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		
J.Deutii		
Names		
Nausea ○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom		
○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom NCI Criteria		
1. Loss of appetite without alteration in eating habits		
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 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. Tondornoss with or without associated symptoms (e.g. warmth, on thema, itshing)		
1. Tenderness with or without associated symptoms (e.g., warmth, erythema, itching) 2. Pain; lipodystrophy; edema; phlebitis		
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 Cook "Cook" and be related as society of the the good action.		
Other (only if applicable – can be related or unrelated to the medication)		
Please specify other symptom here		
O 1 O 2 O 3 O 4 O 5 O Ungradable		
NCI Criteria 1. Mild		
2. Moderate		
3. Severe		
4. Life threatening		
5. Death		

A	Additional other (only if applicable – can be related or unrelated to the medication)				
P	Please specify additional other symptom here				
(1 O 2 O 3 O 4 O 5 O Ungradable				
	CI Criteria				
	Mild				
	Moderate				
	Severe				
	Life threatening				
	Death				

Ad hoc B - Unscheduled Harm/Toxicity Assessment		
Date of Assessment	dd/mm/yyyy	
Vomiting ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	i ○ 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 ○ Ungrada	ble O No symptom	
NCI Criteria1. Mild pain2. Moderate pain; limiting instrumental3. Severe pain; limiting self-care ADL	ADL	
Constipation <a>○ 1 <a>○ 2 <a>○ 3 <a>○ 4 <a>○ 5	○ Ungradable ○ No symptom	
enema		
Dizziness ○ 1 ○ 2 ○ 3 ○ Ungradable NCI Criteria	e ○ No symptom	
Mild unsteadiness or sensation of mo Moderate unsteadiness or sensation of Severe unsteadiness or sensation of	of movement; limiting instrumental ADL	
Dry Mouth ○ 1 ○ 2 ○ 3 ○ Ungradable	e ○ 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	e ○ No symptom	
NCI Criteria 1. Mild pain 2. Moderate pain; limiting instrumental 3. Severe pain; limiting self care ADL		

\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc Ungradable \bigcirc 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		
o.bout		
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		
Moderate symptoms Severe 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		
<u>○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable</u>		
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			
\bigcirc 1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc Ungradable			
NCI Criteria			
1. Mild			
2. Moderate			
3. Severe			
4. Life threatening			
5 Death			

Ad hoc C - Unsched	uled Harm/Toxicity Assessment	
Date of Assessment	dd/mm/yyyy	
Vomiting 0 1 0 2 0 3 0 4 0 5	5 ○ Ungradable ○ No symptom	
NCI Criteria 1. 1-2 episodes (separated by > 5 minu 2. 3-5 episodes (separated by > 5 minu 3. >=6 episodes (separated by > 5 minu 4. Life threatening consequences: urge 5. Death	utes) in 24 hours nutes) in 24 hours; tube feeding, TPN or hospitalisation indicated	
Abdominal pain 1 2 3 Ungrada	ble ○ No symptom	
NCI Criteria1. Mild pain2. Moderate pain; limiting instrumental3. Severe pain; limiting self-care ADL	ADL	
Constipation ○ 1 ○ 2 ○ 3 ○ 4 ○ 5	o ○ Ungradable ○ No symptom	
enema		
Dizziness 1 2 3 Ungradable NCI Criteria 1. Mild unsteadiness or sensation of mo		
3. Severe unsteadiness or sensation ofDry Mouth123Ungradable		
 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	e O No symptom	
NCI Criteria 1. Mild pain 2. Moderate pain; limiting instrumental 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
_ <i></i>
Reflux 1 2 3 Ungradable No symptom
NCI Criteria1. Mild symptoms2. Moderate symptoms3. Severe symptoms
Site reaction 1 02 03 04 05 Ungradable O No symptom
NCI Criteria1. Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)2. Pain; lipodystrophy; edema; phlebitis
Ulceration or necrosis; severe tissue damage; operative intervention indicated Life-threatening consequences; urgent intervention indicated 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 0 2 0 3 0 4 0 5 0 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)		
I	ease specify additional other symptom here	
(1 \bigcirc 2 \bigcirc 3 \bigcirc 4 \bigcirc 5 \bigcirc Ungradable	
Ī	ICI Criteria	
	. Mild	
	. Moderate	
	. Severe	
	. Life threatening	
	. Death	