Participant ID	

Initials of person entering data	

Staff email	

CONFIDENTIAL CASE REPORT FORM

Ondansetron for Nausea and Vomiting

Series 48

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)

Exclusion Criteria
Patients who have received chemotherapy, immunotherapy, targeted therapy, or radiotherapy in the last 5 days
Patients who are only taking Ondansetron as a PRN medication
Patients who have received an alternative $5HT_3$ antagonist in the last 48hrs

Reference: Stephenson J, Davies A. An assessment of aetiology-based guidelines for the management of nausea and vomiting in patients with advanced cancer. Support Care Cancer 2006; 14:348–53.

Baseline (T_0)	
Date of Assessment	DD/MM/YYYY

Demographics

Gender *(please tick)* ○ Male ○ Female ○ Other

Age (yrs)		**Weight (kg)**	

Tick ✓	**Primary life limiting illness** *(please choose only one)*
	Advanced cancer – please specify type of cancer: _____
	End stage renal failure
	Hepatic failure
	Neurodegenerative disease
	AIDS
	Cardiac failure
	Respiratory failure
	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 non-metastatic solid 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)		Patient has no comorbidities

Laboratory Tests (only if available in the last 14 days)	
Test	**Value**
Bilirubin (mg/dL)	
ALT (U/L)	
eGFR (mL/min)	
Corrected Calcium (mg/dL)	

Tick ✓		Is patient currently taking any of these medications? *(tick 'yes' or 'no' to all)*
Yes	**No**	
		Anti-arrhythmic drugs: If yes please specify which is being taken here: _____
		Selective Serotonin Reuptake Inhibitors: If yes please specify which SSRI is being taken here: _____
		Serotonin and Norepinephrine Reuptake Inhibitors: If yes please specify which SNRI is being taken here; _____
		St John's Wort
		Antipsychotic: If yes please specify which antipsychotic is being taken. _____
		Antidepressants (e.g. tricyclic antidepressants, psychostimulants, other antidepressants): If yes please specify which antidepressant is being taken here; _____
		Corticosteroids
		Antimicrobial drug: If yes, please specify which antimicrobial drug is being taken here; _____
		Antimalarial drug: If yes please specify which drug is being taken here; _____
		Tramadol
		Other Opioids
		Apomorphine
		NSAIDS

Baseline T_0 - Medication Commencement

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

Nausea

○ 0 ○ 1 ○ 2 ○ 3

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

○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5

NCI Criteria

0. Nil
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 hospitalization indicated
4. life threatening consequences: urgent intervention indicated
5. Death

Tick ✓	**In the opinion of the clinician commencing Ondansetron what is the presumed/most likely dominant mechanism of nausea and vomiting** *(tick only one)*
	Chemical (e.g., drugs, renal failure)
	Cranial (e.g., brain tumour, infarction)
	Vestibular (e.g., motion sickness, vertigo
	Visceral/serosal (e.g., obstruction of hollow abdominal viscus, stretched liver capsule)
	Impaired gastric emptying (e.g., autonomic dysfunction, drugs)
	Cortical (e.g., Anxiety, pain)
	Multifactorial
	Cause undetermined

Tick ✓	**Current other anti-emetics** *(tick all that patient is taking)*
	Metoclopramide: Will patient continue to take this medication Y/N
	Haloperidol: Will patient continue to take this medication Y/N
	Levomepromazine; Will patient continue to take this medication Y/N
	Steroids: Will patient continue to take this medication Y/N
	Cyclizine; Will patient continue to take this medication Y/N
	Cannabis Will patient continue to take this medication Y/N;
	Olanzapine: Will patient continue to take this medication Y/N
	Prochlorperazine; Will patient continue to take this medication Y/N
	Domperidone; Will patient continue to take this medication Y/N
	Aprepitant or other NK1 antagonist. Will patient continue to take this medication Y/N
	Lorazepam: Will patient continue to take this medication Y/N
	Other anti-emetic: Please specify name and dosage here: Will patient continue to take this medication Y/N

Tick ✓	**Is patient commencing Ondansetron?**
	Regular dose only
	Regular and PRN

Starting Dose of <u>Regular</u> Ondansetron	
	Dose (mgs)
	Frequency - *e.g., Daily (mane), BD, TDS,*
	Route - *oral, oral mucosal, subcutaneous, IV, IMI (if more than one route please record all routes prescribed for administration)*

Starting Dose of <u>PRN</u> Ondansetron *(if applicable)*	
	Dose (mgs)
	Frequency of PRN dose allowed (this is the frequency on top of the regular dose) - *e.g., 4th hourly, 6th hourly, 8th hourly*
	Route - *oral, oral mucosal, subcutaneous, IV, IMI (if more than one route please record all routes prescribed for administration)*

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

☐ **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

☐ **Diarrhoea**

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

NCI Criteria
1. Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline
2. Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline; limiting instrumental ADL
3. Increase of =7 stools per day over baseline; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **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

☐ **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

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

Please specify other harm here _____

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

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

Please specify additional other harm here _____

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

Tick ✓	**Which symptom/harm is considered <u>most</u> troublesome by the clinician?** *(Tick one only)*
	Constipation
	Diarrhoea
	Headache
	Dizziness
	Other
	Additional Other
	Not applicable

T_1 Two days 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
	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 2 days after baseline. *(e.g., weekend)*

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

Nausea

○ 0 ○ 1 ○ 2 ○ 3

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

○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5

NCI Criteria
0. Nil
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 hospitalization indicated
4. life threatening consequences: urgent intervention indicated
5. Death

Current Ondansetron Dose	
	Total dose of Ondansetron given (include both regular and PRN) in the last 24 hours *(mg)*
	How long has the patient been on this dose *(days)*

T_1 - Symptom/Harm Assessment *(Please grade all harms; indicate that each harm has been assessed by ticking the square box next to each)*

☐ **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

☐ **Diarrhoea**

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

NCI Criteria
1. Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline
2. Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline; limiting instrumental ADL
3. Increase of =7 stools per day over baseline; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **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

☐ **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

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

Please specify other harm here _____

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

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

Please specify additional other harm here _____

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

Tick ✓	**Which symptom/harm is considered <u>most</u> troublesome by the clinician?** *(Tick one only)*
	Constipation
	Diarrhoea
	Headache
	Dizziness
	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?			

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

Tick ✓		**Medication changes** *(Tick all that apply)*
		No change to Ondansetron medication/continue current dose
		Ondansetron ceased *(complete medication cessation on page 15)*
		Ondansetron dose reduced - *Please specify new dose in mgs:* _____
		Ondansetron dose increased - *Please specify new dose in mgs:*_____
		Route of administration of Ondansetron changed – Please specify new route here: _____
Yes	**No**	**Have there been any changes to the dose (including cessation) of the current anti-emetics recorded on the CRF at baseline?**
		If yes, please specify changes to the dose of current other anti-emetics here: _____
Yes	**No**	**Has a new anti-emetic been commenced since baseline?**
		If yes, please specify name of medication, dose and frequency of anti-emetic here: _____
Yes	**No**	**Has a medication been added to treat a specific harm?**
		If yes, please specify new medication here: _____

Based on the assessment today has the harm resolved?

○ Yes ○ No ○ Not applicable

T_2 Seven days 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_2)* OR
	Died *(record date of death below)*
	Not able to be contacted / located
	Too unwell
	Other

Date of Death*	DD/MM/YYYY

End survey here

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

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

Nausea

○ 0 ○ 1 ○ 2 ○ 3

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

○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5

NCI Criteria
0. Nil
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 hospitalization indicated
4. life threatening consequences: urgent intervention indicated
5. Death

Current Ondansetron Dose	
	Total dose of Ondansetron given (include both regular and PRN) in the last 24 hours *(mg)*
	How long has the patient been on this dose *(days)*

T_2 - Symptom/Harm Assessment *(Please grade all harms; indicate that each harm has been assessed by ticking the square box next to each)*

☐ **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

☐ **Diarrhoea**

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

NCI Criteria
1. Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline
2. Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline; limiting instrumental ADL
3. Increase of =7 stools per day over baseline; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **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

☐ **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

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

Please specify other harm here _____

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

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

Please specify additional other harm here _____

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

Tick ✓	**Which symptom/harm is considered <u>most</u> troublesome by the clinician?** *(Tick one only)*
	Constipation
	Diarrhoea
	Headache
	Dizziness
	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?			

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

Tick ✓		**Medication changes** *(Tick all that apply)*
		No change to Ondansetron medication/continue current dose
		Ondansetron ceased *(complete medication cessation on page 13)*
		Ondansetron dose reduced - *Please specify new dose in mgs:* _____
		Ondansetron dose increased - *Please specify new dose in mgs:*_____
		Route of administration of Ondansetron changed – Please specify new route here: _____
Yes	**No**	**Have there been any changes (including cessation) to the dose of the current anti-emetics recorded on the CRF at baseline?**
		If yes, please specify changes to the dose of current other anti-emetics here: _____
Yes	**No**	**Has a new anti-emetic been commenced since baseline?**
		If yes, please specify name of medication, dose and frequency of anti-emetic here: _____
Yes	**No**	**Has a medication been added to treat a specific harm?**
		If yes, please specify new medication here: _____

Based on the assessment today has the harm resolved?

○ Yes ○ No ○ Not applicable

Medication Cessation *(complete this page if the intervention/medication of interest is ceased at any point during the study period)*	
Date of Assessment (medication cessation)	DD/MM/YYYY

Tick ✓	Ondansetron 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*

☐ **Nausea**

○ 0 ○ 1 ○ 2 ○ 3

NCI Criteria

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

☐ **Vomiting**

○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5

NCI Criteria

6. Nil
7. 1-2 episodes (separated by > 5 minutes) in 24 hours
8. 3-5 episodes (separated by > 5 minutes) in 24 hours
9. >=6 episodes (separated by > 5 minutes) in 24 hours; tube feeding, TPN or hospitalization indicated
10. life threatening consequences: urgent intervention indicated
11. Death

Tick ✓	Ondansetron was ceased (related to other reasons)
	Harm/toxicity
	Patient unable to take medication
	Other - *Please specify:*

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

Ad hoc A - Unscheduled Harm/Toxicity Assessment

Date of Assessment	DD/MM/YYYY

Harm/toxicity Assessment *(Please grade all harms; indicate that each harm has been assessed by ticking the square box next to each)*

☐ **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

☐ **Diarrhoea**

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

NCI Criteria
1. Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline
2. Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline; limiting instrumental ADL
3. Increase of =7 stools per day over baseline; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **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

☐ **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

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

Please specify other harm here _____

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

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

Please specify additional other harm here _____

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

Tick ✓	**Which symptom/harm is considered <u>most</u> troublesome by the clinician?** *(Tick one only)*
	Constipation
	Diarrhoea
	Headache
	Dizziness
	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?			

Ad hoc B - Unscheduled Harm/Toxicity Assessment

Date of Assessment	DD/MM/YYYY

Harm/toxicity Assessment *(Please grade all harms; indicate that each harm has been assessed by ticking the square box next to each)*

☐ **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

☐ **Diarrhoea**

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

NCI Criteria
1. Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline
2. Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline; limiting instrumental ADL
3. Increase of =7 stools per day over baseline; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **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

☐ **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

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

Please specify other harm here _____

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

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

Please specify additional other harm here _____

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

Tick ✓	**Which symptom/harm is considered <u>most</u> troublesome by the clinician?** *(Tick one only)*
	Constipation
	Diarrhoea
	Headache
	Dizziness
	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?			

Ad hoc C - Unscheduled Harm/Toxicity Assessment

Date of Assessment	DD/MM/YYYY

Harm/toxicity Assessment *(Please grade all harms; indicate that each harm has been assessed by ticking the square box next to each)*

☐ **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

☐ **Diarrhoea**

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

NCI Criteria
1. Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline
2. Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline; limiting instrumental ADL
3. Increase of =7 stools per day over baseline; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **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

☐ **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

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

Please specify other harm here _____

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

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

Please specify additional other harm here _____

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

Tick ✓	**Which symptom/harm is considered <u>most</u> troublesome by the clinician?** *(Tick one only)*
	Constipation
	Diarrhoea
	Headache
	Dizziness
	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?			