Participant ID	

Initials of person entering data	

Staff email	

CONFIDENTIAL CASE REPORT FORM

Pancreatic Enzyme Replacement Therapy (PERT) for Pancreatic Cancer

Series 53

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)

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

Clinician Demographics	
Tick ✓	**Where are you located?** *(Tick one)*
	Australia
	New Zealand (Aotearoa)
	Other, please specify:
Tick ✓	**What is your clinical role?** *(tick whichever applies)*
	Gastroenterologist
	GP
	Surgeon
	Oncologist
	Dietitian
	Nurse Practitioners
	Palliative care doctor
	Other, please specify:

Participant Demographics					
Gender *(please tick)* ○ Male ○ Female ○ Non-binary ○ Prefer not to say					
Age (yrs)		**Weight (kg)**		**Height (cm)**	

Tick ✓	**Ethnicity (as identified on health record)**
	New Zealand/Australia
	Aboriginal Peoples – Australia
	Both Aboriginal and Torres Strait Islander
	Australian not identifying as either Aboriginal or Torres Strait Islander
	African
	Latin American/Hispanic
	Māori– Aotearoa NZ Iwi_____
	Middle Eastern
	Asian
	Chinese
	Indian
	Southeast Asian

	Other Asian
	European
	NZ European
	Australian of European descent
	Other European
	Pacific Peoples (excluding USA)
	Samoan
	Fijian
	Tongan
	Other Pacific
	Torres Strait Islander
	North American Classifications
	White American
	Black American
	Asian American
	Native American/Alaskan Native
	Native Hawaiian/Pacific Islander
	American mixed ethnicity
	Aboriginal Peoples – Canada (include Canadian First Nations, Inuit, Métis)
	Other group not list above; Please specify

Tick ✓	**Place of Care** *(tick whichever applies)*
	Home
	Inpatient – public
	Inpatient – private
	Outpatient – public
	Outpatient – private
	Outpatient – community (e.g. hospice)
	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 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)		

Baseline T_0 – Medication commencement

Tick ✓	Which brand of PERT is patient being commenced on?
	Creon
	Panzytrat
	Other, please specify:

Starting Dose of PERT	
Tick ✓	**Dose (International units)**
	10,000
	25,000
	35,000
	50,000
	70,000
	75,000
	Other, please specify:
Tick ✓	**Frequency**
	TDS
	QID
	With meals
	Before meals
	After meals
	With meals and snacks
	Before meals and snacks
	After meals and snacks
	Allowing patient to choose own dose
	Other, please specify:

Is the patient on a Proton Pump Inhibitor (PPI) such as omeprazole, pantoprazole etc.?	◯Yes ◯ No

Baseline Symptom/Harm Assessment
(Please grade symptoms; indicate that the symptom has been assessed by ticking the square box next to the symptom)

☐ **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

☐ **Ability to eat**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

Criteria
1. Occasional
2. Frequent
3. Complete

☐ **Anorexia**

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

NCI Criteria:
1.Loss of appetite without alteration in eating habits
2.Oral intake altered without significant weight loss or malnutrition;
3. Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake)
4. Life-threatening consequences; urgent intervention indicated

☐ **Belching**

○ 1 ○ 2 ○ Ungradable ○ No symptom

NCI Criteria
1. Increase from baseline
2. Intervention initiated (including OTC medications)

☐ **Bloating**

○ 1 ○ 2 ○ Ungradable ○ No symptom

NCI Criteria
1. No change in bowel function or oral intake
2. Symptomatic, decreased oral intake; change in bowel function

☐ **Diarrhoea**

○ 1 ○ 2 ○ 3 ○ 4 ○ 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

☐ **Fatigue**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

NCI Criteria
1. Fatigue relieved by rest
2. Fatigue not relieved by rest; limiting instrumental ADL
3. Fatigue not relieved by rests, limiting self-care ADL

☐ **Flatulence**

○ 1 ○ 2 ○ Ungradable ○ No symptom

NCI Criteria
1. Mild symptoms; intervention not indicated
2. Moderate; persistent; psychosocial sequelae

☐ **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, dehydration, or malnutrition
3. Oral intake decreased with significant weight loss, dehydration, or malnutrition

☐ **Vomiting**

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

NCI Criteria
1.Intervention not indicated
2. Outpatient IV hydration; medical intervention indicated
3. Tube feeding, TPN, or hospitalization indicated
4. Life-threatening consequences

☐ **Weight gain** *(in the last month)*

○ 1 ○ 2 ○ 3 ○ Ungradable/change not recorded ○ No symptom

NCI Criteria
1. 5 to <10% weight gain
2. 10 to <20% weight gain
3. >= 20% weight gain

☐ **Weight loss** *(in the last month)*

○ 1 ○ 2 ○ 3 ○ Ungradable/change not recorded ○ No symptom

NCI Criteria
1. 5 to <10% weight loss; intervention not indicated
2. 10 to <20% weight loss; nutritional support indicated
3. >= 20% weight loss; tube feeding indicated

☐ **Other (if exists)** (only if applicable-can be related or unrelated to intervention)

Please specify other symptom:_____

○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate
3. Severe

☐ **Additional other (if exists)** (only if applicable-can be related or unrelated to intervention)

Please specify additional other symptom: _____

○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate
3. Severe

Tick ✓	**Which symptom/harm is the <u>most</u> troublesome?** *(Tick one only)*
	Abdominal pain
	Ability to eat
	Anorexia
	Belching
	Bloating
	Diarrhoea
	Fatigue
	Flatulence
	Nausea
	Vomiting
	Weight gain
	Weight loss
	Other
	Additional Other
	Not applicable

T_1 –14 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 14 days after baseline. *(e.g., weekend)*

Has medication been taken as directed?	
○ Yes ○ No, specify:	
Current Dose of PERT	
Tick ✓	**Dose (International Units)**
	10,000
	25,000
	35,000
	50,000
	70,000
	75,000
	Other, please specify:
Tick ✓	**Frequency**
	TDS
	QID
	With meals
	Before meals
	After meals

	With meals and snacks
	Before meals and snacks
	After meals and snacks
	Allowing patient to choose own dose
	Other, please specify:

Is the patient on a Proton Pump Inhibitor (PPI) such as omeprazole, pantoprazole etc.?	◯Yes ◯ No

Cost to patient	
Did the patient have to pay for medication?	◯ Yes ◯ No ◯ N/A
How much? *Specify amount and currency if applicable.*	

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

☐ **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

☐ **Ability to eat**

◯ 1 ◯ 2 ◯ 3 ◯ Ungradable ◯ No symptom

Criteria
1. Occasional
2. Frequent
3. Complete

☐ **Anorexia**

◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ Ungradable ◯ No symptom

NCI Criteria:
1.Loss of appetite without alteration in eating habits
2.Oral intake altered without significant weight loss or malnutrition
3. Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake)
4. Life-threatening consequences; urgent intervention indicated

☐ **Belching**

○ 1 ○ 2 ○ Ungradable ○ No symptom

NCI Criteria
1. Increase from baseline
2. Intervention initiated (including OTC medications)

☐ **Bloating**

○ 1 ○ 2 ○ Ungradable ○ No symptom

NCI Criteria
1. No change in bowel function or oral intake
2. Symptomatic, decreased oral intake; change in bowel function

☐ **Diarrhoea**

○ 1 ○ 2 ○ 3 ○ 4 ○ 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

☐ **Fatigue**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

NCI Criteria
1. Fatigue relieved by rest
2. Fatigue not relieved by rest; limiting instrumental ADL
3. Fatigue not relieved by rests, limiting self-care ADL

☐ **Flatulence**

○ 1 ○ 2 ○ Ungradable ○ No symptom

NCI Criteria
1. Mild symptoms; intervention not indicated
2. Moderate; persistent; psychosocial sequelae

☐ **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, dehydration, or malnutrition
3. Oral intake decreased with significant weight loss, dehydration, or malnutrition

☐ **Vomiting**

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

NCI Criteria
1.Intervention not indicated
2. Outpatient IV hydration; medical intervention indicated
3. Tube feeding, TPN, or hospitalization indicated
4. Life-threatening consequences

☐ **Weight gain** *(since last assessment)*

○ 1 ○ 2 ○ 3 ○ Ungradable/change not recorded ○ No symptom

NCI Criteria
1. 5 to <10% weight gain
2. 10 to <20% weight gain
3. >= 20% weight gain

☐ **Weight loss** *(since last assessment)*

○ 1 ○ 2 ○ 3 ○ Ungradable/change not recorded ○ No symptom

NCI Criteria
1. 5 to <10% weight loss; intervention not indicated
2. 10 to <20% weight loss; nutritional support indicated
3. >= 20% weight loss; tube feeding indicated

☐ **Other (if exists)** (only if applicable-can be related or unrelated to intervention)
Please specify other symptom:_____

○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate
3. Severe

☐ **Additional other (if exists)** (only if applicable-can be related or unrelated to intervention)
Please specify additional other symptom: _____

○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate
3. Severe

Tick ✓	**Which symptom/harm is the <u>most</u> troublesome?** *(Tick one only)*
	Abdominal pain
	Ability to eat
	Anorexia
	Belching
	Bloating
	Diarrhoea
	Fatigue
	Flatulence
	Nausea
	Vomiting
	Weight gain
	Weight loss
	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?			
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?			

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

○ Yes ○ No

Please describe in a few words:

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

Tick ✓	**Medication changes** *(Tick all that apply)*
	No change to PERT medication, continue current dose
	PERT medication reduced - *Please specify new dose:*
	PERT medication increased -*Please specify new dose:*
	PERT medication ceased *(complete medication cessation on page 14)*

Based on the assessment today has the harm resolved?

○ Yes ○ No ○ Not applicable

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

Tick ✓	PERT medication was ceased (related to indication of interest)
	Symptom/s resolved - *Please indicate date symptom resolved: DD/MM/YYYY*
	Symptom/s continued unchanged
	Symptom/s worsened - *Please record NCI grade below*

Please specify which symptom and record grade: _____

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

Tick ✓	PERT medication 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

Symptom Severity Scores

Please grade all harms; indicate that each harm has been assessed by ticking the square box above each

☐ **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

☐ **Ability to eat**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

Criteria
1. Occasional
2. Frequent
3. Complete

☐ **Anorexia**

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

NCI Criteria:
1.Loss of appetite without alteration in eating habits
2.Oral intake altered without significant weight loss or malnutrition
3. Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake)
4. Life-threatening consequences; urgent intervention indicated

☐ **Belching**

○ 1 ○ 2 ○ Ungradable ○ No symptom

NCI Criteria
1. Increase from baseline
2. Intervention initiated (including OTC medications)

☐ **Bloating**

○ 1 ○ 2 ○ Ungradable ○ No symptom

NCI Criteria
1. No change in bowel function or oral intake
2. Symptomatic, decreased oral intake; change in bowel function

☐ **Diarrhoea**

○ 1 ○ 2 ○ 3 ○ 4 ○ 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

☐ **Fatigue**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

NCI Criteria
1. Fatigue relieved by rest
2. Fatigue not relieved by rest; limiting instrumental ADL
3. Fatigue not relieved by rests, limiting self-care ADL

☐ **Flatulence**

○ 1 ○ 2 ○ Ungradable ○ No symptom

NCI Criteria
1. Mild symptoms; intervention not indicated
2. Moderate; persistent; psychosocial sequelae

☐ **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, dehydration, or malnutrition
3. Oral intake decreased with significant weight loss, dehydration, or malnutrition

☐ **Vomiting**

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

NCI Criteria
1.Intervention not indicated
2. Outpatient IV hydration; medical intervention indicated
3. Tube feeding, TPN, or hospitalization indicated
4. Life-threatening consequences

☐ **Weight gain** *(since last assessment)*

○ 1 ○ 2 ○ 3 ○ Ungradable/change not recorded ○ No symptom

NCI Criteria
1. 5 to <10% weight gain
2. 10 to <20% weight gain
3. >= 20% weight gain

☐ **Weight loss** *(since last assessment)*

○ 1 ○ 2 ○ 3 ○ Ungradable/change not recorded ○ No symptom

NCI Criteria
1. 5 to <10% weight loss; intervention not indicated
2. 10 to <20% weight loss; nutritional support indicated
3. >= 20% weight loss; tube feeding indicated

☐ **Other (if exists)** (only if applicable-can be related or unrelated to intervention)
Please specify other symptom:_____

○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria 1. Mild 2. Moderate 3. Severe

☐ **Additional other (if exists)** (only if applicable-can be related or unrelated to intervention)
Please specify additional other symptom: _____

○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria 1. Mild 2. Moderate 3. Severe

Tick ✓	**Which symptom/harm is the <u>most</u> troublesome?** *(Tick one only)*
	Abdominal pain
	Ability to eat
	Anorexia
	Belching
	Bloating
	Diarrhoea
	Fatigue
	Flatulence
	Nausea
	Vomiting
	Weight gain
	Weight loss
	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?			
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

Symptom Severity Scores

Please grade all harms; indicate that each harm has been assessed by ticking the square box above each

☐ **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

☐ **Ability to eat**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

Criteria
1. Occasional
2. Frequent
3. Complete

☐ **Anorexia**

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

NCI Criteria:
1.Loss of appetite without alteration in eating habits
2.Oral intake altered without significant weight loss or malnutrition
3. Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake)
4. Life-threatening consequences; urgent intervention indicated

☐ **Belching**

○ 1 ○ 2 ○ Ungradable ○ No symptom

NCI Criteria
1. Increase from baseline
2. Intervention initiated (including OTC medications)

☐ **Bloating**

○ 1 ○ 2 ○ Ungradable ○ No symptom

NCI Criteria
1. No change in bowel function or oral intake
2. Symptomatic, decreased oral intake; change in bowel function

☐ **Diarrhoea**

○ 1 ○ 2 ○ 3 ○ 4 ○ 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

☐ **Fatigue**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

NCI Criteria
1. Fatigue relieved by rest
2. Fatigue not relieved by rest; limiting instrumental ADL
3. Fatigue not relieved by rests, limiting self-care ADL

☐ **Flatulence**

○ 1 ○ 2 ○ Ungradable ○ No symptom

NCI Criteria
1. Mild symptoms; intervention not indicated
2. Moderate; persistent; psychosocial sequelae

☐ **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, dehydration, or malnutrition
3. Oral intake decreased with significant weight loss, dehydration, or malnutrition

☐ **Vomiting**

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

NCI Criteria
1.Intervention not indicated
2. Outpatient IV hydration; medical intervention indicated
3. Tube feeding, TPN, or hospitalization indicated
4. Life-threatening consequences

☐ **Weight gain** *(since last assessment)*

○ 1 ○ 2 ○ 3 ○ Ungradable/change not recorded ○ No symptom

NCI Criteria
1. 5 to <10% weight gain
2. 10 to <20% weight gain
3. >= 20% weight gain

☐ **Weight loss** *(since last assessment)*

○ 1 ○ 2 ○ 3 ○ Ungradable/change not recorded ○ No symptom

NCI Criteria
1. 5 to <10% weight loss; intervention not indicated
2. 10 to <20% weight loss; nutritional support indicated
3. >= 20% weight loss; tube feeding indicated

☐ **Other (if exists)** (only if applicable-can be related or unrelated to intervention)
Please specify other symptom:_____

○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria 1. Mild 2. Moderate 3. Severe

☐ **Additional other (if exists)** (only if applicable-can be related or unrelated to intervention)
Please specify additional other symptom: _____

○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria 1. Mild 2. Moderate 3. Severe

Tick ✓	**Which symptom/harm is the <u>most</u> troublesome?** *(Tick one only)*
	Abdominal pain
	Ability to eat
	Anorexia
	Belching
	Bloating
	Diarrhoea
	Fatigue
	Flatulence
	Nausea
	Vomiting
	Weight gain
	Weight loss
	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?			
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

Symptom Severity Scores

Please grade all harms; indicate that each harm has been assessed by ticking the square box above each

☐ **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

☐ **Ability to eat**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

Criteria
1. Occasional
2. Frequent
3. Complete

☐ **Anorexia**

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

NCI Criteria:
1.Loss of appetite without alteration in eating habits
2.Oral intake altered without significant weight loss or malnutrition
3. Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake)
4. Life-threatening consequences; urgent intervention indicated

☐ **Belching**

○ 1 ○ 2 ○ Ungradable ○ No symptom

NCI Criteria
1. Increase from baseline
2. Intervention initiated (including OTC medications)

☐ **Bloating**

○ 1 ○ 2 ○ Ungradable ○ No symptom

NCI Criteria
1. No change in bowel function or oral intake
2. Symptomatic, decreased oral intake; change in bowel function

☐ **Diarrhoea**

○ 1 ○ 2 ○ 3 ○ 4 ○ 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

☐ **Fatigue**

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No symptom

NCI Criteria
1. Fatigue relieved by rest
2. Fatigue not relieved by rest; limiting instrumental ADL
3. Fatigue not relieved by rests, limiting self-care ADL

☐ **Flatulence**

○ 1 ○ 2 ○ Ungradable ○ No symptom

NCI Criteria
1. Mild symptoms; intervention not indicated
2. Moderate; persistent; psychosocial sequelae

☐ **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, dehydration, or malnutrition
3. Oral intake decreased with significant weight loss, dehydration, or malnutrition

☐ **Vomiting**

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

NCI Criteria
1.Intervention not indicated
2. Outpatient IV hydration; medical intervention indicated
3. Tube feeding, TPN, or hospitalization indicated
4. Life-threatening consequences

☐ **Weight gain** *(since last assessment)*

○ 1 ○ 2 ○ 3 ○ Ungradable/change not recorded ○ No symptom

NCI Criteria
1. 5 to <10% weight gain
2. 10 to <20% weight gain
3. >= 20% weight gain

☐ **Weight loss** *(since last assessment)*

○ 1 ○ 2 ○ 3 ○ Ungradable/change not recorded ○ No symptom

NCI Criteria
1. 5 to <10% weight loss; intervention not indicated
2. 10 to <20% weight loss; nutritional support indicated
3. >= 20% weight loss; tube feeding indicated

☐ **Other (if exists)** (only if applicable-can be related or unrelated to intervention)
Please specify other symptom:_____

○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria 1. Mild 2. Moderate 3. Severe

☐ **Additional other (if exists)** (only if applicable-can be related or unrelated to intervention)
Please specify additional other symptom: _____

○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria 1. Mild 2. Moderate 3. Severe

Tick ✓	**Which symptom/harm is the <u>most</u> troublesome?** *(Tick one only)*
	Abdominal pain
	Ability to eat
	Anorexia
	Belching
	Bloating
	Diarrhoea
	Fatigue
	Flatulence
	Nausea
	Vomiting
	Weight gain
	Weight loss
	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?			
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?			