Participant ID	

Initials of person entering data	

Staff email	

CONFIDENTIAL CASE REPORT FORM

Paracetamol - Mesothelioma Night Sweats

Rapid Program Series No: 44

IMPACCT Trials Coordination Centre (ITCC)
UTS Rapid Program

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

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

Demographics

Gender ○ Male ○ Female ○ Other

Age (yrs)		**Weight (kg)**		**Height (cm)**	

Yes	**No**	**Is a diagnosis of Mesothelioma confirmed?**

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

Laboratory Tests (only if available)	
Test	**Value**
Haemoglobin (Hb)	
Platelets (mcL)	
CRP (mg/L)	
eGFR (mL/min)	
INR	
BSL (mmol/L)	
ALT (U/L)	

Yes	**No**	**Is patient currently on any systemic therapy?** *(Tick yes or no to all)*
Tick ✓	**Tick ✓**	
		Chemotherapy
		Immunotherapy
		Bevacizumab

Baseline T_0 - Medication Commencement

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

☐ **Night Sweats**

○ 0 ○ 1 ○ 2 ○ 3

NCI Criteria 0. Asymptomatic 1. Mild 2. Moderate night sweats (e.g., need to change pyjamas through the night) 3. Severe (e.g., needing to change bed clothes through the night)

Yes	No	Are the night sweats interfering with the patients sleep?

PARACETAMOL STARTING DOSE	
	Dose (mgs)
	Frequency - *e.g., Daily, BD, TDS, QID, PRN*
	Route - *oral, rectal, IV*

Tick ✓	Other non-pharmacological measures being used *(tick all that apply)*
	Keeping the temperature low in the house at night
	Sleeping with just a sheet
	Using a cold compress
	Using a fan or air conditioning
	Staying hydrated with cold drinks
	Using ice packs
	Avoiding caffeine, alcohol, and spicy foods
	Using relaxation strategies
	No non – pharmacological measures being used

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

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

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.

☐ **Hepatic Failure**

○ 3 ○ 4 ○ 5 ○ no symptom ○ ungradable

NCI Criteria 1. 2. 3. Asterixis; mild encephalopathy; drug induced liver injury (DILI); limiting self-care ADL 4. Life-threatening consequences; moderate to severe encephalopathy; coma 5. Death

☐ **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 is the most troublesome?**
	Nausea
	Hepatic Failure
	Other
	Additional Other
	Not applicable

T_1 – 7 days post Baseline Assessment	
Date of Assessment	DD/MM/YYYY
Time of Assessment (24 hr time)	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 7 days after baseline. *(e.g., weekend)*

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

☐ **Night Sweats**

○ 0 ○ 1 ○ 2 ○ 3

NCI Criteria
0. Asymptomatic
1. Mild
2. Moderate night sweats (e.g., need to change pyjamas through the night)
3. Severe (e.g., needing to change bed clothes through the night)

Yes	No	Are the night sweats interfering with the patients sleep?

Total dose of paracetamol given in the last 24 hours (mg)	
How long has the patient been on this dose (days)	

Tick ✓		Has patient been commenced on any new medications since baseline? (*If yes please specify name of medication, dose, and frequency.*		
Yes	No	**Medication Name**	**Dose**	**Frequency**

Tick ✓	**Other non-pharmacological measures being used** *(tick all that apply)*
	Keeping the temperature low in the house at night
	Sleeping with just a sheet
	Using a cold compress
	Using a fan or air conditioning
	Staying hydrated with cold drinks
	Using ice packs
	Avoiding caffeine, alcohol, and spicy foods
	Using relaxation strategies
	No non – pharmacological measures being used

T_1 –Harm/Toxicity Assessment
(Please grade all harms/toxicities regardless of whether they are attributable to the medication of interest or not; indicate that each harm has been assessed by ticking the square box next to each)

☐ **Nausea**
○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

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.

☐ **Hepatic Failure**
○ 3 ○ 4 ○ 5 ○ no symptom ○ ungradable

NCI Criteria
1.
2.
3. Asterixis; mild encephalopathy; drug induced liver injury (DILI); limiting self-care ADL
4. Life-threatening consequences; moderate to severe encephalopathy; coma
5. Death

☐ **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 is the most troublesome?
	Nausea
	Hepatic Failure
	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?			

Toxicity assessment follow-up

Tick ✓	What is the intended treatment based on today's assessment? *(Tick all that apply)*
	No change to medication of interest/continue current dose
	Medication of interest ceased (complete medication cessation on page 19)
	Medication of interest dose reduced; please specify new dose in mgs:
	Medication of interest increased; please specify new dose in mgs:
	New medication being commenced for night sweats. *Please specify which medication below.* ◯ Corticosteroids ◯ NSAIDS ◯ Other: Please specify: _____

Yes	No	Has a medication been added to treat a specific harm/toxicity? If yes, please specify:

Based on the assessment today has the toxicity resolved?
◯ Yes ◯ No ◯ N/A

T_2 – 14 days post Baseline Assessment	
Date of Assessment	DD:MM: YYYY
Time of Assessment (24 hr time)	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 14 days after baseline. *(e.g., weekend)*

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

☐ **Night Sweats**

○ 0 ○ 1 ○ 2 ○ 3

NCI Criteria
0. Asymptomatic
1. Mild
2. Moderate night sweats (e.g., need to change pyjamas through the night)
3. Severe (e.g., needing to change bed clothes through the night)

Yes	No	Are the night sweats interfering with the patients sleep?

Total dose of paracetamol given in the last 24 hours (mg)	
How long has the patient been on this dose (days)	

Tick ✓		Has patient been commenced on any new medications since baseline? (*If yes please specify name of medication, dose, and frequency.*		
Yes	No	**Medication Name**	**Dose**	**Frequency**

Tick ✓	**Other non-pharmacological measures being used** *(tick all that apply)*
	Keeping the temperature low in the house at night
	Sleeping with just a sheet
	Using a cold compress
	Using a fan or air conditioning
	Staying hydrated with cold drinks
	Using ice packs
	Avoiding caffeine, alcohol, and spicy foods
	Using relaxation strategies
	No non – pharmacological measures being used

T_2 –Harm/Toxicity Assessment
(Please grade all harms/toxicities regardless of whether they are attributable to the medication of interest or not; indicate that each harm has been assessed by ticking the square box next to each)

☐ **Nausea**
○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

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.

☐ **Hepatic Failure**
○ 3 ○ 4 ○ 5 ○ no symptom ○ ungradable

NCI Criteria
1.
2.
3. Asterixis; mild encephalopathy; drug induced liver injury (DILI); limiting self-care ADL
4. Life-threatening consequences; moderate to severe encephalopathy; coma
5. Death

☐ **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 is the most troublesome?
	Nausea
	Constipation
	Acute kidney injury
	Hepatic Failure
	Allergic Reaction
	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?			

Tick ✓	**What is the intended treatment based on today's assessment?** *(Tick all that apply)*
	No change to medication of interest/continue current dose
	Medication of interest ceased (complete medication cessation on page 19)
	Medication of interest dose reduced; please specify new dose in mgs:
	Medication of interest increased; please specify new dose in mgs:
	New medication being commenced for night sweats. *Please specify which medication below.* ◯ Corticosteroids ◯ NSAIDS ◯ Other: Please specify: _____

Yes	No	Has a medication been added to treat a specific harm/toxicity? If yes, please specify:

Based on the assessment today has the toxicity resolved?
◯ Yes ◯ No ◯ N/A

Medication Cessation (complete this page if the medication of interest is 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 grade below: ☐ **Night Sweats** ○ 0 ○ 1 ○ 2 ○ 3 *NCI Criteria* 0. Asymptomatic 1. Mild 2. Moderate night sweats (e.g., need to change pyjamas through the night) 3. Severe (e.g., needing to change bed clothes through the night)

Tick ✓	**Intervention/medication was ceased (related to other reasons)**
	Harm/toxicity
	Patient unable to take medication; please specify reason: _____
	Other: please specify: _____

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

Adhoc 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)*

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

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.

☐ **Hepatic Failure**

○ 3 ○ 4 ○ 5 ○ no symptom ○ ungradable

NCI Criteria
1.
2.
3. Asterixis; mild encephalopathy; drug induced liver injury (DILI); limiting self-care ADL
4. Life-threatening consequences; moderate to severe encephalopathy; coma
5. Death

☐ **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 is the most troublesome?**
	Nausea
	Hepatic Failure
	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?			

Adhoc 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)*

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

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.

☐ **Hepatic Failure**

○ 3 ○ 4 ○ 5 ○ no symptom ○ ungradable

NCI Criteria
1.
2.
3. Asterixis; mild encephalopathy; drug induced liver injury (DILI); limiting self-care ADL
4. Life-threatening consequences; moderate to severe encephalopathy; coma
5. Death

☐ **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 is the most troublesome?**
	Nausea
	Hepatic Failure
	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?			

Adhoc 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)*

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ no symptom ○ ungradable

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.

☐ **Hepatic Failure**

○ 3 ○ 4 ○ 5 ○ no symptom ○ ungradable

NCI Criteria
1.
2.
3. Asterixis; mild encephalopathy; drug induced liver injury (DILI); limiting self-care ADL
4. Life-threatening consequences; moderate to severe encephalopathy; coma
5. Death

☐ **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 is the most troublesome?**
	Nausea
	Hepatic Failure
	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?			