Participant ID	

Initials of person entering data 1	
Initials of person entering data 2	

Staff email 1	
Staff email 2	

CONFIDENTIAL CASE REPORT FORM

Lidocaine Infusion for Pruritus

Series 58

IMPACCT Trials Coordination Centre (ITCC)

UTS IMPACCT Rapid Program

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

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

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

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

Tick ✓	**Primary life limiting illness** *(please choose only one)*
	End stage renal failure
	Liver failure
	Cancer - *Please specify if haematological, type of solid organ:* _____
	Cardiac failure
	Respiratory failure
	Neurodegenerative disease
	Other - *Please specify:* _____

Tick ✓	**Palliative Care Phase**
	1. Stable Phase: The person's symptoms are adequately controlled by established management. Further interventions to maintain symptom control and quality of life have been planned.
	2. Unstable Phase: The person experiences the development of a new problem or a rapid increase in the severity of existing problems either of which requires an urgent change in management or emergency treatment.
	3. Deteriorating Phase: The person experiences a gradual worsening of existing symptoms or the development of new but expected problems. These require the application of specific plans of care and regular review but not urgent or emergency treatment.
	4. Terminal Care Phase: Death is likely in a matter of days and no acute intervention is planned or required.

Tick ✓	**Australian Modified Karnofsky Performance Scale (AKPS)**
	100 - Normal; no complaints; no evidence of disease
	90 - Able to carry on normal activity; minor sign of symptoms of disease
	80 - Normal activity with effort; some signs or symptoms of disease
	70 - Cares for self; unable to carry on normal activity or to do active work
	60 - Requires occasional assistance but is able to care for most needs
	50 - Requires considerable assistance and frequent medical care
	40 - In bed more than 50% of the time
	30 - Almost completely bedfast
	20 - Totally bedfast and requiring extensive nursing care by professionals and/or family

	10 - Comatose or barely rousable
	0 - Dead
	Not able to determine

Charlson Comorbidity Index - Does the patient have any of the following?			
Tick ✓	*(Please tick all that apply)*	**Tick ✓**	*(Please tick all that apply)*
	Myocardial Infarction (history, not ECG changes only)		Hemiplegia
	Congestive Cardiac Failure		Moderate or Severe Renal Disease
	Peripheral Vascular Disease (includes aortic aneurysm ≥ 6 cm)		Diabetes (with end organ damage)
	Cerebrovascular Disease (CVA with mild or no residual or TIA)		Any Tumour
	Dementia		Leukaemia (acute or chronic)
	Chronic Pulmonary Disease		Lymphoma
	Connective Tissue Disease		Moderate or Severe Liver Disease
	Peptic Ulcer Disease		Metastatic Solid Tumour
	Mild Liver Disease (without portal hypertension, includes chronic hepatitis)		AIDS (not just HIV positive)
	Diabetes (without organ damage) (excludes diet-controlled alone)		

Laboratory tests (if available)	
eGFR	
Urea	
Bilirubin	
GGT	

Target Symptom Assessment - Pruritus

Pruritus

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild or localized;
2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts)
3. Widespread and constant; limiting sleep

Tick ✓	**Likely pathogenesis of pruritus** *(tick one)*
	Unknown
	Uraemic
	Cholestatic
	Cutaneous haematological malignancy
	Paraneoplastic
	Drug-related
	Dermatological
	Other - *Please specify:* _____

Date of onset *(if known)*	

Lidocaine commencement

Enter the starting dose below:	
mg over 24hr	
equivalent mg/kg/hr	

Tick ✓	**Other management strategies for pruritus** *(tick all that apply)*	**Dose**
	Topical	
	Emollients	
	Lidocaine patch	*Specify dose*
	Topical corticosteroids	
	Other topical agents *Please specify: _____*	
	Over the counter	
	Antihistamines *Please specify: _____*	*Specify dose*
	Evening primrose oil	
	Prescribed	
	Antidepressant *Please specify: _____*	*Specify dose*
	Bile acid sequestrants *Please specify: _____*	*Specify dose*
	Pregabalin or gabapentin *Please specify: _____*	*Specify dose*
	Rifampicin	*Specify dose*
	Systemic corticosteroids *Please specify: _____*	*Specify dose*
	Other	
	Phototherapy	
	Other - *Please specify: _____*	
	Unknown	

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

Pain

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

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

Somnolence

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation
3. Severe sedation

Dizziness/Lightheadedness

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild unsteadiness or sensation of movement
2. Moderate unsteadiness or sensation of movement
3. Severe unsteadiness or sensation of movement

Perioral Numbness/Paresthesia

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

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

Tinnitus

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild symptoms; intervention not indicated
2. Moderate symptoms
3. Severe symptoms

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

Please specify other symptom here_____

○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate
3. Severe

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

Please specify additional other symptom here_____

○ 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)*
	Pain
	Somnolence
	Dizziness/Lightheadedness
	Perioral Numbness/Paresthesia

	Tinnitus
	Other
	Additional Other
	Not applicable

T_1 – 24 hours post Baseline

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

Tick ✓	**T_1: Assessed/Not assessed reason**
	Assessed today *(continue to complete T_1)* OR
	Symptom resolved *(complete medication cessation form)*
	Died *(record date of death below)*
	Not able to be contacted / located
	Too unwell
	Other

Date of Death*	DD/MM/YYYY

End survey here

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

Target Symptom Assessment - Pruritus

Pruritus

◯ No symptom ◯ 1 ◯ 2 ◯ 3 ◯ Ungradable

NCI Criteria
1. Mild or localized;
2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts)
3. Widespread and constant; limiting sleep

Based on your assessment at T_1, rate clinician impression of change for pruritus <u>compared to Baseline</u>

◯ Improved ◯ No change ◯ Worse

Based on the assessment today has pruritus resolved?

◯ Yes ◯ No ◯ Partial resolution

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

Pain

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

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

Somnolence

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation
3. Severe sedation

Dizziness/Lightheadedness

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild unsteadiness or sensation of movement
2. Moderate unsteadiness or sensation of movement
3. Severe unsteadiness or sensation of movement

Perioral Numbness/Paresthesia

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

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

Tinnitus

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild symptoms; intervention not indicated
2. Moderate symptoms
3. Severe symptoms

Subcutaneous Site Reaction

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Tenderness with or without associated symptoms (e.g.,warmth, erythema, itching)
2. Pain; lipodystrophy; edema
3. Ulceration or necrosis; severe tissue damage

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

Please specify other symptom here_____

○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate

3. Severe

Additional other *(only if applicable – can be related or unrelated to the medication)*
Please specify additional other symptom here_____
○ 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)*
	Pain
	Somnolence
	Dizziness/Lightheadedness
	Perioral Numbness/Paresthesia
	Tinnitus
	Subcutaneous site 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?			
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 medication or treatment regimen/continue current dose
	Dose decreased *(Please specify dose below)*
	Dose increased *(Please specify dose below)*

	Medication ceased *(Complete medication cessation form)*
	New medication commenced: Please specify here: _____ _____

Lidocaine dose	
If the dose has decreased/increased, please specify the new dose:	
mg over 24hr	
equivalent mg/kg/hr	

T_2 – 3-5 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
	Symptom resolved *(complete medication cessation form)*
	Died *(record date of death below)*
	Not able to be contacted / located
	Too unwell
	Other

Date of Death*	DD/MM/YYYY

****End survey here***

Please provide reason if today's assessment is not 3-5 days after baseline. *(e.g., weekend)*

Lidocaine dose	
Please specify the current dose:	
mg over 24hr	
equivalent mg/kg/hr	

Target Symptom Assessment - Pruritus

Pruritus

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild or localized;
2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts)
3. Widespread and constant; limiting sleep

Based on your assessment at T_2, rate clinician impression of change for pruritus <u>compared to Baseline</u>

◯ Improved ◯ No change ◯ Worse

Based on the assessment today has pruritus resolved?

◯ Yes ◯ No ◯ Partial resolution

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

Pain

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

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

Somnolence

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation
3. Severe sedation

Dizziness/Lightheadedness

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild unsteadiness or sensation of movement
2. Moderate unsteadiness or sensation of movement
3. Severe unsteadiness or sensation of movement

Perioral Numbness/Paresthesia

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

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

Tinnitus

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild symptoms; intervention not indicated
2. Moderate symptoms
3. Severe symptoms

Subcutaneous Site Reaction

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Tenderness with or without associated symptoms (e.g.,warmth, erythema, itching)
2. Pain; lipodystrophy; edema
3. Ulceration or necrosis; severe tissue damage

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

Please specify other symptom here_____

○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate
3. Severe

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

Please specify additional other symptom here_____

○ 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)*
	Pain
	Somnolence
	Dizziness/Lightheadedness
	Perioral Numbness/Paresthesia
	Tinnitus
	Subcutaneous site 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?			
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 medication or treatment regimen/continue current dose
	Dose decreased *(Please specify dose below)*
	Dose increased *(Please specify dose below)*
	Medication ceased *(Complete medication cessation form)*
	New medication commenced: Please specify here: _____ _____

Lidocaine dose	
If the dose has decreased/increased, please specify the new dose:	
mg over 24hr	
equivalent mg/kg/hr	

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

Lidocaine dose	
Please specify the dose when lidocaine ceased:	
mg over 24hr	
equivalent mg/kg/hr	

Tick ✓	**Reason 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*
	Related to other reasons
	Harm/toxicity - *Please specify:*
	Unable to continue infusion. *Please specify reason (tick one):* ○ Subcutaneous site reaction ○ Logistical reasons
	Allergy
	Other - *Please specify:*

Pruritus

○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild or localized; topical intervention indicated
2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated
3. Widespread and constant; limiting sleep

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

Pain

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

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

Somnolence

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation
3. Severe sedation

Dizziness/Lightheadedness

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild unsteadiness or sensation of movement
2. Moderate unsteadiness or sensation of movement
3. Severe unsteadiness or sensation of movement

Perioral Numbness/Paresthesia

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

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

Tinnitus

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild symptoms; intervention not indicated
2. Moderate symptoms
3. Severe symptoms

Subcutaneous Site Reaction

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Tenderness with or without associated symptoms (e.g.,warmth, erythema, itching)
2. Pain; lipodystrophy; edema
3. Ulceration or necrosis; severe tissue damage

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

Please specify other symptom here_____

○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria

1. Mild 2. Moderate 3. Severe

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

NCI Criteria 1. Mild 2. Moderate 3. Severe

Ad hoc B - Unscheduled Harm/Toxicity Assessment

Date of Assessment	dd/mm/yyyy

Pain
○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

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

Somnolence
○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria 1. Mild but more than usual drowsiness or sleepiness 2. Moderate sedation 3. Severe sedation

Dizziness/Lightheadedness
○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria 1. Mild unsteadiness or sensation of movement 2. Moderate unsteadiness or sensation of movement 3. Severe unsteadiness or sensation of movement

Perioral Numbness/Paresthesia
○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

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

Tinnitus
○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria 1. Mild symptoms; intervention not indicated 2. Moderate symptoms 3. Severe symptoms

Subcutaneous Site Reaction

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Tenderness with or without associated symptoms (e.g.,warmth, erythema, itching)
2. Pain; lipodystrophy; edema
3. Ulceration or necrosis; severe tissue damage

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

Please specify other symptom here_____

○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate
3. Severe

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

Please specify additional other symptom here_____

○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate
3. Severe

Ad hoc C - Unscheduled Harm/Toxicity Assessment

Date of Assessment	dd/mm/yyyy

Pain

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

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

Somnolence

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation
3. Severe sedation

Dizziness/Lightheadedness

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild unsteadiness or sensation of movement
2. Moderate unsteadiness or sensation of movement
3. Severe unsteadiness or sensation of movement

Perioral Numbness/Paresthesia

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

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

Tinnitus

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild symptoms; intervention not indicated
2. Moderate symptoms
3. Severe symptoms

Subcutaneous Site Reaction

○ No symptom ○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Tenderness with or without associated symptoms (e.g.,warmth, erythema, itching)
2. Pain; lipodystrophy; edema
3. Ulceration or necrosis; severe tissue damage

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

Please specify other symptom here_____

○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate
3. Severe

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

Please specify additional other symptom here_____

○ 1 ○ 2 ○ 3 ○ Ungradable

NCI Criteria
1. Mild
2. Moderate
3. Severe