Participant ID	

Initials of person entering data	

Staff email	

CONFIDENTIAL CASE REPORT FORM

Diuretics for Cancer Related Lymphoedema

Series 26

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)

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

Demographics

Gender *(please tick)*	○ Male ○ Female ○ Other				
Patient Setting *(please tick)*	○ Inpatient ○ Outpatient				
Age (yrs.)		**Weight (kg)**		**Height (cm)**	

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

Tick ✓	**Predominant cause of cancer related lymphoedema** *Please choose only one*
	Tumour bulk
	Previous surgery for cancer
	Previous radiotherapy for cancer
	Chronic venous insufficiency – cancer-related thrombosis

Tick ✓	**Contributing Factors to Lymphoedema** *Tick all that apply*
	Primary lymphoedema (i.e., congenital / inherited)
	Tumour bulk
	Previous surgery
	Previous radiotherapy
	Hypoalbuminaemia – malnutrition
	Hypoalbuminaemia – liver failure
	Congestive cardiac failure
	Renal impairment
	Chronic venous insufficiency - thrombosis
	Chronic venous insufficiency – varicose veins
	Hypothyroidism
	Drug-induced – please specify: _____ *(e.g., calcium channel blocker, NSAID, fludrocortisone, pramipexol, docetaxel, oestrogens)*
	Other – please specify:
	Not applicable

Tick ✓		**Concurrent Treatments for Lymphoedema (other than diuretics):** *Tick all that apply*
Yes	**No**	
		Manual Lymphatic Drainage Massage If yes, when was it commenced? ○ less than one week ago ○ more than a week ago
		Compression Bandaging If yes, when was it commenced? ○ less than one week ago ○ more than a week ago
		Compression stocking If yes, when was it commenced? ○ less than one week ago ○ more than a week ago
		Compression Wraps If yes, when was it commenced? ○ less than one week ago ○ more than a week ago
		Sequential Compression Pumps If yes, when was it commenced? ○ less than one week ago ○ more than a week ago
		Elevation If yes, please specify approx. hours per day:
		Stent If yes, please specify site: _____ If yes, when was it commenced? ○ less than one week ago ○ more than a week ago
		Anticoagulation If yes, please specify nature: _____ If yes, when was it commenced? ○ less than one week ago ○ more than a week ago
		Surgery If yes, please specify nature: _____ If yes, when was the surgery? ○ less than one week ago ○ more than a week ago
		Radiotherapy to reduce tumour bulk If yes, specify site: _____ If yes, when did it commence? ○ less than one week ago ○ more than a week ago
		Chemotherapy to reduce tumour bulk (if yes, was it commenced ○ less than one week ago ○ more than a week ago)
		Steroid to reduce tumour bulk (if yes, was it commenced ○ less than one week ago ○ more than a week ago)
		Subcutaneous Needle Drainage If yes, when did it commence? ○ less than one week ago ○ more than a week ago)
		Other – please specify:

Tick ✓	**Limbs being treated for Lymphoedema** *(tick all that apply)*
	Left arm
	Right arm
	Left leg
	Right leg

Tick ✓	**Other sites on body with Lymphoedema** *(tick all that apply)*
	Chest wall
	Breast (including remaining breast tissue if previous surgery)
	Axilla
	Back
	Abdominal wall
	Genital
	Other- please specify:
	None

Baseline T0 - Medication Commencement	
Date of Assessment	DD/MM/YYYY
Time of Assessment (24hr clock)	HH:MM

Target Symptom Severity

Clinicians - please complete all rating scales to enable us to get the most accurate picture of symptom severity.

☐ **Lymphoedema**

○ 0 ○ 1 ○ 2 – early ○ 2 – late ○ 3

ISL Staging:
0. Swelling is not evident despite impaired lymph transport
1. Accumulation of tissue fluid that subsides with limb elevation; may or may not exhibit pitting
2. Early: Limb elevation along rarely reduces swelling and pitting is manifest
2. Late: There may or may not be pitting as tissue fibrosis is more evident
3. The tissue is hard (fibrotic) and pitting is absent. Skin changes such as thickening, hyperpigmentation, increased skin folds, fat deposits and warty overgrowths develop

How does *your patient* rate the severity of their lymphoedema out of 10? 0 being no symptoms at all and 10 being as bad as it could possibly be? *(Circle the selected number in the box)*

0	1	2	3	4	5	6	7	8	9	10

No Symptom — Moderate symptoms — Worst possible symptoms

Clinician question: How would you rate the severity of your patient's lymphoedema out of 10? 0 being no symptoms at all and 10 being as bad as it could possibly be? *(Circle the selected number in the box)*

0	1	2	3	4	5	6	7	8	9	10

No Symptom — Moderate symptoms — Worst possible symptoms

Medication of Interest	
Tick ✓	**Name of diuretic medication**
	Frusemide
	Bumetanide
	Hydrochlorothiazide
	Indapamide
	Spironolactone
	Other: (please specify)

Diuretic starting dose	
	Dose (mgs)
	Frequency - *e.g., Daily (mane), BD, TDS, QID*
	Route – e.g., *oral, subcutaneous, IV*

Baseline Symptom/Harm Assessment

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

☐ Pain

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1. Mild pain
2. Moderate pain; limiting instrumental ADL
3. Severe pain; limiting self-care ADL

☐ Cellulitis

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1.Localized, local intervention indicated
2. Oral intervention indicated (e.g., antibiotic, antifungal, antiviral)
3. IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ Skin ulceration

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1. Combined area of ulcers <1 cm; non-blanchable erythema of intact skin with associated warmth or oedema
2. Combined area of ulcers 1-2cm; partial thickness skin loss involving skin or subcutaneous fat
3. Combined area of ulcers >2 cm; full-thickness skin loss involving damage to or necrosis of subcutaneous tissue that may extend down to fascia
4. Any size ulcer with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures with or without full thickness skin loss
5. Death

☐ Skin tightness

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not reported

1. Mild
2. Moderate; limiting instrumental ADL
3. Severe; limiting self-care ADL

☐ Limb heaviness

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not reported

1. Mild
2. Moderate; limiting instrumental ADL
3. Severe; limiting self-care ADL

☐ Impairment of limb movement

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not reported

1. Mild
2. Moderate; limiting instrumental ADL
3. Severe; limiting self-care ADL

☐ Hypotension (defined as blood pressure below the normal expected for an individual in a given environment) *(*NB NCI does not have a category for postural hypotension*)*

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1. Asymptomatic, intervention not indicated
2. Non-urgent medical intervention indicated
3. Medical intervention or hospitalization indicated
4. Life-threatening and urgent intervention indicated
5. Death

☐ Acute kidney injury

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1. Creatinine level increase of >0.3mg/dL; creatinine 1.5 - 2.0 x above baseline 2. Creatinine 2 - 3 x above baseline 3. Creatinine >3 x baseline or >4.0mg/dL; hospitalization indicated 4. Life-threatening consequences; dialysis indicated 5. Death

☐ Urinary frequency

○ 1 ○ 2 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1. Present 2. Limiting instrumental ADL; medical management indicated

☐ **Other (if exists)**

Please specify other toxicity here _____

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

☐ **Additional other (if exists)**

Please specify additional other toxicity here _____

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

Tick ✓	**Which symptom/harm is the <u>most</u> troublesome?** *(Tick one only)*
	Pain
	Cellulitis
	Skin ulceration
	Skin tightness
	Limb heaviness
	Impairment of limb movement
	Hypotension
	Acute kidney injury
	Urinary frequency
	Other
	Additional Other
	Not applicable

T_1 3-14 days post Baseline – at clinicians' discretion when maximum benefit has been achieved.	
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

Patient Setting	○ *Inpatient* ○ *Outpatient*

Target Symptom Severity

Clinicians - please complete all rating scales to enable us to get the most accurate picture of symptom severity)

☐ **Lymphoedema**

○ 0 ○ 1 ○ 2 – early ○ 2 – late ○ 3

ISL Staging:
0. Swelling is not evident despite impaired lymph transport
1. Accumulation of tissue fluid that subsides with limb elevation; may or may not exhibit pitting
2. Early: Limb elevation along rarely reduces swelling and pitting is manifest
2. Late: There may or may not be pitting as tissue fibrosis is more evident
3. The tissue is hard (fibrotic) and pitting is absent. Skin changes such as thickening, hyperpigmentation, increased skin folds, fat deposits and warty overgrowths develop

How does *<u>your patient</u>* rate the severity of their lymphoedema out of 10? 0 being no symptoms at all and 10 being as bad as it could possibly be? *(Circle the selected number in the box)*

0	1	2	3	4	5	6	7	8	9	10

No Symptom — Moderate symptoms — Worst possible symptoms

Clinician question: How would you rate the severity of your patient's lymphoedema out of 10? 0 being no symptoms at all and 10 being as bad as it could possibly be? *(Circle the selected number in the box)*

0	1	2	3	4	5	6	7	8	9	10

No Symptom — Moderate symptoms — Worst possible symptoms

Current Diuretic Dose	
	Dose (mgs)
	Frequency - *e.g., Daily (mane), BD, TDS, QID*
	Route – e.g., *oral, subcutaneous, IV*

Today's Weight – if measured (kgs)	

T_1 - Symptom/Harm Assessment

Please grade all harms and indicate that each harm has been assessed by ticking the square box next to each)

☐ Pain

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1. Mild pain
2. Moderate pain; limiting instrumental ADL
3. Severe pain; limiting self-care ADL

☐ Cellulitis

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1.Localized, local intervention indicated
2. Oral intervention indicated (e.g., antibiotic, antifungal, antiviral)
3. IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ Skin ulceration

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1. Combined area of ulcers <1 cm; non-blanchable erythema of intact skin with associated warmth or oedema
2. Combined area of ulcers 1-2cm; partial thickness skin loss involving skin or subcutaneous fat
3. Combined area of ulcers >2 cm; full-thickness skin loss involving damage to or necrosis of subcutaneous tissue that may extend down to fascia
4. Any size ulcer with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures with or without full thickness skin loss
5. Death

☐ Skin tightness

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not reported

1. Mild
2. Moderate; limiting instrumental ADL
3. Severe; limiting self-care ADL

☐ Limb heaviness

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not reported

1. Mild
2. Moderate; limiting instrumental ADL
3. Severe; limiting self-care ADL

☐ Impairment of limb movement

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not reported

1. Mild
2. Moderate; limiting instrumental ADL
3. Severe; limiting self-care ADL

☐ Hypotension (defined as blood pressure below the normal expected for an individual in a given environment) *(*NB NCI does not have a category for postural hypotension*)*

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1. Asymptomatic, intervention not indicated
2. Non-urgent medical intervention indicated
3. Medical intervention or hospitalization indicated
4. Life-threatening and urgent intervention indicated
5. Death

☐ Acute kidney injury

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1. Creatinine level increase of >0.3mg/dL; creatinine 1.5 - 2.0 x above baseline
2. Creatinine 2 - 3 x above baseline
3. Creatinine >3 x baseline or >4.0mg/dL; hospitalization indicated
4. Life-threatening consequences; dialysis indicated
5. Death

☐ Urinary frequency

○ 1 ○ 2 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1. Present
2. Limiting instrumental ADL; medical management indicated

☐ **Other (if exists)**

Please specify other toxicity here _____

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

☐ **Additional other (if exists)**

Please specify additional other toxicity here _____

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

Tick ✓	**Which symptom/harm is the <u>most</u> troublesome?** *(Tick one only)*
	Pain
	Cellulitis
	Skin ulceration
	Skin tightness
	Limb heaviness
	Impairment of limb movement
	Hypotension
	Acute kidney injury
	Urinary frequency
	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, answering the Naranjo questions is not required.

	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 diuretic /continue current dose
		Diuretic ceased *(complete medication cessation on page 13)*
		Diuretic dose reduced - *Please specify new dose in mgs:* _____
		Diuretic dose increased - *Please specify new dose in mgs:*_____
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 ✓	**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*

☐ **Lymphoedema**

◯ 1 ◯ 2 ◯ 3 ◯ Ungradable

ISL Staging:
0. Swelling is not evident despite impaired lymph transport
1. Accumulation of tissue fluid that subsides with limb elevation; may or may not exhibit pitting
2. Early: Limb elevation along rarely reduces swelling and pitting is manifest
2. Late: There may or may not be pitting as tissue fibrosis is more evident
3. The tissue is hard (fibrotic), and pitting is absent. Skin changes such as thickening, hyperpigmentation, increased skin folds, fat deposits and warty overgrowths develop

Tick ✓	**Intervention/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 *(Please grade all harms; indicate that each harm has been assessed by ticking the square box next to each)*

☐ Pain

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1. Mild pain
2. Moderate pain; limiting instrumental ADL
3. Severe pain; limiting self-care ADL

☐ Cellulitis

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1.Localized, local intervention indicated
2. Oral intervention indicated (e.g., antibiotic, antifungal, antiviral)
3. IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ Skin ulceration

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1. Combined area of ulcers <1 cm; non-blanchable erythema of intact skin with associated warmth or oedema
2. Combined area of ulcers 1-2cm; partial thickness skin loss involving skin or subcutaneous fat
3. Combined area of ulcers >2 cm; full-thickness skin loss involving damage to or necrosis of subcutaneous tissue that may extend down to fascia
4. Any size ulcer with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures with or without full thickness skin loss
5. Death

☐ Skin tightness

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not reported

1. Mild
2. Moderate; limiting instrumental ADL
3. Severe; limiting self-care ADL

☐ Limb heaviness

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not reported

1. Mild
2. Moderate; limiting instrumental ADL
3. Severe; limiting self-care ADL

☐ Impairment of limb movement

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not reported

1. Mild
2. Moderate; limiting instrumental ADL
3. Severe; limiting self-care ADL

☐ Hypotension (defined as blood pressure below the normal expected for an individual in a given environment) *(*NB NCI does not have a category for postural hypotension*)*

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1. Asymptomatic, intervention not indicated
2. Non-urgent medical intervention indicated
3. Medical intervention or hospitalization indicated
4. Life-threatening and urgent intervention indicated
5. Death

☐ Acute kidney injury

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1. Creatinine level increase of >0.3mg/dL; creatinine 1.5 - 2.0 x above baseline
2. Creatinine 2 - 3 x above baseline
3. Creatinine >3 x baseline or >4.0mg/dL; hospitalization indicated
4. Life-threatening consequences; dialysis indicated
5. Death

☐ Urinary frequency

○ 1 ○ 2 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1. Present
2. Limiting instrumental ADL; medical management indicated

☐ **Other (if exists)**

Please specify other toxicity here _____

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

☐ **Additional other (if exists)**

Please specify additional other toxicity here _____

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

Tick ✓	**Which symptom/harm is the <u>most</u> troublesome?** *(Tick one only)*
	Pain
	Cellulitis
	Skin ulceration
	Skin tightness
	Limb heaviness
	Impairment of limb movement
	Hypotension
	Acute kidney injury
	Urinary frequency
	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, answering the Naranjo questions is not required.

	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)*

☐ Pain

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1. Mild pain
2. Moderate pain; limiting instrumental ADL
3. Severe pain; limiting self-care ADL

☐ Cellulitis

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1.Localized, local intervention indicated
2. Oral intervention indicated (e.g., antibiotic, antifungal, antiviral)
3. IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ Skin ulceration

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1. Combined area of ulcers <1 cm; non-blanchable erythema of intact skin with associated warmth or oedema
2. Combined area of ulcers 1-2cm; partial thickness skin loss involving skin or subcutaneous fat
3. Combined area of ulcers >2 cm; full-thickness skin loss involving damage to or necrosis of subcutaneous tissue that may extend down to fascia
4. Any size ulcer with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures with or without full thickness skin loss
5. Death

☐ Skin tightness

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not reported

1. Mild
2. Moderate; limiting instrumental ADL
3. Severe; limiting self-care ADL

☐ Limb heaviness

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not reported

1. Mild
2. Moderate; limiting instrumental ADL
3. Severe; limiting self-care ADL

☐ Impairment of limb movement

○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom

1. Mild
2. Moderate; limiting instrumental ADL
3. Severe; limiting self-care ADL

☐ Hypotension (defined as blood pressure below the normal expected for an individual in a given environment) *(*NB NCI does not have a category for postural hypotension*)*

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1. Asymptomatic, intervention not indicated
2. Non-urgent medical intervention indicated
3. Medical intervention or hospitalization indicated
4. Life-threatening and urgent intervention indicated
5. Death

☐ Acute kidney injury

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1. Creatinine level increase of >0.3mg/dL; creatinine 1.5 - 2.0 x above baseline
2. Creatinine 2 - 3 x above baseline
3. Creatinine >3 x baseline or >4.0mg/dL; hospitalization indicated
4. Life-threatening consequences; dialysis indicated
5. Death

☐ Urinary frequency

○ 1 ○ 2 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1. Present
2. Limiting instrumental ADL; medical management indicated

☐ **Other (if exists)**

Please specify other toxicity here _____

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

☐ **Additional other (if exists)**

Please specify additional other toxicity here _____

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

Tick ✓	**Which symptom/harm is the <u>most</u> troublesome?** *(Tick one only)*
	Pain
	Cellulitis
	Skin ulceration
	Skin tightness
	Limb heaviness
	Impairment of limb movement
	Hypotension
	Acute kidney injury
	Urinary frequency
	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, answering the Naranjo questions is not required.

	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 and indicate that each harm has been assessed by ticking the square box next to each.

☐ Pain
○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1. Mild pain
2. Moderate pain; limiting instrumental ADL
3. Severe pain; limiting self-care ADL

☐ Cellulitis
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1.Localized, local intervention indicated
2. Oral intervention indicated (e.g., antibiotic, antifungal, antiviral)
3. IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ Skin ulceration
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1. Combined area of ulcers <1 cm; non-blanchable erythema of intact skin with associated warmth or oedema
2. Combined area of ulcers 1-2cm; partial thickness skin loss involving skin or subcutaneous fat
3. Combined area of ulcers >2 cm; full-thickness skin loss involving damage to or necrosis of subcutaneous tissue that may extend down to fascia
4. Any size ulcer with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures with or without full thickness skin loss
5. Death

☐ Skin tightness
○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not reported

1. Mild
2. Moderate; limiting instrumental ADL
3. Severe; limiting self-care ADL

☐ Limb heaviness
○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom ○ Not reported

1. Mild
2. Moderate; limiting instrumental ADL
3. Severe; limiting self-care ADL

☐ Impairment of limb movement
○ 1 ○ 2 ○ 3 ○ Ungradable ○ No Symptom

1. Mild
2. Moderate; limiting instrumental ADL
3. Severe; limiting self-care ADL

☐ Hypotension (defined as blood pressure below the normal expected for an individual in a given environment) *(*NB NCI does not have a category for postural hypotension*)*

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1. Asymptomatic, intervention not indicated
2. Non-urgent medical intervention indicated
3. Medical intervention or hospitalization indicated
4. Life-threatening and urgent intervention indicated
5. Death

☐ Acute kidney injury

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1. Creatinine level increase of >0.3mg/dL; creatinine 1.5 - 2.0 x above baseline
2. Creatinine 2 - 3 x above baseline
3. Creatinine >3 x baseline or >4.0mg/dL; hospitalization indicated
4. Life-threatening consequences; dialysis indicated
5. Death

☐ Urinary frequency

○ 1 ○ 2 ○ Ungradable ○ No Symptom ○ Not reported

NCI Criteria
1. Present
2. Limiting instrumental ADL; medical management indicated

☐ **Other (if exists)**

Please specify other toxicity here _____

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

☐ **Additional other (if exists)**

Please specify additional other toxicity here _____

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

Tick ✓	**Which symptom/harm is the <u>most</u> troublesome?** *(Tick one only)*
	Pain
	Cellulitis
	Skin ulceration
	Skin tightness
	Limb heaviness
	Impairment of limb movement
	Hypotension
	Acute kidney injury
	Urinary frequency
	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, answering the Naranjo questions is not required.

	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?			