Participant ID	

Initials of person entering data	

Staff email	

CONFIDENTIAL CASE REPORT FORM

Compression and Related Therapies for <u>Cancer-Related</u> Lymphoedema

Series 25

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)

Please note: This series is for patients who are newly commencing compression and related therapies as the **main treatment** for their cancer-related lymphoedema. If the patient is commencing new treatments concurrently (e.g. diuretics, and/or manual lymphatic drainage massage or compression, and/or subcutaneous needle drainage) please select the series pertaining to the treatment identified as the **predominant** treatment.

TABLE OF CONTENTS	**PAGE NO.**

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

Demographics					
Gender *(please tick)* ○ Male ○ Female ○ Other					
Age (yrs)		**Today's weight if measured (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.

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)		

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

Tick ✓	**Predominant Cause of Lymphoedema** (Tick one option only) (NB this study is for cancer-related lymphoedema only)
	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 (ie 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
	Immobility
	Drug-induced – please specify:_____
	(eg calcium channel blocker, NSAID, fludrocortisone, pramipexol, docetaxel, oestrogens)
	Other – please specify:_____
	Not applicable

Tick ✓		**Concurrent Treatments for Lymphoedema (other than compression and related therapies)** *(tick 'yes' or 'no' to all)*
Yes	**No**	
		Diuretics - If yes, 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: _____ Was it commenced: ○ less than one week ago ○ more than a week ago
		Anticoagulation If yes, please specify nature: _____ Was it commenced: ○ less than one week ago ○ more than a week ago
		Surgery – If yes, please specify nature: _____ Was the surgery: ○ less than one week ago ○ more than a week ago
		Radiotherapy (to reduce tumour bulk) - If yes, please specify site: _____ Was it commenced: ○ less than one week ago ○ more than a week ago
		Chemotherapy (to reduce tumour bulk) - If yes, please specify site: _____ Was it commenced: ○ less than one week ago ○ more than a week ago
		Steroid (to reduce tumour bulk) - If yes, please specify site: _____ Was it commenced: ○ less than one week ago ○ more than a week ago

		Subcutaneous needle drainage - If yes, was it commenced: ○ less than one week ago ○ more than a week ago
		Other – please specify: _____
		No concurrent treatments

Tick ✓	**Limbs being treated for Lymphoedema** (Tick all that apply)
	Arm - left
	Arm - right
	Leg - left
	Leg – right
	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:_____
	Not applicable

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

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 *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

Arm Measurements – *only complete for the arm/s you are treating otherwise leave blank*	
Tick ✓	**Position of Patient**
	Sitting – Variations: _____
	Abd. 90 – Variations:_____

Board levels: R / L	Tip of 3rd finger:	Mid-point MCP ulnar: radial:	Mid ulnar styloid:
R / L	Tip of 3rd finger:	Mid-point MCP ulnar: radial:	Mid ulnar styloid:
Hand dominance	R /L ambidextrous		

Side	**Right**	**Left**
MCP (mid-point)		
Ulnar styloid (distal) 0cm		
10cm		
20cm		
30cm		
40cm		
50cm		
60cm		
70cm		

Side	**Right**	**Left**
Fingers Thumb 1.		
2.		
3.		
4.		
5.		

Leg Measurements - *only complete for the leg/s you are treating otherwise leave blank*	
Tick ✓	**Position of Patient**
	Supine – Variations:_____

Board levels: R / L	MTP med: lat:	TMT med: lat:	Mid-point malleoli med: lat:
R / L	MTP med: lat:	TMT med: lat:	Mid-point malleoli med: lat:
Leg dominance	R /L		

Side	**Right**	**Left**
MTP		
TMT		
10cm		
20cm		
30cm		
40cm		
50cm		
60cm		
70cm		
80cm		

Side		**Right**	**Left**
Toes	1.		
	2.		
	3.		
	4.		
	5.		

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

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

☐ **Limb heaviness**

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

NCI Criteria
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

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

☐ **Other symptom** (if exists) *e.g. ischaemia, altered sensation, lymphorrhoea (fluid leakage)*

Please specify other symptom here _____

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

☐ **Additional other symptom** *(only if applicable)*
Please specify additional other symptom here _____

Additional other harm NCI criteria symptom 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
	Other
	Additional Other
	Not applicable

T_1 – At therapist's discretion when maximum benefit has been achieved (minimum 3 therapy sessions; often coincides with time of fitting compression garment)	
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

How many therapy sessions has patient received	

Tick ✓	**Nature of therapies received**
	Manual Lymphatic Drainage Massage
	Compression bandaging
	Compression stocking
	Compression wraps
	Sequential compression pumps
	Other (please describe): _____
	Optional comment: _____

Tick ✓		**Concurrent Treatments for Lymphoedema (other than compression and related therapies)** *(tick 'yes' or 'no' to all)*
Yes	**No**	
		Diuretics - If yes, 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: _____ Was it commenced: ○ less than one week ago ○ more than a week ago
		Anticoagulation If yes, please specify nature: _____ Was it commenced: ○ less than one week ago ○ more than a week ago
		Surgery – If yes, please specify nature: _____ Was the surgery: ○ less than one week ago ○ more than a week ago
		Radiotherapy (to reduce tumour bulk) - If yes, please specify site: _____ Was it commenced: ○ less than one week ago ○ more than a week ago
		Chemotherapy (to reduce tumour bulk) - If yes, please specify site: _____ Was it commenced: ○ less than one week ago ○ more than a week ago
		Steroid (to reduce tumour bulk) - If yes, please specify site: _____ Was it commenced: ○ less than one week ago ○ more than a week ago
		Subcutaneous needle drainage - If yes, was it commenced: ○ less than one week ago ○ more than a week ago
		Other – please specify: _____
		No concurrent treatments

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

Today's Weight – if measured (kgs)	

Arm Measurements – *only complete for the arm/s you are treating otherwise leave blank*	
Tick ✓	**Position of Patient**
	Sitting – Variations: _____
	Abd. 90 – Variations:_____

Board levels: R / L	Tip of 3rd finger:	Mid-point MCP ulnar: radial:	Mid ulnar styloid:
R / L	Tip of 3rd finger:	Mid-point MCP ulnar: radial:	Mid ulnar styloid:
Hand dominance	R /L ambidextrous		

Side	**Right**	**Left**
MCP (mid-point)		
Ulnar styloid (distal) 0cm		
10cm		
20cm		
30cm		
40cm		
50cm		
60cm		
70cm		

Side	**Right**	**Left**
Fingers Thumb 1.		
2.		
3.		
4.		
5.		

Leg Measurements - *only complete for the leg/s you are treating otherwise leave blank*	
Tick ✓	**Position of Patient**
	Supine – Variations:_____

Board levels: R / L	MTP med: lat:	TMT med: lat:	Mid-point malleoli med: lat:
R / L	MTP med: lat:	TMT med: lat:	Mid-point malleoli med: lat:
Leg dominance	R /L		

Side	**Right**	**Left**
MTP		
TMT		
10cm		
20cm		
30cm		
40cm		
50cm		
60cm		
70cm		
80cm		

Side		**Right**	**Left**
Toes	1.		
	2.		
	3.		
	4.		
	5.		

T_1 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

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

☐ **Limb heaviness**

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

NCI Criteria
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

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

☐ **Other symptom** (if exists) *e.g. ischaemia, altered sensation, lymphorrhoea (fluid leakage)*

Please specify other symptom here _____

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

☐ **Additional other symptom** *(only if applicable)*

Please specify additional other symptom here _____

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

Tick ✓	Which symptom/harm is the **most** troublesome? *(Tick one only)*
	Pain
	Cellulitis
	Skin Ulceration
	Skin tightness
	Limb heaviness
	Impairment of limb movement
	Other
	Additional Other
	Not applicable

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

Tick ✓		Medication changes *(Tick all that apply)*
		No change to compression or related therapy
		Compression or related therapy ceased
		Compression or related therapy intensity/frequency reduced – please describe (e.g. poorly tolerated or maximum benefit reached or transitioning to compression garment etc) _____
		Compression or related therapy intensity/frequency increased – please describe _____
Yes	**No**	**Has a medication been added to treat a specific harm? (e.g. antibiotic for cellulitis)** *If yes, please specify new medication here:*

Based on the assessment today has the harm resolved?
○ Yes ○ No ○ Not applicable

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

Tick ✓	Compression or related therapy was ceased (related to lymphoedema)
	Lymphoedema resolved - *Please indicate date 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 receive therapy. Please specify:
	Other - *Please specify:*

What treatment (if any) did you subsequently initiate following the cessation of the compression or related therapy?

Ad hoc A - Unscheduled Harm/Toxicity Assessment

Date of Assessment	DD/MM/YYYY

Harm/toxicity Assessment *(Please grade all symptoms; indicate that each has been assessed by ticking the square box next to each. Please also select 1 option of causation for each symptom)*

☐ **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

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

☐ **Limb heaviness**

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

NCI Criteria 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

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

☐ **Other symptom** (if exists) *e.g. ischaemia, altered sensation, lymphorrhoea (fluid leakage)*

Please specify other symptom here _____

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

☐ **Additional other symptom** *(only if applicable)*

Please specify additional other symptom here _____

Additional other harm NCI criteria symptom 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
	Other
	Additional Other
	Not applicable

Ad hoc B - Unscheduled Harm/Toxicity Assessment

Date of Assessment	DD/MM/YYYY

Harm/toxicity Assessment *(Please grade all symptoms; indicate that each has been assessed by ticking the square box next to each. Please also select 1 option of causation for each symptom)*

☐ **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

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

☐ **Limb heaviness**

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

NCI Criteria 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

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

☐ **Other symptom** (if exists) *e.g. ischaemia, altered sensation, lymphorrhoea (fluid leakage)*

Please specify other symptom here _____

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

☐ **Additional other symptom** *(only if applicable)*

Please specify additional other symptom here _____

Additional other harm NCI criteria symptom 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
	Other
	Additional Other
	Not applicable

Ad hoc C - Unscheduled Harm/Toxicity Assessment

Date of Assessment	DD/MM/YYYY

Harm/toxicity Assessment *(Please grade all symptoms; indicate that each has been assessed by ticking the square box next to each. Please also select 1 option of causation for each symptom)*

☐ **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

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

☐ **Limb heaviness**

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

NCI Criteria 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

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

☐ **Other symptom** (if exists) *e.g. ischaemia, altered sensation, lymphorrhoea (fluid leakage)*

Please specify other symptom here _____

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

☐ **Additional other symptom** *(only if applicable)*

Please specify additional other symptom here _____

Additional other harm NCI criteria symptom 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
	Other
	Additional Other
	Not applicable