

HEALTH PROFESSIONAL BREAST TOXICITY DATA (CTCAEv4.0)

To be completed by the Doctor or Research Nurse ONLY

Study Number

RQ□□□□□-□

Patient Initials

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Date of Birth (dd/mm/yyyy)

□□/□□/□□□□

Date Completed (dd/mm/yyyy)

□□/□□/□□□□

Name + Signature of Person completing the CRF

Time Point

- | | |
|---------------------------------------------------|--------------------------------------------------|
| <input type="checkbox"/> Pre-radiotherapy (RT) | <input type="checkbox"/> 2 years after RT start |
| <input type="checkbox"/> End of RT | <input type="checkbox"/> 3 years after RT start* |
| <input type="checkbox"/> 6 weeks after end of RT* | <input type="checkbox"/> 4 years after RT start* |
| <input type="checkbox"/> 1 year after RT start | * if available |

If information is **Not Known** fill boxes with 9's, if **Not Applicable** with 8's

Is there atrophy within the treated breast?

- 0 = None
1 = Minimal asymmetry; minimal atrophy
2 = Moderate asymmetry; moderate atrophy
3 = Asymmetry >1/3 of breast volume; severe atrophy

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Is there any nipple retraction of the treated breast?

- 0 = None
1 = Asymptomatic; asymmetry with slight retraction and/or thickening of the nipple areolar complex
2 = Symptomatic; asymmetry of nipple areolar complex with moderate retraction and/or thickening of the nipple areolar complex

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Is there oedema of the treated breast?

- 0 = None
1 = Swelling or obscuration of anatomic architecture on close inspection
2 = Readily apparent obscuration of anatomic architecture; obliteration of skin folds; readily apparent deviation from normal anatomic contour; limiting instrumental activities of daily living (ADL)
3 = Gross deviation from normal anatomic contour; limiting self care ADL

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Is there any skin ulceration?

- 0 = None
1 = Combined area of ulcers <1cm nonblanchable erythema of intact skin with associated warmth or edema
2 = Combined area of ulcers 1-2cm; partial thickness skin loss involving skin or subcutaneous fat
3 = Combined area of ulcers >2cm; full thickness skin loss involving damage to or necrosis of subcutaneous tissue that may extend down to fascia
4 = Any ulcer size with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures with or without full thickness skin loss

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Is there any telangiectasia of the tumour bed?

- 0 = None
- 1 = Telangiectasia covering <10% of the treated breast
- 2 = Telangiectasia covering >10% of the treated breast; associated with psychosocial impact

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Is there any telangiectasia outside the tumour bed?

- 0 = None
- 1 = Telangiectasia covering <10% of the treated breast
- 2 = Telangiectasia covering >10% of the treated breast; associated with psychosocial impact

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Is there any skin induration (fibrosis) of the tumour bed?

- 0 = None
- 1 = Mild induration, able to move skin parallel to plane (sliding) and perpendicular to skin (pinching up)
- 2 = Moderate induration, able to slide skin, unable to pinch skin, limiting instrumental activities for daily living (ADL)
- 3 = Severe induration; unable to slide or pinch skin; affecting activities for daily living; limiting self care ADL

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Is there any skin induration (fibrosis) outside the tumour bed?

- 0 = None
- 1 = Mild induration, able to move skin parallel to plane (sliding) and perpendicular to skin (pinching up)
- 2 = Moderate induration, able to slide skin, unable to pinch skin, limiting instrumental activities for daily living (ADL)
- 3 = Severe induration; unable to slide or pinch skin; affecting activities for daily living; limiting self care ADL

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Erythema

- 0 = None
- 1 = Faint erythema or dry desquamation
- 2 = Moderate to brisk erythema; patchy moist desquamation, mostly confined to skin folds and creases; moderate oedema
- 3 = Moist desquamation in areas other than skin folds and creases; bleeding induced by minor trauma or abrasion
- 4 = Life-threatening consequences; skin necrosis or ulceration of full thickness dermis; spontaneous bleeding from involved site; skin graft indicated

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Arm lymphoedema

- 0 = None
- 1 = 5-10% inter limb discrepancy in volume or circumference at point of greatest visible difference; swelling or obscuration of anatomic architecture on close inspection
- 2 = >10-30% inter limb discrepancy in volume or circumference at point of greatest visible difference; Readily apparent obscuration of anatomic architecture; obliteration of skin folds; readily apparent deviation from normal anatomic contour; limiting instrumental activities of daily living (ADL)
- 3 = > 30% inter-limb discrepancy in volume; gross deviation from normal anatomic contour; limiting self care ADL

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Skin hyperpigmentation

- 0 = None
- 1 = Hyperpigmentation or depigmentation covering <10% body surface area (BSA); no psychosocial impact
- 2 = Hyperpigmentation or depigmentation covering >10% BSA; associated with psychosocial impact

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Pneumonitis

- 0 = None
- 1 = Asymptomatic; clinical or diagnostic observations only; intervention not indicated
- 2 = Symptomatic; medical intervention indicated; limiting instrumental activities of daily living (ADL)
- 3 = Severe symptoms; limiting self care ADL; oxygen indicated
- 4 = Life-threatening respiratory compromise; urgent intervention indicated (e.g., tracheotomy or intubation)

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Questions for the patient

Pain

Have you had any pain in your treated breast in the last two weeks?

☐ 0=No
☐ 1=Yes

If yes, how severe is the pain?

☐ 1=Mild
☐ 2=Moderate, limiting usual activities
☐ 3=Severe, stopping activities

Are you taking any medication for this pain?

☐ 0=No
☐ 1=Yes

If yes, please give name of medication and how often you take this.

drug name

dose and frequency

Swollen arm

Do you have a swollen arm?

☐ 0=No
☐ 1=Yes

If yes, does your swollen arm interfere with normal activity?

☐ 1=No
☐ 2=Limiting activity
☐ 3=Limiting self care

Mid-upper arm circumference

Left arm (mm)

Right arm (mm)

Measuring Date (dd/mm/yyyy)

If information is **Not Known** fill boxes with 9's, if **Not Applicable** with 8's