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# Rhenium SCT for non-melanoma skin cancer: Topline Results from EPIC Skin, An international Phase 4 prospective single arm multicentre study

*Baxi et al 2026 Rhenium SCT for non-melanoma skin cancer: Topline Results from EPIC Skin, An international Phase 4 prospective single arm multicentre study, Presented at American College of Radiation Oncology Orlando Feb 6 2026*

# Non-Melanoma Skin Cancer (NMSC): A global view

**NMSCs are one of the most common cancers[1,2]**

**7.7 million cases worldwide in 2017[2]:**

- 5.9 million cases of BCC (~75%)
- 1.8 million cases of SCC (~25%)

**Rates are increasing, likely due to[3]:**

- Earlier detection
- Increased sun exposure
- Longer life spans

References: 1. International Agency for Research on Cancer. Data visualization tools for exploring the global cancer burden in 2020. https://gco.iarc.fr/today/home (accessed July 2021). 2. Global Burden of Disease Cancer Collaboration. Global, Regional, and National Cancer Incidence, Mortality, Years of Life Lost, Years Lived With Disability, and Disability-Adjusted Life-Years for 29 Cancer Groups, 1990 to 2017: A Systematic Analysis for the Global Burden of Disease Study. JAMA Oncol. 2019;5(12):1749-1768. doi:10.1001/jamaoncol.2019.2996. 3. Cancer.Net. Skin Cancer (Non-Melanoma): Statistics. February 2021. https://www.cancer.net/cancer-types/skin-cancer-non-melanoma/statistics (accessed July 2021).
Abbreviations: BCC: Basal cell carcinoma; NMSC: Non-melanoma skin cancer; SCC: Squamous cell carcinoma.

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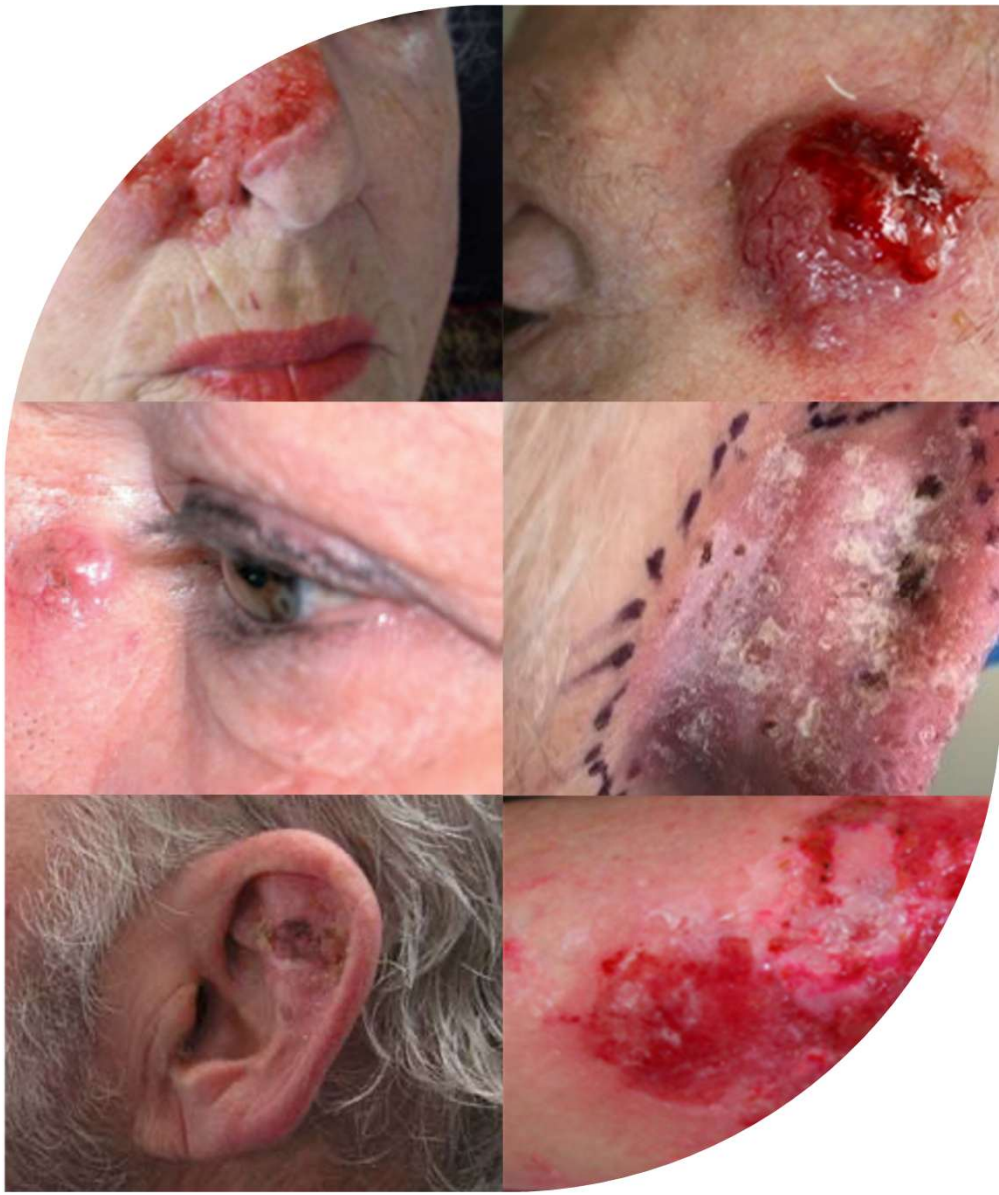
# NMSC: Can have a dramatic impact on quality of life[1]

NMSC can be **difficult to treat** due to:

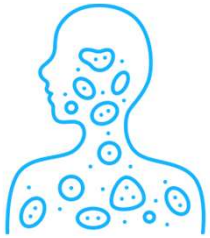
- Lesion size and location (face, lips, ears, etc.)
- Treatment can **be unsatisfactory** due to:
- Disfigurement
- Loss of function
- Need for reconstruction
- Recurrence
- Pain
- Complications
- Waiting lists and/or recovery time



Reference: Philipp-Dormston et al. Patient-reported health outcomes in patients with non-melanoma skin cancer and actinic keratosis: results from a large-scale observational study analysing effects of diagnoses and disease progression. J Eur Acad Dermatol Venereol. 2018;32(7):1138-1146. doi: 10.1111/jdv.14703. Images courtesy of Cipriani, C. - S. Eugenio Hospital, Rome, IT; Sedda, A. - S. Eugenio Hospital, Rome, IT; Castellucci, P - IRCCS Azienda Ospedaliero-Universitaria, Bologna, IT.

# Treatment options in NMSC

| Treatment Approach | Strengths | Trade-offs |
|---|---|---|
| **Mohs / Excision**[1-4] | Highest cure rates / Immediate removal | Scarring/reconstruction/disfigurement risk (cosmesis / functionality); down-time; patient suitability; costs, multiple lesions, anatomically difficult locations, patient comorbidities or preference. |
| **Ablation & topicals**[1-4] | Cheap, office-based convenience for select lesions / high-risk patients | Selection limitations; poorer efficacy/retreatments, patient compliance issues |
| **Radiotherapy**[1-5] | Effective, nonsurgical option with excellent cosmesis | Extensive treatment time, scheduling/logistics |



## Significant unmet need

- >80% patients underestimate surgical scars[6]
- 60% delay in seeking treatment[7]
- ~50-day median time to seek treatment[8]
- 15% poor ECOG status limiting treatment options[9-10]

References:
[1]Peris et al. Eur J Cancer. 2023;192:113254; [2]Stratigos et al. Eur J Cancer. 2023;PLS, [3]Schmults et al J Natl Compr Canc Netw. 2023; 21(11):1181-1203; [4]Bordeaux et al Version 1.2026 NCCN Guidelines for Squamous Cell Skin Cancer; [5]Likhacheva et al. Pract Radiat Oncol. 2020;10:8–20. [6]Fix et al. 2020. JAMA Netw Open; [7] MSCAN/ACD 2025, Australia's National Skin Cancer Scorecard 2025; [8]Deva et al. 2023. International Journal of Integrated Care; [9]Broderick et al., 2014; [10]Szturz et ela. 2016

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# Rhenium-SCT

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## What is Rhenium-SCT?

A single-session, non-invasive epidermal radioisotope therapy that harnesses the beta particles from rhenium-188 decay (17hr half-life) to trigger tumour cell death.

01

## How is it applied?

Applied as a resin, it is administered topically over a film affixed to indicated BCC and SCC lesions, allowing for the treatment of any tumour, without the need for complex planning.

02

## Mechanism of Action

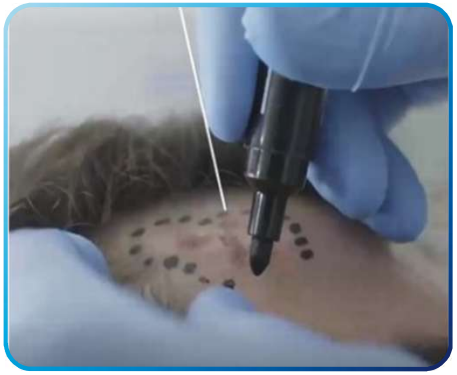
Rhenium 188 decays to produce beta particles that deposit their dose superficially, with 92% of radiation released in the top 3mm of skin, allowing for targeted treatment, whilst minimising unnecessary exposure of healthy tissue.

03

## Patient Experience

Treatment is painless and lasts around 45-180 minutes, depending on lesion size & depth. Patients can return to activities immediately. A delayed radiodermatitis occurs, characterized most commonly by erythema, pruritis and scabbing.

04



## Common patients treated

- Cosmetic or functional considerations
- Comorbidities
- Unable to complete fractionated radiotherapy
- Multiple lesions
- Recurrent lesions
- Remote or rural patients
- Declines surgery

References: 1. Sedda AF, et al. Dermatological high-dose-rate brachytherapy for the treatment of basal and squamous cell carcinoma. Clin Exp Dermatol. 2008;33(6):745-749. doi: 10.1111/j.1365-2230.2008.02852.x 2. Cipriani C, et al. Personalized irradiation therapy for NMSC by rhenium-188 skin cancer therapy: a long-term retrospective study. J Dermatolog Treat. 2020:1-7. doi: 10.1080/09546634.2020.1793890. 3. Castellucci P, et al. High dose brachytherapy with non sealed 188Re (rhenium) resin in patients with non-melanoma skin cancers (NMSCs): single center preliminary results. Eur J Nucl Med Mol Imaging. 2021;48(5):1511-1521. doi: 10.1007/s00259-020-05088-z. 4. Cipriani C, et al. Personalized high-dose-rate brachytherapy with non-sealed rhenium-188 in non-melanoma skin cancer. Int J Nucl Med. 2017;114–112.

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# Rhenium-SCT has been used clinically since 2008

**2008**
- First rhenium-188 publication for NMSC.
- Sedda et al. 53 patients; Mean 51 months follow-up
- Retrospective efficacy and cosmesis.

**2020**
- Retrospective rhenium-188 study of 50Gy to base of lesion
- 55 lesions / 52 patients; Mean 13.6 months. Efficacy & Safety.
- Cipriani et al.

**2021**
- Prospective Re-SCT study.
- 60 lesions / 50 patients; 3x doses. 24-months follow-up
- Castellucci et al.

**2023**
- Dermatologist-led prospective 12-month Re-SCT outcomes.
- 40 lesions / 22 patients; Efficacy, cosmesis and PROs. Tietze et al.

**2024-2025**
- 3x publications + 1 in prep Kronert et al.
- Global, Phase 4, Prospective EPIC-Skin study.
- 225 lesions / 180 patients; Efficacy, cosmesis, toxicity
- 2-pubs; Baxi et al. (6m) ; Cardaci et al. (12m)
- 24-month analysis in progress.

**2025**
- Difficult-to-treat BCC 64 patients; Chessa et al.
- Retrospective 3-year independent Re-SCT outcomes, 124 patients Castellucci et al.

**Reviews:**
- Independent review GEC-ESTRO BRAPHYQS Lozares et al
- Independent meta-analysis of 7 non-overlapping rhenium-188 studies Sadeghpour et al
- 94% complete response rate in NMSC lesions

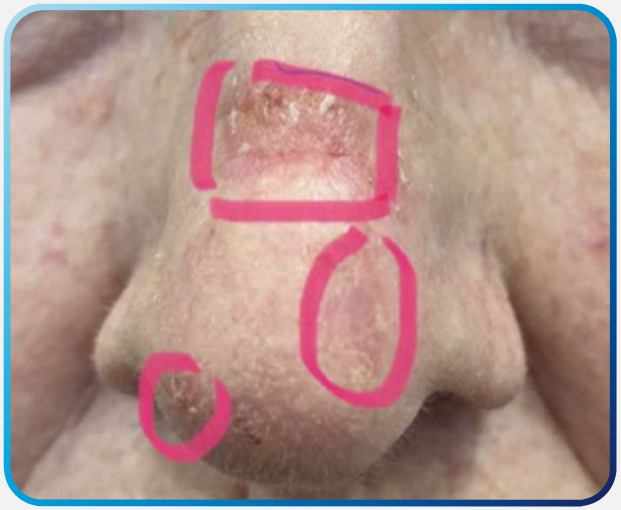
Sedda et al. Clin Exp Dermatol. 2008;33:745–749. Cipriani et al. J Dermatol Treat. 2022;33:969–975. Castellucci et al. Eur J Nucl Med Mol Imaging. 2021;48:1511–1521. Tietze et al. Clin Nucl Med. 2023;48:869–876. . Baxi et al. J Nucl Med. 2024;65:1450–1455. Cardaci et al. Adv Radiat Oncol. 2025;10:101802. Krönert et al Healthcare 2024, 12, 921. Chessa et al. Dermatol Pract Concept. 2025;15:4993. Castellucci et al. J Nucl Med. 2025;00:1–6. Lozares et al. Radiother Oncol. 2025;190:109708. Sadeghpour et al. Front Med. 2025;12:1707729.Abbreviations: NMSC: non-melanoma skin cancer; Re-SCT: Rhenium Skin Cancer Therapy; PROs: patient-reported outcomes; GEC: Groupe Européen de Curiethérapie; ESTRO: European Society for Therapeutic Radiology and Oncology; BRAPHYQS: BRAchytherapy PHYsics Quality Assurance System. ; BCC: Basal cell carcinoma.

# Patient Case:

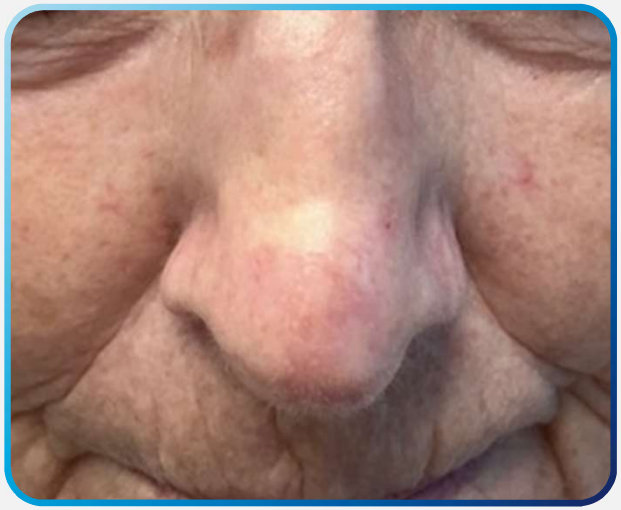
## De Novo Treatment of Multiple Lesions Simultaneously

**Female, 72 years-old**

- Fitzpatrick II – ECOG 0
- BCC (1.9 mm deep; 6cm$^2$ area)
- Nose – multi-focal
- Worsening after multiple prior 5-FU applications
- Referred for Radiotherapy opinion due to substantial disease burden and risk of poor surgical outcomes.
- Treatment with Rhenium SCT



**Before**



**After**

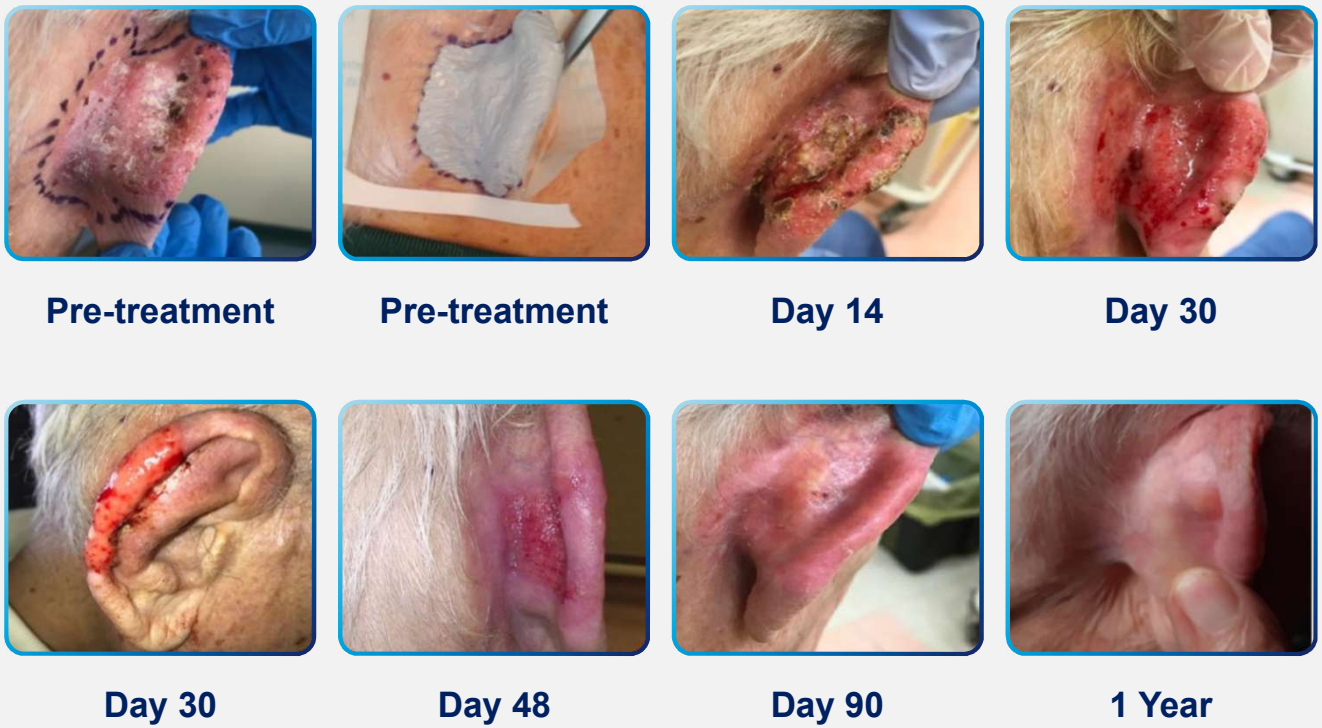
Case courtesy of Sid Baxi, Australia

# Patient Case:

## Lesions in areas with cosmetic considerations

**Male, 93 years-old**

- Fitzpatrick I – ECOG 2
- SCC (2 mm deep; 11cm$^2$ area)
- Entire ear eminence
- No prior treatment
- Surgical comorbidities and inability to attend multiple RT sessions




Castellucci P, Savoia F, Farina A, Lima GM, Patrizi A, Baraldi C, et al. Eur J Nucl Med Mol Imaging. 2021 May;48(5):1706. doi: 10.1007/s00259-021-05363-7

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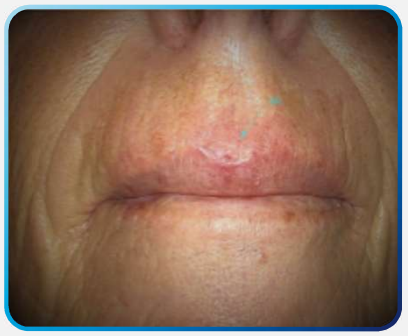
# Patient Case:

## SCC lesion contraindicated for surgery

- 54-year-old Caucasian woman, no relevant medical history; 1-year history of dermatitis on the upper lip treated with topical steroids
- 20 mm erythematous infiltrated plaque on the labial philtrum and upper vermilion border.
- Dermoscopic examination: structureless white and pink background, a polymorphous vascular pattern characterized by hairpin and linear irregular vessels, and white circles around follicular
- Skin biopsy confirmed ulcerated, moderately differentiated 0.635 mm SCC.
- Surgery contraindicated due to technical difficulty of maintaining aesthetics due to location/dimension of lesion



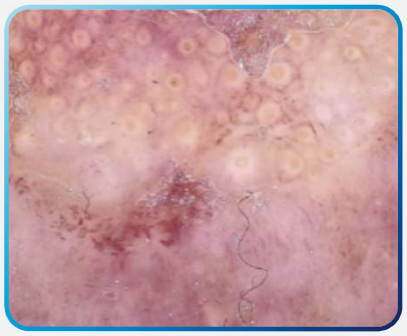


**Figure 1.** Patient at presentation. Erythematous infiltrated plaque on the labial philtrum and upper vermilion border. Dermoscopy shows a polymorphous vascular pattern and white circles around follicular openings

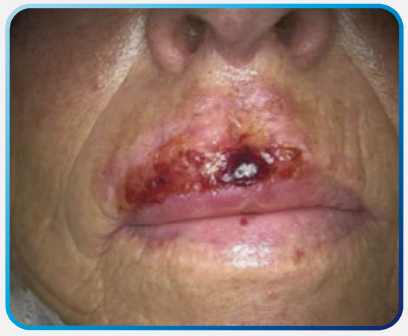
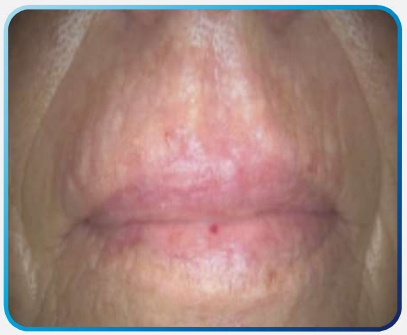


**Figure 2.** Erosions and blood crusts in the treated area after 4 weeks of treatment.



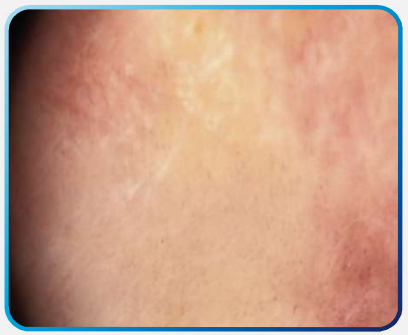


**Figure 3**. After 8 weeks of treatment

Sabbadini, Patta, Lorenzon, Farsad and Nobile 2023. Cutaneous squamous cell carcinoma of the lip successfully treated with rhenium-188 brachytherapy, Dermatology Reports 2023; volume 15

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# Rhenium SCT in NMSC: Study design, baseline and 24-month Clinical Efficacy results from EPIC Skin

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# EPIC-Skin International Prospective Study

## A global, multicenter, single-arm, Phase 4 post-marketing clinical study

- Patients deemed unsuitable for surgery based on clinical determination, screened by plastic surgeons and dermatologists
- **Clinical practice in NMSC radiotherapy is heterogeneous**, with no single standard comparator modality.
- Rhenium-SCT is applicable across multiple clinical scenarios, making **direct head-to-head comparison to a single modality inappropriate**.
- **A pooled historical reference** was therefore selected to contextualise outcomes.
- EPIC Skin was **powered for non-inferiority** to established complete response rates in superficial disease.
- The study design was **informed by multiple formative datasets** and prospectively structured to assess durability, safety, cosmesis, and patient experience.

**7 sites; 5 countries**
(South Africa, Australia, UK, Germany, Austria)

**0, 6-, 12-, 24-month**
time points

**Stage I / II, BCC / SCC;**
- De novo / Recurrent
- 1 - 3 lesions;
- Up to 8cm$^2$ area; < 3mm deep

**Efficacy, cosmesis, toxicity, Safety, QoL, PROs**

Rhenium-Skin Cancer Therapy (SCT) for the Treatment of Non-Melanoma Skin Cancer. (EPIC-Skin); ClinicalTrials.gov ID NCT05135052
Abbreviations: Re-SCT: Rhenium Skin Cancer Therapy; PROs: patient-reported outcomes; BCC: Basal cell carcinoma; SCC: Squamous cell carcinoma; QoL: quality of life

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# Rhenium-SCT: Inclusion & Exclusion

## Inclusion:

- Adults with Stage I or II Basal cell carcinoma (BCC)/Squamous cell carcinoma (SCC), node negative clinically
- ≤ 3mm deep (punch or excisional biopsy verified)
- ≤ 8cm$^2$ (~2.5cm diameter)
- 1-3 lesions
- Not suitable for surgery; patient consent

## Exclusions

- Prior surgery/radiotherapy/laser to that lesion
- Malignant Melanoma
- Lupus and Scleroderma
- Locally advanced or suspected metastatic
- Lesions that cannot be appropriately shielded from healthy tissue (e.g. eyelid)
- Pregnancy and/or Lactation
- With Basal cell naevus syndrome, xeroderma, vitiligo and albinism
- Skin tumours that involve nerves or bony structures
- Any ongoing treatment for malignancy, or in the last 4 weeks prior to study entry

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# EPIC-Skin: Study design

**Primary outcome measure**

- Complete Response (CR) assessed using Modified Visual RECIST tool at 24 months

**Secondary outcome measure**

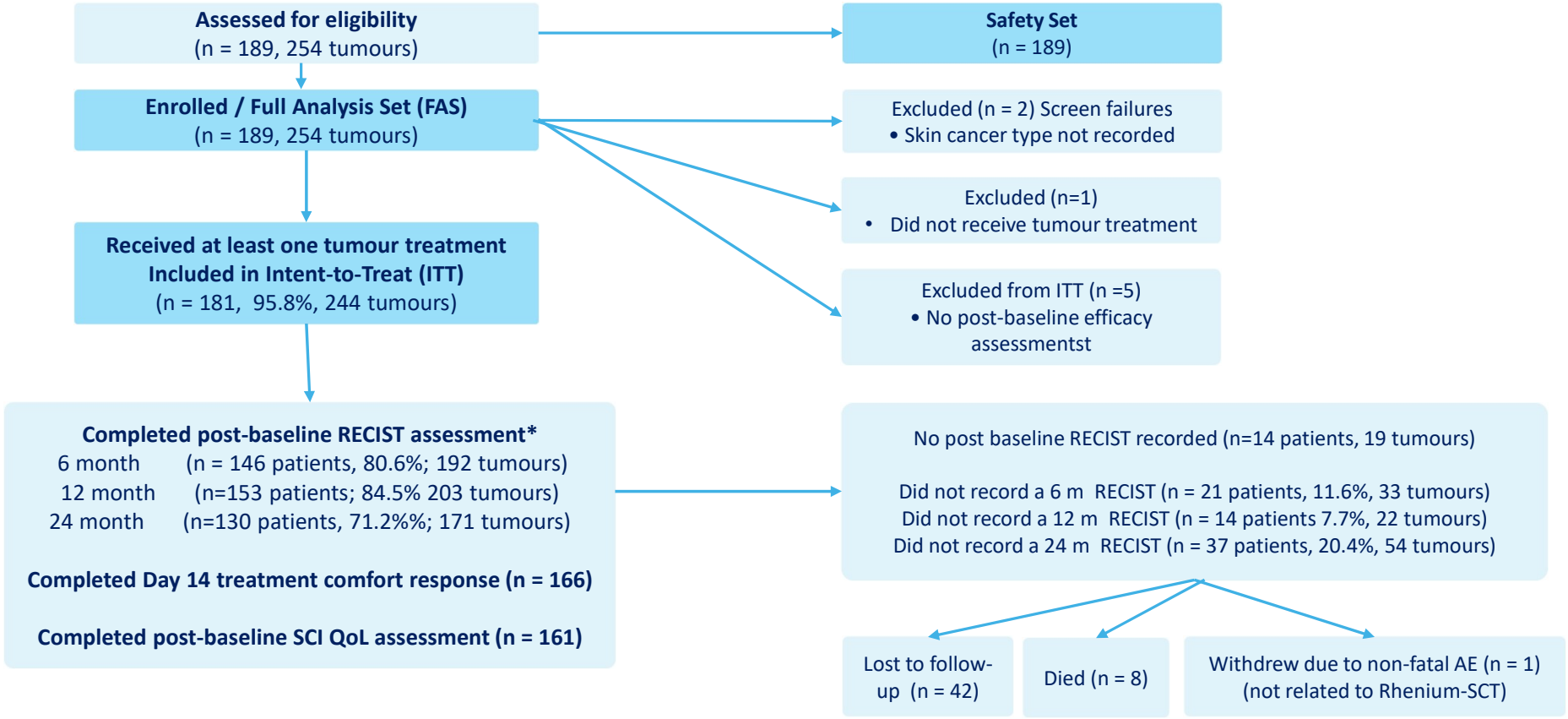
- SKINDEX-16 QoL Questionnaire
- Comfort of Treatment questionnaire
- Cosmetic outcomes by VAS

**Other outcome measure**

- Safety as assessed by CTCAE v5.0


Abbreviations: Re-SCT: Rhenium Skin Cancer Therapy; vRECIST: visual Response Evaluation Criteria in Solid Tumors; SKINDEX-16: QoL: quality of life; VAS: Visual Analogue Scale; CTCAE: Common Terminology Criteria for Adverse Events

# Study Flow Diagram




Abbreviations: vRECIST: visual Response Evaluation Criteria in Solid Tumors. *Proportion of ITT population for each analysis.

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# Patient Demographics and Baseline Characteristics (FAS, n=189)

**71.5 years**
Median age (range 27-95)

**55.4%**
>70 years

**53.3%**
were male

**80%**
Fitzpatrick Type I or II

| Characteristics | Category | Overall n(%) |
|---|---|---|
| Age | Mean (range) | 70.3 (27-95) |
| Age group | <40 | 3 ( 1.6%) |
| | 40-49 | 6 ( 3.3%) |
| | 50-59 | 29 (15.8%) |
| | 60-69 | 44 (23.9%) |
| | 70+ | 102 (55.4%) |
| | missing | 5 (2.6%) |
| Gender | Male | 98 (53.3%) |
| | Female | 86 (46.7%) |
| | missing | 5 (2.6%) |
| FitzPatrick skin type | I | 41 (23%) |
| | II | 101 (56.7%) |
| | III | 32 (18%) |
| | IV | 3 (1.7%) |
| | V | 0 (0.0%) |
| | VI | 1 (0.6%) |
| | missing | 11 (5.8%) |

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# Patient Demographics and Baseline Characteristics (FAS)

| Characteristics | Category | Overall (N=189) n (%) |
|---|---|---|
| Country | Australia | 67 (35.4%) |
| | South Africa | 37 (19.6%) |
| | Austria | 30 (15.9%) |
| | Germany | 32 (16.9%) |
| | United Kingdom | 23 (12.2%) |
| Number of Lesions[1] | 1 | 137 (74.9%) |
| | 2 | 32 (17.5%) |
| | 3 | 14 (7.7%) |
| Surface area of Lesion[2] | | Mean lesion size: 2.27cm$^2$ |
| Depth of Lesion[2] | | Mean lesion depth: 1.40 mm |
| Treatment Time | | Mean treatment time: 119 min (SD 61.0 min) |

* Population is those patients that had at least one treatment (N=183); Overall 227 lesions contained information on surface area. FAS: full analysis set

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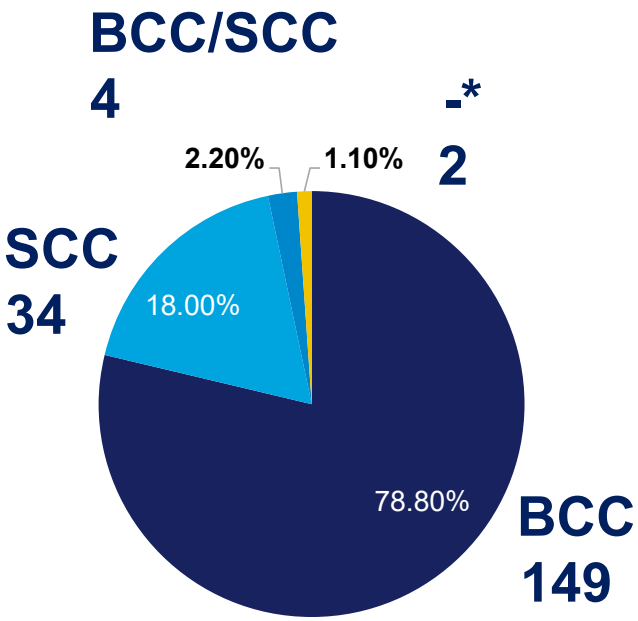
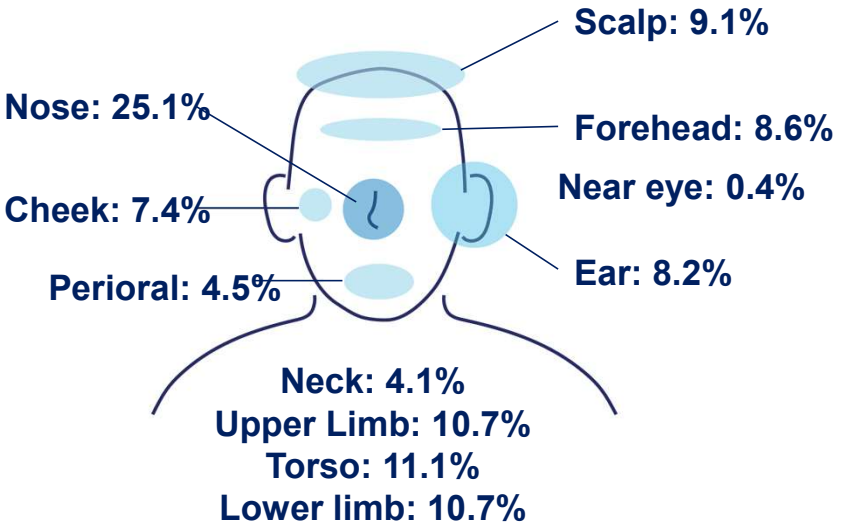
# Lesion Characteristics

## Tumour Type




## Lesion Locations




*Two patients did not have the type of skin cancer (BCC/SCC) recorded. These patients were both screen failures
Of the 183 patients with information in the tumour_details dataset, 137 had a single lesion recorded (74.9%), 32 had two lesions (17.5%), and 14 had three lesions (7.7%).

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# Primary Outcome

## ITT vRECIST assessment at 24 months

| Category | All Tumours | BCC Tumours | SCC Tumours |
|---|---|---|---|
| **Complete response** | **162/171 (94.7%)*** | **123/131 (93.9%)** | **39/40 (97.5%)** |
| **Partial response** | 6/171 (3.5%) | 6/131 (4.6%) | 0 (0.0%) |
| **Stable disease** | 2/171 (1.2%) | 1/131 (0.8%) | 1/40 (2.5%) |
| **Progressive disease** | 1/171 (0.6%) | 1/131 (0.8%) | 0 (0.0%) |

*Global EPIC-Skin longitudinal response analyses are undergoing final harmonisation and validation ahead of manuscript submission

Modified visual RECIST response categories for ITT patient tumours split by tumour type evaluated at 24-month follow-up visits. Total number of tumours at each time point is calculated in the ITT population with vRECIST evaluated

Missing data at not imputed at any time point. RECIST values missing for 73 lesions at 24 months.
Abbreviations: vRECIST: visual Response Evaluation Criteria in Solid Tumors

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# Complete Response over Time

## Rhenium SCT achieved durable efficacy with maturing response as post treatment local skin reactions resolve

| Category | 6m*<br>192 tumours<br>146 patients | 12m#<br>203 tumours<br>153 patients | 24m<br>171 tumours<br>130 patients |
|---|---|---|---|
| **Complete response** | **175/192 (91.1%)** | **185/203 (91.1%)** | **162/171 (94.7%)*** |
| **Partial response** | **15/192** (7.8%) | **10/203 (4.9%)** | **6/171** (3.5%) |
| **Stable disease** | **1/192** (0.5%) | **2/203** (1.0%) | **2/171** (1.2%) |
| **Progressive disease** | **1/192** (0.5%) | **6/203** (3.0%) | **1/171** (0.6%) |

*Global EPIC-Skin longitudinal response analyses are undergoing final harmonisation and validation ahead of manuscript submission

*Interim efficacy and safety analysis were planned once 50% of target patients had recorded a 6-month follow-up visit (106 lesions from 81 patients). Baxi S, Vohra S, Hong A, et al. Effectiveness and patient experiences of rhenium skin cancer therapy for nonmelanoma skin cancer: Interim results from the EPIC-skin study. J Nucl Med. 2024; 65:1450-1455.

#185 treated lesions from 140 patients were available for evaluation at the time of the 12m interim analysis. Cardaci G, et al. 2025. Efficacy, Safety, and Patient Reported Outcomes of Rhenium-Skin Cancer Therapy for Non-Melanoma Skin Cancer: 1-Year Results from the EPIC-Skin Study. Adv Radiat Oncol. 2025 Apr 29;10(7):101802. doi: 10.1016/j.adro.2025.101802. PMID: 40575594; PMCID: PMC12197855.

Modified visual RECIST response categories for ITT patient tumours evaluated at 6, 12, 24-month follow-up visits.. Total number of tumours at each time point is calculated in the ITT population with vRECIST evaluated . Missing data at not imputed at any time point. RECIST values missing for 52, 41, 73 lesions at 6, 12, and 24 months, respectively.

Abbreviations: vRECIST: visual Response Evaluation Criteria in Solid Tumors, CR: Complete response, 6m: 6 months, 12m: 12 months, 24m: 24 months.

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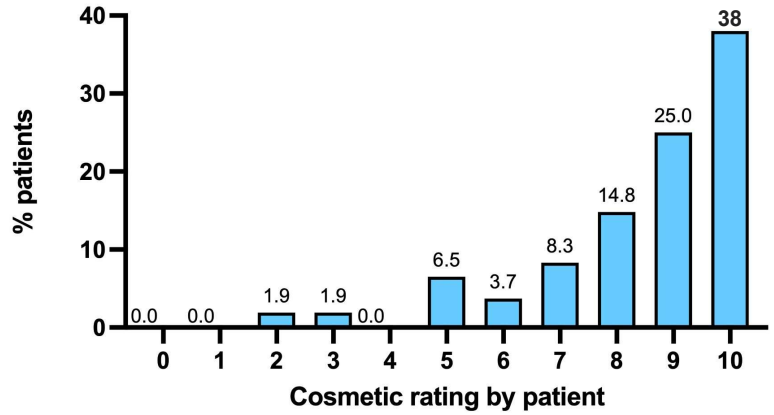
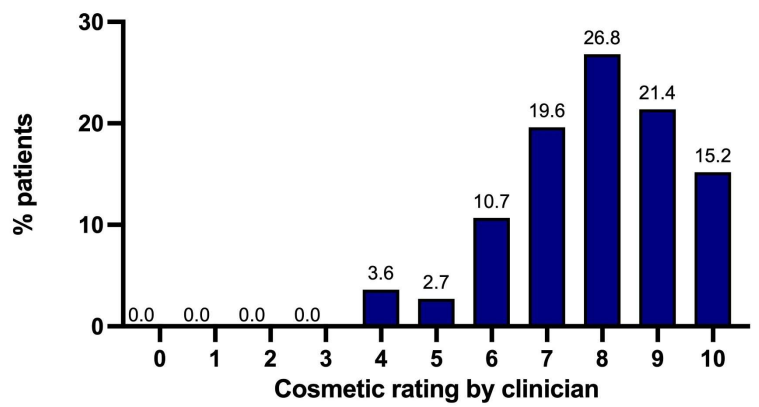
# Secondary Outcome: Cosmesis

## Patients and clinicians report favorable cosmesis outcomes that remained stable over 24m

Average patient cosmetic score: 8.5 (SD=1.88) N=108




Average clinician cosmetic score: 7.9 (SD=1.51) N=112




Both patients and clinicians provided an assessment of the cosmetic appearance of the wound at 24 months post-procedure.
This was done using a 10-point scale: 0 = very poor appearance; 10 = no visible wound

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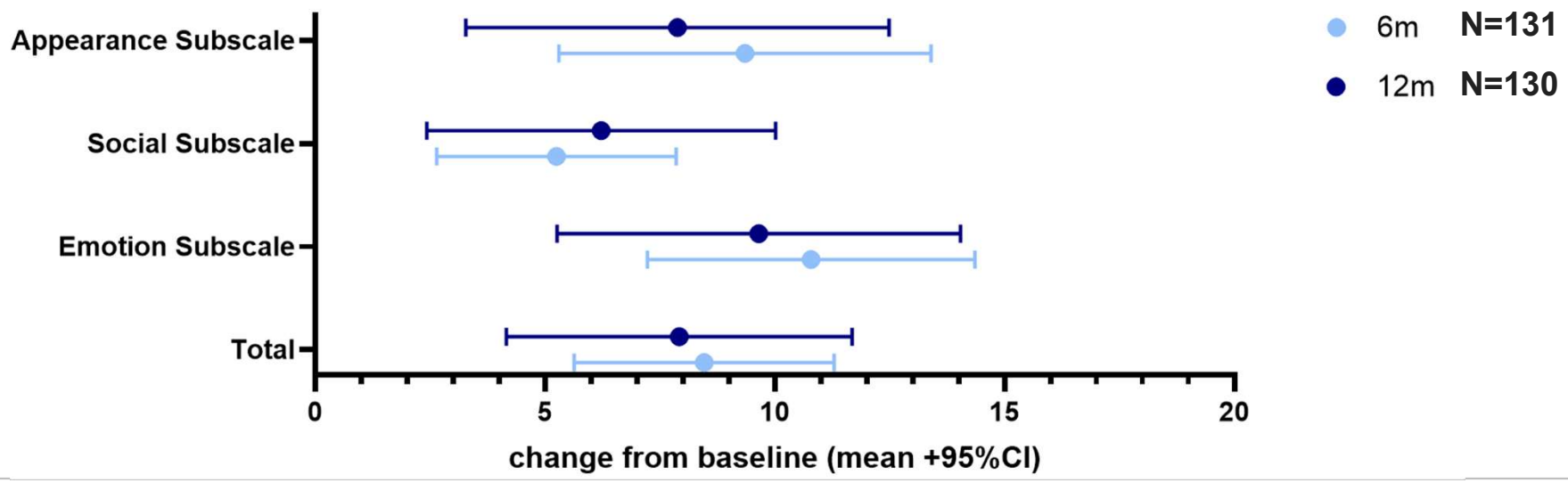
# Secondary Outcome: Comfort of Treatment and Quality of Life

## Patients report no pain and improved skin-directed quality of life following treatment with Rhenium-SCT

### Comfort of Treatment

Of 166 patients with a response on the Day 14 treatment comfort assessment, no pain or discomfort was reported.

### Skin Cancer Index questionnaire Quality of Life




Estimated change from baseline to 6-month and 12-month follow-ups for SCI subscales of the SKINDEX-16 QoL instrument, adjusted for baseline subscale scores. Adjusted repeated measures analysis. *While no MCID exists for the SCI scale, the study describing the instrument found a +9.0 point difference post Mohs surgery (Rhee et al Laryngoscope 2007 Mar;117(3):399-405). Subsequent studies found a +2.36 point difference for Mohs surgery (Sanchez et al J Dermat Treat 2020, 31:5, 491-493), which was deemed statistically significant and consistent with earlier studies (Zhang et al 2018 J Am Acad Dermatol 78(6):1060-1067), and a non-significant -0.6 point difference for excision on the Total scale (Sanchez et al J Dermat Treat 2020, 31:5, 491-493).

# Summary

**EPIC-Skin Phase IV Study**

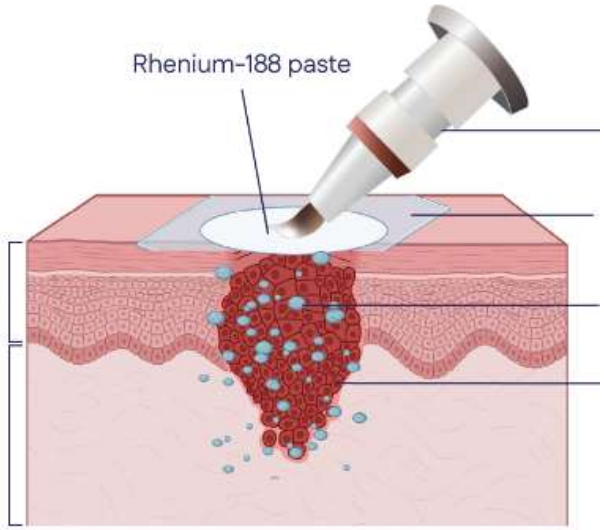
**Rhenium-SCT**
**Single-session 50Gy treatment**

**24-month outcomes**

## 189 patients
**(Median: 72 years)**

## BCC or SCC
**1-8cm$^2$; < 3mm deep**

## 171 tumors
**with 24m month follow-up**




## Efficacy
**94.7%* complete response**

## Treatment Comfort
**100% no pain during procedure**

## QoL
**+7.92 meaningful** improvement in SKINDEX -16 scores from baseline**

## Cosmesis
**8.5/10 Patient-rated mean**

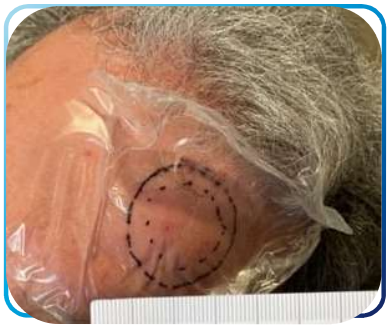
**7.9/10 Clinician rated mean**

*Global EPIC-Skin longitudinal response analyses are undergoing final harmonisation and validation ahead of manuscript submission

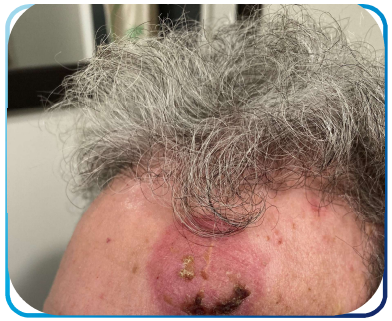
**While no MCID exists for the SCI scale, the study describing the instrument found a +9.0 point difference post Mohs surgery (Rhee et al Laryngoscope 2007 Mar;117(3):399-405). Subsequent studies found a +2.36 point difference for Mohs surgery (Sanchez et al J Dermat Treat 2020, 31:5, 491-493), which was deemed statistically significant and consistent with earlier studies (Zhang et al 2018 J Am Acad Dermatol 78(6):1060-1067), and a non-significant -0.6 point difference for excision on the Total scale (Sanchez et al J Dermat Treat 2020, 31:5, 491-493).

# EPIC Clinical Cases

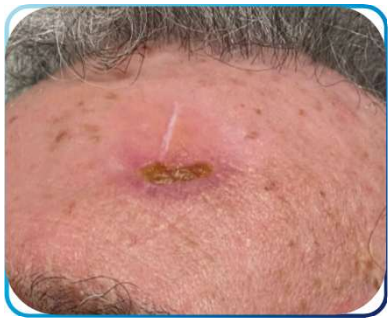
## multiple facial lesions



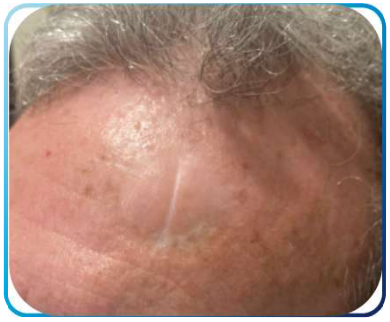
Baseline



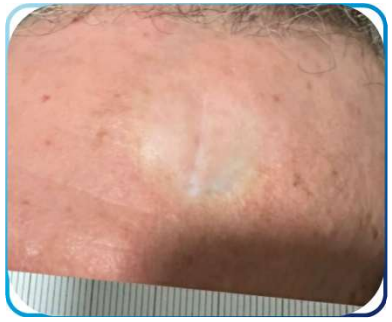
Day 14



Month 3



Month 6



Month 12

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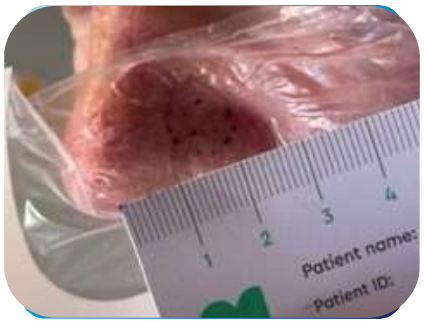
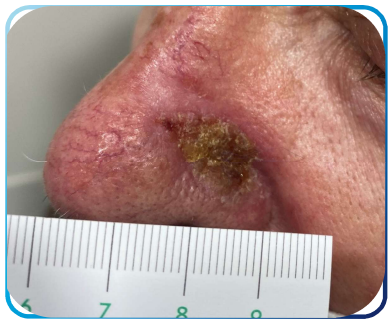
# EPIC Clinical Cases

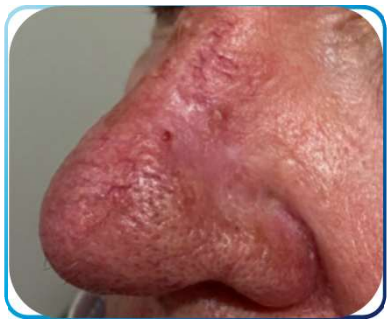
## multiple facial lesions



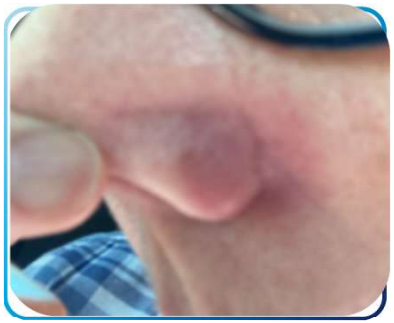

**Baseline**



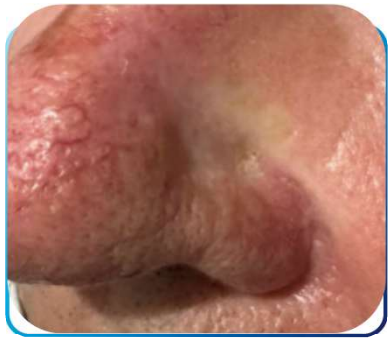
**Day 14**



**Month 3**



**Month 6**



**Month 12**

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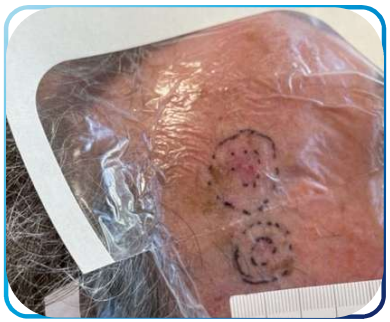
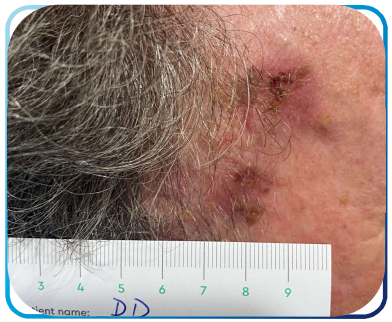
# EPIC Clinical Cases

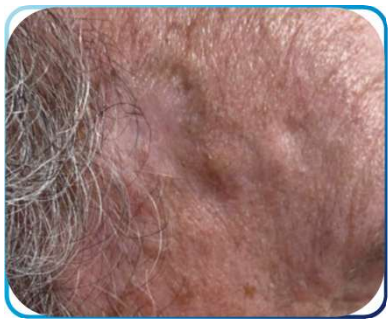
## multiple facial lesions



Baseline



Day 14



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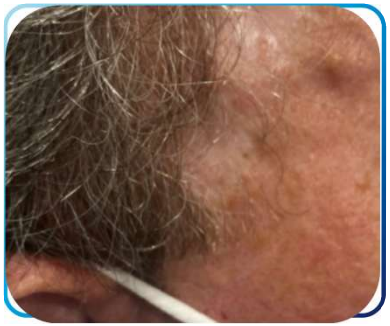
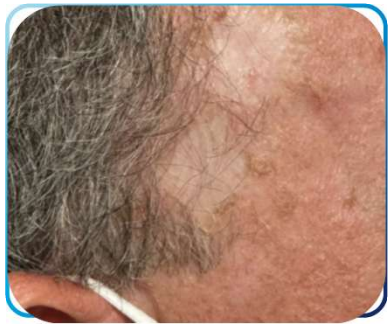


Month 6



Month 12

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# Rhenium SCT in NMSC: 24-month Safety results from EPIC Skin

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# Adverse Events

| | Overall n=189 | |
|---|---|---|
| | Patients[a,b] (%) | Events[c] (%) |
| **Any adverse events** | 73 (38.6%) | 169 |
| **Severity** | | |
| **Mild** | 55 (29.1%) | 104 (61.5%) |
| **Moderate** | 30 (15.9%) | 50 (29.6%) |
| **Severe** | 5 (2.6%) | 7 (4.0%) |
| **Fatal** | 8 (4.2%) | 8 (4.7%) |
| **Relationship to IP** | | |
| **Unrelated** | 17 (9.0%) | 21 (12.4%) |
| **Possible** | 12 (6.3%) | 12 (7.1%) |
| **Probable** | 51 (27.0%) | 131 (7.8%) |
| **Missing** | 5 (2.6%) | 5 (3.0%) |
| **Serious event** | | |
| **No** | 65 (34.4%) | 158 (93.5%) |
| **Yes** | 9 (4.8%) | 9 (5.3%) |
| **Missing** | 2 (1.1%) | 2 (1.2%) |
| **Event leading to withdrawal** | | |
| **No** | 65 (34.4%) | 161 (95.3%) |
| **Yes** | 6 (3.2%) | 6 (3.6%) |
| **Missing** | 2 (1.1%) | 2 (1.2%) |

- **There were 169 AE reported in 73 patients (38.6% of patients reporting at least one AE):**
  - 104 mild (G1) / 50 moderate (G2) / 7 severe (G3) events
  - 6 events leading to study withdrawal (unrelated to IP)
- **Relationship to IP was noted as probable for 131 events, possible for 12 events, unrelated for 21 events, and was missing for 5 events.**
- **9 SAE were included in the study data:**
  - 1 possibly related to the IP (skin induration - moderate)
  - 8 unrelated to IP (7 were fatal SAE)
- **No treatment emergent, treatment related adverse events led to withdrawal from study**

An SAE is any untoward medical occurrence that at any dose (including overdose): Medical Device (MDR 2017/745)
Serious adverse event (SAE) is any adverse event that led to any of the following:
a) death, b) serious deterioration in the health of the subject, that resulted in any of the following:
1) life-threatening illness or injury, 2) permanent impairment of a body structure or a body function, 3) hospitalization or prolongation of patient hospitalization; 4) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function; 5) chronic disease; c) fetal distress, fetal death or a congenital physical or mental impairment or birth defect.
NOTE 1 Planned hospitalization for a pre-existing condition, or a procedure required by the protocol, without serious deterioration in health, is not considered a serious adverse event. Any adverse events that do not satisfy these descriptions are defined as being non-serious

[a]Patients = number of patients with at least one event of this type. Patients are counted up to once in each row. Events = number of events of this type. Patients may contribute multiple events to each row. Percentages are based on the number of patients in the safety set[b], or total number of Adverse events[c]. Abbreviations: G1: AE: Adverse Event, Grade 1; G2: Grade 2; G3: Grade 3; IP: Investigational Product; SAE: Serious Adverse event;

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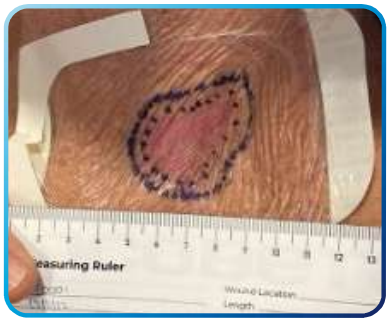
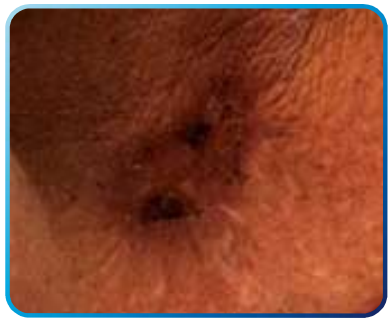
# EPIC Clinical Cases: Adverse events

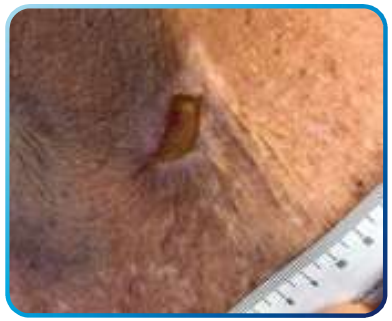
## Severe Skin Induration/Fibrosis - shoulder



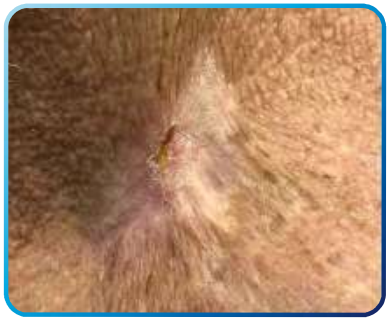
**Baseline**



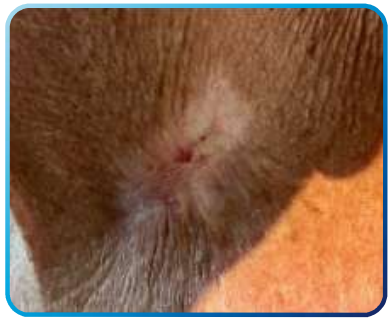
**Day 14**



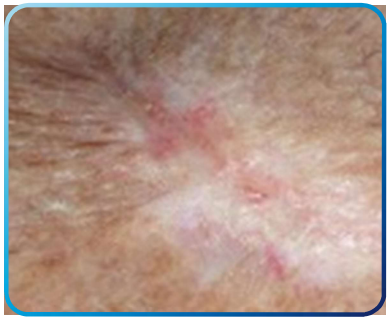
**Month 3**



**Month 6**



**Month 12**



**Month 24**

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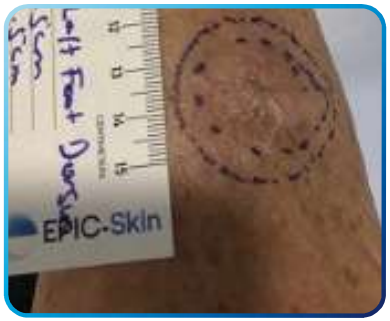
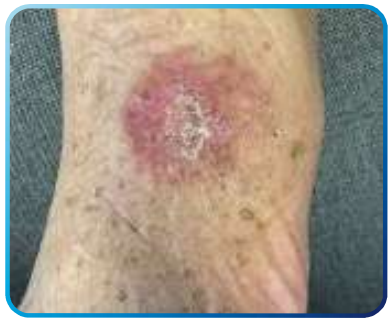
# EPIC Clinical Cases: Adverse events

Severe ulceration, dermatitis, hypopigmentation, telangiectasia – lower limb

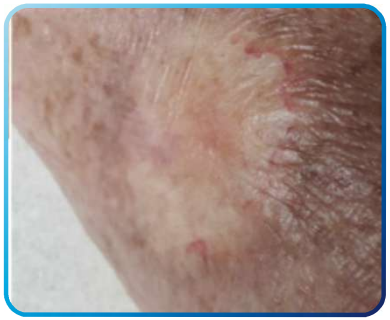



**Baseline**

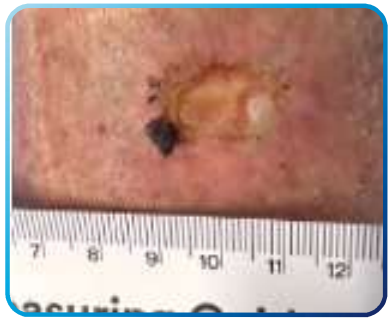


**Day 14**

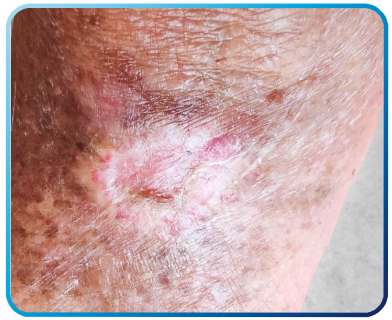
**Month 3**



**Month 6**



**Month 12**



**Month 24**

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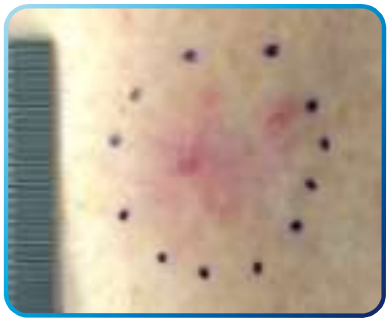
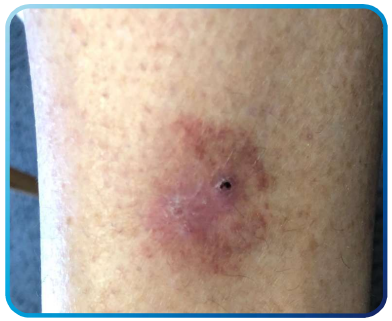
# EPIC Clinical Cases: Adverse events

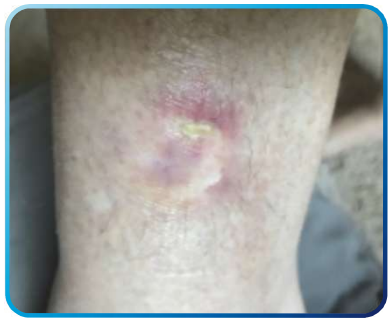
Severe ulceration, severe dermatitis, severe induration – lower limb



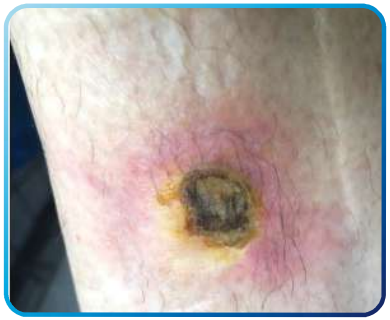
**Baseline**



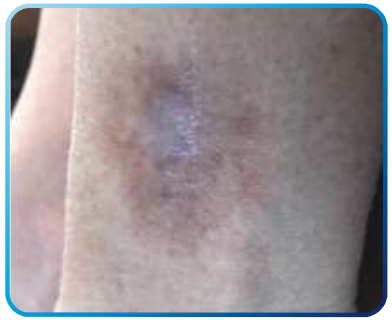
**2 weeks**



**3 months**



**6 months**



**24 months**

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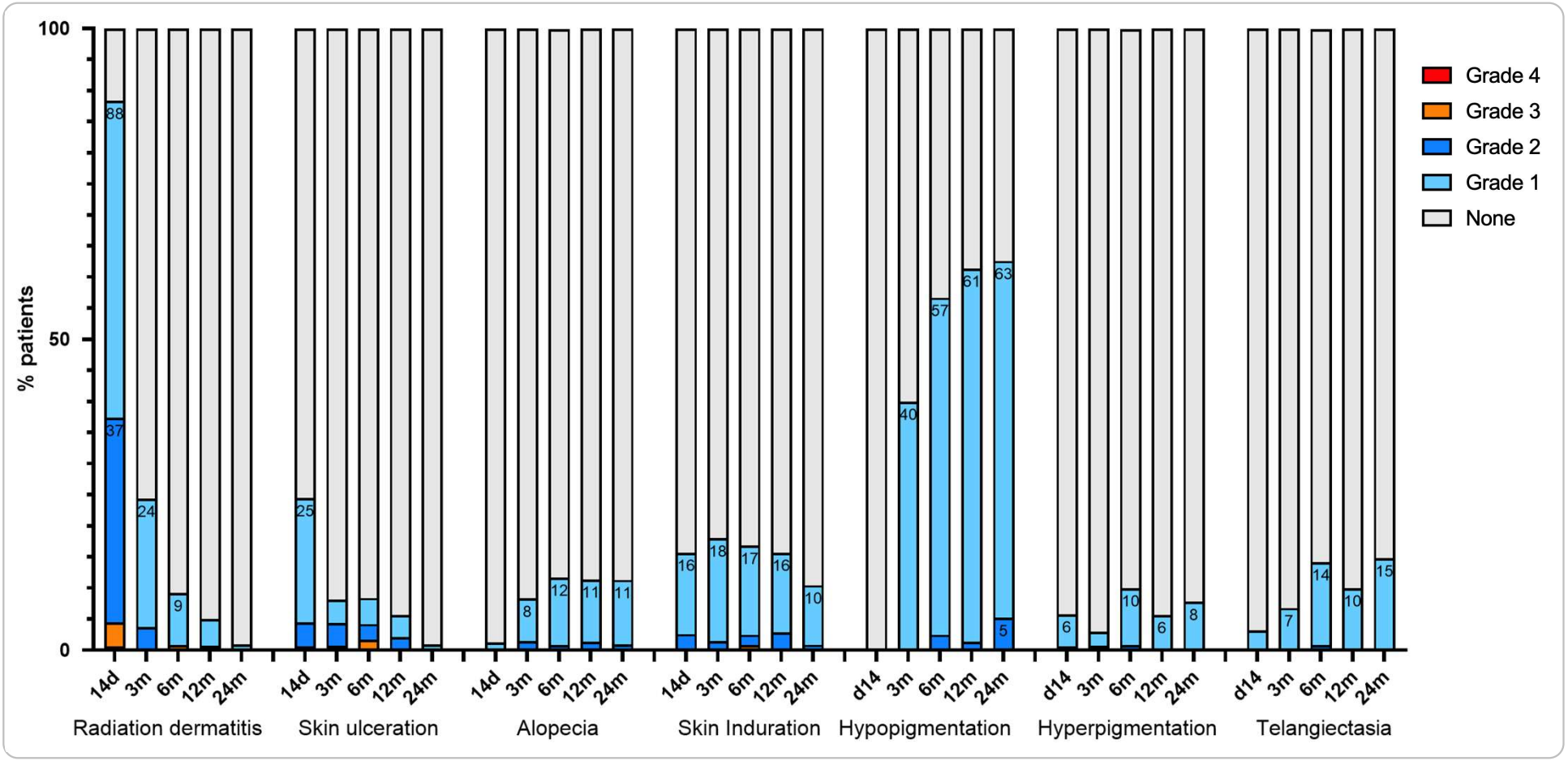
# CTCAE Graded Adverse Events of Interest




For each event type (radiation dermatitis, skin ulceration, alopecia, skin induration, hypopigmentation, hyperpigmentation, telangiectasia), only patients experiencing the event are graphed. Assessment for these events were undertaken at day 14, 3-month, 6-month, 12-month and 24-month visits. Abbreviations: CTCAE:Common Terminology Criteria for Adverse Events; d14: day 14, 3m: 3-month, 6m: 6-month, 12m: 12-month and 24m: 24-month

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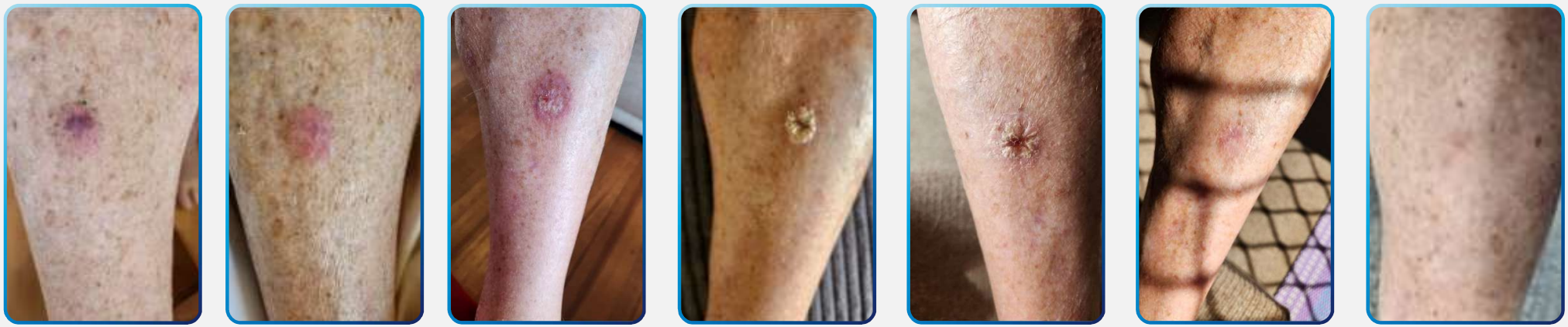
# Typical healing timeline

- **Acute reaction grade correlates with:**
- Depth[1-3] : resolution of reaction = 32 days (mean depth 1.1 mm)[2];
- Surface area[1-3] : resolution of reaction = 65 days (mean area 5cm$^2$)[3]
- Anatomic Zone[3] : face heals quicker than lower limbs[3]
- Age[3]



**0** **2 weeks** **3 weeks** **4 weeks** **6 weeks** **8 weeks** **12 weeks**

1. Tietze JK et al. Clin Nucl Med 2023;48:869–76.; 2. Castellucci P et al. Eur J Nucl Med Mol Imaging 2021;48:1511–21 3. Cipriani C et al. Int J Nucl Med 2017;114–22. Images Courtesy of Sid Baxi

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# Summary of EPIC-Skin 24-month outcomes

**The EPIC-Skin study's 24-month analysis demonstrates that Rhenium-SCT is a safe and effective treatment for BCCs and SCCs, which yields excellent cosmetic outcomes and significant improvements in patient quality of life.**

Single session (~30-180min) radioisotope treatment

EPIC Skin enrolled BCC / SCC / IEC ≤3mm deep, up to 8cm$^2$ (~2.5cm diameter).

Used clinically in lesions with difficult surgical options or unacceptable functional/cosmetic outcomes – Face / Ears / Noses / Peri-oral / Digits / (Penile)

**Efficacy**: The overall response rate was 98.2%,with a complete response rate of 94.7%* (BCC: 93.9%, SCC: 97.5%)

- **QoL**: All average scores showed an increase in QoL from baseline.
- **Cosmesis**: Patients and Clinicians reported favorable cosmesis outcomes that remained stable over 24m
- **Patient Comfort**: 100% reported no pain or discomfort during the treatment session (n=166).

**Safety**: Manageable safety profile consistent with conventional radiotherapy.

- **Early toxicities** include radiation dermatitis (88.4%) and skin ulceration (24.5%).
- **Late toxicities** include hypopigmentation (57.4% Gr1/5.2% Gr2) and telangiectasia (14.8% Gr1)

*Global EPIC-Skin longitudinal response analyses are undergoing final harmonisation and validation ahead of manuscript submission

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# Clinical Relevance of Rhenium SCT in NMSC

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# What matters to patients?

## Rhenium-188 patients prioritise pain avoidance, treatment simplicity, and alternatives to surgery

**Why patients choose Rhenium-SCT**

- Pain avoidance: 84% participated to avoid pain and complications of surgery
- Lower treatment anxiety: Patients were significantly less afraid of Rhenium-SCT than surgery
- Single-visit treatment was valued, particularly after multiple prior procedures

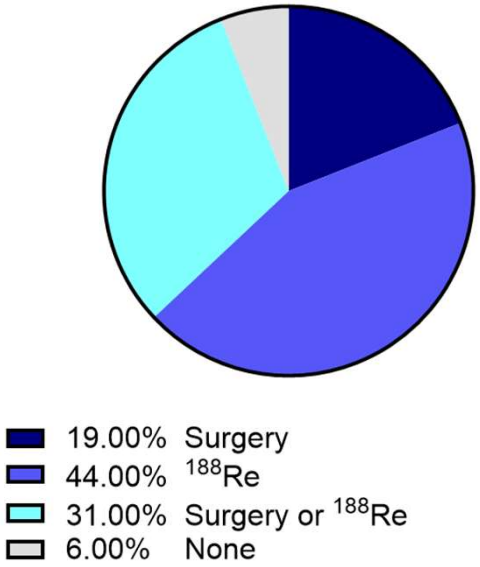
**Experienced pain (patients who had both treatments)**

- Rhenium-SCT was associated with significantly lower pain scores than surgery
- During treatment
- And at 14 days post-treatment

**Clinician-supported decision-making**

- Dermatologists strongly supported Rhenium-SCT in ~50% of cases due to:
  - Lesion size
  - Sensitive anatomical locations
  - High expected surgical morbidity

**Choice of treatment for a new NMSC**




Krönert MIC, Schwarzenböck SM, Kurth J, Heuschkel M, Krause BJ, Emmert S, Tietze JK. Patient-Orientated Evaluation of Treatment of Non-Melanoma Skin Cancer with Rhenium-188 Compared to Surgery. Healthcare (Basel). 2024 Apr 29;12(9):921. doi: 10.3390/healthcare12090921. PMID: 38727478; PMCID: PMC11083370. Abbreviations

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# Conclusions – From a Clinical Perspective

## EPIC establishes Rhenium-SCT as an effective, well-tolerated option for appropriately selected superficial NMSC

| | |
|---|---|
|  | EPIC is the first prospective dataset specifically designed to assess durability, safety, and efficacy of Rhenium-SCT in ≤3 mm lesion |
|  | Rhenium-SCT is an additional tool, not a replacement for surgery, for selected patients. |
|  | Best suited for thin (≤3 mm) BCC/SCC lesions, particularly when:<br>• Surgery is high morbidity, declined, or impractical<br>• Lesions are in cosmetically or surgically challenging locations<br>• Multiple or refractory lesions can be treated in a single visit |
|  | Durable tumour control is achieved when appropriate dose is delivered to tumour depth, with responses continuing to mature as post-treatment skin changes resolve. |
|  | Predictable healing and low procedural pain align with what many patients value |
|  | **Rhenium SCT: another tool in the toolbox for treating selected superficial NMSC** |

Baxi et al 2026 Rhenium SCT for non-melanoma skin cancer: Topline Results from EPIC Skin, An international Phase 4 prospective single arm multicentre study, Presented at American College of Radiation Oncology Orlando Feb 6 2026

# Disclosures and Acknowledgements

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# Global Regulatory Status of Rhenium SCT

**Globally Rhenium-SCT is:**

- MDR-approved in EU – MDR 796214 R000
- AEMPS approved Class IIb Medical Device in Spain – PD/2022/6247(D)
- ARTG-registered in Australia; ARTG Number 400142
- HAS registration medical device in Singapore – Product Number: MDPR251103W0003
- SAHPRA authorised in South Africa – 00003410MD_v1
- Medsafe in New Zealand – 230302-WAND-70RGWT

Abbreviations: MDR: Medical Device Regulation EU: European Union; AEMPS: Agencia Española de Medicamentos y Productos Sanitarios; ARTG: Australian Register of Therapeutic Goods; HSA: Health Sciences Authority; SAHPRA: South African Health Products Regulatory Authority

# Disclosures

- This study is a clinical investigation of the OncoBeta product, Rhenium-SCT.
- Cody Allison and Sasha Grubman are employed by OncoBeta Therapeutics.
- Gerhard Dahlhoff reports administrative support, article publishing charges, equipment, drugs, or supplies, statistical analysis, travel, board membership, consulting or advisory, and writing assistance were provided by OncoBeta GmbH. Gerard Dahlhoff is Chief Medical Officer of Oncobeta gmbh.
- Giuseppe Cardaci reports article publishing charges, equipment, drugs, or supplies, statistical analysis, and writing assistance were provided by OncoBeta GmbH. Giuseppe Cardaci reports a relationship with OncoBeta GmbH that includes: consulting or advisory, speaking and lecture fees, and travel reimbursement.
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- Julia Tietze reports a relationship with OncoBeta GmbH that includes: consulting or advisory
- All discussions refer to investigational purposes only.

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