# **DEVELOPING ALERT THRESHOLDS AND SELF-MANAGEMENT ADVICE FOR PEOPLE RECEIVING IMMUNE CHECKPOINT INHIBITORS - A MASCC MODIFIED DELPHI STUDY**

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## Background

- Immune-related adverse events (irAEs) may be severe and lifethreatening. Early recognition is critical for people receiving immune checkpoint inhibitors (ICI).
- Remote monitoring systems using electronic patient-reported outcomes (ePROs) may help support patients and caregivers to identify potential irAEs and support self-management.
- There is lack of consensus regarding (i) thresholds to advise clinicians about potentially severe irAEs, and (ii) evidence-based advice for patients to self-manage milder side-effects.

### Aim

 To develop consensus around the alert thresholds and self-management advice regarding selected Common Terminology Criteria for Adverse Events (CTCAE) items suggestive of irAEs.

# **Methods**

Two-round online international modified Delphi survey

51 co-authors of major international irAE guidelines and selected immunooncology experts were invited to participate

### *Round* 1 (*R*1):

Reviewed 36 side-effects identified in an Australian modified Delphi study.

Stated whether they agreed or disagreed with the proposed thresholds/ self-management statements. If disagreed, provided free text comments.

≥75% of participants agreed: consensus reached.

<75% agreed: modified alert thresholds or selfmanagement statements based on comments.

International consensus was obtained on appropriate *alert* thresholds and selfmanagement advice for 36 sideeffects suggestive of an irAE.

Alert thresholds and self-management advice can be incorporated into remote monitoring systems to support the safe delivery of ICIs

Reviewed modified alert thresholds and self-management statements that did not reach consensus in R1.

Stated whether they agreed or disagreed with the modifications. If disagreed, provided free-text comments

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## **R1 results**

R1 participant demographics (n=34)

- 18 females (52.9%)
- 41-50 years old (18, 52.9%)

- lung (14, 41.2%)
- management statements.
- fevers/ chills).
- itch).

### **R2 results**

R2 participant demographics (n=31)

- 15 females (48.4%)
- 41-50 years old (17, 54.8%)

- kidney (12, 38.7%)
- rate: 91%)
- statements.

Round 2 (R2):

 $\geq$ 75% of participants agreed: consensus reached.

<75% agreed: steering committee modified alert thresholds or selfmanagement statements based on comments.









• 28 medical/clinical oncologists (82.4%) • Location: Americas (18, 52.9%), Europe (12, 35.3%) • Median duration of experience: 13.5 years • Managed cancers: melanoma (24, 70.6%), breast (14, 41.2%),

33 completed responses received, with 1 incomplete response Consensus was achieved on 29/36 alert thresholds and 33/36 self-

• 7 alert thresholds were raised from CTCAE Grade 1 to 2 based on participant comments and were re-presented in R2 (drowsiness, loss of balance/ coordination, cough, abdominal pain, vomiting, rash, mouth ulcers)

• 3 self-management statements were amended based on participant comments and were re-presented in R2 (eye problems, abdominal pain, and

6 additional self-management statements which achieved consensus but were amended based on participant comments were also re-presented in R2 (headache, vision problems, light-headedness/ dizziness, nausea, vomiting,

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• 24 medical/clinical oncologists (77.5%)
Location: Americas (18, 58.1%), Europe (9, 29%)
Median duration of experience: 13 years
Managed cancers: melanoma (21, 67.7%), lung (12, 38.7%),
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• 30 completed responses received, with 1 incomplete response (response

• Consensus was achieved on 7/7 alert thresholds and 9/9 self-management

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