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Guidance for reporting regimen outcome summary (non-curative) in the SACT dataset

This document aims to provide guidance to clinicians reporting regimen outcomes for non-curative treatments in the systemic anti-cancer therapy (SACT) dataset. This guidance was produced with the collaboration of clinicians to address potential differences in interpretation of 'outcome data', whilst being mindful of the practicalities of recording this in routine clinical practice. We appreciate that non-curative treatment benefit assessment is a complex question and may be considered, to a certain extent, subjective. Each patient is unique; ultimately the appreciation of treatment benefit reported is with the clinical staff.

Note that this document focusses only on solid tumours.

The document is made of three parts:

1. Background and introduction
2. Considerations for assessing non-curative treatment benefit
3. Patient examples

Background and introduction

The SACT dataset collects data in four main areas:

- the patient & their tumour,
- where they were treated and who initiated their treatment,
- treatment details, and
- clinical outcomes.

Treatment outcomes are a key aspect of the SACT dataset. The collection of SACT specific outcomes allows the team to design analyses to evaluate treatment effectiveness and identify variations in clinical practice. Additionally, regimen outcome data are reported as part of our work to support Cancer Drugs Fund (CDF) re-appraisals.

'Treatment outcomes' refer to the clinical outcomes which result from the administration of a treatment regimen in the SACT dataset.

While collecting 'benefit' data will likely bring variability at individual level, it is reasonable to expect to see trends at a population level that will be relevant to clinicians, and other groups.

Relevant SACT fields

1) Intent of treatment

The **intent of treatment** itself is captured as a separate data item (dataset item 15) and includes curative or palliative options:

1. Curative – aiming to permanently eradicate the disease
2. Palliative – aiming to extend life expectancy
3. Palliative – aiming to relieve and/or control malignancy related symptoms
4. Palliative – aiming to achieve remission
5. Palliative – aiming to delay tumour progression

98. Other
99. Not known

Note that multiple answer options can be selected for this item.

2) Treatment outcomes

The **treatment outcomes** are captured differently depending on treatment intent:

For curative treatments, (dataset items 57 and 58): clinicians should state whether the treatment was completed as planned (Yes/No). If the treatment was not completed as planned, then further details are required on the reason(s) why the treatment was not completed.

For non-curative treatments, clinicians are asked to specify whether the patient has 'benefitted' from receiving the treatment (Yes/No). No further information is required for these treatment outcomes at this stage (dataset item 60). **This item is the focus of this guidance document.**

Considerations for assessing non-curative treatment benefit

We recommend assessing the presence or absence of treatment benefit **in light of the original intent of the treatment reported in the dataset** (see list above for "palliative" options).

For example, if the treatment intent was '*4. Palliative - aiming to achieve remission'*, then the benefit recorded should reflect whether the treatment achieved the goal of remission.

If the original aim of the treatment has been met, this is evidence that the treatment has been beneficial, i.e. "Yes" should be selected. If you have selected multiple aims for 'treatment intent', then we recommend that you consider an overall assessment of the success of the aims, alongside the considerations below.

Where it is not completely clear if the treatment intent has been met, or it has not been fully met, the following elements can also be considered:

- Response to treatment
- Impact on symptoms
- Impact on quality of life

To determine true benefit, any clinical benefit to the patient should always be weighed against any toxicities experienced as part of the treatment and their impact on the patient's quality of life.

Below are some examples of what elements may contribute toward a potential benefit:

Tumour

- Biochemical or radiological response
- Unaltered or decreased tumour size
- Reduction in tumour markers
- Prolongation of progression-free survival (PFS)

Patient

- Improvement of malignancy related symptoms (as observed and self-reported)
- Manageable treatment-induced toxicities (as observed and self-reported)

Although we acknowledge that patients may gain varied levels of benefit from treatment over time, for routine reporting through the SACT dataset it is only assessed when the treatment regimen is complete. Therefore, the entire period of treatment administration must be evaluated to answer the 'treatment benefit' data set question.

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Patient examples

The patient examples described below illustrate common patient profiles encountered by oncologists. These are hypothetical and simplified for this exercise and aim to provide examples of treatment benefit in a real-life setting. These are a snapshot of the patient's medical situation when the assessment is being recorded. However, the assessment must be made considering the **entirety of the treatment period**. Note that the focus of this document is on solid tumours only.

Breast patients

	Tumour type	**Patient characteristics**	**Treatment intent (SACT item)**	**Response assessment**	**Toxicity**	**Outcome on completing treatment**	**Suggested outcome (SACT item #60)**
Patient A Chemotherapy	Breast with lung metastases	Patient well, PS1	Palliative - aiming to relieve and/or control malignancy related symptoms	Reduction in number and size of metastases on CT scan, 4-5 months of good symptom control prior to rapid disease progression after the 8th cycle of treatment	Neutropenic sepsis after course 4, successfully treated with antibiotics	Dies from disease progression 20 days after the 8th cycle of treatment	**Benefit**

Patient B Chemotherapy & drainage of fluid	Breast with lung metastases	Pleural effusion and very breathless, PS1	Palliative - aiming to relieve and/or control malignancy related symptoms and aiming to extend life expectancy	Reduction in symptoms	Not recorded	Not known	**Benefit**
Patient C 8 cycles of chemotherapy	Breast with brain metastases	PS1	?	Patient feels well – stable condition on CT scan	Manageable – well tolerated	Not known	**Benefit**
Patient D Chemotherapy	Breast with liver metastases	Unwell patient, PS2	Palliative - aiming to extend life expectancy	Small reduction in metastases size	Side effects lead to significant deterioration in QOL Hospitalised for infection – poorly tolerated	Not known	**No benefit**

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Melanoma patients

	Tumour type	**Patient characteristics**	**Treatment intent (SACT item)**	**Response assessment**	**Toxicity**	**Outcome on completing treatment**	**Suggested outcome (SACT item)**
Patient A Anti-PD-1 antibody monotherapy	Melanoma with liver metastases	80 yo, hypertension, previous TIAs, 3 antihypertensives, otherwise mobile, independent, PS 1	Palliative – aiming to achieve remission	Stable disease after 3 months	No significant immune-related adverse events	Dies of stroke after 5 months of treatment	**No benefit**
Patient B Combination immunotherapy with antiPD-1+anti-CTLA-4 antibodies	Melanoma with low volume lung metastases	45 yo, BRAF wildtype, asymptomatic	Palliative – aiming to achieve remission	Almost complete response by 6 months, maintained over time	Grade 3 colitis after 2 cycles, admitted for 3 weeks, needed infliximab x 2, developed grade 3 hepatitis while in hospital, chronic steroids, discharged, developed grade 2 chronic polyarthropathy	Alive, continues to need treatment for erosive polyarthropathy	**Benefit**
Patient Γ Combination immunotherapy with antiPD-1+anti-CTLA-4 antibodies plus stereotactic radiotherapy to the brain	Melanoma with brain mets	55yo, brain mets progressed on BRAF targeted therapy	Palliative – aiming to extend life expectancy and/or delay tumour progression	Disease progression	Hospitalised with CVA after cycle 1, discharged for EOL care	Death within 3 months of hospitalisation	**No benefit**

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Pancreatic cancer patients

	Tumour type	**Patient characteristics**	**Treatment intent (SACT item)**	**Response assessment**	**Toxicity**	**Outcome on completing treatment**	**Suggested outcome (SACT item)**
Patient 1 Chemotherapy (FOLFIRINOX)	Pancreatic cancer with liver metastases	65 yo, mild fatigue only, PS 1 at start of treatment but PS 2 at month 6	Palliative – extend life expectancy, delay tumour progression	Month 2: minor response Month 4: stable disease Month 6: early signs of progression; treatment stopped by patient choice due to toxicities	Chemo-related toxicities: fatigue, altered bowel habits and loss of taste, weight loss.	Patient does not return to clinic and dies 9 months from starting chemotherapy	**Benefit**
Patient 2 Chemotherapy (Gemcitabine)	Pancreatic cancer with liver metastases	75 yo, mild fatigue, back pain, PS 2	Palliative –delay tumour progression and relieve/control symptoms	Minor increase in liver mets on CT at 3 months, but overall stable disease	Pain controlled, recurrent thrombocytopenia interrupting chemo delivery with each cycle. Multiple extra visits for rescheduled chemo plus admission for fever of unknown origin, leading to treatment stopping after 4 months	Death at 6 months	**No Benefit***

* Rationale: The clinician feels that the symptoms have been controlled, and this was one of the identified treatment intents. However, there is no strong evidence of delayed tumour progression, which was the other goal of treatment. Multiple hospital visits and admissions are considered to have a significant negative impact on the patient's quality of life.