Guidance for assessing ‘Non-curative treatment benefit’ in the SACT dataset (solid tumours)

Public Health England

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SACT dataset Team – November 2020

For more information please consult: http://www.chemodataset.nhs.uk/home

INTRODUCTION

Treatment outcomes = clinical outcomes which result from the administration of a treatment regimen in the SACT dataset. Note that the focus of this document is on solid tumours only.

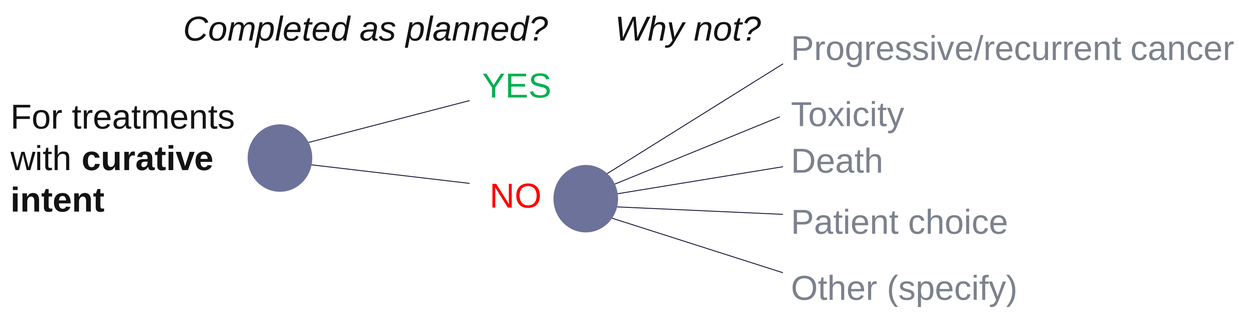
We have designed this document to provide guidance to complete the ‘Non-curative treatment benefit’ (item 60) of the SACT dataset. Benefit assessment at the end of treatment is complex and each patient’s experience is unique; ultimately the assessment of treatment benefit is made by clinical staff.

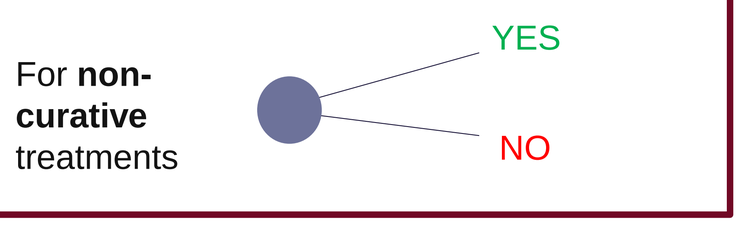
This document is a summarised version of the ‘Non-curative treatment benefit guidance’.

INTENT IN SACT DATASET

Regimen outcomes reporting in the SACT dataset is tied to treatment intent, which is recorded as a separate item. Intent can be either curative or palliative (please see “Guidance” below for details)

OUTCOMES REPORTING IN SACT DATASET



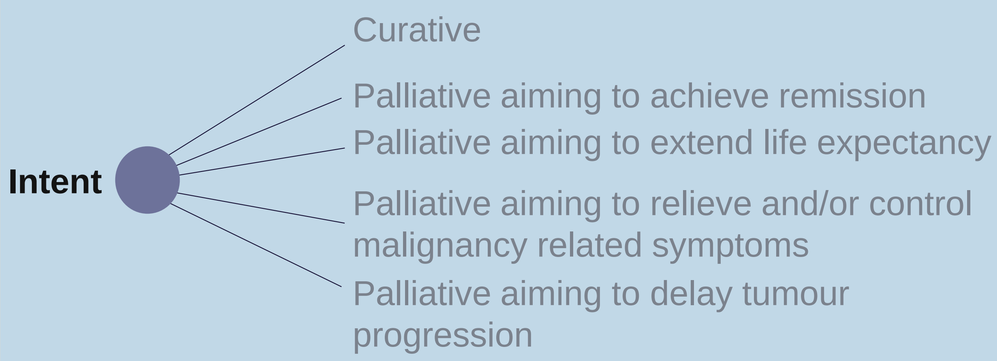


This data item is the focus of this document

GUIDANCE

Consideration #1 – Treatment intent

In order to assess treatment benefit, consider the treatment intent reported in the SACT dataset and whether or not it was fulfilled looking at the entire treatment period.



NB: Multiple goals can be selected – in this situation an overall assessment of success in meeting the goals should be made

Illustration

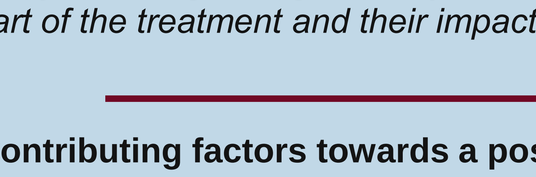
‘Palliative aiming to achieve remission’

Is it likely that the treatment achieved this goal of achieving remission?

YES → Evidence of benefit

Consideration #2 – Other clinical evidence

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



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

Contributing factors towards a positive benefit assessment

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

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

PATIENT EXAMPLES

These examples are hypothetical patient profiles and aim to provide examples of treatment outcomes in a real-life setting. The vignettes are a snapshot of the patient’s medical situation when the assessment is being recorded, however the assessment must be made considering the entire treatment period.

	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, PS 1	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 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 C 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** ⊕

Additional patient examples are available in the ‘Non-curative treatment benefit guidance’. We advise readers **to also read through the entire document.**