SYSTEMIC ANTI-CANCER THERAPY (SACT) STUDY

National Confidential Enquiry into Patient Outcome and Death (NCEPOD)

ASSESSMENT FORM (AF)

CONFIDENTIAL

NCEPOD number: | | | | | | | **Site ID:** | | | | | | | (*To be completed after advisor assessment*)

Reviewed by nurse: ☐ **Reviewed by pharmacist:** ☐ **For Discussion:** ☐

INSTRUCTIONS FOR COMPLETION

Sections of this questionnaire have been extracted by NCEPOD researchers from the questionnaires and casenotes provided for each patient to help Advisors make informed decisions. If you find innaccuracies, or disagree with data extracted, then please make a note on the AF for us to review.

All questions to be completed by the Advisors, unless otherwise indicated:
(NCEPOD staff: 1-3, 6a-6c 8, 29, 30a, 31-32 and 45).

How to complete this questionnaire:

Information will be collected using two methods:
Box cross ☒ and free text, where your clinical opinion will be requested.

This form will be electronically scanned. Please use a black or blue pen. Please complete all questions with either block capitals or a bold cross inside the boxes provided e.g.

Does this hospital administer SACT to patients as:

☒ Inpatients ☐ Outpatients

If you make a mistake, please "black-out" the incorrect box and re-enter the correct information, e.g.

■ Inpatients ☒ Outpatients

Unless otherwise indicated, please mark only one box per question.

Definitions are provided overleaf.

Note: please do not leave any questions blank -

If the part of the record likely to contain the required information for you to answer a question has not been supplied, please mark the box **"Insufficient Data"** where provided.

If, in your opinion, a full set of notes has been provided and you think that information has not been written into the casenotes, please mark the box **"Not documented"** where provided.

If you are unable to make a judgement, or provide an opinion, please mark the box **"Unknown"** where provided.

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DEFINITIONS

Adverse event	An unintended injury caused by medical management rather than by the disease process and which is sufficiently serious to lead to prolongation of hospitalisation, to temporary or permanent impairment or disability to the patient.
Appropriate management (incl. drug treatment)	The expected health benefits of treatment, investigation etc. to an average patient exceed the expected health risks by a sufficiently wide margin to make the intervention worthwhile and the intervention is superior to alternatives (including no intervention).
Clinical outcome	Clinical outcome includes survival times, progression of disease, response to treatment, symptom control, morbidity and mortality.
Essential pre-treatment investigations	Investigations that must be performed prior to prescribing SACT.
Grade 3/4 event	Please see Appendix II.
Most-recent cycle/course	The cycle or course immediately prior to death.
Performance score	e.g. ECOG/WHO/Zubrod score or Karnofsky Performance Score (KPS) (for further details see Questionnaire A, page 3).
SACT	To include all “traditional” cytotoxics - intravenous, oral, subcutaneous, intravesical, intrathecal, or intraperitoneal chemotherapy, monoclonal antibodies, or cytokines, but excluding vaccines, gene therapy and hormonal agents.
Significant	Having or likely to have a major effect; important.
Unexpected post mortem findings	Practical example 1: patient died of a cause other than what was stated on the death certificate. Example 2: patient’s disease was thought to be in remission but advanced disease was found at the post mortem

A. PATIENT DETAILS:

NCEPOD staff *to refer to case notes*
(and for guidance, Questionnaire A, Section A Q1, Q2 and Section C Q8(a), Q9)

1. Age (immediately prior to commencing most-recent **course** of SACT): ☐☐☐ years

2. Gender ☐ Male ☐ Female

3. Primary tumour site (solid tumour and lymphoma)

B. DECISION TO TREAT/CONSENT

Doctor's decision to offer SACT

Advisor *to refer to case notes (and for guidance Questionnaire A, Sections A, B, C and D)*

4. a. In your opinion, was SACT appropriate management for this patient?

☐ Yes ☐ No ☐ Insufficient Data

b. If **NO**, please indicate the reason:

☐ Poor performance score *(See Definitions)*
☐ Co-morbidities - ischaemic heart disease
☐ Co-morbidities - diabetes mellitus
☐ Other *(Please specify)*

c. In your opinion were appropriate drugs used?

☐ Yes ☐ No ☐ Not Documented ☐ Insufficient Data

Patient's decision to accept treatment

Advisor *to refer to case notes*

5. a. Is there evidence in the available case notes that the patient received information to assist them in their decision to accept treatment?

☐ Yes ☐ No ☐ Insufficient data

b. If **YES**, please select all that apply:

i) Verbal information from:

☐ Doctor ☐ Specialist Nurse ☐ Pharmacist

☐ Other *(Please specify)* ☐ Not documented

ii) Written information on:

☐ SACT ☐ Clinical trial

iii) Patient information on:

☐ Cassette/video/DVD

☐ Other e.g. BACUP booklet *(Please specify)*

Consent to treatment

NCEPOD staff *to refer to case notes*

6. a. Was there a signed consent form in the notes for this **course** of SACT?

☐ Yes ☐ No ☐ Insufficient data

b. If **YES**, did it include information on potential toxicity?

☐ Yes ☐ No

c. What grade of doctor obtained the patient's consent to treatment?

☐ Consultant ☐ Associate Specialist

☐ Clinical Assistant ☐ Medical/Clinical Researcher/Fellow

☐ Staff Grade ☐ SPR/ST3 or higher

☐ SHO/ST1-2 ☐ Other *(Please specify)*

☐ Not Documented

Advisor: *From the information recorded above and review of these case notes:*

6. d. If **YES to 6b**, what was recorded on the side effect section of the consent form? *(Please select all that apply)*

- **i)** ☐ The most-frequent toxicities
- **ii)** ☐ The most-serious toxicities
- **iii)** ☐ A record that chemotherapy could be life threatening

e. Based on the case notes, are you concerned that the patient did not receive sufficient information to give informed consent to treatment?

☐ Yes ☐ No ☐ Insufficient data

f If **YES**, please expand on your answer:

7. a. Based on the case notes, did the patient receive any conflicting information from different clinical staff at any stage of the patient journey?

☐ Yes ☐ No ☐ Insufficient data

b. If **YES**, please expand on your answer:

c. Based on the case notes, did the patient receive any inaccurate information at any stage of the patient journey?

☐ Yes ☐ No ☐ Insufficient data

d. If **YES**, please expand on your answer:

C. PRE-TREATMENT ASSESSMENT/PRESCRIPTION

NCEPOD staff *to refer to case notes*

8. Investigations performed prior to most-recent **cycle** of SACT:

Test	Date of test (when most-recent SACT cycle was prescribed, or closest date before - dd/mm/yyyy)	Result					Comments (to be completed by ADVISORS) *n - normal a - abnormal but acceptable u - abnormal and unacceptable*
		Result	Unit Measurement	Insufficient Data	Not Documented	No Evidence That Test Was Requested	
Full blood count	☐☐ ☐☐ ☐☐☐☐ ☐ Insufficient data ☐ Not documented						
Hb		☐☐.☐	☐	☐	☐	☐	☐
WCC		☐☐.☐	☐	☐	☐	☐	☐
Neutrophils		☐☐.☐	☐	☐	☐	☐	☐
Platelets		☐☐☐	☐	☐	☐	☐	☐
Urea & electrolytes	☐☐ ☐☐ ☐☐☐☐ ☐ Insufficient data ☐ Not documented						
Na		☐☐☐	☐	☐	☐	☐	☐
K		☐☐.☐	☐	☐	☐	☐	☐
Urea		☐☐.☐	☐	☐	☐	☐	☐
Creatinine		☐☐☐	☐	☐	☐	☐	☐
Liver function tests	☐☐ ☐☐ ☐☐☐☐ ☐ Insufficient data ☐ Not documented						
Bilirubin		☐☐☐	☐	☐	☐	☐	☐
AST		☐☐☐	☐	☐	☐	☐	☐
ALT		☐☐☐	☐	☐	☐	☐	☐
Adjusted/ Corrected Calcium		☐.☐☐	☐	☐	☐	☐	☐
Magnesium		☐☐.☐	☐	☐	☐	☐	☐

8. *(Continued)*

Test	Date of test (when most-recent SACT cycle was prescribed, or closest date before - dd/mm/yyyy)	Result					Comments (to be completed by ADVISORS) *n - normal a - abnormal but acceptable u - abnormal and unacceptable*
		Result	Unit Measurement	Insufficient Data	Not Documented	No Evidence That Test Was Requested	
(LFTs Contd.) Alk Phos		☐☐☐☐	☐	☐	☐	☐	☐
Creatinine clearance. Complete i) or ii) or iii) to reflect data on chemo prescription	☐☐ ☐☐ ☐☐☐☐ ☐ Insufficient data ☐ Not documented						
i)EDTA clearance		☐☐☐	☐	☐	☐	☐	☐
ii)24hr urine collection		☐☐☐☐	☐	☐	☐	☐	☐
iii)Calculated: cr cl		☐☐☐	☐	☐	☐	☐	☐
Other *(Please specify)*	**Other investigation 1:** ☐ ☐☐ ☐☐ ☐☐☐☐	☐☐.☐	☐	☐	☐	☐	☐
	Other investigation 2: ☐ ☐☐ ☐☐ ☐☐☐☐	☐☐.☐	☐	☐	☐	☐	☐

Assessment prior to most-recent cycle of SACT

Advisor *to refer to above dataset and the case notes:*

9. Is there evidence in the case notes of an assessment of response to treatment during this course of SACT?

☐ Yes ☐ No ☐ Insufficient data ☐ Not applicable

10. a. Is there evidence in the case notes of an assessment of toxicity since the previous **cycle** of SACT?

☐ Yes ☐ No ☐ Insufficient data ☐ Not applicable

b. Is there evidence in the case notes that a toxicity check list was used?

☐ Yes ☐ No ☐ Insufficient data ☐ Not applicable

11. a. **Overall**, is there evidence in the case notes that the essential pre-treatment investigations were performed?

☐ Yes ☐ No ☐ Insufficient data ☐ Not Applicable

b. If **NO**, please list the essential investigations for which there is no record of the investigation having taken place:

c. **Overall**, in your opinion were the results of the pre-treatment investigations acceptable?

☐ Yes ☐ No ☐ Results not documented ☐ Insufficient data

d. If **NO**, is there evidence in the case notes that any problems were addressed?

☐ Yes ☐ No ☐ Insufficient data

e. If **NO**, please specify how the patient should have been managed:

Prescription

*To be completed by **pharmacists** (refer to questions 8-11 and case notes):*

12. In what format was the SACT prescription?

a. Parenteral

☐ Hand-written ☐ Pre-printed prescriptions

☐ Electronic prescribing ☐ Insufficient Data

☐ Not Applicable

b. Oral

☐ Hand-written ☐ Pre-printed prescriptions

☐ Electronic prescribing ☐ Insufficient Data

☐ Not Applicable

13. Is there evidence in the case notes that the SACT prescription was checked by a pharmicist?

☐ Yes ☐ No ☐ Insufficient Data

14. a. Is there evidence in the case notes that the pharmicist identified an adverse event?

☐ Yes ☐ No ☐ Insufficient Data

b. If **YES**, please expand upon your answer:

15. Please check the calculation of the SACT doses given. Were they correctly calculated bearing in mind the height and weight of the patient?

☐ Yes ☐ No ☐ Dose Not Documented ☐ Insufficient Data

16. a. In your opinion, were there any potential drug interactions between SACT and any other medication?

☐ Yes ☐ No ☐ Drugs Not Documented ☐ Insufficient Data

b. If **YES**, please expand upon your answer:

17. Is there evidence in the case notes that SACT was prepared on site?

☐ Yes ☐ No ☐ Insufficient Data

18. Is there evidence in the case notes that the SACT administration was checked by two nurses?

☐ Yes ☐ No ☐ Insufficient Data

19. What method was used to administer SACT? *(Please select one)*

☐ Oral ☐ IV peripheral ☐ IV through central line

☐ Insufficient Data ☐ Not Documented

☐ Other *(Please Specify)*

***Advisor** to refer to case notes and Questionnaire A Q20e:*

20. a. Is there evidence in the case notes of a dose reduction with this **cycle** of SACT?

☐ Yes ☐ No ☐ Dose Not Documented ☐ Insufficient Data

b. If **YES**, please specify why the dose was reduced:

c. If **NO**, do you think there should have been a dose reduction?

☐ Yes ☐ No ☐ Unknown

d. Please expand upon your answer:

21 a. Is there evidence in the case notes that this **cycle** of SACT was delayed?

☐ Yes ☐ No ☐ Insufficient Data

b. If **YES**, please specify why it was delayed:

c. If **NO**, do you think it should have been delayed?

☐ Yes ☐ No ☐ Unknown ☐ Insufficient Data

d. Please expand upon your answer:

22 a. Overall, was it appropriate to give this **cycle** of SACT at the doses given?

☐ Yes ☐ No ☐ Unknown ☐ Insufficient Data

b. If **NO**, please indicate why not: *(Please select all that apply)*

- ☐ Appropriate investigations were not undertaken pre-treatment *(See Definitions)*
- ☐ Abnormal haematology **and/or** biochemistry
- ☐ Progresive disease
- ☐ Doses should have been reduced in view of previous toxicity
- ☐ Patient still suffering toxicity from previous **cycle**
- ☐ Co-morbidity
- ☐ Other *(Please specify)*

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23 a. Is there evidence in the case notes that a General Practictioner was informed of the SACT?

☐ Yes ☐ No ☐ Insufficient Data

b. Is there evidence in the case notes that a General Practictioner was informed of the potential toxicity associated with the SACT?

☐ Yes ☐ No ☐ Insufficient Data

D. SACT ADMINISTRATION/FOLLOW-UP/TOXICITY

Administration of SACT

***Advisor** to refer to case notes*

24 a. Were any immediate complications recorded (e.g. extravasation) that were associated with the administration of SACT?

☐ Yes ☐ No ☐ Insufficient Data

b. If **YES**, please specify:

Grade 3/4 events following the most-recent cycle

***Advisor** to refer to case notes (and for guidance, Questionnaire B, Section C)*

25 a. Did the patient suffer any grade 3/4 event following the most-recent **cycle** of SACT?
(See Appendix II for NCI - Common Toxocity Criteria)

☐ Yes ☐ No *(It may be documented that the patient did not suffer grade 3/4 events)*

☐ Not Documented ☐ Insufficient Data

(If NO, or Insufficient Data, or Not Documented, please go to Section E)

b. If **YES**, on which date did the patient first experience a grade 3/4 event following their most-recent **cycle** of SACT? (dd/mm/yyyy)

☐☐ ☐☐ ☐☐☐☐ ☐ Not Documented

d d m m y y y y

25 c. In your opinion, were the following grade 3/4 events related to SACT?
*(For guidance, please refer to Questionnaire B, question 14. Please select **one** option per event):*

Grade 3/4 event	**Options: A) Definitely B) Probably C) Possibly D) Not related E) Insufficient data F) Not applicable**
Neutropaenia	A ☐ B ☐ C ☐ D ☐ E ☐ F ☐
Febrile Neutropaenia	A ☐ B ☐ C ☐ D ☐ E ☐ F ☐
Infection *(Please specify)* ☐	A ☐ B ☐ C ☐ D ☐ E ☐ F ☐
Thrombocytopaenia	A ☐ B ☐ C ☐ D ☐ E ☐ F ☐
Any thromboembolic complication	A ☐ B ☐ C ☐ D ☐ E ☐ F ☐
Haemorrhage	A ☐ B ☐ C ☐ D ☐ E ☐ F ☐
Renal impairment	A ☐ B ☐ C ☐ D ☐ E ☐ F ☐
Liver impairment	A ☐ B ☐ C ☐ D ☐ E ☐ F ☐
Multi organ failure	A ☐ B ☐ C ☐ D ☐ E ☐ F ☐
Hypokalaemia	A ☐ B ☐ C ☐ D ☐ E ☐ F ☐
Hypomagnesaemia	A ☐ B ☐ C ☐ D ☐ E ☐ F ☐
Hypercalcaemia	A ☐ B ☐ C ☐ D ☐ E ☐ F ☐
Stomatitis	A ☐ B ☐ C ☐ D ☐ E ☐ F ☐
Vomiting	A ☐ B ☐ C ☐ D ☐ E ☐ F ☐
Diarrhoea	A ☐ B ☐ C ☐ D ☐ E ☐ F ☐
Arrhythmia	A ☐ B ☐ C ☐ D ☐ E ☐ F ☐
Myocardial ischaemia	A ☐ B ☐ C ☐ D ☐ E ☐ F ☐
Anaphylactic reaction	A ☐ B ☐ C ☐ D ☐ E ☐ F ☐
Tumour lysis syndrome	A ☐ B ☐ C ☐ D ☐ E ☐ F ☐
Other *(Please specify)* ☐	A ☐ B ☐ C ☐ D ☐ E ☐ F ☐

25 d. Is there evidence in the case notes that there was a delay of more than 24 hours in the patient reporting symptoms of a grade 3/4 event?

☐ Yes ☐ No ☐ Time or Date Not Documented ☐ Insufficient Data

e. If **YES to 25d**, what was the time interval between the patient developing symptoms and reporting them to a healthcare worker?

☐☐ days *(please round up to nearest day)*

26 a. Is there evidence in the case notes of a delay of more than 24 hours in the patient being reviewed following the patient's report of symptoms?

☐ Yes ☐ No ☐ Insufficient Data ☐ Not Applicable

b. If **YES**, how long was the delay?

☐☐ days *(please round up to nearest day)* ☐ Not Documented

27. How was the patient **first** assessed?

☐ Phone conversation
☐ Chemotherapy helpline
☐ Urgent hospital review same day
☐ Urgent hospital appointment
☐ Urgent hospital admission
☐ Current inpatient assessment
☐ Routine hospital appointment
☐ General Practitioner review
☐ Attendance A&E department
☐ Insufficient Data
☐ Not Documented
☐ Other *(Please specify)*

28. Please specify the date of hospital review:

☐☐ ☐☐ ☐☐☐☐ ☐ Not Documented ☐ Not Applicable

d d m m y y y y

E. ANY ADMISSION DURING LAST 30 DAYS OF LIFE:

NCEPOD staff *to refer to Questionnaire B for guidance*

29 a. Was the patient an inpatient during their last 30 days of life?

☐ Yes ☐ No ☐ Insufficient Data

(If NO, please go to Section F)

b. Was the patient admitted as an inpatient more than once following their most-recent **cycle** of SACT?

☐ Yes ☐ No ☐ Insufficient Data

c. Please complete the table below in **chronological order** ending with the admission immediately prior to death:

If patient admitted more than once during their last 30 days of life , please ask for "Section E" insert (separate inserts to be completed for each admission).

i) Admission 1: (Immediately following the most-recent SACT, or closest date if already an inpatient) Please state the time and date of the admission:

Time *(24 hour clock)* ☐☐ ☐☐ (h h m m) ☐ Not Documented ☐ Insufficient Data

Date *(dd/mm/yyyy)* ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y) ☐ Not Documented ☐ Insufficient Data

Subsequent discharge (if applicable)

Time *(24 hour clock)* ☐☐ ☐☐ (h h m m) ☐ Not Documented ☐ Insufficient Data ☐ Not Applicable

Date *(dd/mm/yyyy)* ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y) ☐ Not Documented ☐ Insufficient Data ☐ Not Applicable

29 c. *(continued)*

ii) Admission 2:

Time *(24 hour clock)* ☐☐ ☐☐ (h h m m) ☐ Not Documented ☐ Insufficient Data ☐ Not Applicable

Date *(dd/mm/yyyy)* ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y) ☐ Not Documented ☐ Insufficient Data ☐ Not Applicable

Subsequent discharge (if applicable)

Time *(24 hour clock)* ☐☐ ☐☐ (h h m m) ☐ Not Documented ☐ Insufficient Data ☐ Not Applicable

Date *(dd/mm/yyyy)* ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y) ☐ Not Documented ☐ Insufficient Data ☐ Not Applicable

iii) Admission 3: (immediately prior to death):

Time *(24 hour clock)* ☐☐ ☐☐ (h h m m) ☐ Not Documented ☐ Insufficient Data ☐ Not Applicable

Date *(dd/mm/yyyy)* ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y) ☐ Not Documented ☐ Insufficient Data ☐ Not Applicable

Subsequent discharge (if applicable)

Time *(24 hour clock)* ☐☐ ☐☐ (h h m m) ☐ Not Documented ☐ Insufficient Data ☐ Not Applicable

Date *(dd/mm/yyyy)* ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y) ☐ Not Documented ☐ Insufficient Data ☐ Not Applicable

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Admission process

NCEPOD staff *to refer to case notes(and for guidance, Questionnaire B Q6c):*

30 a. Based on the case notes, to which specialty was the patient first admitted?

- ☐ Oncology
- ☐ Haemato-Oncology
- ☐ General Haematology
- ☐ General Medicine
- ☐ General Surgery
- ☐ Palliative Care
- ☐ MAU
- ☐ Direct to ICU/ITU/HDU
- ☐ Not Documented
- ☐ Insufficient Data
- ☐ Other *(Please Specify)* _____

Advisor *to refer to case notes:*

30 b. In your opinion, was the patient admitted under an appropriate **first** specialty?

☐ Yes ☐ No ☐ Specialty Not Documented ☐ Insufficient Data

c. If **NO**, in your opinion, did this have a significant effect on the clinical outcome *(See Definitions)*?

☐ Yes ☐ No ☐ Unknown (cannot provide opinion)

d. Please expand upon your answer:

NCEPOD staff *to refer to case notes:*

31 a. Please state the time and date of the patient **first** being assessed by a doctor (all grades):

Time *(24 hour clock)* ☐☐ ☐☐ (h h m m) ☐ Not Documented ☐ Insufficient Data

Date *(dd/mm/yyyy)* ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y) ☐ Not Documented ☐ Insufficient Data

b. On what time and date is there evidence in the notes that the patient was **first** reviewed by a consultant physician or oncologist/haemato-oncologist?

Time *(24 hour clock)* ☐☐ ☐☐ (h h m m) ☐ Not Documented ☐ Insufficient Data

Date *(dd/mm/yyyy)* ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y) ☐ Not Documented ☐ Insufficient Data

32 a. If the patient was not admitted under the care of an oncologist/haemato-oncologist was the patient transferred to an oncologist or haemato-oncologist specialty?

- ☐ Yes
- ☐ No
- ☐ Specialty Not Documented
- ☐ Insufficient Data
- ☐ Not Applicable

b. If **YES**, please state time and date of the transfer to oncology/haemato-oncology ward:

Time *(24 hour clock)* ☐☐ ☐☐ (h h m m) ☐ Not Documented ☐ Insufficient Data ☐ Not Applicable

Date *(dd/mm/yyyy)* ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y) ☐ Not Documented ☐ Insufficient Data ☐ Not Applicable

Advisor *refer to case notes:*

33 a. Is there evidence in the case notes of any delays in the admission process?

☐ Yes ☐ No ☐ Not Documented ☐ Insufficient Data

b. Is there evidence in the case notes of a delay in the patient being assessed by a doctor (all grades)?

☐ Yes ☐ No ☐ Insufficient Data

c. If **YES**, what was the the time interval between admission and assessment?

☐☐ ☐☐ (h h m m) hours *(Please round up to the nearest hour)* ☐ Not Documented

34. In your opinion, was the time to consultant review appropriate for the patient's condition?

☐ Yes ☐ No ☐ Not Documented ☐ Insufficient Data

35 Is there evidence in the case notes of a delay in transfer to the oncology/haemato-oncology ward?

☐ Yes ☐ No ☐ Not Documented ☐ Insufficient Data

Investigations

36 a. In your opinion, were all appropriate investigations requested?

☐ Yes ☐ No ☐ Insufficient Data

b. If **NO**, in your opinion, which investigations were omitted?

c. In your opinion, did this have a significant effect on the clinical outcome? *(See Definitions)*

☐ Yes ☐ No ☐ Unknown

d. If **YES**, please expand upon your answer:

37 a. In your opinion, were any inappropriate investigations requested?

☐ Yes ☐ No ☐ Insufficient Data

b. If **YES**, in your opinion, did this have a significant effect on the clinical outcome? *(See Definitions)*

☐ Yes ☐ No ☐ Unknown

c. If **YES**, please expand upon your answer:

38 a. Is there evidence in the case notes of any delays in the **undertaking** of investigations?

☐ Yes ☐ No ☐ Not Documented ☐ Insufficient Data

38. b. Is there evidence in the case notes of any delays in the **reporting** of investigations?

☐ Yes ☐ No ☐ Not Documented ☐ Insufficient Data

39. a. If there were any delays in the patient's admission or investigations (i.e. if YES to either 33a, 33b, 35, or 38), please provide a brief list of examples with timeline:

b. In your opinion, did the delay have a significant effect on the clinical outcome *(See Definitions)*?

☐ Yes ☐ No ☐ Unknown

c. If **YES**, please expand on your answer:

*To be completed by **pharmacists** (refer to questions 24-25)*

NB: This section only needs to be completed if the answer to question 25a was YES

40 a. How was the grade 3/4 event treated e.g. with antibiotics, GCSF (please inicate **"Not Documented"** if there is not evidence in the notes, or **"Insufficient Data"** if notes missing):

☐ Unknown ☐ Insufficient Data ☐ Not Documented

Pharmacists *(Continued)*

40. b. Was this appropriate?

☐ Yes ☐ No ☐ Insufficient Data

c. If **NO**, please expand on your answer:

Appropriate End of Life Care

41. Is there evidence in the case notes that a palliative care team was involved?

☐ Yes ☐ No ☐ Insufficient Data

To be completed by pharmacists *(refer to Section E and case notes):*

42. a. Please list all supportive care medicine prescribed during this admission:

To be completed by **advisor**

42. b. Is there evidence in the case notes that all appropriate supportive care medicines were prescribed? (e.g. analgesics, anti-emetics etc.)

☐ Yes ☐ No ☐ Insufficient Data

c. If **NO**, what additional drugs should have been prescribed?

d. In your opinion, did this omission have a significant effect on the clinical outcome? *(See Definitions)*

☐ Yes ☐ No ☐ Unknown (cannot provide opinion)

e. If **YES**, please expand upon your answer:

43. Is there evidence of the following in the case notes?

a.	An advanced directive	☐ Yes	☐ No	☐ Insufficient Data
b.	Preferred Place of Care certificate	☐ Yes	☐ No	☐ Insufficient Data
c.	End of Life Pathway	☐ Yes	☐ No	☐ Insufficient Data

44. a. Is there evidence in the case notes of a delay in the discharge planning process?

☐ Yes ☐ Not Documented ☐ Insufficient Data

b. If **YES**, please expand upon your answer:

Resuscitation status

NCEPOD staff *to refer to case notes*

45. a. Is there evidence in the case notes of a Do Not Attempt Resuscitation (DNAR) statement?
(i.e. on a DNAR form/pro forma or written in the notes)

☐ Yes ☐ No ☐ Insufficient Data

b. Was a Do Not Attempt Resuscitation (DNAR) statement received?

☐ Yes ☐ No

c. If **YES to 45b**, what grade of doctor signed the DNAR order?

☐ Consultant ☐ Associate Specialist

☐ Clinical Assistant ☐ Medical/Clinical Researcher/Fellow

☐ Staff Grade ☐ SPR/ST3 or higher

☐ SHO/ST1-2 ☐ Not documented

☐ Other *(Please specify)*

d. If a DNAR decision was made, is there evidence in the case notes that this decision was discussed with:

i) The patient?	☐ Yes	☐ No	☐ Insufficient Data
ii) The patient's relatives?	☐ Yes	☐ No	☐ Insufficient Data

F. CAUSE OF DEATH:

Advisors *to refer to case notes (for guidance, see Questionnaire B, Section D)*

Place of death

46. Where did the death occur?

- ☐ In an ambulance
- ☐ Accident and Emergency department
- ☐ MAU
- ☐ Haematology/Oncology ward
- ☐ General medical ward
- ☐ General surgical ward
- ☐ ICU/ITU/HDU
- ☐ Palliative care ward
- ☐ Community hospital
- ☐ In a hospice
- ☐ At home *(or elsewhere in the community including a nursing home if normal place of residence)*
- ☐ Insufficient data
- ☐ Not Documented
- ☐ Other *(Please specify)*

47. In your opinion, was the death of this patient related to SACT? *(Please Select One)*

- ☐ Not at all
- ☐ Some toxicity, but patient would have died at about the same time from disease progresssion, or co-morbidity.
- ☐ A major contribution to hastening death
- ☐ The patient died as a direct result of complications caused by SACT
- ☐ Unknown
- ☐ Insufficient data
- ☐ Other *(Please specify)*

Death certificate

Advisor *to refer to case notes (and for guidance, Questionnaire B, question 22)*

48 a. In your opinion, was the cause of death filled in correctly on the death certificate?

☐ Yes ☐ No ☐ Insufficient Data ☐ Unknown

48. b. If **NO**, how would you have filled it in?

Ia.

Ib.

Ic.

II.

Post Mortem Examination

49. a. Is there evidence in the case notes that a post mortem examination was conducted?

☐ Yes ☐ No ☐ Insufficient Data

b. If **YES**, were there any unexpected findings?

☐ Yes ☐ No ☐ Insufficient Data (Post mortem examination conducted, but no report supplied with case notes)

c. Please expand on your answer:

d. If **NO** post mortem examination was performed, do you think one would have been useful?

☐ Yes ☐ No

e. Please expand on your answer:

G. OVERALL CARE:

Adverse events *(See Definitions)*

50. a. Is there any evidence in the avilable case notes of any adverse event being reported to Risk Management (or similar body)?

☐ Yes ☐ No ☐ Insufficient data

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50. b. If **YES**, please summarise the main lessons learned following the investigation of the adverse event:

c. Based on the case notes, did the investigation of the adverse event result in a change in practice?

☐ Yes ☐ No ☐ Not documented

d. Please expand upon your answer:

Overall Summary

51. a. In your opinion, were there any areas where there was potential for improvement in the care of the patient?

☐ Yes ☐ No ☐ Insufficient data

b. If **YES**, please select all that apply :

☐ Inappropriate decision to treat with SACT
☐ Adverse event in prescribing
☐ Adverse event in dispensing
☐ Adverse event in administration
☐ Poor communication between patient and clinician
☐ Poor communication between clinicians
☐ Delay in admission for toxicity
☐ Delay in treating toxicity
☐ Inappropriate investigation of toxicity
☐ Inappropriate management of toxicity
☐ Delay in discontinuation of SACT
☐ Other *(Please Specify)*

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52. a. Please indicate what your **overall** view is of the case. Practice was:

- ☐ 1 - Good practice - a standard that you would accept from yourself, your trainees and your institution.
- ☐ 2 - Room for improvement: aspects of **clinical** care that could have been better.
- ☐ 3 - Room for improvement: aspects of **organisational** care that could have been better.
- ☐ 4 - Room for improvement: aspects of **clinical and organisational** care that could have been better.
- ☐ 5 - Less than satisfactory: several aspects of clinical and/or organisational care that were well below a standard that you would accept from yourself, your trainees and your institution.
- ☐ 6 - Insufficient information submitted to asses the quality of care.

b. If you selected an option between 2 and 5 , please expand on your answer:

53. Occasionally NCEPOD will refer cases that have been identified as 5 (Less than satisfactory) when it is felt that further feedback to the Trust concerned is warranted. This is usually due to an area of concern particular to the hospital, or clinician involved, and not for issues being highlighted across the body of case notes. In cases that are referred, the advisors have concerns that the pattern of practice fell below a standard, which indicates that the practitioner, or team, or Trust is likely to put future patients at risk, if not addressed.

This process has been agreed by the NCEPOD Steering Group and the GMC.

The Medical Director of the Trust is written to by the Chief Executive of NCEPOD explaining our conerns. This process has been in operation for many years and the responses received, although not requested or acted upon, have always been positive in that they feel we are dealing with concerns in the most appropriate manner.

Please note that the advisor who identified the case will not be identified.

If you feel that this case should be considered for such action, please cross this box: ☐

54. a. Are there any particular issues, which you feel should be highlighted in the final report? ☐ Yes ☐ No

b. If **YES**, please specify:

c. Please check this box if you think we should consider this as a vignette: ☐

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