UK SACT Board

Guidance on the contents of a SACT protocol

Recommendations for information to be included in a SACT protocol

Version 2.0

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1. The UK Systemic Anti-Cancer Therapy (SACT) Board

The UK SACT Board provides guidance, oversight and support for the continuing development of SACT services in the UK. Its core membership comprises representatives of The Royal College of Radiologists (RCR), the Royal College of Physicians (RCP), the Association of Cancer Physicians (ACP), the British Oncology Pharmacy Association (BOPA) and the UK Oncology Nursing Society (UKONS). The Board also has representation from the four UK nations and from other organisations closely involved in SACT services, including the Royal College of Pathologists.

2. Purpose of Document

To give guidance to healthcare professionals working in the UK when writing or checking a SACT protocol for approval within an organisation.

3. Scope of Document

This document only covers SACT protocols for use within an organisation.

For gene therapy medicinal products please see '*Requirements for Governance and Preparation of Gene Therapy'* from the Specialist Pharmacy Service.

4. Limitations

This document does not replace the internal governance required when approving individual protocols.

5. Contents of SACT protocol

It is recommended that SACT protocol contains the following information in the order shown below. This does not preclude other relevant information being included in any section.

Where there a section or point is not relevant, this can be omitted to facilitate a concise easy to follow protocol document.

5.1. Disease/tumour type

5.1.1. Protocols should be prepared for individual disease/tumour type, however, multiple disease/tumour sites can be assigned to one protocol where this is clinically relevant.

5.2. Name of protocol

5.2.1. Avoid use of any abbreviations

5.2.2. Use Tall man lettering where relevant

5.2.3. Use wording that makes it clear what the regimen contains

5.2.4. Where there are different drugs in different cycles (different templates) ensure this is clear. (e.g Epirubicin, Cyclophosphamide (EC) x4 21q then Paclitaxel Day 1,8,15 x4 q21)

5.3. Indication and patient population

5.3.1. State the cancer type that the regimen is treating

5.3.2. Include any specific patient demographics where relevant

5.3.3. Where national specific funding has been published this indication **may** be included

5.4. Therapeutic intent of the regimen

5.4.1. Select from the following:

- Curative
- Non curative

5.5. Treatment context

5.5.1. Include the treatment context:

- Neoadjuvant
- Adjuvant
- SACT only
- Children, Teenagers and Young Adults (CTYA) only (neoadjuvant and adjuvant)

Accurate recording of neoadjuvant (before the main therapy), adjuvant (after the main therapy), if the treatment has no other element (SACT only) or is both adjuvant and neoadjuvant (CTYA only).

5.5.2. Include the radiotherapy schedule if SACT is to be given concurrently with radiotherapy

5.6. Unlicensed or Off Label use and tier of evidence

5.6.1. Include information if any part of the protocol is being given off license (unlicensed in this indication) or off label (such as shorter infusion time).

5.6.2. State what tier of evidence the protocol is based on.

5.7. Patient review information

5.7.1. For each cycle (or group of cycles) – state the healthcare professional group(s) (e.g. clinician, pharmacist, nurse, NMP etc) that can carry out the review and how (e.g. telephone, person etc).

Ensure national guidance is followed.

5.8. Number of cycles

5.8.1. Where there is more than one cycle template – state the number of cycles or length of treatment for each template must be clear

5.8.2. Where this is indeterminate, this should be stated

5.9. Length of cycle for all templates

5.10. Administration days

5.10.1. State all administration days within a cycle.

5.10.2. For transplant conditioning protocols: specify the administration dates in relation to the day of stem cell return (i.e. day 0)

5.11. Investigations

5.11.1. Include pre treatment evaluation/ baseline/ prior to cycle 1: Investigations and blood tests are required before starting a course e.g. FBC, LFTs, cardiac function, CT, hepatitis B status etc

5.11.2. Include investigations and blood tests required prior to each subsequent cycle

5.12. Monitoring

5.12.1. State the monitoring required throughout the course e.g. LFTs, CT, cardiac function etc

5.12.2. Include other essential monitoring criteria e.g. irradiated blood etc

5.12.3. Stopping rules with regards to toxicities/adverse events/response to treatment

5.13. Pre-medication

5.13.1. Include relevant pre-medications required

5.13.2. State time intervals required prior to SACT treatment if relevant

5.14. Details of SACT drugs

5.14.1. Specify dosing details including variable/titrating dosing and any specific calculations and capping requirements

5.14.2. State duration and sequence of administration where applicable

5.14.3. Specify routes of administration for each drug

5.14.4. Add maximum lifetime doses where applicable

5.14.5. It is recommended that the above information is set out in a summary table format with drug name, dose, route, day and administration details.

5.14.6. A comprehensive version of the table can be included with the addition of pre-medication, flushes and supportive medicines.

5.15. General administration guidelines – Injectable

5.15.1. Include administration details e.g. protection from light.

5.15.2. State the extravasation/infiltration risk of each component

- Vesicant
- Exfoliant
- Inflammitant
- Irritant
- Neutral

5.15.3. Include infusion information including any specific administration set and filter requirement where applicable

5.15.4. State infusion time period and any recommendations on time limits

5.15.5. Add infusion titration information where applicable

5.15.6. Specify monitoring requirements during administration e.g. BP, urinalysis, infusion related reactions etc

5.15.7. Include access requirements e.g. central access mandatory or recommended).

5.15.8. State maximum lifetime / cumulative dose if relevant

5.16. General administration guidelines – Oral

5.16.1. Include administration guidance for oral agents to be included in full

5.16.2. Add administration details such as what to do if vomit/ missed dose, timing in relation to food

5.16.3. State monitoring requirements during administration if applicable

5.16.4. Specify strength of tablets/capsules

5.17. Supportive drugs with each cycle

5.17.1. State antiemetics, GCSF and other supportive drugs required for the prevention and treatment of toxicities.

5.17.2. Include an explanation for each supportive drug to describe if it is required or recommended together with brief purpose.

5.18. Other medication

5.18.1. State flushes

5.18.2. Include relevant pre and post hydration

5.19. Dose modifications / dose delay / toxicity management

5.19.1. Include haematological, renal, hepatic impairment and relevant other toxicities.

5.19.2. State where dose modification or delay is not considered best practice (e.g. due to curative intent) and what supportive measures could be used to maintain dose intensity

5.19.3. Include any paediatric age or weight dose modifications if appropriate.

It is recommended that this information is clearly set out in a table where relevant – for examples see Appendix 1

5.20. Side Effects / Adverse effects

5.20.1. State emetogenicity of the regimen

5.20.2. Specify common/very common toxicities

5.20.3. Specify clinically significant toxicities

5.20.4. Add recommended management of toxicities outside of standard guidelines

It is recommended that this information is clearly set out in a table where relevant – for examples see Appendix 2

5.21. Drug, food, herbal interactions

5.21.1. Include class effects (with one or two examples) rather than list all individual medicines

It is recommended that this information is clearly set out in a table where relevant – for examples see Appendix 3

5.22. Contra-indications and precautions

5.22.1. Include clinically significant contra-indications

5.22.2. Add alcohol content if relevant

5.23. Key patient counselling and education points

5.23.1. Include specific side effects https://www.cancerresearchuk.org/health-professional/treatment-and-other-post-diagnosis-issues/consent-forms-for-sact-systemic-anti-cancer-therapy

5.23.2. Add oral administration doses

5.23.3. Consider influence on driving

5.23.4. Include contraception and fertility information

5.23.5. Consider pregnancy / breast feeding information if available

5.23.6. Add live vaccine recommendations

5.24. References

5.24.1. Include all references used

5.25. Disclaimer

5.25.1. It is recommended to include a disclaimer similar to:

Whilst every effort is made to ensure the accuracy of the information in a given protocol it cannot be guaranteed that the protocol is fully up to date. Cancer treatment can be dynamic in nature. Decisions on SACT must therefore be based on the independent judgement of the clinician with reference to changing information on the medicine (eg, available literature and SmPC) and evolving medical practices.

5.26. Version control

6.1.1 Version number

6.1.2 Approved by consultant oncologist or consultant haematologist (relevant to protocol), cancer pharmacist and SACT nurse with sufficient experience and approved by the organisation to carry out this task

6.1.3 Make it clear within the protocol that the organisational approval process has been followed.

6 Evidence Source

6.1. The reference used to develop each protocol must be recorded within the protocol document.

6.2. **Tier ONE evidence**:

6.2.1. It is recommended, where possible, that the following is used as evidence:

- Licensed treatment via SmPC
- National or international guidelines/appraisals. E.g. National Institute for Health and Care Excellence (NICE), Scottish Medicines Consortium (SMC), All Wales Medicines Strategy Group (AWMSG), European Society for Medical Oncology (ESMO), American Society of Clinical Oncology (ASCO), National Comprehensive Cancer Network (NCCN), British Society for Haematology (BHS) etc.
- Appropriate outcome in Phase 3 trial evidence and published in peer review journal

6.3. **Tier TWO evidence**:

6.3.1. If Tier 1 level of evidence is not possible then it is recommended that the following is used as evidence:

- Appropriate outcome in Phase 2 trial evidence and published in peer review journal
- Licensed treatment but off label (I.e. different tumour group) with published evidence in unlicensed tumour group
- Licensed outside of UK for indication required

6.4. **Tier THREE evidence**:

6.4.1. If Tier 2 level of evidence is not possible then a named patient protocol can be prepared for a ‘one off treatment’ depending on tumour specific expression. It is recommended that:

- The level of evidence should be at a minimum of Phase 1 trial data.
- There should be no other appropriate treatment option (including clinical trials)
- Access to an early access scheme has been considered.
- The ‘named patient protocol’ for a patient must be verified by an independent consultant oncologist/ haematologist within that tumour site.
- Patient consent must have documented:
    - that this is based on a lower level of evidence and it is unlicensed/off label use.
    - the threshold’s / outcomes that would indicate treatment dose review or discontinuation.
    - the discussion and risks and benefits are documented with clarity and evidence of patient involvement in decision making

- The named patient protocol prescribing is discussed at the organisations governance meeting

Examples of when this might arise are:

- A rare cancer diagnosis, in which large randomised control trials are near impossible to develop and complete.
- A rare cancer subtype only seen in <1% of the population.
- A rare mutation requiring a particular targeted drug.
- Treatment for a rare adverse event needing to utilise published expert opinion.
- A cohort of patients which are routinely excluded from clinical trials e.g. pregnancy, paediatrics, patients with brain metastases, patients with significant renal or hepatic impairment but require urgent cancer treatment.
- Specific genetic testing of tumour sites specific to that patient

7 References

British Oncology Pharmacy Association (BOPA). (2022). *BOPA Recommendations for the use of Tall Man Lettering for systemic anti-cancer treatments (SACT) in the United Kingdom v1.0 - BOPA*. [online] Available at: https://www.bopa.org.uk/resources/bopa-recommendations-of-the-use-of-tall-man-lettering-for-systemic-anti-cancer-treatments-sact-in-the-united-kingdom-v1-0/ [Accessed 17 Feb. 2025].

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SPS - Specialist Pharmacy Service. (2024). *Requirements for Governance and Preparation of Gene Therapy*. [online] Available at: https://www.sps.nhs.uk/articles/requirements-for-governance-and-preparation-of-gene-therapy [Accessed 17 Feb. 2025].

8 Acknowledgements and Disclaimer

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Change History

Draft	Date	Lead Author/Editor	Summary of Change
2.0	17th Feb 2025	Netty Cracknell	Extensive review by MDT team across all four devolved nations. Adopted to UKSACT Board from BOPA.

Disclaimer

The information contained in this document is a consensus view related to current SACT review and prescribing. It should be used in conjunction with any local policies/procedures/guidelines and should be approved for use according to local clinical governance processes. Care has been taken in the preparation of the information contained within this guidance. Nevertheless, any person seeking to consult the guidance, apply its recommendations or use its content is expected to use independent, personal medical and/or clinical judgement in the context of the individual clinical circumstances or to seek out supervision of a qualified clinician. The UK SACT Board makes no representation or guarantee of any kind whatsoever regarding the content of this document or its use or application and disclaims any responsibility for its use or application in any way.

9 Appendix 1: Dose modifications / dose delay / toxicity management

Haematological toxicity		
	Parameters	Management
ANC x 10^9/L	0.5 to less than 1.5	
	less than 0.5	
	Febrile neutropenia	
Platelets x 10^9/L	50 to less than 100	
	less than 50	

Renal impairment		
	Parameters	Management
Creatinine clearance (mL/min)	30 to 50	
	less than 30	

Hepatic impairment		
	Parameters	Management
Hepatic dysfunction	Mild	
	Moderate	
	Severe	

Mucositis and stomatitis		
	Parameters	Management
Grade 2	Delay treatment until toxicity has resolved to Grade 1 or less and reduce doses for subsequent cycles as follows: 1st occurrence	
	2nd occurrence	
	3rd occurrence	
Grade 3 or Grade 4	Delay treatment until toxicity has resolved to Grade 1 or less and reduce doses for subsequent cycles as follows: 1st occurrence:	
	2nd occurrence	
	3rd occurrence	

10 Appendix 2: Side Effects / Adverse effects

Immediate (onset hours to days)		
	Parameters	Management
Nausea and vomiting		
Early (onset days to weeks)		
	Parameters	Management
Diarrhoea		
Fatigue		
Neutropenia		
etc		
Late (onset weeks to months)		
	Parameters	Management
Alopecia		
Anaemia		
etc		

11 Appendix 3: Drug, food, herbal interactions

Drug X		
	Interaction	**Clinical management**
Drug		
Herb		
Food		
General		
	Interaction	**Clinical management**
Warfarin		
Digoxin		
Antiepileptics		
Vaccines		
etc.		