Guidance on the contents of a SACT protocol

A guide for members on what information
is recommended to be included in a SACT protocol

British Oncology Pharmacy Association

Version 1.0

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Contents

1. Purpose of Document

1.1 To give guidance to pharmacists and clinicians working in the UK when writing or checking a SACT protocol for approval within an organisation.

2. Scope of Document

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

2.2 For gene therapy medicinal products please also see governance and preparation requirements from the Specialist Pharmacy Service.

3. Limitations

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

4. Contents of SACT protocol

4.1. It is recommended that the SACT protocol contains the following information. The order is not important but it is recommended that the name is first for clarity on what protocol the information relates to.

4.2. Name of protocol

4.2.1. Avoid use of any abbreviations

4.2.2. Use of Tall man lettering where relevant

4.2.3. Worded in such a way that it in clear what the regimen contains

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

4.3. Indication

4.3.1. To include the cancer type that the regimen is treating and any specific patient demographics where relevant

4.3.2. To include if to be given concurrently with radiotherapy

4.4. Therapeutic intent of the regimen

4.5. Number of cycles

4.5.1. Where there are more than one cycle template – the number of cycles of each template to be clear

4.5.2. Where this is indeterminate that this is stated

4.6. Length of cycle for all templates

4.7. Administration days

4.7.1. All administration days within a cycle should be stated.

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

4.8. Doses of all SACT drugs including:

4.8.1. Dosing details including variable/titrating dosing and any specific calculations and capping requirements

4.8.2. Infusion information including any specific administration set and filter requirement where applicable

4.8.3. Duration and sequence of administration where applicable

4.8.4. Routes of administration for each drug

4.8.5. Administration details

4.8.6. Where oral SACT is part of the regimen, administration guidance for oral agents to be included in full

4.8.7. Drug stability and shelf life of compounded products

4.8.8. Storage conditions

4.8.9. Maximum lifetime doses where applicable

4.9. Supportive drugs with each cycle

4.9.1. Such as hydration, antiemetics, GCSF and other supportive drugs required for the prevention and treatment of toxicities.

4.9.2. For each supportive drug an explanation is recommended to describe if it is required or recommended together with the purpose.

4.10. Dose modifications

4.10.1. Include, haematological, renal, hepatic impairment and any other toxicities.

4.10.2. Include any paediatric age or weight dose modifications.

4.11. Pre-assessment and monitoring

4.11.1. What investigations and blood tests are required before starting a course e.g FBC, LFTs, cardiac function, CT, hepatitis B status etc

4.11.2. What investigations and blood tests are required prior to each cycle

4.11.3. What monitoring is required throughout the course e.g LFTs, CT, cardiac function etc

4.11.4. Access requirements (e.g is central access mandatory or recommended).

4.11.5. Any other essential monitoring criteria such as irradiated blood etc

4.11.6. Stopping rules

4.12. Side Effects / Adverse effects

4.12.1. Emetogencity of the regimen

4.12.2. Common side effects

4.12.3. Significant side effects

4.13. Contra-indications and precautions

4.13.1. To include clinically significant contra-indications and interactions to other medicines as well as herbal preparations/OTC and food.

4.14. Extravasation risk of each component

4.15. Key patient counselling points

4.16. Unlicensed or Off Label use Use

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

4.17. The evidence used to write the protocol

4.17.1. State what tier of evidence used (see section 5)

4.17.2. Include full references

4.18. Disclaimer

4.18.1. 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. Because of the dynamic nature of cancer treatment, decisions on SACT must 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.

4.19. Approval Process

4.19.1. Version control

4.19.2. Within the protocol it is clear that the organisational approval process has been followed.

5. Evidence Source

5.1. The reference used to develop each protocol must be recorded within the protocol document. See 4.17.

5.2. **Tier ONE evidence**:

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

- Licensed treatment via SmPC
- National or international guidelines such as NICE, ESMO, ASCO, NCCN etc
- Appropriate outcome in Phase 3 trial evidence

5.3. **Tier TWO evidence**:

5.3.1. 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
- Licensed treatment but off label (I.e. different tumour group) with published evidence in unlicensed tumour group
- Licensed outside of UK for indication required

5.4. **Tier THREE evidence**:

5.4.1. 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.
- The patient consent must have documented that this is based on a lower level of evidence and it is unlicensed/off label use.
- The named patient protocol prescribing is discussed at the organisations governance meeting

Examples of when this might arise:

- 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

5.5. In all cases the patient should be presented to an MDT for treatment decision where recommended.

5.6. In all cases organisation governance processes should be followed when approving protocols for use.

6. Glossary of Terms

SACT	Systemic Anti-Cancer Therapy. To include all therapies that can be used to treat cancer. i.e chemotherapy, monoclonal antibodies, TKIs, ATMPs etc

7. References

7.1 Standards for Reducing Risks Associated with ePMA for SACT Version 2.0. BOPA. May 2019

7.2 Gene Therapy Medicinal Products. Governance and Preparation Requirements. Version 2 October 2019. Specialist Pharmacy Service. Accessed here 7th April 2020. https://www.sps.nhs.uk/wp-content/uploads/2019/09/PAN-UK-PWG-for-ATMPs-Gene-Therapy-Guidance-issue-2.pdf

7.3 Guidance Notes to Support the Completion of Systemic Anti-cancer Therapy (SACT) Protocols. Produced by Scottish Oncology Pharmacy Practice Group. Aug 2018.

8. Acknowledgements

8.1 The authors would like to thank everyone who contributed to this document.

9. Document control

Title	BOPA: Guidance on contents of SACT protocol. Version 1.0
Authors / Editors version 1.0	Netty Cracknell, Lead Cancer pharmacist, Ramsay Health Care UK Arif Meghani, Senior Oncology Pharmacist, Cancer Centre London Jared Bannister National Clinical Specialist, Onco-Pharmacy Spire Healthcare Dharmisha Chauhan, Sarcoma, Skin and Melanoma Specialist Pharmacist, The Royal Marsden NHS Foundation Trust Nick Duncan, Consultant Haematology Pharmacist, University Hospitals Birmingham NHS Foundation Trust
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Change History

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Proposed Target Audience	All BOPA Members.
Proposed Circulation List	All BOPA Members. All chief pharmacists. Oncologists and haematologists.
Contact details	netty.cracknell@ramsayhealth.co.uk