Standard Operating Procedure for the development (or update) and approval of Systemic Anticancer Therapy Protocols (SACT) and upload to the Kent and Medway Cancer Collaborative (KMCC) website

1.0 Objective

The purpose of this standard operating procedure (SOP) is to describe the process to be followed when developing and validating systemic anticancer therapy (SACT) protocols within the Kent and Medway Cancer Collaborative, and to set out the mandatory content of the protocols. Protocols requests should be made by the Kent and Medway wide Non-surgical Oncology Sub-Groups (NOGs; the haematology equivalent group is known as the HOG).

2.0 Scope

This SOP will cover all oncology and haematology protocols, excluding clinical trials and paediatrics. This will encompass NHSE MHRA EAMs schemes, and complex supportive care regimens which require a protocol as identified by the Kent and Medway Chemotherapy Group. Algorithm deviations, one-off requests, and access schemes offered by manufacturers (for licensed drugs which have not been through the NICE process) should be considered within the context of the 'Policy for the Management of Algorithm Deviations and the use of Unfunded Medicines' and are outside the scope of this SOP. For free of charge medicines, reference should be made to the document: **Access to Free of Charge Drugs Outside of Clinical Trials (via Access Schemes or Early Access to Medicine Schemes) v1**

3.0 Method

3.1 NOG/HOG identifies need for new protocol or amendment to existing protocol at NOG/HOG meeting or, where urgent, virtually via email using NOG/HOG distribution list. If NHSE commission a new treatment between NOG/HOG meetings, the group will decide via email whether a KMCC protocol is required.

3.2 References collated (clinical papers, abstracts, Summary of Product Characteristics, material from pharmaceutical companies, "Dosage Adjustment for Cytotoxics in Hepatic and Renal Impairment" North London Cancer Network January 2009 and clinical trial protocols where relevant) and examples of protocols, where in use, across the UK. If the originator stipulates a specific reference source, they must provide this. The KMCC team will not proceed with the protocol until this information is supplied.

3.3 The protocol is developed using the Kent and Medway SACT Protocol Template (see Appendix 1) and the checklist in appendix 2. Any queries during development of the protocol are directed to the appropriate professional via email or within the NOG/HOG meeting.

3.4 The draft SACT protocol is saved within the DRAFT folder of the specific tumour group of the Shared Folders on the document management system. Where the protocol is new or the amendments complex, the draft is to be reviewed by the KMCC pharmacist before circulating for final checking.

3.5 A new or amended protocol is circulated via email to 2 pharmacists (usually KMCC Pharmacist and NOG pharmacist) and the relevant Consultant Oncologist / Haematologist(s) (member of NOG/HOG) for approval. Where a minor amendment is

made, all 3 individuals may not be required to approve the change (see section 4.0). When protocols cover multiple tumour sites, they must be agreed by a consultant from each of the relevant NOGS, however if an amendment only affects one tumour site, a single approval is accepted. All resources not in the public domain should be circulated with the protocol for checking.

3.6 Following circulation, amendments are made to the draft document within the document management system in line with comments received by the pharmacists and/or consultants. The version number of the protocol should be updated as described in section 5.0.

3.7 The updated draft is re-circulated to the individuals required for final sign off as described in section 4.0.

3.8 Confirmation of approval is received either via email or via PDF 'sign and fill' and stored within the 'Protocol' folders of the document management system.

3.9 The Pharmacy Technician completes a KMCC 'Request for Change' (RFC) form to add or update the protocol to the KMCC website, under the Network Chemotherapy Protocols Page. The KMCC pharmacy technician will send the RFC to the KMCC website administrator copying in the KMCC Pharmacist who will approve the RFC prior to the website administrator actioning the change.

3.10 The electronic document is then moved from the DRAFT to the FINAL folder of the specific tumour group of the Shared Folders on the document management system. Any superseded protocols should be moved into the superseded folder.

3.11 The website administrator uploads the document to the KMCC website and when complete, advises the pharmacy technician who checks the document has been uploaded correctly.

3.12 Once the protocol is uploaded to the KMCC website and the regimen is live on Aria, the e-prescribing system administrator or KMCC pharmacy technician will send an email notification to the relevant NOG(s)/HOG(s), the KMCC Chemotherapy Group (which includes Lead Oncology/Haematology Pharmacists).

4.0 Responsibilities

For full structure of responsibilities see Figure 3 of Organisational Processes and Governance Structure for SACT Protocols and Electronic Prescribing Regimens http://www.kmcc.nhs.uk/medicines-and-prescribing-incorporating-sact-pathways/network-chemotherapy-prescription-proformas-protocols-nhs-staff-use/

The table below indicates the individuals authorised to approve amendments. The amendment can be made by the KMCC Pharmacy Technician or an authorised oncology / haematology pharmacist.

Protocol amendment	Authorisation to approve
Formatting issues	T, P or C
Spelling errors	T, P or C
Page numbers	T, P or C
Protocol name	P or C
Regimen number	P or C
Indication - if in line with a new commissioning decision (e.g new CDF indication)	P or C
Administration instructions (including diluent)	P or C
Medication form (eg liquids / tablets)	P or C
Brand name (if applicable)	P or C
References	P or C
Indication – other than new commissioning decision	P & C
Frequency and number of cycles	P & C Or if in line with commissioning criteria P or C
Monitoring parameters	P & C
Treatment intent	P & C
Drug	P & C
Dose	P & C
Route	P & C
Order of administration	P & C
Infusion duration / rates	P & C P or C (if within SPC)

KMCC technician = T
Oncology / haematology pharmacist who is trained and deemed competent to check SACT protocols by their Trust Chief Pharmacist = P
Consultant = C

NB: A consultant may be a consultant oncologist or haematologist or a consultant Nurse or Consultant Pharmacist working within their area of clinical practice. A Consultant Pharmacist must be deemed competent by their Trust Chief Pharmacist and a Consultant Nurse deemed competent by the Chief Nurse.

NB: shaded cells indicate full approval.

5.0 Version numbers

A decimal point system is used for version control. All drafts can be differentiated by the use of a decimal point:
e.g. v0.1 or v1.1
All final documents are given a version number with a whole number
e.g. v1.0 or v2.0
A second decimal point will be used to differentiate a minor amendment not requiring full approval.
e.g. v0.4.1

Example:
v0.4 has been signed off by a clinician. There is a subsequent change requested which would be classified as a minor amendment. The protocol would then become v0.4.1
Within the approvals records there would then be v0.4 authorised by the clinician and v0.4.1 authorised by the pharmacist / pharmacy technician.

References:

1) Organisational Structure and Governance Processes for a Central Collaborative Team Supportive the Maintenance of Oncological Treatment Guidelines (treatment algorithms) and Systemic Anti-Cancer Therapy (SACT) Protocols in Oncology and Haematology across the Kent and Medway Cancer Collaborative (including the maintenance of the SACT prescription on an electronic prescribing system) v9
http://www.kmcc.nhs.uk/medicines-and-prescribing-incorporating-sact-pathways/network-chemotherapy-prescription-proformas-protocols-nhs-staff-use/
2) Algorithm Deviation Policy Version 5
http://www.kmcc.nhs.uk/medicines-and-prescribing-incorporating-sact-pathways/network-chemotherapy-prescription-proformas-protocols-nhs-staff-use/
3) Cisplatin Hydration Guidelines
http://www.kmcc.nhs.uk/medicines-and-prescribing-incorporating-sact-pathways/network-chemotherapy-prescription-proformas-protocols-nhs-staff-use/
4) Guidance on capping of BSA for the purposes of calculating cytotoxic chemotherapy v1
http://www.kmcc.nhs.uk/medicines-and-prescribing-incorporating-sact-pathways/network-chemotherapy-prescription-proformas-protocols-nhs-staff-use/
5) KMCC anti-emetic guidelines
http://www.kmcc.nhs.uk/medicines-and-prescribing-incorporating-sact-pathways/sact-pathways-guidelines-for-the-management-of-sact-induced-adverse-reactions-and-nursing/
6) KMCC filgrastim guidelines
http://www.kmcc.nhs.uk/medicines-and-prescribing-incorporating-sact-pathways/sact-pathways-guidelines-for-the-management-of-sact-induced-adverse-reactions-and-nursing/

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Appendix 1:

Indication	
Treatment Intent	
Frequency and number of cycles	
Monitoring Parameters pre-treatment	*Sections to be included as appropriate:* • Hepatic impairment • Renal impairment: • Infusion-related reactions: • Management of adverse reactions and dose adjustments: • Interactions with tests • Dose Modification • Common drug interactions(for comprehensive list refer to BNF/SPC): • Missed dose • If oral SACT include statement around following Trust policy • Guidance on driving / using equipment • Patient information documents
References	

NB For funding information, refer to CDF and NICE Drugs Funding List

Day	Drug	Dose	Route	Infusion Duration	Administration
	TREATMENT DRUGS IN BOLD				
TTO	Drug	Dose	Route	Directions	

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Appendix 2

The criteria set out in this checklist are not exhaustive and additional information may be required.

	Check that:	**Prepared by**	**Checked by**
1	Correct KMCC template has been used.		
2	Name of protocol / regimen is clear to include brand name if required (due to pharmacokinetic, bioavailability or licensing issues). The brand name should be in the regimen title and in the administration details.		
3	The disease type has been stated.		
4	Indication correct.		
5	Therapeutic intent stated.		
6	Number of cycles to include maximum duration of therapy if required.		
7	Length of cycle included.		
8	Wording unambiguous (e.g. repeat 'every 3 weeks' not '3 weekly').		
9	Any mandatory tests prior to treatment are included and required parameters stated (e.g. DTPA/ ECG). Ensure consistency between drugs of the same therapeutic class where appropriate.		
10	Where routine monitoring is required during treatment (e.g. echo every 3 months) this should be included in the protocol.		
11	Where routine monitoring parameters are not met (e.g. CrCl, Hb, WBC etc.) and dose interruptions or modifications are required, guidance is provided or referenced.		
12	The most significant drug interactions are included.		
13	Significant adverse reaction including infusion related reactions (monitoring and management) are stated.		
14	Ensure reference to any patient alert/information cards is included if relevant.		
15	All the correct drugs are prescribed and treatment drugs are in **bold**.		
16	Drug doses are correct.		
17	Correct form of drug is stated.		
18	Drug doses are stated for the correct number of doses or days.		
19	Order of drug administration is correct. e.g. The most vesicant drug is given first, drugs with high incidence of hypersensitivity reaction given first.		

20	Routes of administration are appropriate (IV administration <10mins is a bolus, >/=10mins is an infusion).		
21	Maximum doses are stated if applicable.		
22	The total daily dose is stated if applicable.		
23	Doses are in mg wherever possible.		
24	BSA is capped if appropriate. As ARIA is capped at BSA 2.0, for adjuvant or neo-adjuvant treatments, a statement should be included on the protocol to advise the clinician to consider using actual BSA.		
25	Timings are correct where relevant.		
26	Diluents and concentrations are appropriate.		
27	If filters and/or specific disposables (e.g. non PVC bag and giving sets) are required, these are stated. NB For paclitaxel ensure non PVC bag and giving set is stated.		
28	If vinca alkaloids are listed, they are added to at least 50ml sodium chloride 0.9%.		
29	If pre-medication is required a reminder is given before chemotherapy.		
30	Appropriate anti-emetics are included and are in accordance with network anti-emetic guidelines.		
31	Supportive drugs are included if appropriate. (e.g. hydration, mesna etc.) N.B hydration should be prescribed as per network approved hydration schedule for cisplatin.		
32	TTO's are included where appropriate.		
33	BNF severe warnings included.		
34	Filgrastim listed where appropriate and in line with KMCC guidance (should be started at least 24 hours after chemotherapy).		
35	Intrathecal drugs are not included.		
36	If oral SACT is listed ensure that the following statement is included "For oral self-administration: refer to local Trust policy on oral anti-cancer medicines and supply Patient Information Leaflet and Macmillan information sheet" Formulation and strengths are listed. Number of days treatment and day of treatment supply is stated.		
37	The use of steroids within immunotherapy protocols should be agreed by the NOG.		

38	"algorithm deviation" is included if appropriate.		
39	Approvals record is present and current to include: written by / check by, date, disclaimer, protocol number, version, superseded version, authorising consultant.		
40	Page 1 of x is correct.		
41	References used for the protocol are listed and used for checking the protocol.		
42	Protocol to be saved into PDF format for electronic sign off.		n/a