Organisational Structure and Governance Processes for a Central Collaborative Team Supporting 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)

1.0 Introduction

This document provides a framework for the governance of Chemotherapy Protocols across Kent and Medway, and outlines the organisational structure for a central collaborative team. This team supports the maintenance of oncological treatment guidelines (treatment algorithms) as specified by the Non-Surgical Oncology Sub-Groups (NOGs), and Systemic Anti-Cancer Therapy (SACT) protocols in Oncology and Haematology across the Kent and Medway Cancer Collaborative (including the maintenance of the SACT regimen on an Electronic Prescribing System).

Figure 1 describes the central collaborative resource which includes; KMCC pharmacy technician, electronic prescribing system administrator, KMCC pharmacist. The Trust pharmacists contribute to the workplan. The governance processes are overseen by the Chair of the electronic prescribing subgroup (of the KMCC Chemotherapy Group), the Chair(s) of the NOG(s) and the Chair of the KMCC Chemotherapy Group.

Figure 2a describes the governance process for the maintenance of KMCC Oncological Treatment Guidelines, and Figure 3 describes the process for the maintenance of chemotherapy protocols and the electronic regimens on the electronic prescribing system.

The processes for Clinical Trial protocols are to mirror those of the standard clinical protocols but will need to link in with the Research and Development approvals and amendments processes. Figure 2b describes the governance process for the creation and maintenance of clinical trials electronic prescribing protocols.

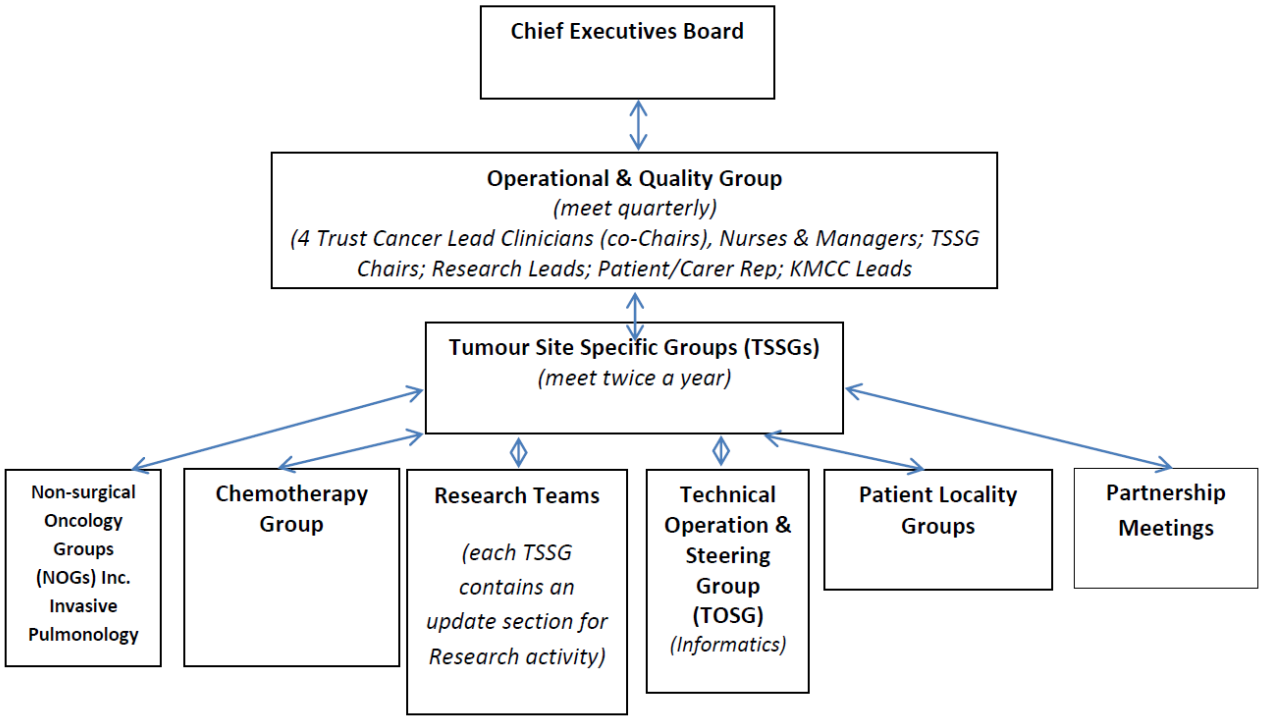
The SACT protocol provides full prescribing and monitoring details and is in the format of a pdf document which once finalised, is available on the KMCC website. The KMCC SACT protocol template can be found in appendix 1. The KMCC protocol is the master document from which the SACT regimen is built on the electronic prescribing system. The SACT regimen on the electronic prescribing system provides the information necessary for a prescription to be generated, but does not contain full monitoring information as outlined in the protocol.

A paper based SACT protocol is an essential part of the governance process, for the following reasons:

- For more complex protocols, the Aria SACT regimen will not meet Quality Indicators for chemotherapy, as it is not possible to incorporate more complex information into the Aria regimen, relating to, for example, the management of adverse events and/ or dose adjustments.
- Aria cannot provide a backup of the complete protocol, as it only creates a backup template prescription which does not contain the details held within the Plan Summary.

- Whilst frequent amendments are required to SACT protocols, issues with version updates on Aria have already been identified as posing a risk, and as such, it is not ideal to make regular amendments to the Aria SACT regimen. Changes to protocols often relate to aspects of the protocol which do not affect the SACT prescription itself.

The reporting structure of the e-prescribing sub-group of the Kent & Medway Chemotherapy Group will continue through the existing structure as below. This will enable all operational, structural and governance issues to be escalated for resolution and will take on the business as usual support in order to replace the E-prescribing Programme Board.



The contract for Aria MedOnc is between Varian and Maidstone and Tunbridge Wells NHS Trust. As such, the Director of Informatics at MTW will be responsible for contract monitoring and will achieve this through quarterly contract monitoring meetings.
The MTW Director of Informatics may members of staff from the other NHS Trusts in the Collaborative or from the Collaborative Pharmacy Team as necessary.

2.0 Validation of KMCC SACT protocols and Regimens on the Electronic Prescribing System

All SACT protocols should be validated by 2 Oncology/ Haematology Pharmacists and a Consultant Oncologist / Haematologist specialising in the relevant tumour group (this would normally be the Chair of the NOG, but this work may be delegated). The KMCC technician may be involved in the development or writing of the protocol, but the protocol will still require validation by 2 pharmacists.

All SACT regimens on the electronic prescribing system must be validated by an Oncology / Haematology Pharmacist, a Consultant Oncologist / Haematologist and a chemotherapy trained nurse. The Pharmacist and the Consultant may have been involved in the validation of the full SACT protocol, but this is not mandatory.

2.1 Abridged validations on Electronic Prescribing System

The SOP for an abridged validation of SACT regimens is used when minor amendments are required to the SACT regimen on the electronic prescribing system. These amendments will always require a second check by an authorised pharmacist. In addition, the SOP sets out when validation is also required by a consultant oncologist / haematologist and chemotherapy nurse.

NB Abridged validation only applies to the regimen on the electronic prescribing system. Any change made to the SACT paper-based protocol itself requires full validation as outlined above.

3.0 Algorithm deviations, one-off requests, access schemes and compassionate use medicines

3.1 Site Specific Requests

3.1.1 Algorithms deviations, one-off requests and access schemes offered by manufacturers (for licensed drugs which have not been through the NICE process)

These should be considered within the context of the 'Policy for the Management of Algorithm deviations and the use of unfunded medicines'. Each request should be escalated to the individual Trust Drugs and Therapeutics Committee (or relevant decision making group). The relevant Trust is then responsible for ensuring the SACT regimen is built and validated on the electronic prescribing system, and works with the Collaborative System Administrator to ensure the regimen is available only at the relevant site.

3.1.2 Compassionate supply (unlicensed medicines)

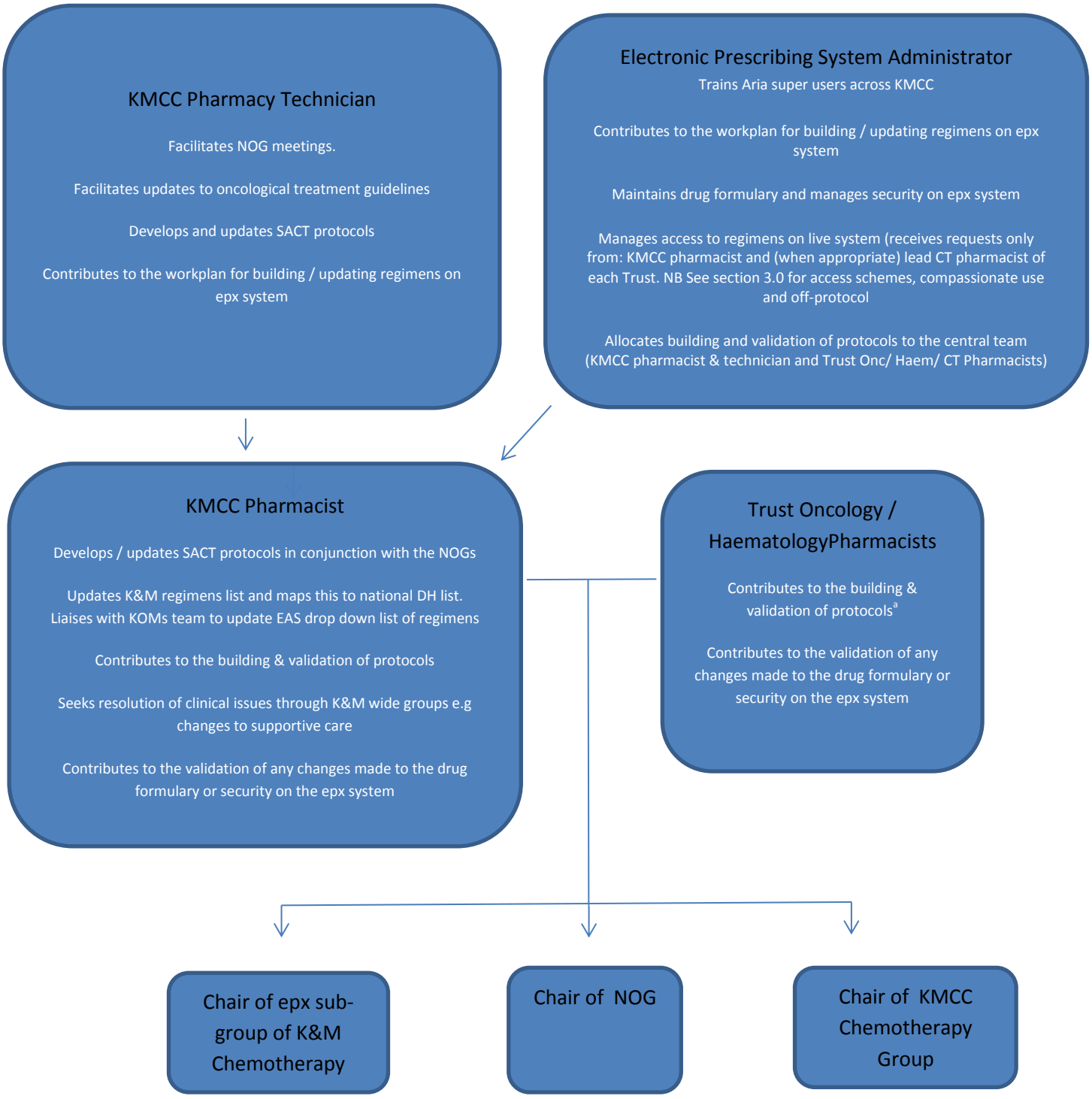
The treating clinician should make a request through the individual Trust Drugs and Therapeutics Committee (or relevant decision making group). The relevant Trust is then responsible for ensuring the SACT regimen is built and validated on the electronic prescribing system and works with the Collaborative System Administrator to ensure the regimen is available only at the relevant site.

3.2 KMCC requests via Non-Surgical Oncology Sub-Groups

3.2.1 Managed access schemes agreed as part of the NICE process and NHSE MHRA EAMs schemes

These should follow the usual governance process as outlined in figures 2 and 3

Figure 1: Organisational Structure for a central collaborative team supporting the governance of SACT treatment guidelines and SACT protocols (including SACT regimen on the electronic prescribing system)



[a] Whilst it is anticipated that the majority of the building will be undertaken by the central team, to ensure skills are maintained and resilience in the workforce, all Trusts will contribute to the building of regimens on the electronic system.

Key:

Accountability →

Figure 2a: Governance Process for Maintenance of SACT Treatment Algorithms as Outlined in the KMCC Oncological Treatment Guidelines

		Individual responsible	Timeline (day)
1	NOG instigates a new chemotherapy protocol or change to existing protocol or other revision to oncological treatment guidelines	NOG	1
	Where there is a request for a new protocol or an amendment to and existing protocol, the protocol is developed as outlined in figure 3		
2	Oncological treatment guidelines updated and circulated to NOG members	KMCC technician	8
3	Comments collated, further changes made, and document re-circulated	KMCC technician	14
4	Changes ratified by Chair of the NOG	NOG Chair	15
5	Request for Change completed and authorised for update on KMCC website	KMCC technician / pharmacist	16
6	Oncological treatment guidelines uploaded onto KMCC website	KMCC admin	23
7	Notification and link to updated document sent to the KMCC Chemotherapy Group and relevant NOG	KMCC technician	24

Figure 2b: Governance Process for Maintenance of Clinical Trial Protocols that include SACT Treatment Regimens

		Individual responsible	Timeline (day)
1	Clinician indicates an interest in opening a particular trial that includes SACT treatment regimens(s) to local Clinical Trials Pharmacist	Clinician PI	
2	Feasibility and R&D approval process is undertaken	R&D Department	
3	Clinical Trials Pharmacist is made aware that trial is near to opening and that SACT prescription template needs to be created	R&D Department/ Clinical Trials Pharmacist	
4	Clinical Trials Pharmacist contacts Collaborative Pharmacy Team who confirm with other Trusts if any other centre will be opening the trial and at what stage in the approval process each site has reached	KMCC technician / Pharmacist/ePx System Administrator	
5	Collaborative Pharmacy Team allocate the treatment protocol to an appropriate Clinical Trials Pharmacist to produce the paper SACT prescription template.	KMCC technician / ePx System Administrator / Clinical Trials Pharmacist	
6	Clinical Trials Pharmacist sends SACT prescription template to Collaborative Pharmacy Team to co-ordinate build in Aria	KMCC technician / Pharmacist/ Clinical Trial Pharmacists/ technicians[a]	
7	Validation of build and checking of the SACT prescription template is undertaken by a second, appropriate Pharmacist (Clinical Trials or a Clinical Pharmacist with the necessary competencies for clinical trials management), PI and Nursing staff	Trust Pharmacist/ PI/ Nursing Team	
8	Pharmacist / technician that has undertaken the build makes any necessary changes to the build	KMCC technician /	

		Pharmacist/ Trust Pharmacist	
9	Protocol is deemed ready for use and so Collaborative Pharmacy Team make protocol live in Aria and inform all sites that the protocol is available	KMCC technician / Pharmacist	
	Where there is a request for a new protocol or an amendment to an existing protocol, the protocol is developed as outlined in figure 3 but using appropriate Pharmacists as necessary (e.g. Clinical Trial Pharmacists)		

[a] Responsibilities of the Clinical Trials Pharmacist may also be undertaken by a Clinical Pharmacist with the necessary competencies for clinical trials management

Figure 3: Governance Process for Maintenance of KMCC SACT Protocols on KMCC website and SACT regimens (non-trial) on the Electronic Prescribing System

		Individual Responsible	Timeline (day)[b]
1	NOG instigates a new chemotherapy protocol or change to existing protocol.	NOG Chair	1
2	a. KMCC SACT protocol developed or updated using agreed template (appendix 1).	KMCC technician or Pharmacist	3
	b. Protocol number assigned by KMCC team.	KMCC technician	3
	c. Protocol name and number added to KMCC regimens spreadsheet	KMCC technician	3
	d. SACT Protocol checked by 1st pharmacist	KMCC Pharmacist or delegated[a] haematology / oncology pharmacist.	5
	e. Protocol forwarded to second pharmacist and Consultant Oncology / Haematologist for checking / validation. NB. If the directive to change the protocol is clearly made within the NOG meeting and minuted / documented, it may not be necessary to contact NOG clinician for a change to an existing protocol	NOG Chair (or delegated[a] clinician) and 2nd haematology / oncology pharmacist (usually NOG pharmacist)	5
3.	a. Once confirmation received from NOG Chair that the protocol is correct, building of regimen on electronic prescribing system allocated to a trained pharmacist / technician. A log should be kept on the Building and Validation of Protocols Spreadsheet.	ePx System Administrator	10
	b. Where there is a change to an existing protocol a Change Control Form for the electronic prescribing system should be completed.	System Administrator	10

4	a. Regimen built / updates on electronic prescribing system using Aria Regimen Building SOP NB This step is independent of the second pharmacist check of the protocol. i.e building the regimen on the electronic prescribing system may commence before the 2nd Pharmacist check of the protocol has been completed.	KMCC technician / ePx System Administrator / KMCC pharmacist / Trust Pharmacist	17
5.	Regimen validated on electronic prescribing system by pharmacist, nurse & NOG Chair or deputising consultant using Aria regimen validation SOP or abridged validation of minor amendments SOP. NB If the 2nd pharmacist validation of the protocol was not completed prior to the build of the regimen on the epx system, the pharmacist validating the regimen on the epx system, should undertake the 2nd pharmacist validation of the protocol themselves or ensure this has been completed prior to validation of the regimen on the epx system.	KMCC pharmacist / Trust Pharmacist Chemotherapy Nurse Consultant Haematologist / Oncologist	31
6	KMCC protocol uploaded onto KMCC website	KMCC Technician / KMCC admin	32
7	Epx validation paperwork checked, protocol assigned to site(s), report for template prescription run and stored on MTW server, Mangoapps and paper copy filed at MTW. Access and Final Release SOP followed and checklist completed.[c]	System Administrator and KMCC Pharmacist	33
8	Updated KMCC regimen spreadsheet sent to KOMs team to update EAS regimens drop down list	KMCC Technician	33
9	K&M chemotherapy group, NOG and Lead Oncology Pharmacist at each Trust notified via email when a protocol goes live / amendment made.	KMCC Technician	33
10	Local Chemotherapy Group and /or Local Electronic Prescribing Group informed via email of changes / amendments via their Lead Oncology Pharmacist or electronic prescribing pharmacist / technician.	Trust Pharmacist / Technician	34
11	Problems / issues escalated. System issues logged on Epx risks & issues log. Clinical issues logged on NOG agenda (running draft). Collaborative system issues raised where necessary with Varian. NB: The Epx risks & issues log will be reviewed at each Epx sub-group meeting. A representative from that group (usually the Collaborative Pharmacist or the Chair of the epx sub-group) will attend the quarterly Varian contract meeting.	System issues – System administrator Clinical issues – KMCC Pharmacist	-

	Downtime & technical maintenance of the electronic prescribing system Technical maintenance of the electronic prescribing system, and technical issues resulting in downtime of the system will be managed by Computer Sciences (MTW) in the same way as has taken place during the implementation period. NB During downtime of the system, each Trust is responsible for their own business continuity plans.	Computer Sciences (MTW)	

[a]A task should only be delegated to an individual who is trained and deemed competent in that area.

[b]Timeline may vary depending on urgency of request for new protocol / amendment. If an urgent change / new protocol is requested, the process will be expedited as appropriate. 'Day' relates to working days.

[c]This reflects current process. Future location of documents in currently under discussion.

Appendix 1: KMCC SACT protocol template

Kent and Medway SACT Protocol Template

Regimen Title

Indication	
Treatment Intent	
Frequency and number of cycles	
Monitoring parameters pre-treatment	
Management of adverse events & dose reductions	*(where complex this will be added as an appendix)*
Reference(s)	
Funding	Refer to the SACT funding spreadsheet

Day	Drug	Dose	Route	Infusion Duration	Administration Details
TTO	Drug	Dose	Route	Directions	

Protocol No		Kent and Medway SACT Protocol Disclaimer: No responsibility will be accepted for the accuracy of this information when used elsewhere.	
Version		Written by	
Supersedes version		Checked by	
Date		Authorising consultant (usually NOG Chair)	