

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**

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Table of Contents

- 1.0 INTRODUCTION3**
- 2.0 ALGORITHM DEVIATIONS, ONE-OFF REQUESTS, ACCESS SCHEMES AND COMPASSIONATE USE MEDICINES.....5**
 - 2.1 Site Specific Requests5**
 - 2.1.1 Algorithms deviations, one off requests and access schemes offered by manufacturers (for licensed drugs which have not been through the NICE process) 5
 - 2.1.2 Free of Charge Drugs 5
 - 2.2 KMCC requests via Non-Surgical Oncology Sub-Groups5**
 - 2.2.1 Managed Access Schemes Agreed as Part of NHSE MHRA EAMs Schemes..... 5
- 3.0 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)6**
- 4.0 Figure 2: Governance Process for Maintenance of Clinical Trial Protocols that include SACT Treatment Regimens.....7**
- 5.0 Figure 3: Governance Process for Maintenance of KMCC SACT Protocols on KMCC website and SACT regimens (NON-TRIAL) on the Electronic Prescribing System8**
- 6.0 Glossary 10**
- 7.0 Document Administration 11**

SOP No	N/A	Version	11	Supersedes version	10	Page 2 of 11
Written By	C Waters	Authorised by	SACT Governance Group	Date	June 2023	
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1.0 INTRODUCTION

This document provides the 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 regimens on an Electronic Prescribing System).

[Figure 1](#) describes the central collaborative resource which includes; KMCC pharmacy technician, electronic prescribing system administrator, KMCC pharmacists and the KMCC Administrator. The Trust pharmacists contribute to the workplan. The governance processes are overseen by the Chair of the SACT governance group, and the Chair(s) of the NOG(s) and the HOG.

KMCC SOP 003 describes the maintenance of KMCC Oncological Treatment Guidelines, and [Figure 3](#) provides an overview of 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 2](#) describes the governance process for the creation and maintenance of clinical trials electronic prescribing regimens.

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 KMCC SOP 004. 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 always contain the full monitoring information as outlined in the protocol.

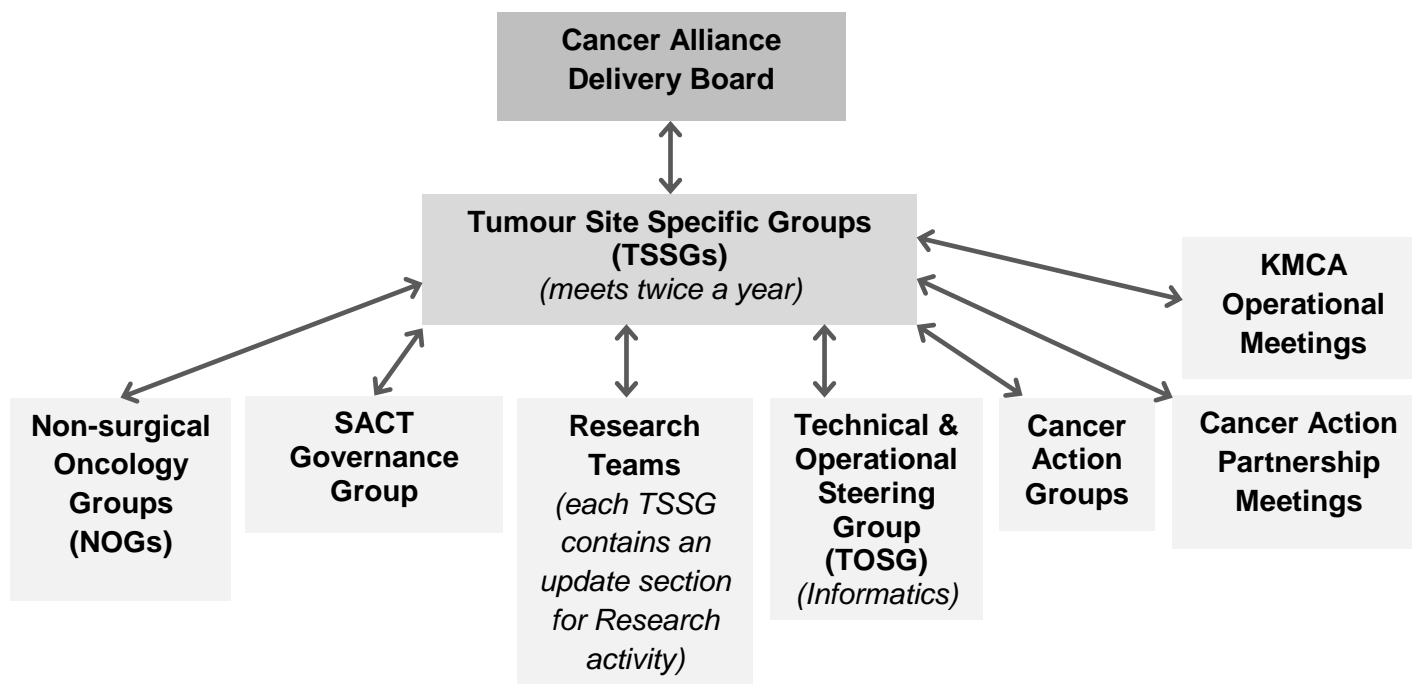
A SACT protocol is an essential part of the governance process, for the following reasons:

- ➔ For more complex protocols, on the current eprescribing system SACT regimen will not meet Quality Indicators for chemotherapy, as it is not possible to incorporate more complex information into the regimen, relating to, for example, 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.

The reporting structure of the SACT governance group will enable all operational, structural and governance issues to be escalated for resolution.

NB: KMCC SOPs are available on the KMCC website <http://www.kmcc.nhs.uk/kent-and-medway-cancer-collaborative-kmcc/>

SOP No	N/A	Version	11	Supersedes version	10	Page 3 of 11
Written By	C Waters	Authorised by	SACT Governance Group	Date	June 2023	
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The contract for the current electronic prescribing system is between system supplier 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 request members of staff from the other NHS Trusts in the Collaborative or from the Collaborative Pharmacy Team to attend as necessary.

SOP No	N/A	Version	11	Supersedes version	10	Page 4 of 11
Written By	C Waters	Authorised by	SACT Governance Group	Date	June 2023	

2.0 ALGORITHM DEVIATIONS, ONE-OFF REQUESTS, ACCESS SCHEMES AND COMPASSIONATE USE MEDICINES

2.1 Site Specific Requests

2.1.1 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.

2.1.2 Free of Charge Drugs

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.

Reference should be made to the KMCC Position Statement Access to Free of Charge Drugs Outside of Clinical Trials (via access schemes or early access to medicines schemes).

2.2 KMCC requests via Non-Surgical Oncology Sub-Groups

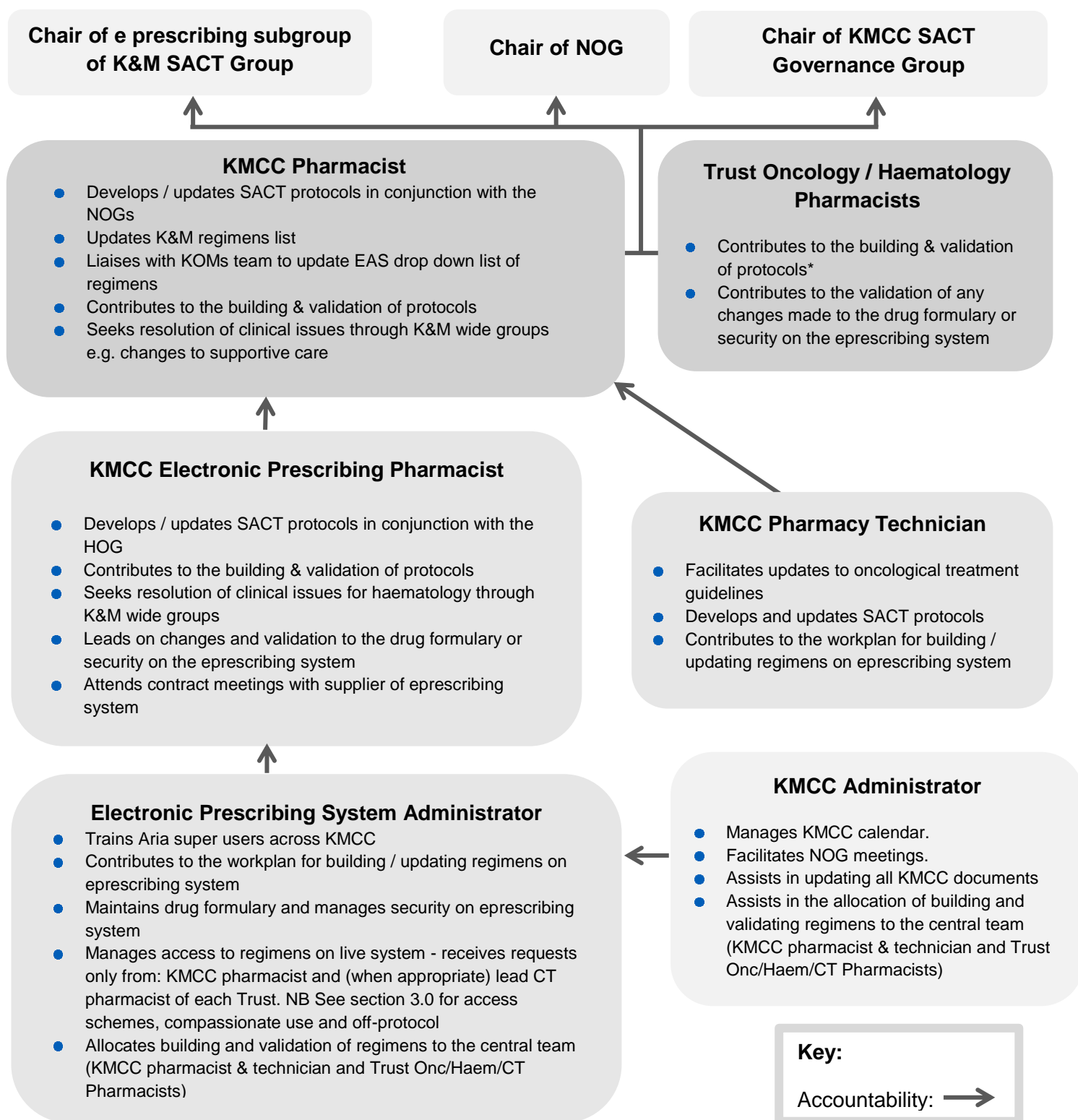
2.2.1 Managed Access Schemes Agreed as Part of NHSE MHRA EAMs Schemes

These should follow the usual governance process as outlined in [figures 2](#) and [3](#).

Reference should be made to the KMCC Position Statement Access to Free of Charge Drugs Outside of Clinical Trials (via access schemes or early access to medicines schemes).

SOP No	N/A	Version	11	Supersedes version	10	Page 5 of 11
Written By	C Waters	Authorised by	SACT Governance Group	Date	June 2023	
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3.0 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)



*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.

SOP No	N/A	Version	11	Supersedes version	10	Page 6 of 11
Written By	C Waters	Authorised by	SACT Governance Group	Date	June 2023	
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4.0 FIGURE 2: GOVERNANCE PROCESS FOR MAINTENANCE OF CLINICAL TRIAL PROTOCOLS THAT INCLUDE SACT TREATMENT REGIMENS

		Individual Responsible	Timeline (days)
1	Clinician indicates to the local Clinical Trials Pharmacist, an interest in opening a trial that includes SACT treatment regimen(s)	Clinician PI	
2	Feasibility and R&D approval process is undertaken	R&D Department	
3	Clinical Trials Pharmacist co-ordinates the compilation and approval of a SACT prescription template/treatment protocol	R&D Department / Clinical Trials Pharmacist	
4	Clinical Trials Pharmacist sends SACT prescription template/treatment protocol to an appropriately trained pharmacist or technician for building.	KMCC Technician / Pharmacist / Clinical Trials Pharmacist / Technician*	
5	Validation of build is undertaken by a second, appropriately trained Pharmacist (Clinical Trials or a Clinical Pharmacist with the necessary competencies for clinical trials management), PI and Nurse.	Clinical trials pharmacist / Trust Pharmacist / PI / Nursing Team	
6	Regimen builder makes any requested changes to the build	KMCC Technician / Pharmacist / Clinical Trials Pharmacist / Technician*	
7	Validation of ARIA build is completed and regimen made live by KMCC pharmacy team or, in their absence an appropriately trained pharmacist.	KMCC Technician / Pharmacist / Clinical Trials Pharmacist / Technician*	

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)

5.0 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 (days) ^b
1.	NOG instigates a new chemotherapy protocol or change to existing protocol.	NOG	1
2	KMCC SACT protocol developed or updated using agreed template (see KMCC SOP 004)	KMCC technician or Pharmacist	3
3	Protocol number assigned by KMCC team and protocol name and number added to KMCC regimens spreadsheet (see KMCC SOP 001).	KMCC technician or Pharmacist	3
4	SACT Protocol circulated and checked as per KMCC SOP 004	KMCC Technician, Pharmacist and 2nd haematology / oncology pharmacist ^a (usually NOG pharmacist) plus NOG Chair (or delegated ^a clinician)	5
5	Building of regimen on electronic prescribing system allocated to a trained pharmacist / technician. A log should be kept on the ARIA regimen and KMCC protocol workplan. 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.	eprescribing System Administrator and KMCC Administrator	10
6	Regimen built / updates on electronic prescribing system using Aria Regimen Building SOP KMCCEP023	KMCC technician /eprescribing System Administrator / KMCC EP pharmacist / Trust Pharmacist	17
7	Regimen validated on electronic prescribing system by pharmacist, nurse & NOG Chair or deputising consultant using Aria regimen validation SOP KMCCEP023 or abridged validation of minor amendments SOP KMCCEP005. NB: If the 2nd pharmacist approval of the protocol was not completed prior to the build of the regimen on the eprescribing system, the pharmacist validating the regimen on the eprescribing system, should undertake the 2nd pharmacist approval of the protocol or ensure this has been completed prior to validation of the regimen on the eprescribing system.	KMCC EP pharmacist / Trust Pharmacist Chemotherapy Nurse Consultant Haematologist / Oncologist	31
8	KMCC protocol finalised (KMCC SOP 004)	KMCC Technician / KMCC Administrator	32

9	Access and Final Release SOP KMCCEP004 followed and checklist completed. Notification sent in line with SOP	System Administrator and KMCC EP Pharmacist	33
10	Updated KMCC regimen spreadsheet sent to KOMs team to update EAS regimens drop down list (KMCC SOP 001)	KMCC Technician or Pharmacist	33
11	<p>Problems / issues escalated. System issues logged on local eprescribing risks & issues log and added to next eprescribing group agenda. Serious issues should be escalated immediately to the System Administrator who will raise it with the eprescribing supplier where necessary. Clinical issues logged on NOG agenda (running draft).</p> <p>NB: The eprescribing risks & issues will be reviewed at each eprescribing sub-group meeting. A representative from that group (usually the Collaborative Pharmacist or the Chair of the eprescribing sub-group) will attend the quarterly contract meeting of the eprescribing supplier.</p>	<p>System issues – System administrator KMCC EP Pharmacist</p> <p>Clinical issues – KMCC Pharmacist</p>	
12	<p>Downtime & technical maintenance of the electronic prescribing system and technical issues resulting in downtime of the system will be managed by Computer Sciences (MTW).</p> <p>NB: During downtime of the system, each Trust is responsible for their own business continuity plans.</p>	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. 'Days' relates to working days.

6.0 GLOSSARY

Acronyms in common usage throughout KMCC documentation

BNF	British National Formulary
BOPA	British Oncology Pharmacist Association
CNB	Cancer Network Board
COSHH	Control of substances hazardous to health regulations.
CYP	Children & Young People (in relation to the IOG)
DCCAG	Diagnostic Cross Cutting Advisory Group
DOG	Disease Orientated Group (NSSG/TSSG/TWG)
DVH	Darent Valley Hospital
DGT	Dartford and Gravesham NHS Trust
EK	East Kent
EKHUFT	East Kent Hospitals University Foundation Trust
EPS	Electronic Prescribing System
FP10(HNC)	Prescriptions issued by hospital doctors for dispensing in the community
GP	General Practitioner
HoP	High Level Operational Policy
IOSC	Improving Outcomes: A Strategy for Cancer
IV	Intravenous
K&C	Kent & Canterbury Hospital, Canterbury, (EKHUFT)
KMCC	Kent & Medway Cancer Collaborative
KMCRN	Kent & Medway Cancer Research Network
KOMS	Kent Oncology Management System
LSESN	London & South East Sarcoma Network
MFT	Medway Foundation Trust
MTW	Maidstone & Tunbridge Wells NHS Trust
NHS	National Health Service
NMP	Non-medical prescriber
NPSA	National Patient Safety agency
NOG	Non Surgical Oncology Group <i>(Permanent oncologist sub group of the DOGs with a specific responsibility for chemo/rad pathways and advice to the DOG, Network and GEOGRAPHICAL LOCATIONS on new drugs)</i>
PoC	Pathway of Care <i>(Network agreed disease site specific clinical guidelines)</i>
QEQM	Queen Elizabeth the Queen Mother Hospital, Margate (EKHUFT)
QoL	Quality of life
QSI	Quality service information system
QST	Quality Surveillance Team
RAT	Research and Trial Group <i>(Permanent sub-group of the DOGs with a specific responsibility for taking forward the clinical trials agenda)</i>
RMH	Royal Marsden Hospital
RNOH	Royal National Orthopaedic Hospital
SACT	Systemic Anti-Cancer therapy
SACT regimen	Systemic Anti-cancer prescription on the electronic prescribing system
SACT protocol	Systemic Anti-cancer protocol on KMCC website

SOP No	N/A	Version	11	Supersedes version	10	Page 10 of 11
Written By	C Waters	Authorised by	SACT Governance Group	Date	June 2023	
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TTO	Treatment to take home
QVH	Queen Victoria Foundation Trust Hospital East Grinstead
UCLH	University College Hospital London
WHH	William Harvey Hospital, Ashford (EKHUFT)
WK	West Kent

7.0 DOCUMENT ADMINISTRATION

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