NORTH CANCER ALLIANCE – LEAD AUTHOR RESPONSIBILITIES

Lead Authors are appointed individuals in the development of Clinical Management Guidelines and SACT Protocols.

For CMGs, the Lead Author may be the Pathway Board Clinical Director or a nominated clinician with significant interest and involvement in that tumour group..

For SACT Protocols, a Lead Oncologist/ Haematologist and Lead Pharmacist from the same NHS Board are appointed as co-authors to lead the development on behalf of the region.

The table on the right notes the key responsibilities of Lead Authors in the development of CMGs and SACT Protocols.

Lead Authors are required to lead the development of CMG and SACT Protocols according to the process outlined in this document.
Lead Authors should undertake the first review of current CMGs and Protocols and produce the first draft for discussion with review group
This initial review must include comparison with WOSCAN and SCAN CMGs and SACT Protocols.
Lead Authors should ensure clinical practice across the North of Scotland is documented, including identifying variance.
Lead Authors are required to take an impartial view in achieving consensus on clinical practice and reflect this in documents, and escalate where consensus can not be achieved.
Lead Authors must offer the opportunity for formal comments to be submitted and recorded by the regional team. Lead Authors have final say on changes to CMGs or SACT Protocols.
Lead Authors must ensure there is justification recorded where changes suggested are not reflected in CMGs or SACT Protocols.
The Lead Authors should work collaboratively with the NCA team to progress the development of CMGs and SACT Protocols
Lead Authors must ensure all three cancer centres have been consulted and accept the final draft of CMGs and SACT Protocols as representative.
Lead Authors must add their names to approved CMGs and SACT Protocols
Lead Authors must take a leading role in implementation of CMGs and SACT Protocols.
Lead Authors must ensure variance is recorded and where clinical consensus can not be achieved, this is escalated accordingly.

NORTH CANCER ALLIANCE – WHAT TRIGGERS A REVIEW OF CLINICAL MANAGEMENT GUIDELINES (CMG)?

It is the responsibility of the tumour-specific Clinical Director to ensure Clinical Management Guidelines (CMGs) are reflective of current clinical practice.

The requirement for CMGs is described by the CEL 30 (2012) which notes the requirement that there is 'a co-ordinated regional approach to their development in place' which will 'support a consistent approach to care delivery'.

Review cycle every three years	Pathway Boards must undertake a full review of CMGs every three years if not completed within the previous three years.
Clinical Director	With responsibility for the CMG, the Clinical Director can at any time propose a review of a CMG through the tumour-specific Pathway Board.
Change in clinical practice	Where identified, changes in clinical practice will warrant a review of the CMG to ensure it is representative of current practice. Any clinician can trigger this through a discussion with the tumour specific Clinical Director and/or raised at the Pathway Board.
Regional variance	Where a variance is identified in clinical practice it will trigger a CMG review to ensure clinical practice is concurrent with best practice. Please note this does not mean adopting practice of other boards / regions, but is a platform for scrutinising our own practice and ensuring CMG is representative for best patient outcomes.
Changes to SACT components of CMG	These changes do not always require a full review of a CMG. An appendix of approved SACT protocols is available within each CMG, and links to the full SACT protocols provided. SACT changes may only require changes to the CMG and not the SACT Protocol itself, therefore no full review is required.
SMC approval of new SACT medicines or new indications	The Scottish Medicines Consortium (SMC) will approve approximately 2-4 new SACT medicines / new indications per month. These can trigger a review of CMG and the development of related SACT protocols.
Approval of new SACT medicines / new indications	Area Drug Therapeutic Committees (ADTC) for each health board across the North of Scotland review separate submissions for approved new SACT medicines / new indications. As part of the North Cancer Lead Pharmacists Group this is a standing agenda item to provide oversight regionally to reduce variance and ensure SACT protocols are developed timeously to reflect prescribing changes.
Regional Lead Pharmacist anticipates inclusion of new SACT regimens	Where it is expected that new SACT medicines / new indications may be approved, the review process can be started, liaising with the SACT Lead Author to trigger the review of SACT elements of CMGs.
Quality and Service Improvement	As part of the Pathway Board actions in response to Quality Performance Indicator (QPI) results, survival analysis or any other work undertaken, this may require a review of a CMG.
National recommendation	At any time, the region may be required to undertaken a review of CMGs.

NORTH CANCER ALLIANCE - DEVELOPMENT OF CLINICAL MANAGEMENT GUIDELINES (CMGs) PROCESS

SUBSTANTIVE CLINICAL MANAGEMENT GUIDELINE

SACT PROTOCOLS

Stage 1: Requirement for North Cancer tumour-specific CMG development / review identified – please see "NCA – What Triggers a CMG Review?" process (hyperlink to be inserted).

Stage 2: Tumour-specific CMG Lead Author identified (if not Pathway Board Clinical Director) – please see Lead Author responsibilities

Stage 3: Pathway Board group extended to include additional CMG review group members

Stage 4: Lead Author develops CMG or adapts from current CMG, reflecting current / proposed clinical practice. New draft circulated around Review Group, comments collated by North Region team, Lead Author makes corrections to CMG as required

Stage 5: Final draft of CMG sent out for final consultation with Review Group

Stage 6: CMG circulated to wider clinical community, register of comments received, Clinical Director responsible for considering corrections to CMG, final draft reissued with register of comments once consultation period concludes.

Stage 2: Identify participants to undertake review and development of specific Regional SACT Protocol

Stage 3(i): Review / Retrospective Development
Miss out Stage 3 where a signed-off local protocol already exists in the North

Stage 3 (ii): New Protocol Development
Development of Regional SACT Protocols by nominated lead pharmacist & nominated lead consultant*

Stage 4: Review 1 undertaken by Regional Lead Pharmacist and thereafter by identified supporting pharmacists & consultants. Comments returned to and collated by Regional Cancer Team

Stage 5: Corrections / amendments applied as appropriate by nominated Lead Pharmacist and Lead Consultant

Stage 6: Revised draft regional SACT protocol produced – Review #2 as revised regional SACT Protocol goes out to supporting pharmacists & consultants for review and final comments. Agreed SACT protocols also provided to SACT Governance Group for regional oversight

*Consultant – oncologist or haematologist

Where clinical consensus can not be reached on CMG and SACT Protocol development, escalation via North Cancer Alliance (NCA) governance structure.

Approval Stage 1: Agreed CMG formally approved by tumour-specific Pathway Board and documented in action note of meeting.

Approval Stage 2: North Cancer Alliance writes to the Medical Directors of the North of Scotland boards to notify them of approval of the clinical management guideline and ask for support in its implementation.

CMG published according to regional and board processes.

North Cancer Alliance