Options Appraisal
National Systemic Anti Cancer Therapy (SACT) Protocols

UK Chemotherapy Board

Version 1.0
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CONTENTS

1. EXECUTIVE SUMMARY

1.1. Introduction

1.1.1. A systemic anti-cancer therapy (SACT) protocol is a document (source of information) that is intended to provide guidance on the optimal prescribing and administration of cancer treatments for healthcare professionals. They are based on evidence-based medicine and include practical information to ensure treatment can be delivered safely to the patient. SACT protocols are not guidelines and will only be available in organisations once they have passed the relevant local governance processes of the organisation and are approved for use in the electronic prescribing system.

1.1.2. There is currently no standardisation for SACT protocols in the UK. This could lead to substandard care, inconsistency in practice and increased risk regarding patient safety. There is significant duplication of work and inefficient resource use, as each department delivering SACT develops their own protocol set. There may be a significant number of organisations not using written SACT protocols before building and approving SACT treatments on prescribing systems.

1.1.3. In the UK this ***duplication of producing protocols costs at least an estimated £1.1 million to £1.8 million each year*** in staff time. This number will only increase as the number of new and updated/complex regimens become available.

1.2. Objective

1.2.1. National SACT protocols aim to improve patient outcomes, increase patient safety and reduce treatment variation by providing nationally consistent evidence-based best practice treatment protocols for information to support health professionals in the delivery of cancer treatments at the point of care.

1.3. Benefits

1.3.1. The benefits of national SACT approved protocols are improvements in efficiency, safety, standardisation of practice, clarity, international equivalence, consistency in SACT outcome data and non cash releasing savings (releasing time to enable staff to carry out other duties). In addition, there is the possibility of a more rapid, safe and consistent implementation of NICE guidance, as well as potential advantages in service planning.

1.4. Proposal

1.4.1. By having national SACT protocols there will have a structure in place to ensure clinical staff have access to high quality information to be able to safely treat patients. This is particularly important as health products continue to evolve, increase in complexity and become more personalised.

1.4.2. The UKCB have produced this document to showcase a potential solution for the provision of national SACT protocols within the UK called the National SACT Protocol Programme.

1.5. Costs

1.5.1. Estimated **Capital costs of website: £120k to 170K**

1.5.2. Estimated **Operational costs of staffing: £220K to £275K**

1.6. Next Steps

1.6.1. Agree from all stakeholders across all four nations to pursue this programme.

1.6.2. Agree the chosen option with or without a 3-year initial ‘test of change’ programme.

1.6.3. Develop a business case to secure funding.

2. INTRODUCTION

2.1. What is a SACT Protocol?

2.1.1. A SACT protocol is a document (source of information) that is intended to provide guidance on the optimal prescribing and administration of cancer treatments for healthcare professionals. They should be used in conjunction with the health professionals' clinical judgement and expertise as well as individual patient factors to determine safe and effective cancer treatment.

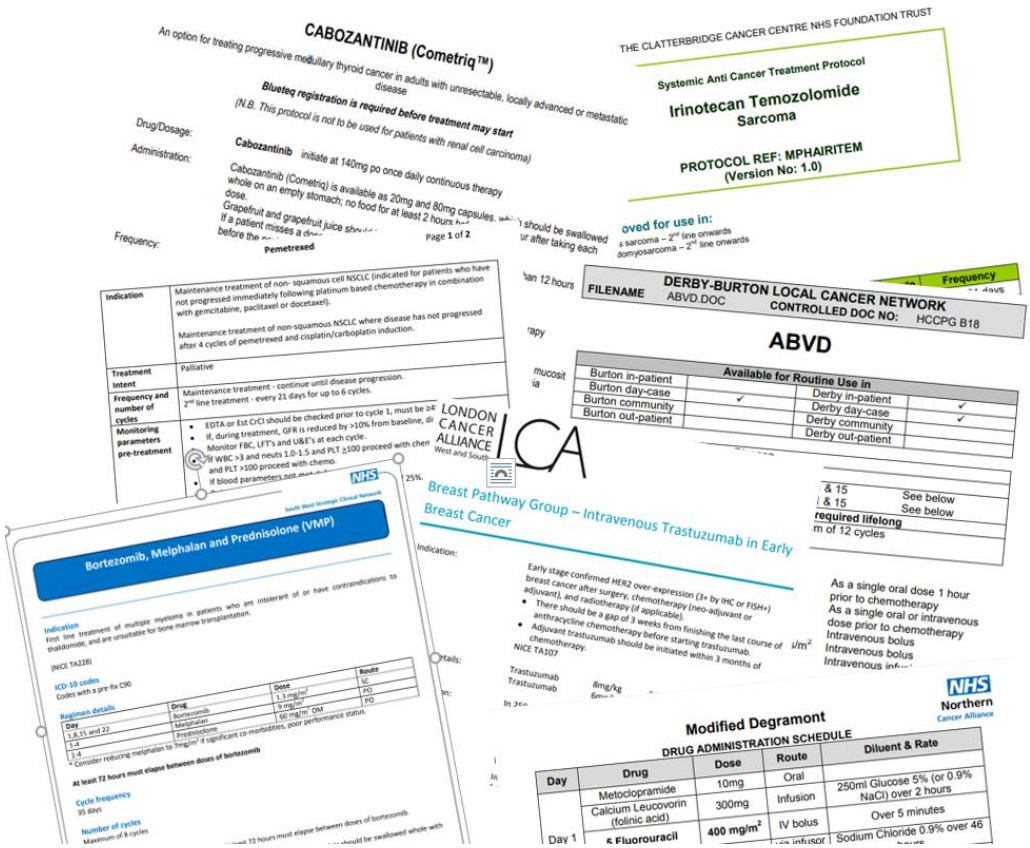
2.1.2. The content of a SACT protocol is underpinned by robust, evidence-based practice and is designed to provide a practical framework to support front-line staff to interpret complex information to ensure treatment is delivered to patients safely and effectively. SACT protocols are a medicines information resource.

2.1.3. The aim of national SACT protocols is to improve patient outcomes and reduce treatment variation by providing evidence-based best practice treatment protocols for information to support health professionals in the delivery of cancer treatments at the point of care.

2.1.4. SACT protocols are not guidelines on which treatment to give. SACT protocols only contain information to provide a course of treatment which has already been agreed with the patient. It is a source of medicines information.

2.1.5. SACT protocols will be available on electronic prescribing systems within an organisation once they have passed the relevant governance processes of the organisation and are approved for use.

Diagram 1: Examples of SACT protocols from across England



3. BACKGROUND

3.1. Current Situation

3.1.1. Currently within the UK, pharmacists and clinicians duplicate work in preparing, reviewing and approving SACT protocols at each individual hospital or organisation throughout the UK.

3.1.2. There may be a number of organisations not using written SACT protocols before building and approving SACT treatments on prescribing systems. There is a significant risk to patients due to lack of clinical governance processes before high-risk information is input as a template into a clinical system.

3.1.3. The NHS England Long Term Plan, launched in January 2019, states workforce shortages are currently one of the biggest challenges facing the health service. The tables below illustrate the estimated time and staffing commitment to produce a new protocol or update an existing protocol.

3.1.4. There may be delays in implementation of certain treatments not only due to production of a SACT protocols but also at the point of building and checking protocols on the e-prescribing system. This is based on opinion from a section of oncology pharmacists.

3.1.5. Table 1 and 2 show the estimated hours and costs to produce a written SACT protocol, this estimate does not include the time required to input the protocol into an electronic system. These figures are based on clinical opinion from a section of oncology pharmacists. Please note that protocols for more complex regimens incorporating a number of SACT agents and their supportive care can take significantly longer (e.g. Ifosfamide or methotrexate containing regimens).

Table 1: Estimated hours and costs for ONE new SACT protocol for a newly approved drug (not previously used therefore more time required to prepare).

	Approx. time (hrs)* **	**Cost per hour****	**Overall Costs*****
Pharmacist band 8a* to write	4	£32.68	£130.72
Pharmacist band 8a* to check	2	£32.68	£65.36
Medical Consultant to check	1	£70.15	£70.15
Nurse band 6** to check	1	£23.95	£23.95
Total	**9**		**£290.18**

*this could be a band 8b/8c pharmacists in some organisations
** this could be a band 7 nurse in some organisations
***does not include time required to put into electronic systems and validate
***top of agenda for change band + 20% on costs see appendix 3
****costs in London will be higher.

Table 2: Estimated hours and costs for ONE new SACT protocol for a newly approved indication for an existing drug (some information already collated so less time required to prepare).

	Approx. time (hrs)***	Cost per hour****	Overall Costs*****
Pharmacist band 8a* to write	2	£32.68	£65.36
Pharmacist band 8a* to check	1	£32.68	£32.68
Medical Consultant to check	0.5	£70.15	£35.08
Nurse band 6** to check	0.5	£23.95	£11.98
Total	**9**		**£145.10**

*this could be a band 8b/8c pharmacists in some organisations
** this could be a band 7 nurse in some organisations
***does not include time required to put into electronic systems and validate
***top of agenda for change band + 20% on costs see appendix 3
****costs in London will be higher.

3.1.6. New Cancer Indications: Within England for the period of September 2020 to August 2021 there were 38 new NICE cancer indications. Of this approximately 21 where newly approved SACT (not previously used) and approximately 17 where newly approved indication for an existing SACT. This does not reflect the number of SACT protocols needed. E.g. NICE TA 737 20th Oct 2021: Pembrolizumab with platinum- and fluoropyrimidine-based chemotherapy for untreated advanced oesophageal and gastro-oesophageal junction cancer https://www.nice.org.uk/guidance/ta737/chapter/1-Recommendations is one approval but could produce at least four different combinations.

3.1.7. For a Trust in UK, between September 2020 to August 2021 there were 88 new protocols: 35 were new drug regimens and 53 were currently used SACT drugs but used in new indications. This includes version changes, updates of existing protocols and other such changes.

3.1.8. For a Trust in UK, Between April 2020 and March 2021 there were 123 new protocols: 26 were new drug regimens and 97 were currently used SACT drugs but used in new indications. This includes version changes, updates of existing protocols and other such changes.

Estimated for one organisation
26 to 35 x £290.18 new +
53 to 97 x £145.10 existing

= £15,235 to £24,231 each year in staff time

and the numbers of new SACT and combinations are expected to continue to rise

3.1.9. Duplication:

3.1.9.1. There are approximately 131 hospitals within England providing SACT services. Due to some areas using regional SACT protocols, and potential for some organisations not using written SACT protocols (input direct into electronic prescribing system), we estimate this duplication is carried out in 66 (50%) hospitals in England. These figures are based on clinical opinion from a section of oncology pharmacists.

3.1.9.2. There are approximately 4 regions/organisations in Scotland that produce SACT protocols.

3.1.9.3. There is 1 region in Northern Ireland that produce SACT protocols.

3.1.9.4. There are approximately 4 regions in Wales that produce SACT protocols.

3.1.9.5. Therefore, it is estimated that the minimum number of SACT protocol development duplication across the UK is 75 times. This would equate to potentially £1,142,624 to £1,817,325 of duplicated work done each year.

In the UK this duplication costs an estimated

£1.1M to £1.8M each year in staff time

3.2. SACT protocol contents

3.2.1. There is currently no UK wide standardisation for SACT protocols. The name of the protocol, the type and breadth of information and the level of evidence used differs between organisations. Protocols can cover the regimen description and main toxicities alone, or include detailed information on treatment requirements, supportive therapies, and nursing support recommendations.

3.2.2. Standardisation of naming conventions would provide benefits to downstream organisations where significant staff input is required to rationalise the data provided from NHS organisations.

3.2.3. This lack of standardisation could lead to differences in SACT protocols between organisations and potential variations in care. Risks regarding the safety of patients may occur.

3.2.4. Where organisations are not using written SACT protocols before building and approving SACT treatments on prescribing systems there is a significant risk to patients due to lack of clinical governance processes before high-risk information is entered as a template into a clinical system. Errors such as incorrect doses, missing SACT or supportive therapy as well as incorrect infusions times or dilutions may occur.

3.2.5. Where SACT protocols are produced to a high quality there is significant duplication of work across the country. There is also no national consistency, which will only come from a nationally led process.

Table 3: Data contained in the protocol for 'Advanced Breast Cancer – trastuzumab emtansine (Kadcyla®)' within England for six anonymous organisations selected at random.

Area of protocol*	Organisation						Notes
	1	2	3	4	5	6	
Name of protocol	√	√	√	√	√	√	Variation
Indication	√	√	√	√	√	√	Variation
Therapeutic intent	√	√	√	√	√	√	Variation
Number and length of cycles	√	√	√	√	√	√	
Administration days	√	√	√	√	√	√	
Doses of all SACT drugs	√	√	√	√	√	√	
Supportive drugs with each cycle	√	Unclear	Unclear	√	√	√	Not always clear
Dose modifications	√	√	√	√	√	√	Variation
Pre-assessment and monitoring	Unclear	X	√	√	√	√	Variation in detail
Side Effects / Adverse effects	Limited	Limited	√	√	Limited	√	Variation in detail
Contra-indications and precautions	Limited	X	√	√	√	√	Variation in detail
Extravasation risk of each component	√	X	X	√	√	X	
Patient counselling points	Unclear	X	Unclear	Unclear	Unclear	Unclear	Unclear
Unlicensed / Off Label use	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	
Evidence used	Limited	√	√	√	√	√	
Disclaimer	X	X	X	√	X	X	
Approval Process	√	√	√	√	√	√	
Funding/commissioning	√	√	√	√	√	Unclear	

*based on BOPA *Guidance on the contents of a SACT protocol*.

3.3. Global comparison

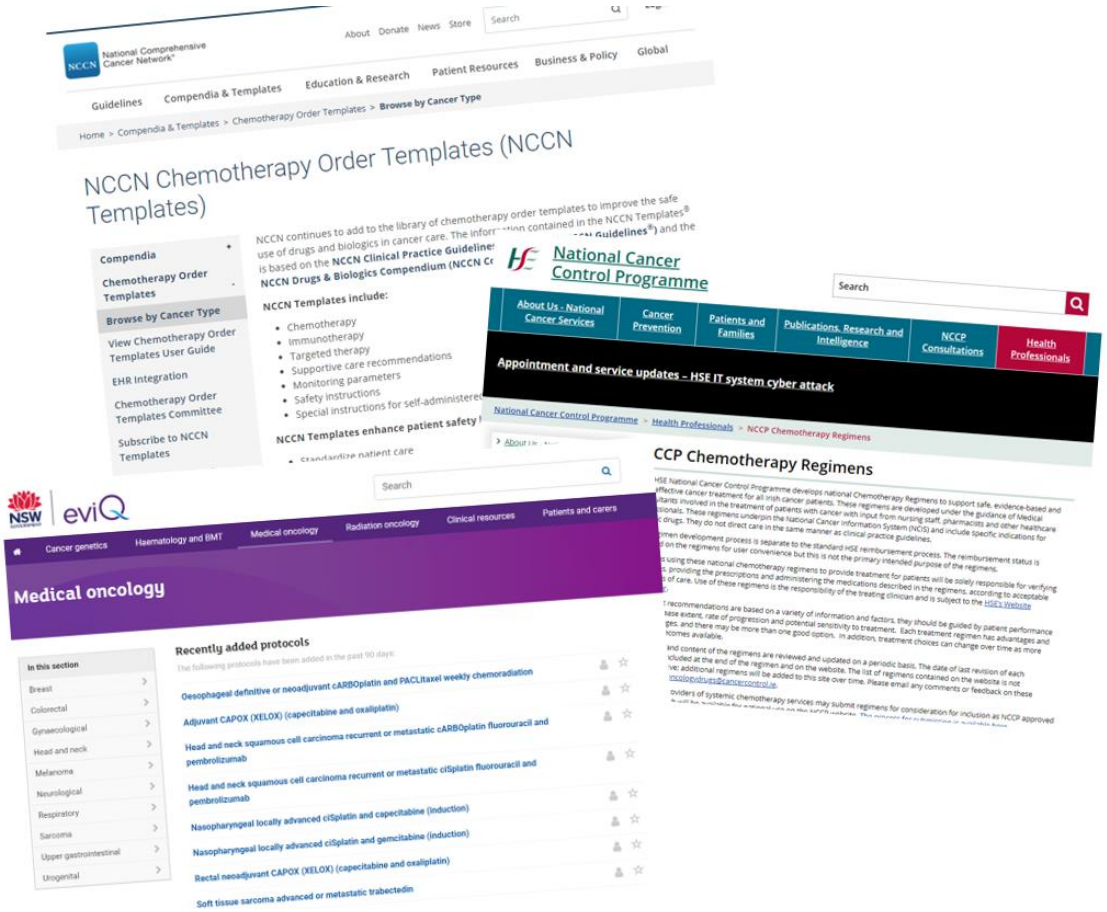
3.3.1. A first world cancer service is expected to have SACT protocols available to all staff at the point of care, which are produced to a high standard and have been managed through a robust governance process. They should be consistent across the country. This based on best practice.

3.3.2. Australia have national SACT protocols available. These are based within the website. https://www.eviq.org.au/medical-oncology. Funding information (government): https://www.eviq.org.au/pages/about-us/eviq-and-cancer-institute-nsw

3.3.3. Ireland have national SACT protocols available. These are based within the website https://www.hse.ie/eng/services/list/5/cancer/profinfo/chemoprotocols/ Funding information (government): https://www.hse.ie/eng/services/list/5/cancer/about/background.html

3.3.4. USA - National Comprehensive Cancer Network (NCCN) have national Chemotherapy Order Templates available. These are based on the website (via a subscription) https://www.nccn.org/compendia-templates/nccn-templates-main/browse-by-cancer-type and also via an XML API in HL7 FHIR format for direct integration into EHR and prior authorization systems (accessible via a licensure agreement with NCCN) https://www.nccn.org/compendia-templates/nccn-templates-main/ehr-integration. This is funded by paid subscriptions.

Diagram 2: Examples of national SACT protocol websites from outside the UK



3.4. Part of a bigger picture?

3.4.1. Across the NHS and UK there are various streams of work ongoing regarding standardisation and SACT treatment. The National SACT Protocol Programme will support, complement and strengthen the following:

3.4.1.1. The English 'Just do it' national Aseptics programme: National SACT product specifications

Cross reference this work in the SACT protocols. (e.g. state specific bag size as stated in specification within protocol).
Potential to link to specification pages within protocols website.
'Just do it' work is dm+d coded.
Work with Scottish aseptics stakeholders regarding product standardisation

3.4.1.2. England dose banding work / Scotland dose banding work

May not be consistent but can be cross referenced in SACT protocols.
https://www.england.nhs.uk/commissioning/spec-services/npc-crg/group-b/b02/dose-banded-chemotherapy-standardised-product-specifications/

3.4.1.3. National SACT dataset

To have one national UK name for a SACT protocol. This will assist with data collection and analysis. For English (established) and Scottish (in development) SACT datasets.
http://www.chemodataset.nhs.uk/home

3.4.1.4. CRUK Regimen Specific Consent forms

To have one national UK name for a SACT protocol. Cross reference this work in the SACT protocols. Complement the work in place. Potential to link in future the two programmes.
https://www.cancerresearchuk.org/health-professional/treatment-and-other-post-diagnosis-issues/consent-forms-for-sact-systemic-anti-cancer-therapy

3.4.1.5. Funding status

Clear information at each protocol on commissioning/funding parameters and relevant links to forms/ further information where required for clearly commissioned regimens (e.g. Blueteq in England) to help ensure approved use only.

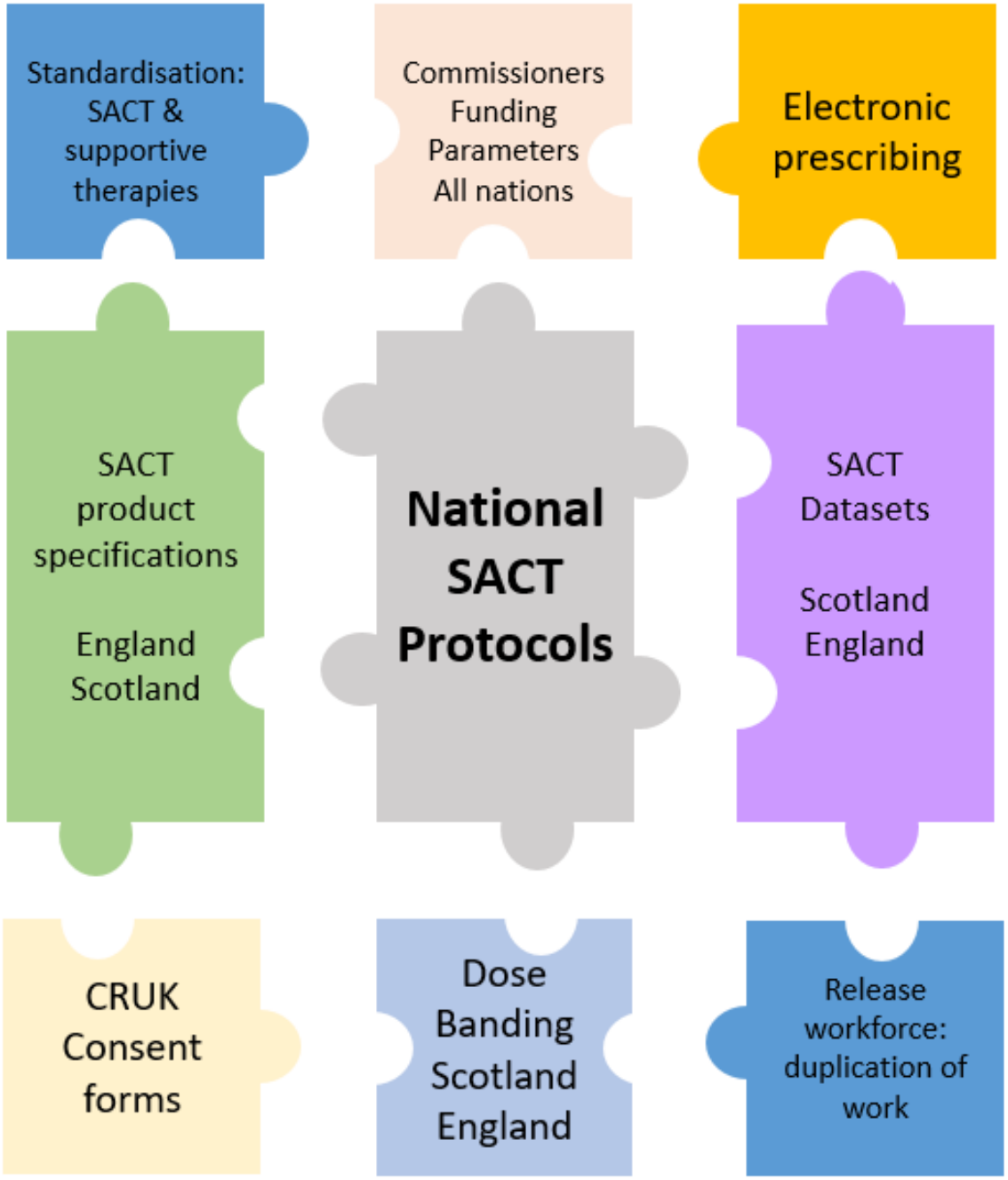
3.4.1.6. Potential partnerships

Across the UK, there are several cases where potential partnerships are looking to be formed to reduce SACT protocols duplication within small regions. This is currently occurring in Wales, Scotland, and the Surrey and Sussex areas. A national solution will save this duplication of time.

3.4.1.7. Integrated Care Systems (ICS)

Support ICS to provide evidence-based medicine information on SACT services. SACT services may be one of the specialised services which are devolved to ICS's. As new/smaller groups, these ICS's will need robust, evidence driven protocols to help with commissioning decisions. National SACT protocols could bring clarity on what is commissioned and enhance patient safety. There is also the potential for reduced/maintained CNST contributions and reduced risk of litigation (from patient harm / unwarranted variation in access to treatments.

Diagram 3: The UK SACT puzzle



4. BENEFITS

The benefits of UK wide SACT approved protocols broadly fall into the following categories:

1. Improved efficiency
2. Increase safety
3. Standardisation
4. Improved clarity
5. Reduce access delays
6. International equivalence
7. Planning for the future of SACT

4.1. Improved efficiency

4.1.1. Improve efficiency of the NHS by reducing duplication of work by consultants, pharmacists and nurses.

4.1.2. As demand in cancer treatments increases, the pressure on the workforce increases. To allow consultants, senior pharmacists and senior nurses to utilise their time in other ways, other than the duplication of work supports the workforce longer term.

4.2. Increase safety

4.2.1. Increase patient safety by the production of high quality protocols using evidence-based medicine for use by a variety of health care professionals (HCPs) involved in the treatment of cancer. With standardisation of naming, this will also improve patient safety when staff move between organisations.

4.3. Standardisation

4.3.1. Standardise the naming of the SACT protocol across the UK. Important to align with consent forms, product standardisation and data collection.

4.3.2. By improving data quality, provide more accurate toxicity and outcome data for each protocol to guide optimisation of practice.

4.3.3. Reduce variation between organisations on how patients are treated and managed.

4.3.4. Standardise SACT treatment across the country in line with other standardisation projects and programmes.

4.3.5. Support, complement and strengthen various streams of ongoing work regarding standardisation and SACT treatment. See 4.4.

4.3.6. Potential to standardise the use of supportive therapies in line with evidence-based medicine with the potential of consensus meetings to align the country and obtain ‘buy in’ with the programme. e.g cisplatin hydration, antiemetics, antifungals, PCP prophylaxis etc

4.3.7. Potential to drive patient safety by ensure that pre-prescribing tests are ordered and potentially results received (link to eP) before treatment is commenced. E.g. Hepatitis B testing to prevent reactivation of inactive hepatitis B infection, DPYD deficiency before treatment with fluoropyrimidines.

4.4. Improve clarity

4.4.1. Standardisation would help to improve the accuracy of reporting of SACT usage and outcome data at a national level by resolving the variance in current practices in naming. This will also help staff when moving between organisations and improve patient safety. The wide range of names used within the UK for the same regimen currently weakens data analysis and is labour intensive.

4.4.2. Improve clarity of treatment criteria on commissioned agents within each of the devolved nations. This can be included on pdfs produced and also available on the website at the point of accessing SACT protocol data.

4.4.3. Improve the clarity of administration directions of each SACT within a protocol. Some organisations do not include nurse involvement and this inclusion for national SACT protocols will ensure that the protocol can be given safely by an appropriately trained nurse with current expertise and all relevant information to hand.

4.5. Potentially reduce access delays if present

4.5.1. Potential to help comply with home county policy timelines for implementation as SACT protocols will be done at point of license and therefore in advance of approvals ready for healthcare teams to prepare the service at the point of funding.

4.6. International equivalence

4.6.1. Internationally there are national SACT protocols available in at least Australia, USA and Ireland. Having UK national SACT protocols will bring us in line with our international counterparts.

4.7. Planning for the future of SACT

4.7.1. With a database of national SACT protocols and the structure in place to write, approve and launch on a website, this will be invaluable in years to come when the advent of advanced therapy medicinal products (ATMPs), gene therapy and as other such treatments become increasingly mainstream. The specialist knowledge used at the tertiary centres and large teaching hospitals can be used to help District General Hospitals (DGHs) and other organisations to safely introduce and administer treatment to patients – without the cost and time penalty that comes with mass duplication of work. Variations in practice would be minimised.

5. PROPOSAL

5.1.1. The UKCB have produced this document to showcase a **potential solution for the provision of national SACT protocols within the UK** called the **National SACT Protocol Programme**.

5.1.2. By having a National SACT protocol library resource we will have a structure in place to ensure clinical staff have access to high quality information to then be able to safely treat our patients. This is particularly important as health products continue to evolve, increase in complexity and become more personalised (with a likely increase in demand in number and complexity of protocols required).

6. THE END RESULT

6.1. Summary

6.1.1. The final objective is to have a free to access website containing the approved national SACT protocols. The website will be continually updated and expanded as new treatments are approved/licensed.

6.1.2. The website will primarily be a clinical information only website but the solution has taken into account the need to potentially include commissioning/ funding information and links to other relevant information sources.

6.2. <u>The SACT protocols will</u>:

6.2.1. be written within a set template (specific headings). They shall contain clinical information based on evidence-based medicine. The template will follow the 2020 BOPA guidelines: BOPA Guidance on the contents of a SACT protocol.

6.2.2. only be available on the website to the public/members following approval by a strict governance process (see diagram 5).

6.3. <u>The website will:</u>

6.3.1. have all the approved SACT protocols listed by disease site/ alphabetical. There will also be the ability to switch between the two options and search.

6.3.2. have the ability at the point of viewing the SACT protocol to filter for commissioning parameters from each of the devolved nations (if needed). Once a commissioning setting is saved it will automatically default to that commissioning choice or choices and be automatically shown when accessing the website. If the decision is made to have a medicines information only type resource, then this will not be required.

6.3.3. have the potential to link to commissioning documents or websites. E.g. Blueteq/ NICE/ SMC/ AWMG/ McMillian/ CRUK

6.3.4. aim to publish a new SACT protocol on the day of license within the UK.

6.3.5. have the ability to version control on the website and alert users to changes made. Include a track change similar to SPC website on text.

6.3.6. have the ability to mark a protocol as pending changes and state what changes are in process, such as commissioning, MHRA alert etc.

6.3.7. have the function for organisations to join as ‘member organisations’. This is available within the UK only, and free of additional charges.

As a ‘member organisation’ there would be the possibility to download (if required):

- PDFs of the protocols which would include commissioning information if relevant (selected in profile)

- PDFs of the protocols which would include wording tailored to the organisation showing governance approval process (editable per organisation) if required

- an ‘uploadable regimen template’ to ‘plug’ into electronic prescribing systems or direct access to input into the organisational electronic prescribing system ready for internal validation and approval before being available to prescribe.

Diagram 4: Potential example of a SACT protocol on a website (not logged in)

Note: this is an example only and is unlikely to reflect the exact final product.

7. THE SOLUTION

7.1. Summary

7.1.1. The website and SACT protocol build is a long term programme which will require capital investment as well as ongoing operational costs.

7.1.2. This section covers the overall solution and estimated outlined costs of staffing.

7.1.3. If this proposal is to be taken further, then a full cost breakdown and analysis must be carried out, including costs for website development, before monies are committed and the programme formed.

7.2. Website development

7.2.1. A full specification of the website would be required with the current UK electronic prescribing solutions suppliers as well as clinical input from consultants, pharmacists and nurses.

7.2.2. The formation of international API standards would be beneficial long term to open up a global market for future electronic prescribing solutions. Working with the current national SACT protocol teams across the globe to try and ensure that one international standard is used.

7.2.3. The ability to have an easy to use, monitor, update and manage 'Membership organisational' account would be essential.

7.3. Website hosting

7.3.1. There are currently three options:

7.3.1.1. To utilise the reputation of a well-known pharmacy advice service website such as the Specialist pharmacy service website (SPS https://www.sps.nhs.uk) or other pharmacy advice service, where product specifications are being hosted and where drug monographs are embedded.

7.3.1.2. To utilise an existing NHS Trust website, such as a tertiary cancer centre, however underlying structure of the website may be an obstacle.

7.3.1.3. An external website could be built which would be specific to the needs of the programme.

7.4. Programme Staff

7.4.1. The suggested team of staff required to carry out the programme consists of the following:

7.4.2. Paid by the National SACT Protocol Programme

Potentially hosted by a variety of tertiary centres/large teaching hospitals across the UK.

Suggested job roles to be confirmed as part of the next programme step.

7.4.2.1. Cancer Pharmacists Band 8a x 2 wte.
Suggested Job Roles: to write, update and monitor for potential changes of the SACT protocols. This could be split posts with clinical element (may help to retain staff long term and keep them up to date).

7.4.2.2. Project Officer Band 6 x 1 wte
Suggested Job Roles: meeting coordinator, minute taker, reminder, consortium organiser. To co-ordinate the approvals of the SACT protocols through the governance process (to be agreed as next project steps).

7.4.2.3. Programme manager Band 8c x 0.5 wte
Suggested Job Roles: Overall to work with all parties to ensure solution is fit for use and ensure the National SACT Protocol Programme runs effectively and smoothly. Leading, managing developing and coordinating the programme across four nations with significant numbers of stakeholders. Significant experience of the management of complex clinical projects and digital requirements.

Table 4: Estimated costs of staff per annum for the National SACT Protocol programme

Staff	Band	Hours	Cost per annum*
Cancer Pharmacist	8a	1 wte	£63,862.80
Cancer Pharmacist	8a	1 wte	£63,862.80
Project Officer	6	1 wte	£46,832.40
Programme manager	8c	0.5 wte	£45,524.40
		Total	**£220,082****

* top of agenda for change band + 20% on costs see appendix 3
** costs in London will be higher

7.4.3. Part of current clinical job role
At no additional cost to the National SACT Protocol programme

7.4.3.1. National Steering Group. Formed from: representatives from each consortium, clinical representation from all devolved nations, person responsible for funding from all devolved nations, links from other national projects and programmes, UKCB and others. Further criteria and ToR to be established as part of next programme step.

7.4.3.2. Commissioning/funding criteria support from each devolved nation to ensure each SACT protocol has the relevant up to date information for commissioning parameters, if any. This this may be cancer pharmacists embedded/employed within commissioning organisations. Further criteria to be established as part of next programme step.

7.4.3.3. Consortiums of healthcare professionals – based on the format of Consortium of Consultants already in place by the regimen specific consent forms project (potential to utilise the existing consortium in place could be explored, although this would likely require expansion):

7.4.3.3.1. Consortium of senior cancer site specific band 8 pharmacists. Ideally made from tertiary centres and large teaching hospitals where job role is specific to tumour site. To ensure the SACT protocol will cover real life situations in clinical practice. Further criteria to be established as part of next programme step with British Oncology Pharmacy Association (BOPA).

7.4.3.3.2. Consortium of senior SACT nurses to check administration details, time in chair and usability of the SACT protocol at the point of administration. Further criteria to be established as part of next programme step with UK Oncology Nursing Society (UKONS).

7.4.3.3.3. Consortium of Consultant support for each tumour site to final check the SACT protocol. Exploration of current model to be utilised as part of next programme step.

7.4.3.4. Legal support to be sourced from host Trust(s) regarding:

- Disclaimers on website
- Disclaimers printed documents / pdfs
- Intellectual property rights
- Errors on published SACT protocols and potential subsequent consequences

Further criteria to be established as part of next programme step

7.5. Governance – Suggested protocol approval process

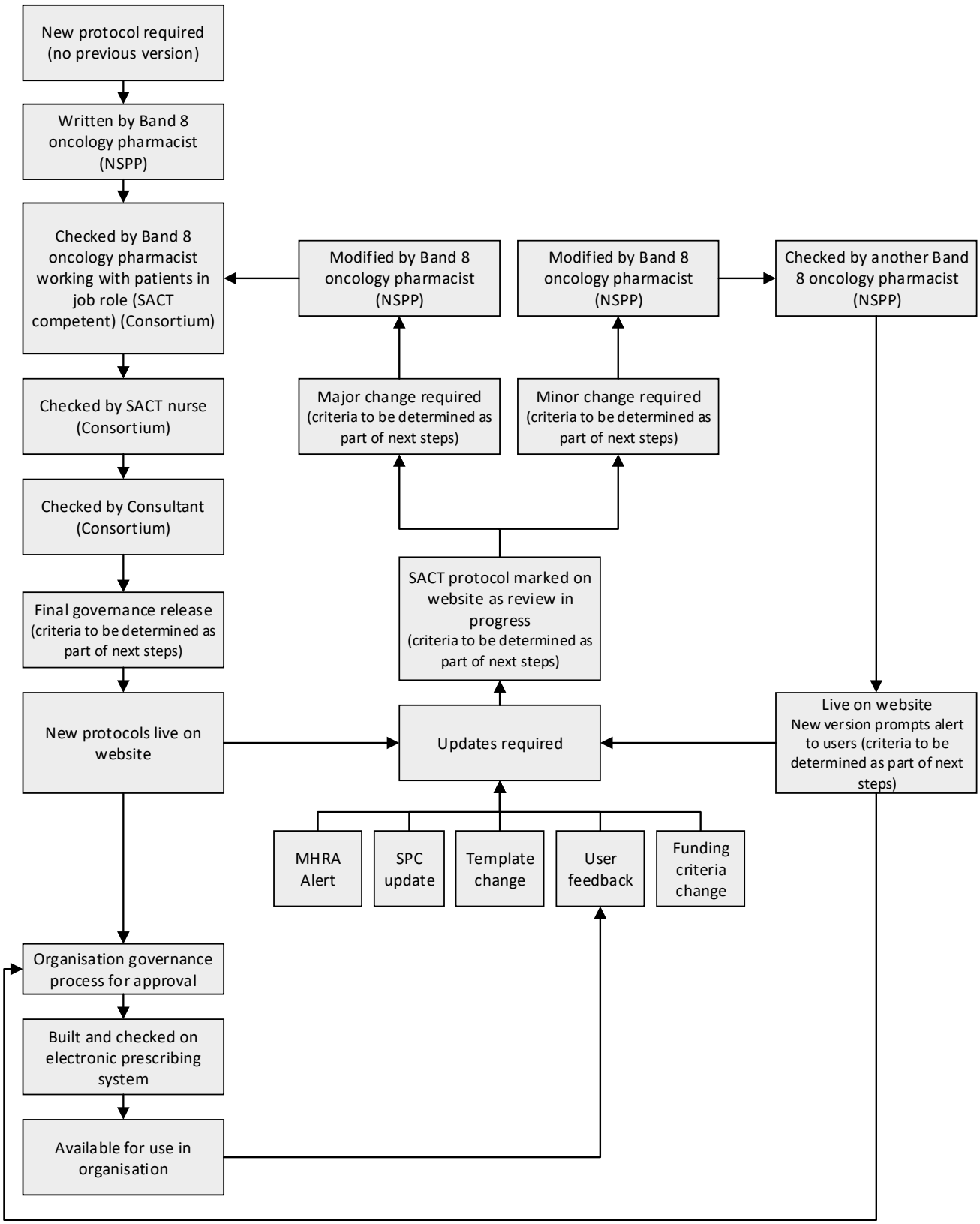
7.5.1. The SACT protocol will require a template. This will be based on the BOPA guidelines with MDT feedback. Template to be established as part of next programme step.

7.5.2. The SACT protocols are to be written by a band 8 pharmacist, checked by a band 8 pharmacist working with patients within their job role (SACT competent), checked by a SACT nurse and checked by a consultant. There will be a final governance release that checks of all stages have been carried out to the relevant standard required. Further details of this stage to be established as part of next programme step. See diagram 5 for example protocol approval process.

7.5.3. Final governance approval at each organisation.

7.5.4. Prior to protocols being written, it will be necessary to standardise the use of supportive therapies. This would be in line with evidence-based medicine with the potential of consensus meetings to align the country and obtain ‘buy in’ with the programme . E.g cisplatin hydration, antiemetic use. Criteria of what is required to be included at this stage to be established as part of next programme step e.g. classes of drugs referred to – not specific names.

Diagram 5: Example protocol approval process



7.6. Governance – Protocol list

7.6.1. To start with newly licensed SACT agents.

7.6.2. Then work back to include what has been licensed within the last 5 years.

7.6.3. After this to include established gold standard SACT protocols (including unlicensed clearly commissioned SACT protocols).

7.6.4. Criteria of what protocols to be included to be established as part of next programme step.

7.7. Governance – Protocol expiry and version control

7.7.1. Each SACT protocols to have no set expiry date. However, to be updated according to SPC changes, template changes, MHRA advice etc. Criteria at this stage (and if scheduled reviews are necessary) to be established as part of next programme step.

7.7.2. Version control on the website will require the ability to 'alert' though email or otherwise any user that has 'subscribed' to a protocol if there is a change or an update required (e.g. in the case of commissioning changes, MHRA alert etc.). Criteria to be established as part of next programme step.

7.7.3. A clear document history will be recorded so all changes are clear at each different version. The website will therefore have the ability to track changes to versions on text similar to SPC changes with a summary produced.

7.7.4. The SOP for processes to contain how updated versions are approved (what requires a full approval process and a modified process for example in commissioning changes). Criteria of what is required to be included at this stage to be established as part of next programme step.

8. POTENTIAL COSTs

8.1. Staffing

8.1.1. The current costs for staffing across the UK is £1,142,624 to £1,817,325. However, in the formation of this programme this money will not be released. Instead, it will improve patient safety and free up existing staff time to carry out other duties such as improve capacity, direct patient care and education of staff.

8.1.2. The cost of staffing for the programme would be £220,082 a year.

8.2. Website

8.2.1. The costs above do not include the costs for the website hosting, software development, technical oversight and ongoing support. Whether this is part of the SPS/pharmacy service site/Trust or a new website. The costs of these options are significant and need to be fully scoped out as part of the next steps. This could be in the region of £120-170K depending on the options chosen.

8.2.2. Subsequent costs for a Website developer to maintain the website at 1 wte band 7 is estimates at £55K a year (Based on estimated salary from an independent website solution company).

ESTIMATED: Capital Costs:
Website costs: **£120-170K**

ESTIMATED: Operation Costs
Staffing costs: **£220k per year**
Website costs: **£55k per year**

9. CHALLENGES

9.1. Four nations

9.1.1. Working across all four nations with different healthcare systems will need to be actively managed. Further scoping at this stage to be established as part of next programme step.

9.2. Legal

9.2.1. The potential legal ramifications of the website must be mitigated and therefore legal advice must be sought in the event of an incident where the SACT protocol was used incorrectly or an error was on the document.

9.2.2. Legal advice from all nations will be required on the programme. Criteria of what is required to be included at this stage to be established as part of next programme step. Discussions with UKMI may be warranted to help inform decisions.

9.3. Uptake within UK by organisations

9.3.1. It would be beneficial to state in NHS contracts (England/Wales/NI) and national SACT standards (Scotland) that the National SACT protocols are to be used where available.

9.3.2. Approach NHS resolution around reducing risk by using national standardised up to date protocols. This may help with Clinical Negligence Scheme for Trusts (CNST) costs.

9.4. Commissioning / Funding across the Nations

9.4.1. Within the UK, the four devolved nations have different commissioning / funding /payment of SACT services. If it is decided to include this information in the website (rather than develops a medicine information website), then this is summarised below in table 5 together with the potential solution for supporting the funding updates.

Table 5: Summary of devolved nations funding of SACT services and how they can support the website updates

Nation	Commissioning / Funding	Support of funding criteria updates
England	NHSE specialist commissioning for all SACT services. Can link to Blueteq form where needed.	Lead cancer pharmacist in position. Commissioning pharmacists across England with potential to input commissioning parameters.
Wales	No overall commissioning body – seven individual health boards.	Dedicated resource and agreement on where hosted. To be determined.
Scotland	Thirteen NHS Boards. Three cancer networks.	Dedicated resource and agreement on where hosted. To be determined.
Northern Ireland	Health and Social Care board (HSCB) commissions specialist services including Oncology & Haematology.	The Regional Cancer Pharmacy team have the potential to input into website/SACT protocols the relevant commissioning parameters

9.5. Electronic prescribing link to National SACT protocols

9.5.1. To work with multiple suppliers to ensure the ability to download an 'uploadable regimen template' to 'plug' into electronic prescribing systems or direct access to input into the organisational electronic prescribing system ready for internal validation and approval before being available to prescribe.

9.5.2. This will require input from the outset of the website and will need to inform part for the website specifications.

9.5.3. List of ePMA/eP solutions in the UK:

Beacon / EPIC
Cerner
Chemocare
IQemo
Meditech
Mosaiq
Varian/Aria
WellSky

9.6. Continuity of Programme

9.6.1. There will need to be some provision in place to ensure that the programme team can adequately cover annual leave and sickness etc.

9.6.2. There will need to be consideration of website functions such as continuity, uptimes, and ability to send to nhs.net emails as well as navigate firewalls.

9.7. Funding for the National SACT Protocol Programme

9.7.1. The funding of the programme for capital and ongoing costs could be through the NHS. Further details are unknown at this time and criteria of how this is possible to be established as part of next programme step.

9.7.2. The initial set up of the website and development could potentially be supported by a consortium with the ABPI and NHS.

9.8. Risks of the programme

9.8.1. As stated above there are several risk to the programme including working across the four nations, legal issues, uptake of the work and funding.

9.8.2. To reduce the long term risk, it may be beneficial to undertake a 3-year initial 'test of change' programme with a view to a substantive business case.

10. IDENTIFICATION OF OPTIONS

10.1. Short-listing of options

The list of options can be analysed as follows in order to identify those options suitable for more detailed appraisal:

Option		Rationale	Short-list?
1	Do nothing	The NHS is wasting approx. 500K per year on duplication of work. To do nothing will continue this waste.	N
2a	Programme staff hosted by NHS trust Website hosted by NHS trust website	Potential for tertiary/large teaching NHS trusts to host the national SACT protocol programme staff. Website displayed and hosted on a NHS website.	Y
2b	Programme staff hosted by NHS trust Website hosted by SPS or other pharmacy advice service	Potential for tertiary/large teaching NHS trusts to host the national SACT protocol programme staff. Website displayed and hosted on the SPS or other pharmacy advice service website.	Y
2c	Programme staff hosted by NHS trust Website hosted externally to NHS	Potential for tertiary/large teaching NHS trusts to host the national SACT protocol programme staff. Website displayed and hosted an external website built specifically for the purpose.	Y

11. OPTIONS APPRAISAL

11.1. Option 1: Do nothing

Area	Advantages	Disadvantages
Efficiency	-	No improvement in efficiency. Continue to duplicate work at cost. Limited workforce inefficient. Limited workforce not being used to best advantage.
Standardisation	-	Carry on with variation across UK Issues around naming of protocols and data collections No tie in with other national projects.
Clarity	No change needed to existing processes and protocol naming at each organisation	Possible issues with clarity around naming of protocols, data collection, administration directions and therefore patient safety.
Access delays	-	Potential access delays continue
International equivalence	-	Not delivering a first world cancer service to patients
Planning for the future of SACT	-	No structure in place for future
Legal	No legal changes needed	Potential issues with access delays, lack of clarity or standardisation from other organisations and areas.
Funding for National SACT Protocol programme staff and website	No external funding needed. No need to work jointly with other commissioners in devolved nations	Cost duplication loss continues of approx. £450K per year
Other	No changes so no work needed short term	

11.2. Option 2a/2b/2c: Programme staff hosted by NHS trust

Area	Advantages	Disadvantages
Efficiency	Improvement in efficiency. Allow limited workforce to carry out other duties such as patient care/capacity/education.	-
Standardisation	Improve standard of SACT protocols and standardise how treatment is given UK Improve patient safety Improve data collection by standardisation of naming protocols. Work with other projects in UK around SACT treatments.	-
Clarity	Improved clarity of naming of protocols, data collection, administration directions and therefore patient safety.	Change required at organisational level in potential changing names of protocols.
Access delays	Access delays due to writing and approval of protocols mitigated.	-
International equivalence	Will be seen to be leading in SACT clinical practice. Part of a first world cancer service to patients.	-
Planning for the future of SACT	Structure in place for future treatments. Improved patient safety as using experience in clinical trials to help write and check protocols for DGHs etc.	-
Legal	Could utilise trust legal team	Legal advice needed.
Funding for National SACT Protocol programme staff and website	Potential cost savings of 450K a year.	Funding required. Need to work jointly with other commissioners in devolved nations for a solution.
Other	Could utilise trust HR/OD processes and polices. Could support rotation of pharmacists and nurses into clinical/protocol teams Support succession planning for junior staff Easier link into clinical trials teams	Need to ensure uptake by placing in contracts.

11.3. Option 2a: Website hosted by NHS trust website

Area	Advantages	Disadvantages
Legal	-	Legal advice needed and may be complex if hosted by one NHS trust. Who 'owns' the data.
Use within UK	-	Potential issue with access or fitting in with existing website structure.
Funding for website	Part of NHS so may limit some costs	-
Other	-	May not have the ability to download an 'uploadable regimen template' to 'plug' into electronic prescribing systems

11.4. Option 2b: Website hosted by SPS or other pharmacy advice service

Area	Advantages	Disadvantages
Legal	-	Legal advice needed and may be complex if hosted by SPS or other pharmacy advice service. Who 'owns' the data.
Use within UK	Use an already established website with good reputation and drug monographs embedded already. Use the same website where product standardisation will be hosted.	Potential issue with access or fitting in with existing website structure.
Funding for website	Part of NHS so may limit some costs	
Other	-	May not have the ability to download an 'uploadable regimen template' to 'plug' into electronic prescribing systems

11.5. Option 2c: Website hosted externally to NHS

Area	Advantages	Disadvantages
Legal	-	Legal advice needed and may be complex if hosted outside of NHS.
Use within UK	No issues with a predetermined website structure. No restrictions will what the website could do.	May have issues with uptake if use an external website with no previous history.
Funding for website	-	Need to source an external website company. Likely to be very expensive.
Other	Will have the ability to download an 'uploadable regimen template' to 'plug' into electronic prescribing systems	

12. NEXT STEPS

12.1.1. Agree from all stakeholders across all four nations to pursue the programme.

12.1.2. Agree the chosen option with or without a 3-year initial 'test of change' programme.

12.1.3. Set up the National Steering Group to take this forward

12.1.4. Develop a business case to secure funding.

13. GLOSSARY OF TERMS

ATMP	Advanced therapy medicinal products i.e. CART-T therapy etc.
BOPA	British Oncology Pharmacy Association
Cancer Pharmacist	A pharmacist who has undergone appropriate training within cancer care
Off label	A medicine that is being used for a specific treatment that is outside of its stated product licence within the UK
Protocol	Document containing all relevant information for the safe prescribing and administration of a regimen
Regimen	A researched named combination of medicines for a specific Cancer
SACT	Systemic Anti-Cancer Therapy. To include all therapies that can be used to treat cancer. i.e. chemotherapy, monoclonal antibodies, TKIs, ATMPs, oral cancer treatments etc.
SOP	Standing Operating Procedure
Unlicensed	A medicine not licensed within the UK

14. REFERENCES

- Cancer Institute NSW. eviQ Cancer Treatments Online Program Governance. Version 1.0 December 2018
- NHS. The NHS Long Term Plan. January 2019. https://www.longtermplan.nhs.uk/wp-content/uploads/2019/08/nhs-long-term-plan-version-1.2.pdf
- 2020 BOPA guidelines: BOPA Guidance on the contents of a SACT protocol. Version 1.0. https://www.bopa.org.uk/resources/bopa-guidance-on-contents-of-sact-protocol/

15. APPENDIX 1: UKCB Working Group Members

Netty	Cracknell	Lead Cancer Pharmacist, Ramsay HealthCare. Representing UK Chemotherapy Board and BOPA
Richard	Allen	Medical Affairs Partner, Roche, Representing BOPA
Catherine	Bale	Consultant Medical Oncologist & SACT Lead, Wales Cancer Network
Sophie	Barrett	Consultant Medical Oncologist & SACT Lead, NHS Greater Glasgow & Clyde
Jenny	Breslin	Deputy Pharmacy Production Manager
Adam	Dangoor	Consultant Medical Oncologist, England
Robert	Duncombe	Chief Pharmacist, The Royal Marsden Hospital
Fionnuala	Green	Regional Lead Cancer Services Pharmacist, Northern Ireland
Matthew	Greening	Deputy Head of Technical Services and Lead PN pharmacist
Sophie	Harding	Advanced Oncology Pharmacist, Velindre Cancer Centre
Janine	Mansi	Consultant Medical Oncologist Guy's and St Thomas' NHS Trust
Maire	McGrady	Regional Lead Cancer Services Pharmacist, Northern Ireland
Calum	Polwart	Specialist Clinical Pharmacist, England
Rosie	Roberts	Chemotherapy Specialist Nurse & Acute Oncology Project Manager, Wales
Sally	Seymour	Deputy Chief Pharmacist Cancer, Aseptic and Research Services, Royal Surrey NHS Foundation Trust, England
Nisha	Shaunak	Lead Pharmacist for Oncology, Guy's and St Thomas' & Specialised Cancer Commissioning Pharmacist

16. APPENDIX 2: Stakeholders who have been consulted in advance of publication of this document

Andrew	Davies	Director of Hospital Pharmacy, Pharmacy & Medicines Optimisation team – Improvement Directorate
Mary	Maclean	National Clinical Lead - Cancer Medicines, Healthcare Improvement Scotland
Tim	Root	Assistant Head (Medicines Assurance), NHS Specialist Pharmacy Service
Colette	Scrace	Programme of Care Manager- Cancer programmes, Specialised Commissioning, NHS England and Improvement
Steve	Williamson	NHS England Lead Cancer Pharmacist

17. APPENDIX 3: AGENDA FOR CHANGE PAY BANDS

Agenda for change top of band rates 2021/2022 used in calculations
https://www.nhsbands.co.uk/

Band	Annual rate top of band	Hourly rate top of band	Annual rate top of band + 20% add on costs	Hourly rate top of band + 20% add on costs
4	£24,882	£12.73	£29,858.40	£15.28
5	£31,534	£16.13	£37,840.80	£19.36
6	£39,027	£19.96	£46,832.40	£23.95
7	£45,839	£23.45	£55,006.80	£28.14
8a	£53,219	£27.23	£63,862.80	£32.68
8b	£63,861	£32.67	£76,633.20	£39.20
8c	£75,874	£38.91	£91,048.80	£46.69
Consultant	£114,003	£58.46	£136,803.60	£70.16