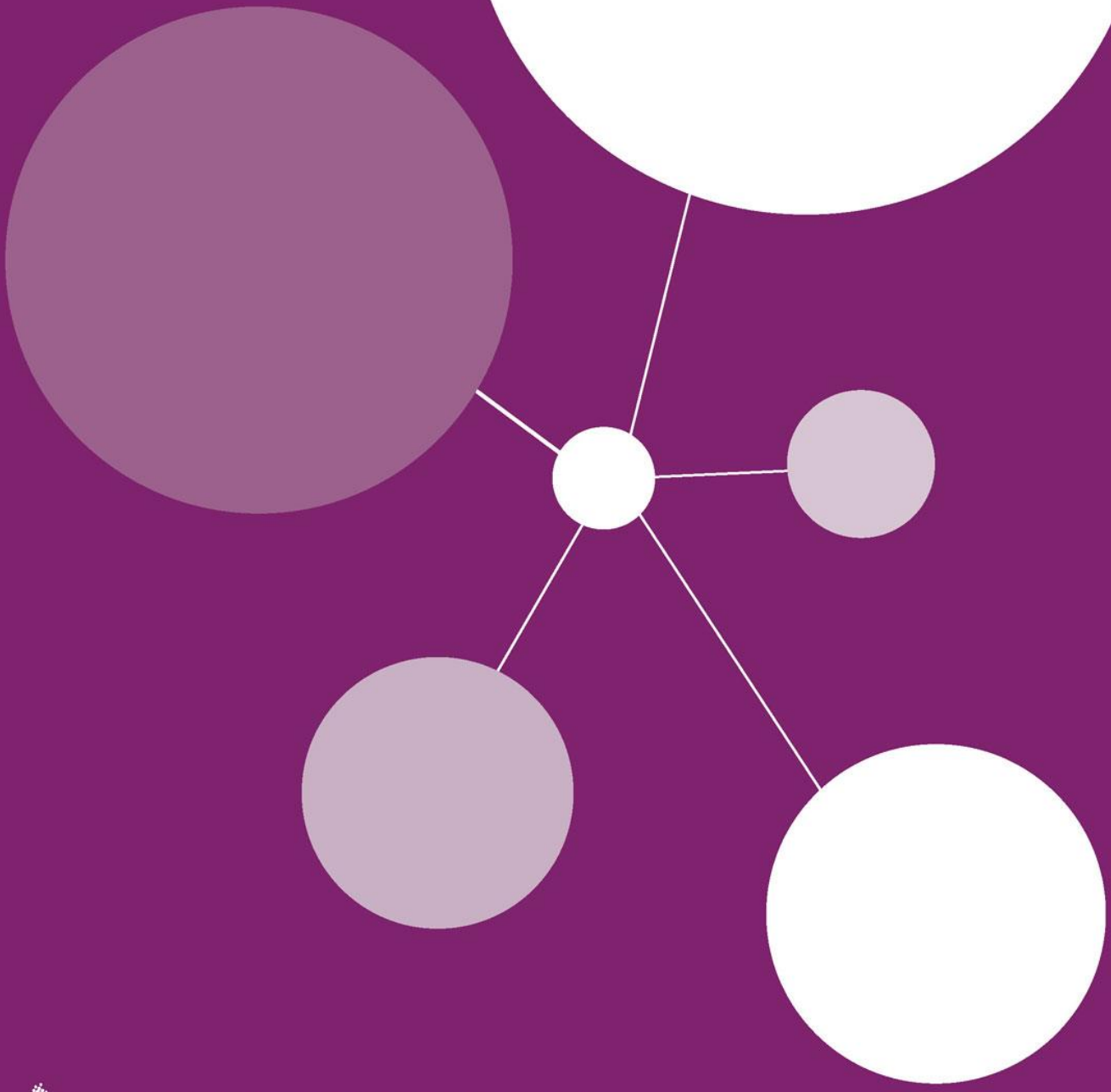
NCRI
National
Cancer
Research
Institute

NCRI Skin Cancer Clinical Studies Group

Annual Report 2017-18



Partners in cancer research

NCRI Skin Cancer CSG
Annual Report 2017-18

1. Top 3 achievements in the reporting year

Achievement 1

Oral Presentation of the AVAST-M final analysis at ASCO 2017

Dr Pippa Corrie presented the final overall survival data of the AVAST-M study of adjuvant bevacizumab in resected high melanoma in an oral presentation at American Society of Clinical Oncology (ASCO) annual meeting. This was the flagship UK adjuvant trial led by the CSG and though negative was rewarded with an oral presentation. It included important data from the translational studies (the PROM programme led by Professor Mark Middleton) showing the first evidence that ctDNA may have useful prognostic value in this setting.

Achievement 2

Increase non-melanoma skin cancer portfolio

Support is secured from the UKDCTN (UK Dermatological Clinical Trials Network) for pre-trial feasibility studies with clinicians and patients to support the SCC-ASRT trial proposal. Following feedback on the COMMISSAR proposal (which addressed both surgical and radiotherapy questions for primary cSCC) we have shaped a proposal with a narrower focus led by Dr Agata Rembielak: High risk primary cutaneous Squamous Cell Carcinoma in head and neck region treated by adequate surgical excision with or without Adjuvant Radiation Therapy (SCC-ART).

Achievement 3

Increased collaboration with other National Cancer Research Institute (NCRI) groups

The Melatools programme, led by Dr Fiona Walter (with involvement from Primary Care CSG and the SPED Advisory Group) working on GP and patient interventions to promote the early diagnosis of melanoma has evaluated:

- Primary care patients at higher risk of melanoma using a smartphone app for skin-self-examination to prompt timely presentation with suspicious lesions in a feasibility RCT (report in preparation)

- GPs using an electronic clinical decision aid based on the National Institute for Health and Care Excellence (NICE)-recommended 7-point checklist, and assessment using routine collected data at national level (report in preparation)

We will build on this within the CSG to extend this work.

A trial proposal to evaluate the treatment of immunotherapy toxicity, an increasing area of medical need has been developed. An outline bid has been submitted to the National Insititute for Health Research (NIHR) Health Technology Assessment (HTA) for the Giraffe Trial, a trial of Gastrointestinal Immune-Related Side Effects in Patients with Cancer. The proposal (led by Dr Neil Steven) was discussed at the NCRI and NIHR Research in Acute Oncology and Cancer of Unknown Primary Workshop.

2. Structure of the Group

Dr Pippa Corrie has competed 2 terms as Skin Cancer CSG Chair and has been succeeded by Professor Poulam Patel. Dr Catherine Harwood has stepped down as Chair of the Non-Melanoma Skin Cancer (NMSC) Subgroup Chair and Dr Neil Steven was appointed as Subgroup Chair in February 2018. We have 2 new surgeons, including a former a trainee member, as members of the Group. We have 2 active consumer representatives, Ms Patricia Fairbrother, leading on NMSC and Dr Ros Cook leading on melanoma.

3. CSG & Subgroup strategies

Main CSG

Secure two high recruiting multicentre clinical trials for metastatic BRAF wild type and BRAF mutant melanoma patients

DANTE, a large phase III trial evaluating the optimal duration of anti-pd-1 ab in advanced melanoma (Professor Sarah Danson – NIHR HTA November 2016). This trial will open in every network and most centres, helping to further build the melanoma trials network. If positive, will have significant patient benefit and also cost benefits to the NHS.

INTERIM, a phase II study of intermittent scheduling of BRAF pathway inhibitors in melanoma (Dr Pippa Corrie, Research for Patient Benefit (RfPB), NIHR August 2016) – Important study with significant translational element aimed at to optimising scheduling of dual BRAF/MEK pathway inhibition. Sample collection for translational research funded (Professor Mark Middleton - Cancer Research UK (CRUK): May 2017).

Both trials have opened this year and centres are being initiated. We must support and promote these trials and work with the CRN to ensure delivery.

2 academic melanoma trials have recruited below target - the SELPAC study in Uveal melanoma -target re-adjusted, and PERM - closed due to poor recruitment. The UK was recently initially not selected for a key international industry sponsored adjuvant trial, in part due to poor perceived UK set-up times and recruitment. We need to demonstrate efficient opening and recruitment in the melanoma network if we are to attract trials and trial funding, particularly important industry collaborations.

Portfolio development of non-melanoma skin cancer

Please see NMSC Subgroup strategic aims.

Portfolio Development: Continue to diversify the skin cancer portfolio beyond interventional systemic therapy trials

Melanoma early diagnosis:
The Melatools programme, led by Fiona Walter, and working on GP and patient interventions to promote the early diagnosis of melanoma has evaluated:

- Primary care patients at higher risk of melanoma using a smartphone app for skin-self-examination to prompt timely presentation with suspicious lesions in a feasibility RCT (report in preparation)
- GPs using an electronic clinical decision aid based on the NICE-recommended 7-point checklist, and assessment using routine collected data at national level (again, report in preparation)

We will build on this within the CSG to extend this work.

Surgical Trials:

A proposal for trial of surgical technique to reduce fluid collection following lymph node dissection is being worked on and will be discussed in further detail by the group. Discussions regarding a potential study are underway with a company who have developed a magnetic ferro particles for sentinel node detection.

Raise awareness and profile

The Skin Cancer CSG continues to raise awareness through engagement with the clinical community and with patients and the public. An important vehicle for this is Melanoma Focus which is the national multi-disciplinary society which has a large patient presence. This has 2 meetings a year: the annual national meeting and a regional meeting,

The CSG has a regular slot to raise awareness of the NCRI work and study portfolio. We are working with the Melanoma Focus team on developing an app/website to help patients locate appropriate clinical studies. The NCRI is also represented at the annual melanoma patient conference.

We will continue to present our work at National and International meetings as exemplified by the high profile oral presentation at ASCO 2017 (as mentioned above).

Strengthen UK wide and international working

The CSG continues to work with the Local Clinical Research Networks (LCRN) Skin Cancer Sub-Specialty Leads (SSLs).

We continue to liaise with international co-operative groups including the European Organisation for Research and Treatment of Cancer (EORTC) Melanoma group, the Australia New Zealand Melanoma Trials Group (ANZMTG) and Eastern Cooperative Oncology Group (ECOG) Melanoma group. We are part of the International Rare Cancers Initiative (IRCI) Uveal Melanoma Group.

The Skin Cancer CSG has participated in two recent NCRI workshops held in March 2018. In the Brain Metastases workshop, CSG members presented on and led a breakout session on melanoma brain metastases. These are recognised as being of critical importance to patients, both for the impact on prognosis and on sense of self.

Potential trials discussed included: (i) investigating surgical technique across all cancer types (ii) investigating formally the benefits and harms of stereotactic radiosurgery for multiple targets alongside systemic therapy (ii) the role and sequencing of brain intervention in people with high volume disease at presentation. In the NCRI and NIHR Research in Acute Oncology and Cancer of Unknown Primary Workshop a proposal was presented for A Trial of Gastrointestinal Immune-Related Side Effects in Patients with Cancer (The Giraffe Trial), subsequently submitted as an outline to the NIHR HTA call. This has also been submitted to the Lung Cancer CSG Annual Trials Meeting for discussion in June 2018 in the Dragon's Den session.

Optimise CSG structure and function

As mentioned above, there is a new CSG Chair and a new Subgroup Chair. We continue to maintain a broad range of specialties including surgeons, medical and clinical oncologist, dermatologists, GP, pathologist, statistician and Consumer representation

The CSG has one Subgroup: the Non-Melanoma Skin Cancer Subgroup

We will review this at the forthcoming strategy day and discuss if any task groups are required.

Non-Melanoma Skin Cancer Subgroup (Chair, Dr Neil Steven)

Support initiatives in providing an evidence base for treatment of the common keratinocyte skin cancers (SCC and BCC)

Over successive meetings, the strategy has emerged to focus resource on the settings with the poorest outcomes with current treatment: metastatic cSCC, high risk primary cSCC and MCC. Whereas immune therapy is now available as standard of care for people with advanced MCC, patients with metastatic cSCC are poorly served, with a lack of effective treatments or trials. A better understanding of the pathophysiology of cSCC might translate into new trials for this group. Nonetheless, we recognise that low risk primary BCC and cSCC represent a huge clinical workload and practice-changing trials in those diseases might have significant impact.

The UK-Keratinocyte Cancer Collaborative (UKKCC), led by Professor Irene Leigh is a new initiative in 2017 and includes three of the Subgroup members on its steering group. In an initial study, NHS datasets were linked to pathology data for a large cohort of patients with cSCC. A proposal is submitted to the British Association of Dermatologists (BAD) will extend this project to allow linkage with radiotherapy, surgical procedures, with and systemic therapy creating a 'virtual' tissue bank of cutaneous SCC. It will be important for the CSG to engage with the UKKCC to consider how a better pathological understanding of cSCC will translate into therapeutic hypotheses.

Support research for rarer non-melanoma skin cancers such as Merkel cell carcinoma and DFSP

- The Rational MCC trial led by Dr Steven enters the third and final year of the feasibility phase. This trial has successfully recruited from open centres to the observation component with MDT-led treatment decisions (Rational Review). However, it faces major challenges firstly in recruiting to the main trial (Rational Compare) randomising between radiotherapy and surgery as the first definitive treatment for primary MCC, and secondly in opening sufficient sites. The latter reflects significant organisational issues, with the treatment modalities being delivered in different hospitals in many specialist MDT. A rescue plan is in operation to address these issues site-by-site and to maximise the potential output for the Review study.
- Patients with MCC are poorly served in terms of advocacy and information provided by a specialist charity. The Neuroendocrine Tumour (NET) Patient Foundation approached the

NMSC Subgroup to look for collaboration. Members are developing a patient information sheet with the charity for widespread use and which also highlights the importance of clinical trial participation.

Fund a clinical trial in management of high risk primary SCC

Detailed feedback on the COMMISSAR proposal (which addressed both surgical and radiotherapy questions for primary cSCC) have shaped a proposal with a narrower focus led by Dr Rembielak. This is called High risk primary cutaneous Squamous Cell Carcinoma in head and neck region treated by adequate surgical excision with or without Adjuvant Radiation Therapy (i.e. SCC-ART). There has been clinician input from the Royal College of Radiologists Skin Cancer Study Day December 2017, extensive discussion in the CSG Subgroup and further development coordinated by the CRUK Clinical Trials Unit, and PPI input. Funding is secured from the UKDCTN for pre-trial feasibility studies with clinicians and patients to be completed in 2018. There is currently an outline for a pragmatic randomised phase II trial inclusive of MDT-driven practice in two key areas of controversy, i.e. the definition of "high risk" cSCC and the dose and schedule of radiotherapy. The data on clinical practice and outcomes, plus feasibility, would shape the eligibility and interventions in a subsequent randomised phase III trial.

Develop a trial for low risk BCC (CIRCLE)

Two proposals related to the management of BCC, one comparing radiotherapy of excision (ROSEBAC) and the other comparing topical treatment, curettage or local excision for low risk BCC (CIRCLE) are on hold to permit focus on the SCC-ART and pending an understanding of how the organisational challenges of comparing surgery with radiotherapy for a skin primary can be addressed in the Rational MCC trial.

4. Task groups/Working parties

The Skin Cancer CSG had no task groups or working parties during the reporting year.

5. Funding applications in last year

Table 2 Funding submissions in the reporting year

Cancer Research UK Clinical Research Committee (CRUK CRC)				
Study	**Application type**	**CI**	**Outcome**	**Level of CSG input**
May 2017				
Sample collection associated with the INTERIM trial of intermittent BRAF targeted therapy in advanced melanoma	Full application	Professor Mark Middleton	Supported	Developed & fully supported by CSG
November 2017				
DANTE-Trans: A sample collection associated with a randomised trial to evaluate the treatment duration of anti-PD1 antibody therapy in patients with metastatic melanoma	Sample Collection (Full Application)	Dr Pippa Corrie	Not Supported	Developed & fully supported by CSG
Other committees				
Study	**Committee & application type**	**CI**	**Outcome**	**Level of CSG input**
A Trial of Gastrointestinal Immune-Related Side Effects in Patients with Cancer (The Giraffe Trial)	HTA (outline)	Dr Neil Steven	Pending July 2018	Lead by Subgroup Chair with full CSG support

6. Consumer involvement

Patricia Fairbrother

I am the patient representative on the Skin Non-Melanoma Subgroup and am actively involved as a member of the main CSG. As a recurring skin cancer patient, I am interested in the research that this Group is involved in and therefore particularly keen to be kept up to date with current research applications.

I was recently appointed to the steering and executive committees of the UK Dermatology Clinical Trials Network which has widened my area of interest in dermatology and brings another dimension to my patient representation experience. The Skin NMSC Subgroup recently submitted an application for funding to the UKDCTN and I was at the meeting where the application was submitted and subsequently awarded funding.

I continue to be a patient representative member of the East Midlands Skin Clinical Advisory Group, which is vital in order to be kept up to date with current clinical practice. I also assist in the formatting of patient surveys especially non-melanoma.

Challenge: It is my ambition to see a non-melanoma patient support group formed nationwide. As well as support for one another, my aim would be for researchers to submit queries and questions to the group as and when the need arose. However, this ambition needs huge support from health professionals and is a daunting task for any one volunteer patient representative to manage and run such a group!

Priority: Continuous, robust dialogue between the health professionals on the CSG and the patient representatives in order that they are kept well informed regards research opportunities. Thus, giving strength and meaning to their place on the Group.

Ros Cook

I commented on a patient information sheet for BARCO, a dermatoscope study, and on the applications for DANTE Trans and Giraffe, a study on the GI side effects of immunotherapy. I participated in the NCRI Brain Metastases Workshop.

I reviewed cancer and other disease type charities' websites for their presentation of information for patients on open clinical trials and have reported on this. I participate in patient feedback sessions to develop the Melanoma UK/Vitaccess app.

By passing back information to my local melanoma support group, I encourage members' involvement in NCRI initiatives, such as the NCRI James Lind Alliance Priority Setting Partnership on Living with and Beyond Cancer.

For education, I attended the Focus on Melanoma Meeting and Melanoma Patient Conference and took Future Learn courses on Clinical Trials and Targeted Cancer Therapy although absence of funding limits possibilities. There was a teleconference with my mentor before the November CSG.

7. Priorities and challenges for the forthcoming year

Priority 1

Update research strategy

A strategy day is planned for later this year involving the CSG, LCRN subspecialty leads and key stakeholders. We will also work with the NCRI team working with the James Lind Alliance to have a wider perspective on research priorities.

Priority 2

Secure funding for the SCC_ART trial High risk primary cutaneous Squamous Cell Carcinoma in head and neck region treated by adequate surgical excision with or without Adjuvant Radiation Therapy (i.e. SCC-ART).

Priority 3

Develop the portfolio with screening /early diagnosis, psychological and surgical study proposals – at least 1 of each.

Challenge 1

Securing funding for academic multi-centre trials

We have recently had secured funding for 2 large trials- INTERIM and DANTE and funding for sample collection in INTERIM, but not DANTE-Trans. Other ways of exploiting DANTE for its enormous scientific value are being pursued. For example, Dr Trevor Lawley is leading a CRUK programme grant application (submitted 7 June 2018) to study the microbiome of patients receiving immunotherapy and patients recruited to DANTE will be a major source of samples and prospective outcome data.

We have not yet secured funding for a SCC/BCC study. We have reshaped our last proposal and sought significant other input to strengthen the study and plan to resubmit.

We have looked to other agencies HTA and RfPB and will continue to explore different funding routes.

Challenge 2

Recruitment into trials on the portfolio

We have recently had studies recruiting rarer patient groups struggle with recruitment, for a variety of reasons, this could potentially have an adverse knock on effect on our ability to attract funding and, in particular, attract important industry studies. As part of the Rational MCC study we are looking to quantify and address some of the issues. Also as part of the feasibility work for SCC-ART we may have better insight into the specific areas in skin cancer MDT working that can be improved to benefit clinical trials. The LCRN SSLs will be an important resource in identifying and addressing these issues.

We will liaise with the NIHR CRN and the CTUs to collect some specialty specific data on our set up and recruitment figures. The current data has not been interrogated to give specialty &

site-specific data, this will be important in challenging some of the continuing industry perceptions about trial set up and requirement in the UK.
Challenge 3 **Having a clear view of the research priorities form a wider stakeholder group** We do not have a clear view of the research priorities for a patient and public point of view. These strands are being looked at in various forums, but may not give enough granularity to be helpful for skin cancer. A clear list of priorities would help design the high priority trials and improve our ability to attract funding.

8. Appendices

Appendix 1 - Membership of main CSG and subgroups

Appendix 2 – CSG and Subgroup strategies
- A – Main CSG Strategy
- B – Non-Melanoma Skin Subgroup Strategy

Appendix 3 - Portfolio Maps

Appendix 4 – Top 5 publications in reporting year

Appendix 5 – Recruitment to the NIHR portfolio in the reporting year

Professor Poulam Patel (Skin Cancer CSG Chair)

Appendix 1

Membership of the Skin Cancer CSG

Name	Specialism	Location
Dr Mazhar Ajaz	Clinical Oncologist	Kent
Dr Agata Rembielak	Clinical Oncologist	Manchester
Dr Ros Cook	Consumer	Hertfordshire
Ms Patricia Fairbrother	Consumer	Derby
Mr Simon Rodwell	Consumer	Suffolk
Dr Catherine Harwood	Dermatologist	London
Dr Rubeta Matin	Dermatologist	Oxford
Professor Charlotte Proby	Dermatologist	Dundee
Dr Fiona Walter	General Practitioner	Cambridge
Professor Sarah Danson	Medical Oncologist	Sheffield
Dr Avinash Gupta*	Medical Oncologist	Manchester
Professor Poulam Patel (Chair)	Medical Oncologist	Nottingham
Dr Miranda Payne	Medical Oncologist	Oxford
Professor Christian Ottensmeier	Medical Oncologist	Southampton
Dr Paul Craig	Pathologist	Cheltenham
Dr Christina Yap	Statistician	Birmingham
Mr Marc Moncrieff	Surgeon	Norwich
Dr Suzanne Murphy*	Surgeon	Cambridge

* denotes trainee member

Membership of the Subgroups

Non-Melanoma Skin Cancer Subgroup		
Name	**Specialism**	**Location**
Dr Pat Lawton**	Clinical Oncologist	Nottingham
Dr Jenny Nobes	Clinical Oncologist	Norwich
Dr Agata Rembielak	Clinical Oncologist	Manchester
Ms Patricia Fairbrother	Consumer	Derby
Dr David Slater**	Dermapathologist	Sheffield
Dr Catherine Harwood	Dermatologist	Birmingham
Dr John Lear**	Dermatologist	Manchester
Dr Jack Mann	Dermatologist	Essex
Dr Jerry Marsden	Dermatologist	Birmingham
Dr Rubeta Matin	Dermatologist	Oxford
Dr Charlotte Proby	Dermatologist	Dundee
Dr Neil Steven (Chair)	Medical Oncologist	Birmingham
Dr Paul Craig**	Pathologist	Cheltenham
Professor Fiona Bath-Hextall**	Professor of Evidence Based Healthcare	Nottingham
Dr Christina Yap	Statistician	Birmingham
Mr Marc Moncrieff	Surgeon	Norwich
Dr Carrie Newlands**	Surgeon	Surrey

* denotes trainee member
**denotes non-core member

Appendix 2

CSG & Subgroup Strategies

A – Main CSG Strategy

Skin Cancer CSG Strategy: December 2015 – December 2018

This strategy timeline has been produced to define the Skin Cancer Research Strategy Plan and its implementation. It runs from December 2015 until December 2018, and will be reviewed and updated at each CSG meeting (ND supported by All)
The document is composed of the following:

Page 2 – 7: NCRI Skin Cancer CSG Strategy: plan of implementation, containing agreed strategic objectives (1-6), specific actions, CSG leads and proposed deadlines.

Page 8 – X: Overview and detailed breakdown of the entire strategy timeline

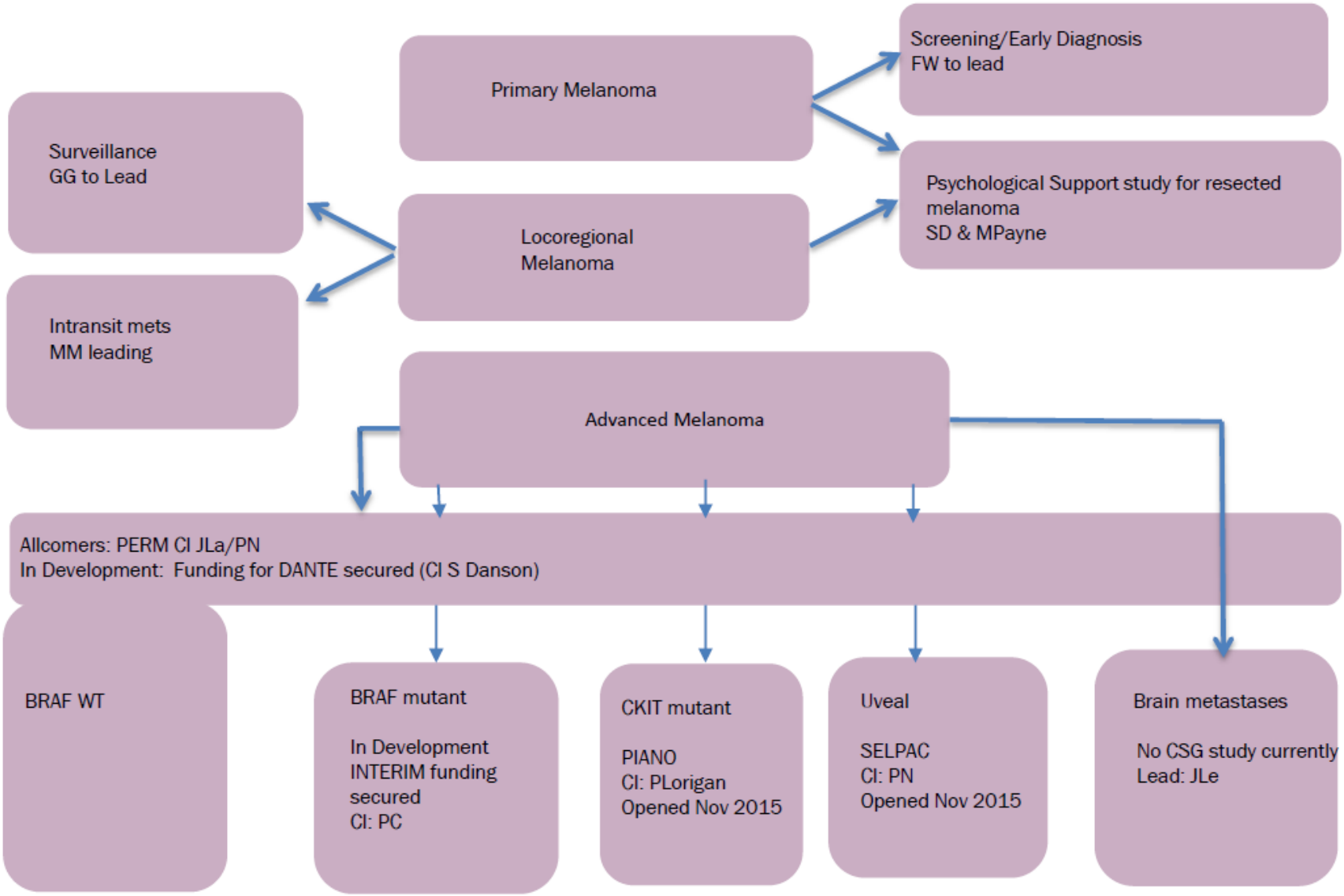
Skin Cancer CSG Members		Responsibility
PC	Pippa Corrie	CSG chair
CH	Catherine Harwood	Non-melanoma skin cancer subgroup chair
JLa	James Larkin	Melanoma - cutaneous
SD	Sarah Danson	Melanoma – rare
CP	Charlotte Proby	SPED representative
MM	Marc Moncrieff	Surgical studies
JLe	Jim Lester	Radiotherapy – melanoma
FW	Fiona Walter	Primary care
EB	Ewan Brown	Melanoma
GG	Girish Gupta	Dermatology
KW	Keith Wheatley	Statistics
SR	Simon Rodwell	PPI Lead - melanoma
PF	Patricia Fairbrother	PPI Lead – non-melanoma skin cancer
MA	Mazhar Ajaz	Radiotherapy
CO	Christian Ottensmeier	Translational research lead
AR	Agata Rembielak	Radiotherapy – non-melanoma
NS	Neil Steven	Non-melanoma - rare
ND	Nanita Dalal	PA
NK	Nicola Keat	NCRI Exec

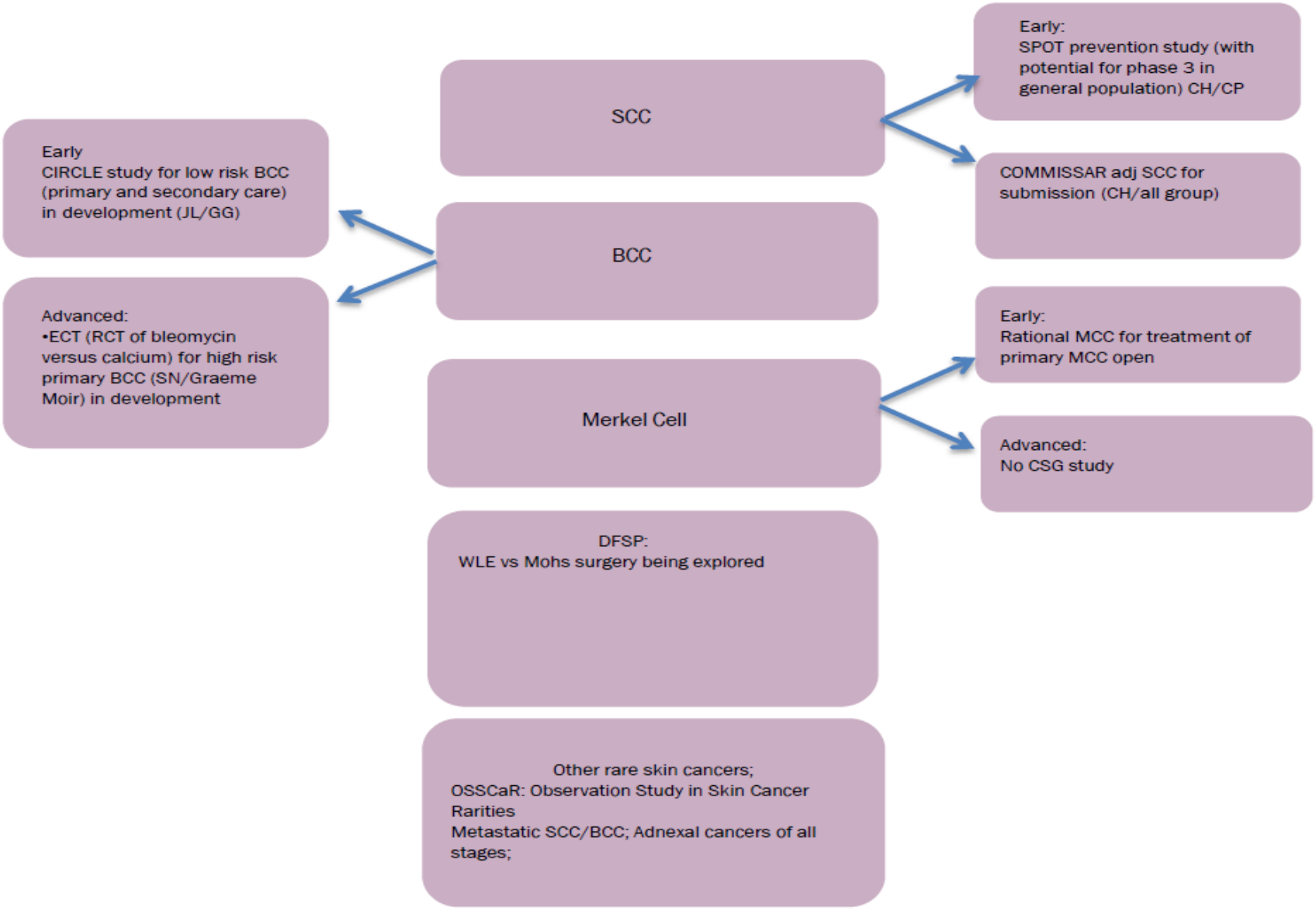
Strategic objective	Action	CSG Lead	Date	Outcomes
1a. Portfolio development (general)	Establish a set of priorities for the development and set up of studies that takes account of the NIHR portfolio, international agenda, available funding opportunities and clinical need	ALL	Document key priorities at Strategy Day 24 Nov15	Review Portfolio priorities 6-monthly at CSG meetings
1b. Portfolio development - melanoma	Ensure cohesive strategy of melanoma clinical trials, taking into account: - Opportunities within the international agenda, avoiding competition with key Pharma studies - The need for a high recruiting study studies - Balance between late and early phase studies - Multicentre studies with good regional coverage - All disease stages - All subgroups – rare forms & biomarker specific subgroups - Interaction with CRN subspecialty leads	ALL SD & PC leading on DANTE and INTERIM trials	Secure funding for 2 metastatic melanoma trials, DANTE and INTERIM in 2016	Funding for DANTE and INTERIM secured
1c. Portfolio development – non-melanoma skin cancer	Secure new studies for common and uncommon non-melanoma skin cancer •SCC •BCC •Merkel cell •Rarer non-melanoma skin cancers	CH/GG/CP/RM	Commissar funding application by May 2016; further development of CRICLE BCC study	Commissar funding application rejected; to revise and resubmit new study proposal; CIRCLE study to be submitted by end 2017
1d. Interaction with Cross Cutting groups	Identify leads within the CSG to link with the following cross cutting CSGs and advisory groups: •Primary Care •Screening, Prevention and Early Diagnosis (SPED) Advisory Group •TYA •CTRAD •CNS CSG	FW CP SD JLe JLe	Dec 2016	Proposal to work with other CSGs wrt immunotherapy toxicity management research opportunities – to take forward at May 2017 NCRI-NIHR meeting

Strategic objective	Action	CSG Lead	Date	Outcomes
1e. National Cancer Intelligence Network (NCIN)	Establish clear link with skin cancer Clinical Reference Group (CTYA SSCRG) Explore with NCIN the use of data to inform study design and take over long term follow-up	?? ?? and ALL	Report 6 monthly at CSG meeting	NCIN has restrutured, now NCRAS. Need to explore new ways of interacting
2. Key research priority areas	**Surgery:** Working group to take forward new study for localised disease **Early phase:** Increase the availability of NIHR adopted early phase studies for melanoma patients • Liaise with CIs and study sponsors to request NIHR adoption • Inform colleagues re opportunities re commercial early phase/ combinations alliance programmes • Increase no. of melanoma study outline proposals being submitted for funding/endorsement **Radiotherapy:** Establish new study for brain mets pts involving RT **Translational:** •Work with key clinical and scientific groups to develop a translational research strategy: link with potential GeCIP **Melanoma screening pilot study:** Working group to take new proposal forward	MM/PC Jla handing over to SD JLe Jla hading over to CO FW, CP, PC	May & Nov 2016 Ongoing Ongoing Early 2017 Ongoing	Outline proposal in advanced stage, to seek funding in 2017 JLe to work with CNS MDT to explore potential RT+/-SRS study Apply for INTERIM and DANTE sample collections FW to update on progress towards screening study May 2017
3a. Raising awareness and profile	Regular dissemination of study recruitment activity and outcomes through newsletters, annual meetings and Annual Report to all stakeholders Consider dedicated annual NCRI skin cancer trials meeting Communications about new studies with CRN subspecialty leads Submission of abstracts to : •NCRI Cancer Conference •International cancer conferences: ESMO/ECC/ASCO/AACR/SMR •NCIN Conference	PC/ND/SA All Annual NCRI-NIHR meeting ALL	Ongoing March 2016 May 2017 Ongoing	CSG trainee to be responsible for summarising CSG meetings to share with LCRH SSLs Current preference is to use the biannaul Melanoma Focus Meetings to share verbal clinical trials updates/portfolio trial summary booklet

Strategic objective	Action	CSG Lead	Date	Outcomes
3b. Ensuring successful delivery of studies through integration with NIHR CRN: Cancer	CSG members to commit to delivering studies developed by the CSG Interaction with LCRN Subspecialty Leads to determine placement of new studies and address barriers to actively recruiting patients Monitor recruitment to portfolio studies, esp those developed by the CSG to ensure delivery to time and target Contribute as far as possible to NIHR CRN: Cancer Speciality Objectives so they reflect what LCRNs need to deliver to ensure skin cancer patients can access the full portfolio of studies within England	ALL PC/ALL ALL ALL	Ongoing Ongoing Ongoing Ongoing	Recruit CSG-led studies to time and target Good regional placement of studies Meet NIHR CRN Speciality Objectives
3c. Maximise output from clinical trials	Establish working groups for new studies within 6 weeks of funding award to facilitate swift set up, including representation from CI, CRCTU, NIHR CRN: Cancer	CI/CTUs	Ongoing	
4. Strengthen UK wide and international working	Refine prioritisation process for international clinical trials to be submitted for funding to optimise the timing and success of applications Utilise IRCI for international studies of rare cancer types, where appropriate Work closely with UK representative on EORTC melanoma group steering committee Work closely with Melanoma Focus to integrate research and service	All ?? Invite representation at CSG meetings Invite representation at CSG meetings	Ongoing Ongoing May 2016 May 2016	Plorigan is EORTC link SRodwell continues currently as PPI and Melanoma Focus Lead

Strategic objective	Action	CSG Lead	Date	Outcomes
5. CSG structure and function	Establish Primary Melanoma Screening Working Party	FW	May 2016	Active
	Establish Secondary Melanoma Screening Working Party	GG	May 2016	Not taken forward
	Consider case for Translational Research Working Party	ALL	May 2016	Not taken forward
	Consider need for Working Party to develop brain mets strategy	JLe	May 2016	Not taken forward but needs prioritising
	Identify mentors for trainee registrars in the CSG	PC, MM	Nov 2016	
	Identify mentors for PPI members	PC & CH	Sept 2015	
6. Patient and Public Involvement and Impact	Ensure consumers are associated with the development of every new study at an early stage	All	Ongoing	CSG representative(s) invited to speak at the now annual Melanoma Patient Conference
	Consider developing research studies to address key questions of concern to PPI representatives and other consumers	SR/PF to bring new questions to the group	Ongoing	


Primary Melanoma
Screening/Early Diagnosis
FW to lead
Surveillance
GG to Lead
Locoregional
Melanoma
Psychological Support study for resected melanoma
SD & MPayne
Intransit mets
MM leading
Advanced Melanoma
Allcomers: PERM CI JLa/PN
In Development: Funding for DANTE secured (CI S Danson)
BRAF WT
BRAF mutant
In Development
INTERIM funding secured
CI: PC
CKIT mutant
PIANO
CI: PLorigan
Opened Nov 2015
Uveal
SELPAC
CI: PN
Opened Nov 2015
Brain metastases
No CSG study currently
Lead: JLe

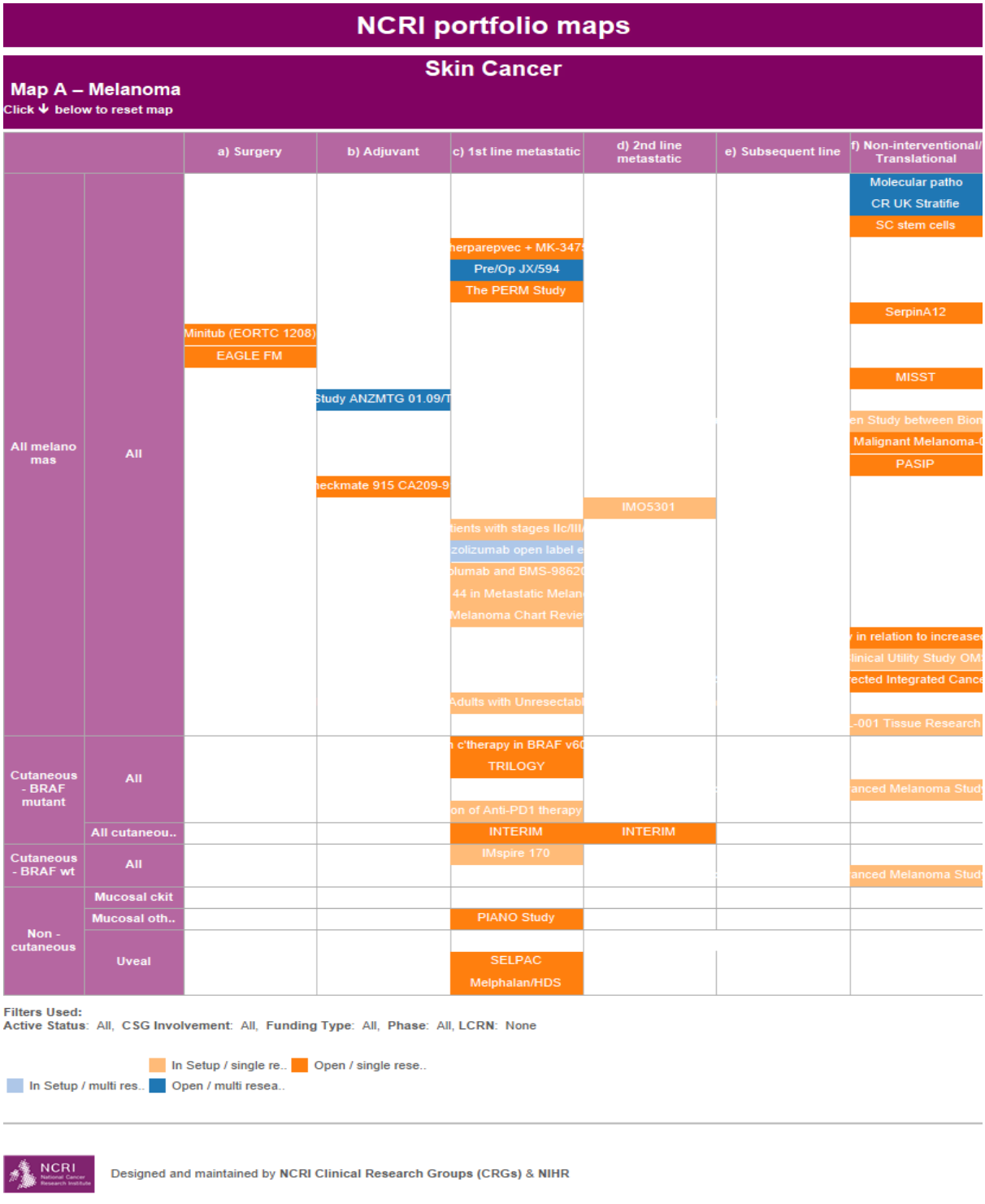

SCC
Early:
SPOT prevention study (with potential for phase 3 in general population) CH/CP
COMMISSAR adj SCC for submission (CH/all group)
BCC
Early
CIRCLE study for low risk BCC (primary and secondary care) in development (JL/GG)
Advanced:
•ECT (RCT of bleomycin versus calcium) for high risk primary BCC (SN/Graeme Moir) in development
Merkel Cell
Early:
Rational MCC for treatment of primary MCC open
Advanced:
No CSG study
DFSP:
WLE vs Mohs surgery being explored
Other rare skin cancers;
OSSCaR: Observation Study in Skin Cancer Rarities
Metastatic SCC/BCC; Adnexal cancers of all stages;

B – Non-Melanoma Skin Cancer Subgroup Strategy

This is incorporated into the main CSG strategy, see above.

Appendix 3

Portfolio maps



NCRI portfolio maps

Skin Cancer

Map B – Non-melanoma

Click ↓ below to reset map

		a) Pre-diagnosis	b) Neoadjuvant	c) Surgery	d) Adjuvant	e) Metastatic	f) Non-interventional/ other
All	All						Molecular patho CR UK Stratifie Head and neck skin malignancy SC stem cells Patient Reported Outcome Measure In Skin Cancer Reconstruction Study
Basal cell carcinoma	All						3D Reconstruction of Basal Cell Carcinomas (3DBCC)
Merkel cell	All				Rational MCC		
Other	All						4SC AG -Advanced Stage (Stage IIB-IVB) MF or SS NB-UVB phototherapy in relation to increased risks of skin cancers
Squamous cell carcinoma	All					Phase 2 Study of Pembrolizumab in Participants With R/M cSCC	

Filters Used:
Active Status: All, **CSG Involvement**: All, **Funding Type**: All, **Phase**: All, **LCRN**: None

Open / single rese..
Open / multi resea..

NCRI National Cancer Research Institute

Designed and maintained by **NCRI Clinical Research Groups (CRGs)** & **NIHR**

Appendix 4

Top 5 publications in the reporting year

Trial name & publication reference	Impact of the trial	CSG involvement in the trial
1. Adjuvant Nivolumab versus Ipilimumab in Resected Stage III or IV Melanoma (CHECKMATE 238. Weber J et al, N Engl J Med. 2017 Nov 9;377(19):1824-1835.	Resulted in significantly longer recurrence-free survival and a lower rate of grade 3 or 4 adverse events than adjuvant therapy with ipilimumab.	Supported by the CSG
2. Adjuvant bevacizumab as treatment for melanoma patients at high risk of recurrence: Final results for the AVAST-M trial. Corrie P et al. J Clin Oncol (2017) 35, 2017 (supplement abstract 5901).	Major national adjuvant trial	CSG led
3. AVAST-M; Circulating tumor DNA predicts survival in patients with resected high risk stage II/III melanoma. Lee RJ, et al Annals Oncol 2018; 29: 490-6.	Impact of ctDNA in prognosis after resection of high risk melanoma	CSG led
4. Adjuvant Dabrafenib plus Trametinib in Stage III BRAF-Mutated Melanoma. Long G et al, New England Journal of Medicine (2017) 377:1813-1823	New standard of care	CSG supported
5. Adjuvant Pembrolizumab versus Placebo in Resected Stage III Melanoma. Eggermont AMM et a New England Journal of Medicine (2018) 378:1789-1801	New standard of care	CSG supported

Appendix 5

Recruitment to the NIHR portfolio in the reporting year

In the Skin Cancer CSG portfolio, 6 trials closed to recruitment and 12 opened.

Summary of patient recruitment by Interventional/Non-interventional

Year	All participants		Cancer patients only		% of cancer patients relative to incidence	
	Non-interventional	Interventional	Non-interventional	Interventional	Non-interventional	Interventional
2013/2014	534	403	530	403	4.3	3.3
2014/2015	622	217	609	175	4.9	1.4
2015/2016	504	234	504	228	4.09	1.85
2016/2017	182	320	182	312	1.48	2.53
2017/2018	2117	321	2097	321	17.02	2.61