

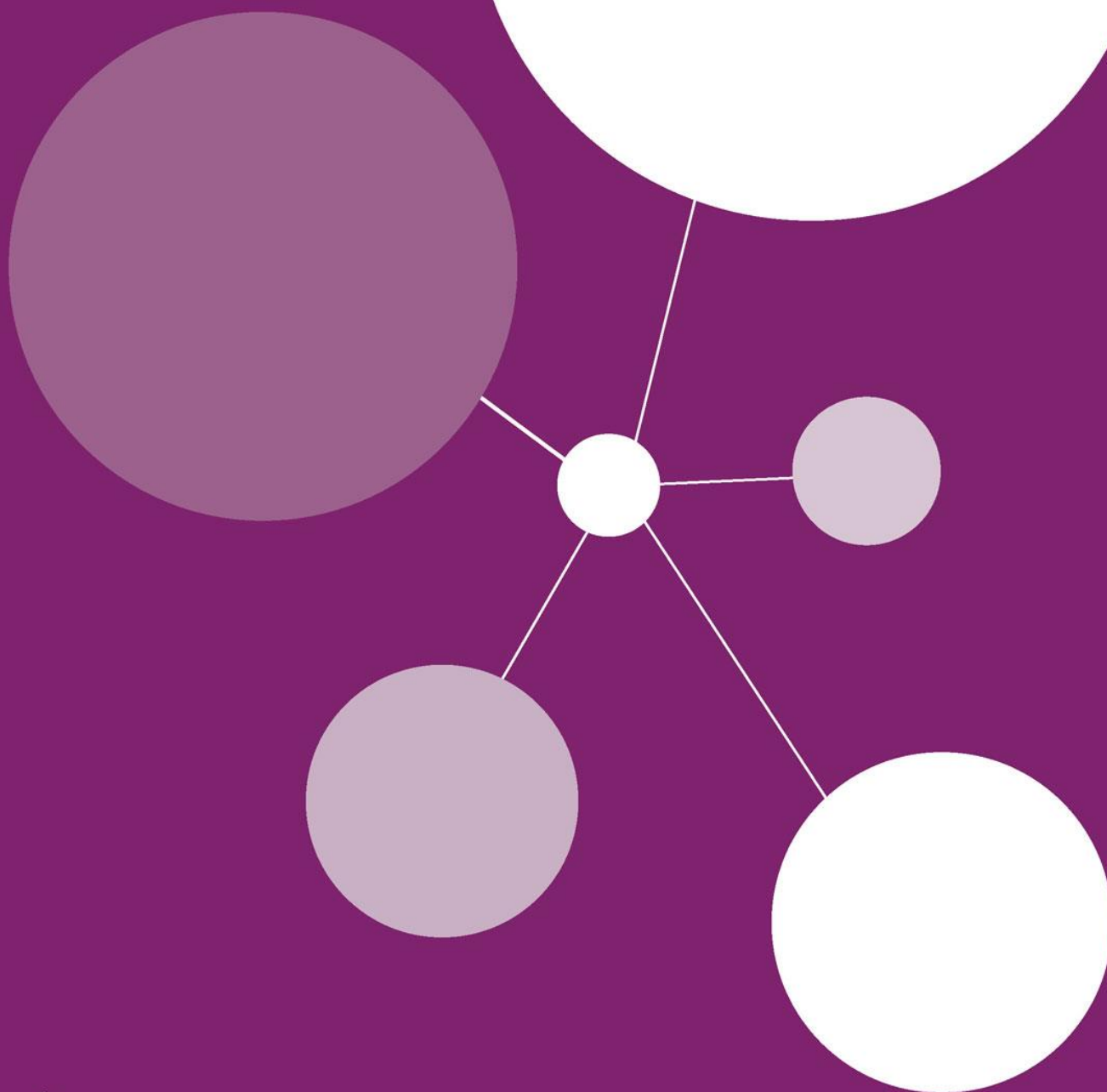


NCRI

National
Cancer
Research
Institute

NCRI Skin Group

Annual Report 2018-19



Partners in cancer research

NCRI Skin Group Annual Report 2018-19

1. Top 3 achievements in the reporting year

Achievement 1

Publication of the final results of AVAST-M study & of translation research associated with the study

The final results of the AVAST-M study were published in Annals of Oncology. This was a 1343 patient study of adjuvant bevacizumab in high risk resected melanoma with significant additional translational research. The overall findings of the clinical study showed no survival benefit of adjuvant bevacizumab. The measurement of Vit D levels and importance in predicting outcome have been analysed in a cohort of the AVAST-M trial patients.

Vitamin D did not correlate with known prognostic markers, nor predict for DFI or OS, but there was some evidence of benefit for patients with stage II disease treated with bevacizumab. (BJC). The translation research from the study demonstrated that monitoring of ctDNA may have a useful prognostic value in this setting and has led to the development of further studies using ctDNA to guide treatment choices in melanoma (Annals of Oncology) .

Achievement 2

Developing the next 3-year strategy for the Skin CSG

A very constructive strategy meeting was held to update the Groups overall strategy for the next 3 years. Participants included the current group and subgroups, key members of the skin cancer research community and Skin Cancer Sub Specialty Leads for the NIHR CRN. The meeting also included sessions transitional research and biobanks and the NCRI work on Living with & Beyond Cancer.

The previous strategy was reviewed and areas for change and update were identified. In the main section the strategic aims remain largely similar. The key changes will be in the structure of the group with the aim of increasing the groups output. This will include having a smaller Executive Group which meets more often and the creation of more subgroups: an Early Disease /Primary Care Subgroup and a Melanoma Subgroup. New areas of activity have also

been identified including work on patient & carer information and decision making in the (new for melanoma) adjuvant space.

Achievement 3

Early Diagnosis

The current work led by Fiona Walters including the MelaTools programme (NIHR-funded), GP and patient interventions to promote the early diagnosis of melanoma, examining diagnostic approaches to skin cancer in primary care continues to be very fruitful. There are now 5 Cochrane Systematic Reviews examining different techniques to aid early diagnosis eg: Dinnes J, Deeks JJ, Chuchu N, Ferrante di Ruffano L, **Matin RN**, Thomson DR, Wong KY, Aldridge RB, Abbott R, Fawzy M, Bayliss SE, Grainge MJ, Takwoingi Y, Davenport C, Godfrey K, **Walter FM**, Williams HC, Cochrane Skin Cancer Diagnostic Test Accuracy Group. Dermoscopy, with and without visual inspection, for diagnosing melanoma in adults. *Cochrane Database of Systematic Reviews* 2018.

This will provide an excellent platform for future clinical studies.

2. Structure of the Group

Over the last year the structure has remained largely the same with the main group and the one subgroup, non-melanoma skin cancers. Christian Ottensmeier, Mazhar Ajaz, Sarah Danson, our trainee member Suzanne Murphy and consumer representative Rosemary Cook have rotated off the Group and were thanked for their hard work as members.

We have recruited new members Kara Heelan, Consultant Dermatologist at the Royal Marsden Hospital and Ruth Board Consultant Medical Oncologist at the Royal Preston Hospital to the Group.

We have two active trainee members Mark Stares and Victoria Woodcock. Both contribute actively at the meeting and in particular contributed to the strategy day. Mark is establishing a melanoma trainees group (as seen effectively with the Breast Group) and Victoria is working on the Trial database initiative with Melanoma Focus.

3. Skin Group & Subgroup strategies

Skin Group Strategy

Portfolio Development: Melanoma

2 new trial proposals for melanoma are under development

- **GASMAN** – General Anaesthesia techniqueS in MAligNancy

A Randomised Controlled Trial of Inhalational Anaesthesia versus Total Intravenous Anaesthesia (TIVA) in surgery for malignancy. The primary aim of this prospective, randomised controlled trial is to investigate whether Total Intra Venous Anaesthesia (TIVA), when compared to Inhalational Anaesthesia (INHAL), is associated with improved survival for patients undergoing planned curative surgical resection of palpable melanoma or SCC (Stage 3B or above). The study outline has been discussed at BAPRAS and feasibility is being carried out. Led by Rowan Pritchard-Jones

- **CHILI** – Checkpoint Inhibitor mediated Liver Injury. This study aims to optimise the management of immune related hepatitis due to checkpoint inhibitors. This is a 2-part study – a retrospective part which will aim to detail current management in terms of treatment and re-challenge following hepatitis. The second, prospective part is a phase II aiming to de-escalate treatment (we currently probably overtreat) and a to define a re-challenge protocol. Led by Poulam Patel & Prof Guru Aithal (Hepatologist)

At the strategy meeting: other areas identified for development were:

- Mucosal & Uveal melanoma
- Neoadjuvant treatment
- Information & Decision making (LWBC)
- Rx after Checkpoint inhibitors

Increasing international collaborations

The feasibility part of MeIMART (melanoma margins surgical study) completed – This is a study that was led by ANZAC melanoma group and through collaboration with the CSG and UK investigators, the UK made a significant contribution to demonstrating feasibility. Funding for Phase III currently being sought (initial bid to CRUK not successful)

Increasing Interaction with Translational research groups

DANTE-PET – led by Pippa Corrie- translational PET imaging to be incorporated into the DANTE trial. Full application being worked up for CRUK.

Strategic aim 4

Project underway with Melanoma Focus /NIHR CRN and Skin Cancer CSG to develop a HCP and patient & carer friendly search trials database.

Strategic aim 5

Restructuring of Group – as above in achievements

Strategic aim 6

Early Diagnosis – as above in achievements

Non-Melanoma Skin Cancer Subgroup (Chair, Dr Neil Steven)**Development of trials in Squamous Cell Skin Cancer**

SCC-AFTER: Management of high risk primary cutaneous squamous cell carcinoma in the head and neck region after surgery.

Following preliminary feasibility work funded through a 10K grant from UK Dermatology Clinical Trials Network, the NCRI Skin Cancer CSG, Birmingham CRUK CTU and Oxford University Nuffield Department of Population Health have developed SCC-AFTER, a 1000 patient prospective, multi-centre phase III RCT to evaluate the role of Adjuvant RT in completely or closely excised high-risk primary c SCC. The trial is being presented to CTRad at the 10th Anniversary Symposium and then for funding to CRUK or NIHR HTA led by Dr Agata Rembielak.

Development of new trials in rarer NMSC & to increase UK wide links

A National Meeting on MCC, SCC and other rare skin cancers was held this year. Excellent, multi-disciplinary participation with discussion of current managements, areas of unmet need and uncertainty and new initiatives for clinical studies, including trial ideas, data bases and virtual tissue banks for rare skin cancers. This was an important forum to further develop the work of the NMSC sub-group. Led by Dr Neil Steven

4. Task groups/Working parties

The Skin Group 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	Funding amount
May 2018					
Not applicable					
November 2018					
DETECTION: Circulating tumour DNA guidEd Therapy for stage IIB/C BRAF mutant- positive mElanoma after surgiCal resecTION	Experimental Medicine Award	Dr Paul Lorigan	Preliminary		
Other committees					
Study	Committee application type	& CI	Outcome	Level of CSG input	Funding amount

6. Consumer involvement

Patricia Fairbrother

Over the past year, Patricia has been involved in supporting her regional skin cancer clinical group as a patient representative. There has been concentration in the consumer involvement area this year on constructing a non-melanoma cancer patient survey, and she has aided this project along with an abstract written by Dr Helen Cooper, GP with a special interest in dermatology, relating to the survey results are to be included at the BAD annual conference in Liverpool.

Patricia has been engaged in teleconferences and a face-to-face meeting of the NMSC Subgroup, with a particular focus on the design of a potential new study cSCC-AFTER, Keratocanthoma, rational MCC and more.

Patricia remains a member of the UKDCTN executive committee, and attended the BAD AGM last year in Edinburgh and will be attending in Liverpool this year.

7. Priorities and challenges for the forthcoming year

Priority 1

Establish the new CSG structure and working groups

A key priority is to form the 2 new subgroups – a Melanoma Treatment Subgroup and a Skin Cancer Early Diagnosis/Prevention Subgroup and to establish ways of working for new smaller ‘steering group’.

The Melanoma Subgroup will further refine the ideas discussed at the strategy group. We will have specific leads for uveal & mucosal melanomas. These will be important for ensuring the best use intranational initiatives such as IRCI. An early task will be to have a clear project map of trials we will aim to develop this subgroup will also take the lead in ensuring the agenda for looking and monitoring long term toxicities is progressed along with the supportive care CSG and other initiatives such as TIC-TOC.

The Skin Cancer Early Diagnose & Prevention (SPED) Group will aim to bring together several strands of work from different for including the Primary Care CSG (Fiona Waters) and the Skin Cancer Cochrane group (who are currently reviewing the data on skin cancer diagnostic devices). An early aim will be to develop larger scale trials to test the various approaches to early diagnosis and screening.

Priority 2

Develop new trials in melanoma:

- GASMAN
- CHILI
- Decision Aid/Info study

- Brain metastases study

Development of the first 2 studies is already underway. Over this year we aim to have these submitted for funding.

Early discussions are underway and expertise is being brought together to (being led by Ruth Board) investigate use of decision tools and info for adjuvant therapy. This will draw on the established data in other cancers.

Following a workshop led by the Brain CSG, areas for clinic trials in this area have been identified. Over this coming year, these will be developed into clinical trials funding applications.

Priority 3

Development of the New trials for NMSC

Obtaining funding for the **SCC After** trial is a priority for the Group.

The SPOT trial examined secondary prevention of SCC has been completed and based on the lessons from this a new study is be developed: SPRIINT-a- randomised phase III topical 5fU versus nicotinamide versus sunscreen as secondary prevention in immune competent and non-transplant immune suppressed.

Challenge 1

Ensuring that new structure allows good cross fertilisation among the subgroup members

With less members on the main group, we will lose some input and so will need ways of working that ensure the impact of this is minimal. We will aim to mitigate this through the Subgroup Chairs and inviting individual subgroup members to join meetings (via teleconference) on a needs basis. As part of the reorganisation we will also try to include more project management and further information on IT solutions- shared documents etc (e.g. Outlook360 tools)

Challenge 2

Time pressures

This is not peculiar to skin cancer research- increasingly NHS active researchers are finding the increased pressures of clinical service commitments are impacting on research. Unfortunately, there are no easy solutions to this. The project management tools discussed along with more regular meetings (again, virtual) may help us to deliver and keeps projects on track.

Challenge 3

Funding of research

Again, not peculiar to skin cancer research. It seems to be increasingly difficult to obtain funding for certain types of trials, perhaps the more pragmatic ones with less TR. Extending the

reach to other funding bodies such as NIHR is helping and the group will continue to optimise grant applications and look at a range of funding bodies.

8. Collaborative partnership studies with industry

Collaborations with industry continue on an adhoc basis.

As a Group we continue to maintain a dialogue regarding placement of industry studies in the UK and advise on centres to ensure best access for patient to new treatments.

Dr Corrie is currently developing a protocol for RAF Inhibitors with Pierre Fabre which will be worked up with the CSG. The creation of a Melanoma Subgroup will increase our partnership with industry. Similarly, the studies in the early diagnosis arena will increase collaborations with the devices industry.

9. Appendices

Appendix 1 - Membership of Skin Group and Subgroups

Appendix 2 – Skin Group and Subgroup strategies

A – Skin Group 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 Group Chair)

Appendix 1

Membership of the Skin Group

Name	Specialism	Location
Dr Agata Rembielak	Clinical Oncologist	Manchester
Dr Mark Stares*	Clinical Research Fellow	Glasgow
Dr Victoria Woodcock*	Clinical Research Fellow	Oxford
Dr Ros Cook	Consumer	Hertfordshire
Ms Patricia Fairbrother	Consumer	Derby
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 Neil Steven	Medical Oncologist	Birmingham
Dr Paul Craig	Pathologist	Cheltenham
Dr Christina Yap	Statistician	Birmingham
Mr Jong Kim	Surgeon	Manchester
Mr Marc Moncrieff	Surgeon	Norwich
Mr Rowan Pritchard Jones	Surgeon	Merseyside
Dr Suzanne Murphy*	Surgeon	Cambridge

* denotes trainee member

Membership of the Subgroup

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
Dr Victoria Woodcock*	Clinical Research Fellow	Oxford
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 – Skin Group Strategy

Strategic objective	Action	CSG lead	Date	Outcome
1a Portfolio Development MELANOMA	Ensure cohesive strategy of melanoma clinical trials taking into account: Opportunities within international agenda Need for high recruiting studies Balance between early & late phase Multicentre studies accessible to more centres All melanoma subgroups/rare forms Interaction with CRN subspecialty leads	Current studies GASMAN –RP-J CHILI-PP To develop (leads TBA) Mucosal/ocular 2 nd line post CI Brain mets	Current studies April 2020 April 2020 To develop (leads TBA) Mucosal/ocular 2 nd line post CI Brain mets	Current studies GASMAN –grant application CHILI – grant application To develop (leads TBA) Firm proposal Firm proposal
1b Portfolio Development NON-MELANOMA	Secure new studies for common and rare non melanoma skin cancers SCC BCC Merkel cell Rarer non- melanoma skin cancers	SCC AFTER – AG SPRIINT CP MCC- NS	April 2020 April 2020	Secured funding Grant application
1c interaction with NCRI- cross cutting gps	Develop studies with cross cutting groups Primary care - evaluation of screening tools TYA CT RAD - RT in SCC CNS CSG- brain mets	FW/ RM MP AG AGu	April 2020 April 2020 April 2020	New group- trial proposals Secured funding Grant applications

Strategic objective	Action/ Area for development	CSG lead	Outcome
2. Key Research Priority Areas	<p>Melanoma</p> <p>Early Diagnosis/ Screening</p> <p>Adjuvant therapy- Info needs/decision aids (LWBC)</p> <p>Duration of Rx (DANTE)</p> <p>Resistance to B-RAF (INTERIM)</p> <p>Surgery (GASMAN -+ others- Neoadjuvant/In transit)</p> <p>Immunotherapy toxicity (CHILI + others)</p> <p>NMSC SCC – Adjuvant Rx Secondary prevention Role of immunotherapy</p> <p>MCC- treatment & Translational Research (Rationell MCC)</p> <p>Rare subtype Tissue bank & Database</p>	<p>New subgroup FW/RM/CP</p> <p>RB</p> <p>SD</p> <p>PC</p> <p>RP-J</p> <p>PP</p> <p>AR CP TBA</p> <p>NS</p>	<p>New studies</p> <p>New Study</p> <p>Continued recruitment</p> <p>Continued recruitment</p> <p>Funded Trial Funded Trial</p> <p>Funded Trial</p> <p>New Proposals</p> <p>Continuation and expansion</p>

Strategic objective	Action	CSG lead	Date	Outcome
3a Raising Awareness & Profile	<p>Regular dissemination of study recruitment, activity and outcomes through newsletters, annual meetings and annual reports to all stakeholders</p> <p>Annual CSG/ NIHR Subspecialty leads meeting – in person/virtual with regular interim updates of new studies</p> <p>Presentation of clinical trial finding to national and International meetings ASCO/ESMO/SMR/AACR</p> <p>Creation of a user friendly Clinical trials database For health professional and patients to suppleemt trials portfolio maps</p>	All	Ongoing April2020	<p>More recruitment & engagement</p> <p>More presentatians /Profile</p> <p>New database- More recruitment</p>
3b Ensure successful delivery od studies though integration with NIHR CRN	<p>CSG members to commit to recruiting into CSG led studies</p> <p>Interaction with LCRN subspecialty lead to determine study placement and identification of barriers to recruitment</p> <p>Monitor recruitment and delivery of portfolio studies</p>	All	Ongoing	Faster recruitment Better engagement
3c Effective set up of new studies	Establish working group for new studies within 6 weeks of funding award with representation from CI,CTU,NIHR CRN	CI/CTU	Ongoing	Faster recruitment

Strategic objective	Action	CSG lead	Date	Outcome
4. Strengthen UK Wide & International Links	<p>Continue current links with international groups EORTC ANZAC IRCI</p> <p>Establish new links – with main melanoma cooperative groups including DCOG/ECOG/SWOG</p> <p>Continue to work with translation groups in particular those collecting tissue and data to ensure optimal co-ordination</p> <p>Work with Melanoma Focus and integraqte research & Service</p>	All PP All All	ongoing	<p>Better co-ordination of trials</p> <p>more research into rarer subtypes</p> <p>Improved TR</p> <p>More recruitment & awareness</p>
Optimise Structure and Function to deliver objectives	<ol style="list-style-type: none"> 1. Establish and primary care/Screening subgroup 2. Establish a melanoma subgroup 3. .Identify Mentors for trainee registaras 4. Identify mentors for PPI 	FW/RM PP PP PP	Oct 2019 Oct 2019 ASAP ASAP	
Patinet & Public Involvement and Impact	<ol style="list-style-type: none"> 1. Ensure early involvement with consumers in study development 2. Increased consumer invovlement with LWBC themes 	All	May 2019	

Appendix 3 – Portfolio maps

NCRI Portfolio Maps							
Skin Cancer							
Map A – Melanoma							
↻ below to reset map							
		a) Surgery	b) Adjuvant	c) 1st line metastatic	d) 2nd line metastatic	e) Subsequent line	f) Non-interventional/ Translational
All melanomas	All	Minitub (EORTC 1208)					Molecular patho
		EAGLE FM					CR UK Stratifie
							SC stem cells
			Study ANZMTG 01.09/10				MISST
					IMO5301		PASIP
				Ipilimumab open label e			
				44 in Metastatic Melan			
							Leukocyte accumulation i
							Clinical Utility Study OM
							-001 Tissue Research
All cutaneous - BRAF mutant	Other						Dermoscopy in the S
							The PRIMM Study
			MK3475-716				MICROBIOME
				IMM-101-015	IMM-101-015		
						opsies and blood biomar	
					and Nivolumab in melan		
				Pembrolizumab on Ad			RP2 +/- PD1 Blockade
							skin transformation into
							ve study of patient and
							DANTE trial Interviews
Cutaneous - BRAF wt	All					VEC Observational Stud	
							MK4621-002
						ants-Advanced Tumors	
						002 BMS-986253 IL8 w	
Non-cutaneous	All						pression in cancer (PE
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NCRI Portfolio Maps

Skin Cancer

Map B – Non-melanoma

⌵ 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
							SC stem cells
							Outcome Measure In Skin Cancer
							immunoregulation of skin cancer and
							Utility of Digital Dermoscopy in the Skin Cancer Clinic
							PDL1 expression in cancer (PECan study)
Basal cell carcinoma	All						HPV in skin transformation into cancer
Merkel cell	All					Patients with Metastatic Merkel	
Other	All						Imaging leukocyte accumulation in cancers
							ANZMTG 02.12 RADICAL
							RP2 +/- PD1 Blockade in solid
Squamous cell carcinoma	All					Pembrolizumab in Participants With	
							SMA0217

Filters Used:

Active Status: All, CSG Involvement: Data collection in progress, Funding Type: All, Phase: All, LCRN: None

In Setup / single re..
Open / single rese..
In Setup / multi res..
Open / multi resea..
Suspended / multi ..



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

Developed by Mayden® Analytics



Appendix 4

Top 5 publications in the reporting year

- *This section remains incomplete and will be provided as an amendment*

Trial name & publication reference	Impact of the trial	CSG involvement in the trial
1.		
2.		
3.		
4.		
5.		

Appendix 5

Recruitment to the NIHR portfolio in the reporting year

In the Skin Group portfolio, 13 trials closed to recruitment and 24 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
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
2018/2019	1915	196	1882	196	11.83	1.23