

NCRI Executive guidelines for the restructured Groups

This pack contains condensed Annual Reports for the following Groups:

- Primary Care Group
- Psychosocial Oncology & Survivorship (POS) Group
- Supportive & Palliative Care Group

In June 2018, the above-named Groups were made aware of a NCRI Executive decision to restructure. As such, it was agreed that the groups should discontinue any progression against their strategy until the new structure was in place.

A shortened Annual Report has been submitted for each of these Groups.

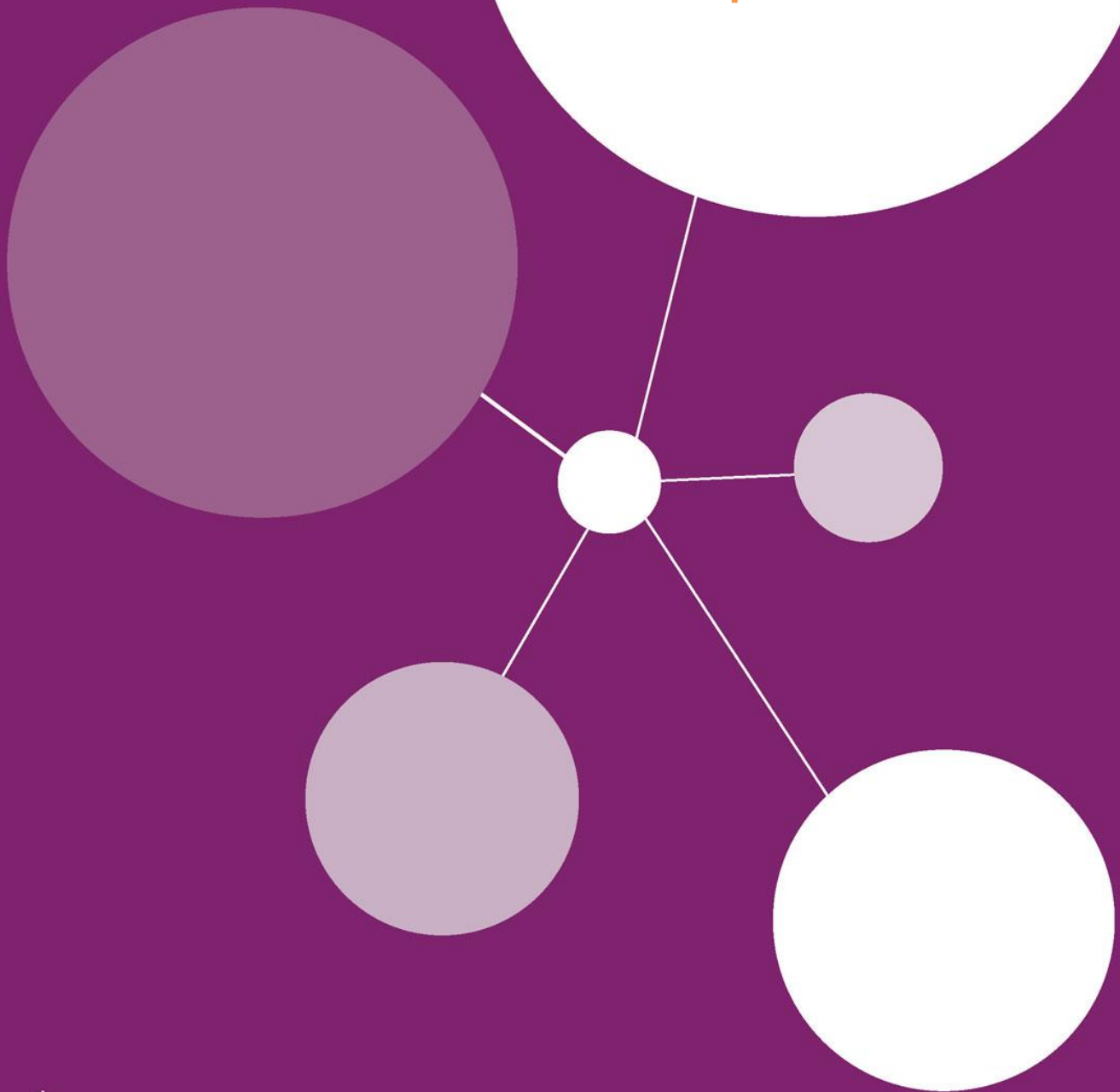


NCRI

National
Cancer
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NCRI Primary Care Group

Annual Report 2018-19



Partners in cancer research



NCRI Primary Care Group Annual Report 2018-19

1. Top 3 achievements in the reporting year

Achievement 1

Successful recruitment across large portfolio of studies. For example:

1) The BEST3 trial has recruited over 13000 patients across 150 GP practices. The trial is now closed to recruitment and is in follow up.

2) The first round of the Yorkshire Lung Screening Trial which involves LDCT screening for those at risk of Lung Cancer on mobile vans in the community is underway. To date, over 22,000 individuals have been included in this randomised trial from 32 GP practices and the 1000th participant to undergo an LDCT scan on the van happened in March 2019. The trial is on target to include approximately 63,000 individuals with 7000 having LDCT screening and is co-recruiting to a number of important additional studies investigating smoking cessation interventions utilising scan images (YESS study) and biomarkers that have been funded by Yorkshire Cancer Research. (Rhian Gabe is co-applicant and lead statistician of YLST, and Richard Neal is the primary care lead and co-applicant on YLST, the YESS and biomarkers studies).

Achievement 2

Growing international profile. For example, CanTest has continued with its vision to increase the capacity and sustainability of cancer detection research in the UK and internationally. In Spring 2019 over 60 senior academics and early career researchers from across the world attended the CanTest International School for Cancer Detection Research in Primary Care at Jesus College Cambridge. A blog providing further details of the event can be found here: <https://www.cantest.org/news/second-successful-cantest-school-celebrates-week-of-shared-learning/>

Achievement 3

Funding success. For example, this year, the PREDICT study (Prostate Risk Evaluation using Diagnostic Innovations in Community Testing) has had funding confirmed by Prostate Cancer UK for a pilot phase that will involve invitation of men to prostate cancer screening. The target

population is aged 50-69, or aged 45-49 with higher than average risk of prostate cancer (Black ethnicity or positive family history). Screening interventions including STHLM3 multiplex risk model, clinical risk models and PSA will be evaluated in the context of an mpMRI-based pathway for diagnosis of prostate cancer. If the pilot phase is a success, then the plan is to extend recruitment to a full study of 20,000 men over 3 years across the UK and biobank samples for future research. Maximising recruitment via primary care in community settings is key to this study. Rhian Gabe is Co-Cl and lead methodologist (Primary Care CSG, Screening subgroup Chair), alongside Co-Cl and clinical lead Hashim Ahmed (Prostate Cancer CSG Chair). Fiona Walter (Primary Care CSG) and Rakesh Heer (Localised Prostate subgroup chair) are co-applicants.

2. Structure of the Group

There have been significant structural changes to the CSG in the reporting year. Professor Richard Neal has stepped down as Chair and there is currently no Chair of the Group. Richard was thanked for all his hard work, time and commitment to the Group over the years as both Chair and member. Jan Rose, our consumer member, has also stepped down and was thanked for her considerable effort and commitment.

We welcomed new trainees Dr Pauline Williams and Dr Dipesh Gopal and Margaret Johnson as our new consumer member.

The Survivorship Subgroup is currently under restructure as part of the new cross-cutting theme. Our Primary Care CSG and members from each of the subgroups have been supportive of this initiative, having engaged through attending key meetings and actively inputting on circulated proposals. The Screening and Early Diagnosis Subgroups both have new Chairs (Dr Katriina Whitaker and Dr Rhian Gabe respectively). We have been tasked with compiling this annual report.

One potential plan is for the Screening and Early Diagnosis Sub-groups to become part of a newly formed CSG that would coordinate development of a strategic portfolio of studies in the area of screening and early detection of cancer. We intend to engage with the current SPED advisory group to investigate the best way forward with respect to potential restructuring. There have been no major objections to this to date, with the caveat that primary care is strongly represented. With so many changes ahead, both Subgroups have put on hold recruitment of new members.

To address the overlapping areas of remit between NCRI Psychosocial Oncology and Survivorship (POS), Supportive and Palliative Care (S&PC) and Primary Care (PC) Groups, a restructure of these cross-cutting Groups has been agreed to ensure a more efficient and aligned approach moving forward. The work of the NCRI Cancer of Unknown Primary (CUP) and Acute Oncology Working Parties has also been encompassed into this new cross cutting structure. In the new structure an Executive Group and Workstreams will be created, replacing the previous main Group and Subgroups. The Executive Group will take a strategic role, providing oversight of the research landscape and proactively identifying opportunities for the work of the Group. The Workstreams will also identify new opportunities and develop new trials within their focus areas; reporting to the Executive Group regarding any changes in the research landscape relating to their area and providing reports on their progress.

Membership of the Executive Group will include:

- the Executive Group Chair
- the Chair of each of the five Workstreams (see below for further details)
- a consumer representative
- the relevant Research Delivery Manager
- funder representatives (as appropriate)

The following five Workstreams will be initiated, covering each of the listed topic areas:

MUO/CUP Workstream	Acute Care and Toxicities Workstream	Late Consequences Workstream	Advanced Disease and End of Life Care Workstream	Methodology Workstream
Acute Oncology Type I	Acute Treatment Toxicities	Late Toxicities	Palliative Care	PROMs
Primary Care Pathway	Acute Cancer Toxicities	Psychosocial Aspects	Hospice	Touch Screen/Apps
CUP Biology & Therapy	Psychosocial Impacts of Treatment	Primary Care follow-up	Bereavement Care	Quality of Life/ Health Economics
	Prehabilitation		Primary Care	Output Measures/ Trial Design
	Primary/Secondary Care Interface		Psychosocial Aspects	Qualitative Research
				Modelling
				Primary Care Data Linkage

3. Funding applications in last year

Table 2 Funding submissions in the reporting year

Cancer Research UK (CRUK)					
Study	Application type	CI	Outcome	Level of CSG input	Funding amount
May 2018					
Selection of Eligible People for Lung Cancer Screening using Electronic Primary Care DaTa: Development of new risk prediction models.	Early Detection Committee	D Baldwin	Funded	W Hamilton is CI	£352,945
Ethnic inequality in diagnosis and outcomes in cancer	Cancer Research UK PRC Fellowship	T Martins	Funded	In W Hamilton's group	Unknown
November 2018					
COLO-SPEED	CRUK Catalyst	C Rees	Not funded	Dolwani (Screening subgroup and co-applicant)	
Cancer Screening and statistics programme	Renewing Programme Award	P Sasieni	Funded	A Lim is co-investigator, leading on cervical screening self-sampling and novel technologies.	Unknown
Implementing LDCT screening for lung cancer in high-risk groups: exploring the attitudes of GPs and their self-efficacy to support patients during the screening pathway	Project Award	J Waller	Not funded	R Neal is collaborator	
Population based germline testing for targeted cancer screening and prevention	Cancer Research UK	R Manchanda	Pending	R Neal is CI K Whitaker provided letter of support on behalf of the CSG	Unknown
Cancer risk tools and their influence on clinical judgement'	Cancer Research UK Population Research Committee	O Kostopoulou	Pending	ED subgroup submitted scores on behalf of CSG	

A safety-netting intervention (Shared Safety Net Action Plan) to support earlier diagnosis of cancer in primary care: a feasibility study	Cancer Research UK Population Research Committee	R Lawton	Pending	ED subgroup submitted scores on behalf of CSG R Neal is CI	
Low Energy liquid diets and Adenoma Prevention: the LEAP trial	Cancer Research UK Population Research Committee	R Beeken and S Smith	Pending	R Neal/K Whitaker provided a letter of support for primary care element of the intervention	Unknown
Understanding socioeconomic inequalities in colorectal cancer outcomes	Cancer Research UK Population Research Committee	K Whitaker	Pending	K Whitaker is ED chair	£237,006
Early diagnostic potential and molecular mechanisms of thrombocytosis in lung cancer patients.	Cancer Research UK Early detection committee	G Pula	Pending	R Neal and W Hamilton (ED subgroup members) are co-is	£471,386
Other committees					
Study	Committee & application type	CI	Outcome	Level of CSG input	Funding amount
A pragmatic implementation feasibility clinical trial of offering HPV self-sampling to cervical screening non-attenders within the NHS cervical screening programme in England	NHS Cancer Transformation Funds	A Lim	Funded	A Lim (CI), J Waller leading on acceptability survey within the pilot.	£808,350
PREDICT - Prostate Risk Evaluation using Diagnostic Innovations in Community Testing	Prostate Cancer UK	H Ahmed, R Gabe	Funded	R Gabe is Co-CI. F Walter is co-applicant. Link with Prostate CSG (H Ahmed, Prostate CSG Chair, R Heer subgroup Chair)	£650k (pilot), £4.5M – full study, dependent on success of pilot.
Maximising acceptability of risk stratification in the NHS breast screening programme	Breast Cancer Now PhD	J Waller	Funded	J Waller is CI	£104,930

Exploring patients' values and preferences for colorectal cancer screening	National School for Primary Care research	J Usher-Smith	Funded	J Usher Smith is CI	£13,635
CATTO 2018: A prospective randomised study of screening for bladder and kidney cancer in populations with high disease specific mortality risk	Yorkshire Cancer Research	J Catto	Pending	Screening subgroup peer reviewed, providing feedback and R Gabe provided a letter of support on behalf of the group	Unknown
Aspirin as an adjunct to screening - development of a decision aid	Tenovus	S Smits, S Dolwani	Funded	Dolwani (Screening subgroup and co-applicant)	£28,782
Adapting the Safety Net Shared Action Plan intervention for the South Asian community to promote greater patient involvement in achieving a faster cancer diagnosis in primary care.	Yorkshire Cancer Research	J O'Hara	Pending	R Neal (ED sub-group member) is CI	Unknown
Diagnosing cancer in the older and frail people: improving outcomes, and preventing harm.	Peter Sowerby Foundation	R Neal	Pending	R Neal is PI	£1,998,417
Policy Research Unit in Cancer Awareness, Screening and Early Diagnosis	Department of Health	S Duffy	Funded	W Hamilton is Early Diagnosis Lead. F Walter, Y Lyratzopoulos, R Neal, J Waller are ED or screening subgroup members	£4,997,576
Safety netting and re-consultation for lung cancer symptoms: GP and patient perspectives	Roy Castle Lung Foundation	G Black	Funded	G Black is ED subgroup member, K Whitaker is CI	£120,899

4. Collaborative partnership studies with industry

The University of Leeds has a collaboration agreement with PinPoint Data Science and will be rolling out a biomarker / AI rule out test for cancer in primary care in the coming year, based upon algorithm development and validation to date. This should come onto the portfolio in 2019-20.

5. Appendices

Appendix 1 – Top 5 publications in reporting year

Appendix 2 – Recruitment to the NIHR portfolio in the reporting year

Dr Katriina Whitaker (Early Diagnosis Subgroup Chair)

Dr Rhian Gabe (Screening Subgroup Chair)

Appendix 1

Top 5 publications in the reporting year

Trial name & publication reference	Impact of the trial	CSG involvement in the trial
<p>1. Barrett's oEsophagus trial 3 (BEST3): study protocol for a randomised controlled trial comparing the Cytosponge-TFF3 test with usual care to facilitate the diagnosis of oesophageal pre-cancer in primary care patients with chronic acid reflux. Offman et al, BMC Cancer, 18:784</p>	<p>This protocol paper describes the BEST3 Trial which assesses whether Cytosponge™ -TFF3 (Trefoil Factor 3) test for patients with reflux symptoms is effective in increasing the detection of Barrett's oesophagus in primary care. It is hoped that this research will establish whether the Cytosponge™ -TFF3 test offers earlier detection and an alternative approach to invasive endoscopy. This will build on the previous multi-site BEST1 and BEST2 trials, providing the last step before this test could be adopted into mainstream practice in the UK.</p>	<p>Portfolio study. Fiona Walter (ED subgroup member) is a co-investigator on the trial and part of the BEST3 Trial team</p>
<p>2. Improving cancer symptom awareness and help-seeking among adults living in socioeconomically deprived communities in the UK using a facilitated health check: A protocol for the Awareness and Beliefs About Cancer (ABACus) Randomised Control Trial. Moriarty et al, BMC Public Health, 19:285</p>	<p>Cancer survival rates are lower in disadvantaged communities, possibly due to low awareness of symptoms and delayed help-seeking. It is important that people increase their knowledge of cancer symptoms, so that they know when to seek medical advice, and therefore possibly detecting cancer earlier, which will improve their outlook. This protocol paper describes how an interactive online</p>	<p>Portfolio study. Richard Neal (ED subgroup member) is a co-investigator on the trial.</p>

	health check questionnaire will be delivered in deprived communities by trained advisors.	
3. Development of an intervention to expedite cancer diagnosis through primary care: a protocol. Stanciu et al, BJGP Open, 2(3)	This protocol paper described the programme of work outlined under the WICKED portfolio study. The work sets out to develop a behaviour change intervention to expedite diagnosis through primary care and contribute to improved cancer outcomes.	Richard Neal (ED subgroup member) leads this work with Prof Clare Wilkinson.
4. Acceptability of non-speculum clinician sampling for cervical screening in older women: A qualitative study. Freeman M, Waller J, Sasieni P, Lim AW, Marlow AV. Journal of Medical Screening. 25 (4):205-210	This study demonstrated that Human papillomavirus testing on non-speculum clinician-collected vaginal samples could be an acceptable alternative cervical screening method for older women. Offering this approach could increase screening uptake in older women who find conventional cervical screening to be less acceptable with ageing or the menopause.	Anita Lim and Jo Waller (Screening subgroup members) helped lead this Cancer Research UK funded work.
5. Determinants of willingness to receive healthy lifestyle advice in the context of cancer screening. Stevens C, Vrinten C, Smith SG, Waller J, Beeken RJ. British Journal of Cancer 119: 251–257	This cross-sectional population base survey showed a high willingness to receive lifestyle advice at cancer screening, suggesting this context may provide an opportunity to support behaviour change.	Jo Waller (Screening subgroup members) helped lead this Cancer Research UK and Yorkshire Cancers Research funded work.

Appendix 5

Recruitment to the NIHR portfolio in the reporting year

In the Primary Care Group portfolio, 7 trials closed to recruitment and 3 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	829	1	709	1	-	-
2015/2016*	27657	2412	6915	2391	-	-
2016/2017*	10128	2370	9884	1315	-	-
2017/2018*	6538	7035	4574	6627	-	-
2018/2019	3875	11493	3752	10381		

*includes data of studies both led by Cancer and supported by Primary Care and led by Primary Care and supported by Cancer

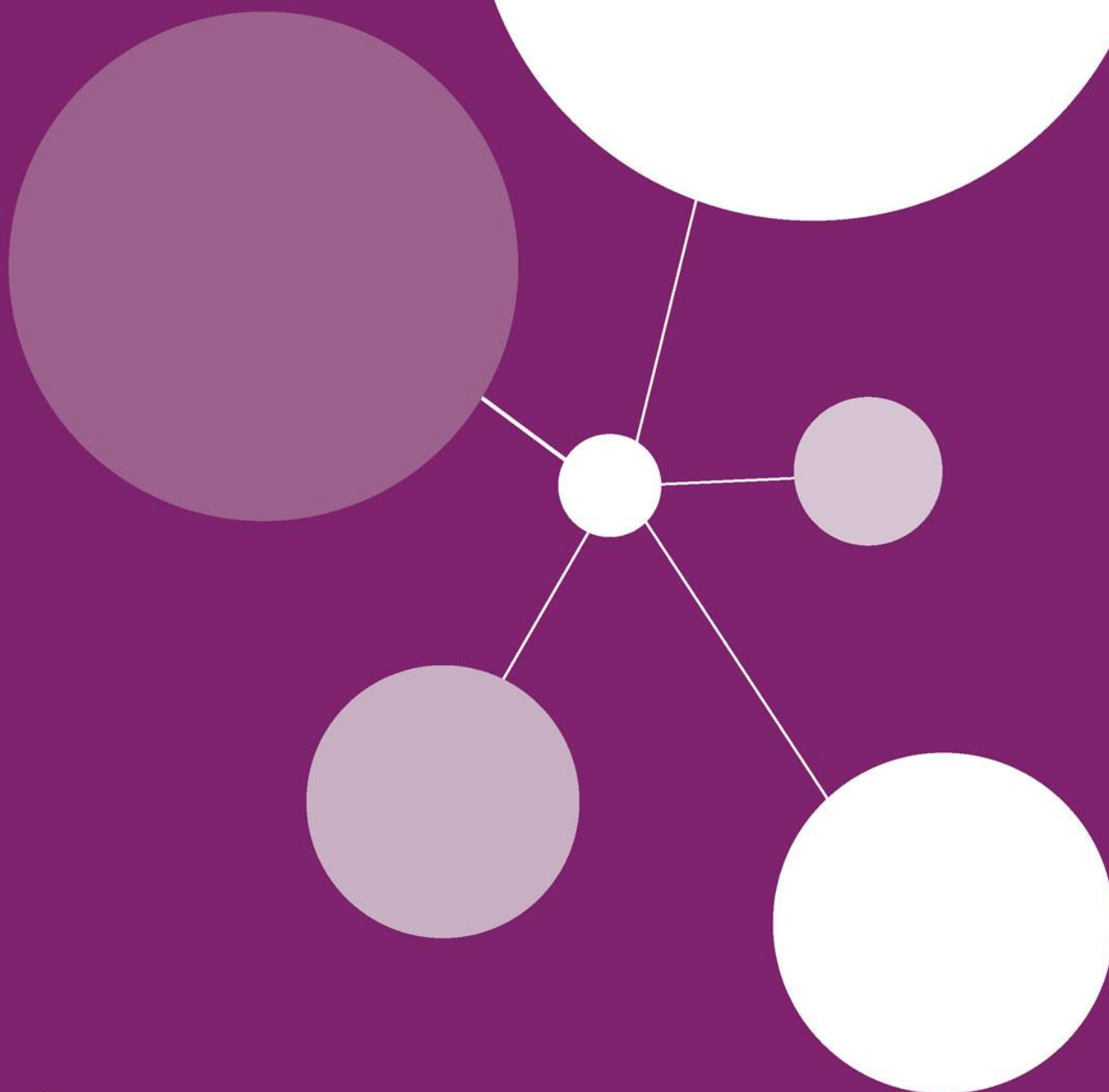


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1. Top 3 achievements in the reporting year

Achievement 1

Publication of the final results of the Macmillan-funded EPiC study in JNCI: *Kyte, D, Retzer, A., Keeley, T., Ahmed, K., Armes, J., Brown, J. M., Calman, L., Copland, C., Efficace, F., Gavin, A., Glaser, A., Greenfield, D. M., Lanceley, A., Taylor, R. M., Velikova, G., Brundage, M., Mercieca-Bebber, R., King, M. T., Calvert, M. (in press) Systematic evaluation of Patient-Reported Outcome protocol content and reporting in cancer trials. JNCI.* and an outstanding oral presentation award at the International Society for Quality of Life Research (ISOQOL) 25th Annual Conference, Dublin, IRE. Planning a workshop during NCRI Cancer Conference 2020.

Achievement 2

Oral presentation and e-poster at 2018 NCRI conference *Healthcare professionals attitudes to e-cigarettes for patients with cancer (CRUK TAG funded study)*. Dr Jo Brett, Oxford Brookes, with co-applicants from subgroup Prof Eila Watson and Prof Mary Wells. This received considerable press attention e.g. from The Telegraph, Medical Xpress, Heart FM and Talk radio.

Achievement 3

Programme Grant submitted to NIHR, led by subgroup members Prof Linda Sharp and Prof Eila Watson and involving Prof Mary Wells 'Improving outcomes for Women diagnosed with early breast cancer through improving adherence to adjuvant Endocrine Therapy (SWEET)'. Awaiting final feedback after second round review.

2. Structure of the Group

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				Primary Care Data Linkage

3. Funding applications in last year

Table 2 Funding submissions in the reporting year

Cancer Research UK Research Committee (CRUK)					
Study	Application type	CI	Outcome	Level of CSG input	Funding amount
May 2018					
Not applicable					
November 2018					
Advancing survival cancer outcomes trial (ASCOT): long term follow-up	Project Award	A Fisher, R Beeken	Awarded	CSG member led	£640,000
Committee date?					
CRUK pioneer grant submitted January 2019 (Sims, Campbell) Molecular effect of exercise on breast tumours	Pioneer grant	A Sims, A Campbell, Mel Leggate	Unsuccessful	CSG member led	£200,000
Other committees					
Study	Committee & application type	CI	Outcome	Level of CSG input	Funding amount
Patient-centred models for surveillance and support of cancer survivors with bowel and breast cancer	Yorkshire Cancer Research	Galina Velikova	Awarded	CSG member led, endorsed by the CSG	£789,711
Development of a paediatric version of the Sarcoma Assessment Measure (SAM-Paeds): a specific tool for assessing quality of life in children with sarcoma	CCLG	Maddie Adams (CI) Rachel Taylor (co-applicant)	Awarded	CSG member Co-applicant (RT)	£71,489
The diagnostic experience of sarcoma patients; secondary analysis of the SAM study	Sarcoma UK	Lorna Fern (CI) Rachel Taylor (co-applicant)	Awarded	CSG member Co-applicant (RT))	£23,464
Using a mobile phone application to promote physical activity in those living with and beyond cancer	Yorkshire Cancer Research	A Fisher, A Roberts	Awarded	CSG member led/CSG supported	£620,000

PRiSMs – establishing a self-management clinic for myeloma patients	RM Partners London Cancer Vanguard	A Fisher (with K Yong, UCLH)	Awarded	CSG member led	£50,000
Bolt-on additional translational study of PREPARE-ABC trial (Sims, Saxton). Molecular effect of exercise on bowel tumours	Ethics committee approval and protocol	A Sims, J Saxton	Awarded	CSG member led	As required, funding for pilot in hand
Targeted therapies for cancer: understanding patient experiences and assessing unmet needs	Macmillan Cancer support project	Linda Sharp	Pending	CSG member led	£246,000
'Improving outcomes for Women diagnosed with early breast cancer through improving adherence to adjuvant Endocrine Therapy (SWEET)'	NIHR Programme Grant	Linda Sharp and Eila Watson	Pending	CSG member led	£2,422,620
Development of a module to supplement the EORTC Core instrument for the assessment of Health Related Quality of Life in Adolescents and Young Adults (AYAs) aged 14-39 years with cancer & Validation of the EORTC QLQ-C30 with 12-17 year olds with cancer	EORTC	Rachel Taylor (co-applicant)	Pending	CSG member Co-applicant (RT))	229,197 EUR
Incorporating the patient voice in sarcoma research: How can we assess health-related quality of life in this heterogeneous group of patients?	EORTC	Rachel Taylor (co-applicant)	Pending	CSG member Co-applicant (RT)	148,469 EUR
Improving outcome through Collaboration in Osteosarcoma	Bone Cancer Research Trust	Rachel Taylor (co-applicant)	Pending	CSG member Co-applicant (RT))lead for PRO)	£449,631
Cancer in the prison population: Assessing disease burden, experiences	NIHR HS&DR	Rachel Taylor (co-applicant)	Pending	CSG member Co-applicant (RT)), lead for phase 3)	£542,633

of diagnosis and of receiving and providing cancer care					
Support and information needs for young people when active treatment ends	Teenage Cancer Trust	Rachel Taylor (PI)	Pending	CSG member led	£40,008
Development and testing of a patient reported outcome tool to capture the experience of people treated with immunotherapy.	Application to Macmillan Research Grants Scheme	Mike Horton (co-applicant)	Pending	Subgroup member co-applicant	Unknown
Supporting physical activity in lung cancer patients through development of an app	Application to Macmillan Research Grants Scheme	Lynn Calman	Pending	Subgroup member co-applicant	£241,000
The management of oligo metastatic disease	Application to Macmillan Research Grants Scheme	Lynn Calman	Pending	Subgroup member co-applicant	£146,000
Understanding the needs of lung cancer patients on immunotherapy	Application to Macmillan Research Grants Scheme	Lynn Calman	Pending	Subgroup member co-applicant	£250,000
Understanding the needs of cancer patients living in areas of deprivation	Application to Macmillan Research Grants Scheme	Lynn Calman	Pending	Subgroup member co-applicant	£120,000
Patient-reported outcomes assessment to support accelerated access to advanced cell and gene therapies: PROmics.	UK Research & Innovation Innovate UK program	Derek Kyte	Pending	CSG member led	£1,100,000
TYA survivors and sun protection	Children with Cancer	G Pugh	Pending	CSG member led	£92,000
Carnegie-funded PhD stipend submitted, February 2019 (Campbell, Sims) Molecular effect of exercise on breast tumours	The Carnegie Trust PhD stipend	A Campbell, A Sims, Mel Leggate	Pending	CSG member led	£65,000
Understanding and improving clinician and patient communication about cancer prognosis	Macmillan Cancer Support project	Eila Watson	Unsuccessful	Subgroup members involved (Mary Wells,	£134,502

				Susan Restorick- Banks)	
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4. Collaborative partnership studies with industry

Subgroup lead Dr Kyte is Co-I on a recently successful bid (PROmics) to the UK Research & Innovation Innovate UK programme in collaboration with industry partners including health technology companies Dignio and Datatrial. The project will investigate patients' experience of cell and gene therapies. (Calvert M, [Kyte D](#) et al. Patient-reported outcomes assessment to support accelerated access to advanced cell and gene therapies: PROmics. £1.1m. UK Research & Innovation Innovate UK program. Dec 2018 - 30 months)

Gill Hubbard is collaborating with a stoma support garment supplier to research support garment use and associations with lifestyle behaviours and quality of life.

Following from one of the strategic objective of NCRI POS to establish closer collaboration with industry, Richard Simcock has been discussing possible research ideas for sub-studies with patient-centred and psychosocial focus to be nested within Roche trials. One specific potential trial was discussed, but there is no further progress as yet.

5. Appendices

Appendix 1 – Top 5 publications in reporting year

Appendix 2 – Recruitment to the NIHR portfolio in the reporting year

Professor Galina Velikova (Psychosocial Oncology & Survivorship Group Chair)

Appendix 1

Top 5 publications in the reporting year

Trial name & publication reference	Impact of the trial	CSG involvement in the trial
<p>LAPCD (Life After Prostate Cancer Diagnosis)</p> <p>Downing A, Wright P, Hounsome L, Selby P, Wilding S, Watson Wagland R, Kind P, Donnelly DW, Butcher H, Catto JWF, Cross W, Mason M, Sharp L, Weller D, Velikova G, McCaughan E, Mottram R, Allen M, Kearney T, McSorley O, Huws DW, Brewster DH, McNair E, Gavin A, Glaser AW. Quality of life in men living with advanced and localised prostate cancer: A United Kingdom population-wide patient-reported outcome study of 30,000 men. <i>Lancet Oncol</i> 2019 Mar;20(3):436-447. doi: 10.1016/S1473-0245(18)30780-0. Epub 2019 Jan 31.</p>	<p>The largest population-based survey of prostate cancer patients in the UK.</p>	<p>LAPCD population study funded by Prostate Cancer UK and Movember. Glaser and Gavin are Co-PIs and members of NCRI POS subgroup. The CSG endorsed the study and contributed to PROMs selection and the clinical advisory group (Velikova)</p>
<p>EPiC study</p> <p>Kyte, D, Retzer, A., Keeley, T., Ahmed, K., Armes, J., Brown, J., Calman, L., Copland, C., Efficace, F., Gavin, A., Glaser, A., Greenfield, D. M., Lanceley, A., Taylor, R. M., Velikova, G., Brundage, M., Mercieca-Bebber, R., King, M. T., Calvert, M. (in press) Systematic evaluation of Patient-Reported Outcome protocol content and reporting in cancer trials. <i>JNCI</i> 2019</p>	<p>The significance of this study is shown by the high-impact publication in JNCI. The results show worrying facts that PROs are collected but not reported by almost half of trials.</p>	<p>EPiC trial led by Kyte (CSG member, subgroup lead). The subgroup was actively involved during the study contributing to results interpretation. Future plans include an attempt to secure a plenary presentation and deliver a Workshop at NCRI Cancer Conference 2020.</p>
<p>Swallowing Intervention Package study</p> <p>Patterson J, Toft K, MacAulay F, McLachlan K, Roe J, King E, Wells M Feasibility and outcomes of Fiberoptic Endoscopic</p>	<p>This output is the analysis of the use of Fiberoptic Endoscopic Evaluation of Swallowing</p>	<p>This study was reviewed by members of the CSG before submission. It involved Mary Wells as PI and Nick Hulbert-Williams as a co-applicant. This was a feasibility study of</p>

<p>Evaluation of Swallowing following prophylactic swallowing rehabilitation in head and neck cancer (in press) Clinical Otolaryngology</p>		<p>a swallowing intervention package to improve swallowing outcomes and quality life in patients undergoing chemoradiotherapy for head and neck cancer.</p>
<p>CREW cohort study</p> <p>Cummings, A., Grimmett, C., Calman, L., Patel, M., Permyakov N. V., Winter, J., Foster, C. (2018). Comorbidities are associated with poorer quality of life, functioning and worse symptoms in the 5 years following colorectal cancer surgery: Results from the ColoRECTal Wellbeing (CREW) cohort study Psychooncology. 2018 Oct;27(10):2427-2435. doi: 10.1002/pon.4845. Epub 2018 Sep 13. PubMed PMID: 30070052; PubMed Central PMCID: PMC6221152</p>	<p>Large population-based study of colorectal cancer patients</p>	<p>Led by CSG members Foster and Calman</p>
<p>Sarcoma Assessment Measure study (Rachel Taylor PI – Sarcoma UK funded)</p> <p>Storey L, Fern L,, Martins A, Wells M, Bennister L, Gerrand C, Onasanya M, Whelan JS, Windsor R, = Woodford J, and Taylor RM A Critical Review of the Impact of Sarcoma on Psychosocial Wellbeing." Sarcoma. vol. 2019, Article ID 9730867. https://doi.org/10.1155/2019/9730867</p>		<p><i>This study is ongoing and involves CSG members Rachel Taylor, Lesley Storey, Mary Wells and is a collaboration between the POS CSG and Sarcoma CSG. The first published output is a systematic review</i></p>

Appendix 5

Recruitment to the NIHR portfolio in the reporting year

In the Psychosocial Oncology & Survivorship Group portfolio, 7 trials closed to recruitment and 17 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	1919	310	1909	310	-	-
2015/2016	2649	374	2369	359	-	-
2016/2017	1095	541	713	496	-	-
2017/2018	2401	712	2190	692	-	-
2018/2019	4191	301	3205	284	-	-



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1. Top 3 achievements in the reporting year

Achievement 1

The two new subgroups (Early Stage Disease and Acute Treatment Toxicities and Survivors and Late Effects) have now appointed new chairs and have settled into productive work with face to face meetings and teleconferences. The importance of these subgroups – and also the long-running Advanced Disease and End of Life subgroup - is reflected in their all being transformed into Workstreams in the new NCRI Cross-cutting Group (name TBC). The Group wishes to acknowledge the critical contributions of the former interim chairs of these subgroups, who have both now left the Group but are continuing to collaborate with the Group: Prof Annie Young who steered the Early Stage Disease and Acute Treatment Toxicities subgroup (new chair Dr Gillian Prue); Prof Anthony Maraveyas who oversaw the early days of the Survivors and Late Effects subgroup (now chaired by Prof Sara Faithfull); and Dr Matthew Maddocks who has chaired the Advanced Disease and End of Life subgroup for several years and is now stepping down.

Achievement 2

The Group has been successful again this year in competitive grants, notably with

- (1) **MICA** – a translational study of a novel interleukin-1 α antibody (bermekimab) for the management of cachexia in NSCLC, pancreatic or ovarian cancer, funded by MRC Biomedical Catalyst – Developmental Pathway Funding Scheme Award with US industry partner Xbiotech (CI Barry Laird, co-applicant CSG chair Sam Ahmedzai);
- (2) **PRECISE** – Individualised supervised exercise for pancreatic cancer patients, funded by Pancreatic Cancer UK and Yorkshire Cancer Research (CI Gillian Prue, chair of Early Stage Disease subgroup);
- (3) **OPTCARE Breathe** – NIHR funded evaluation of a short-term respiratory and palliative care intervention for people with advanced respiratory disease (CI Irene Higginson, co-applicant CSG subgroup lead Matthew Maddocks).

The Survivors and Late Effects subgroup has submitted a grant in response to a **NHS Digital** call, focusing on testing the efficacy of wearable technologies in patients with chemotherapy-induced peripheral neuropathy (CI Sara Faithfull).

In addition, **ARTISTix** – a RCT of iv steroids \pm infliximab for gastrointestinal side-effects of immunotherapy (CI Gareth Griffiths with co-applicant CSG member Annie Young) was rejected by NIHR HTA but was invited to re-submit in a new call.

Achievement 3

The Group has started to have success in industry engagement, which has been in our strategy for three years but has so far eluded us. The first example is the collaboration with a US biotech company Xbiotech, which is contributing \$600k to the MICA trial of its interleukin-1 α antibody for management of cachexia in lung, pancreatic and ovarian cancers (main funder MRC Biomedical Catalyst – Developmental Pathway Funding Scheme).

Second, we are also working with a company on a IIR application to design a ‘real world’ study of the longterm patient experience of the licensed PARP inhibitor Niraparib. This is a collaboration with the Gynaecological Cancer Group and could be extended to PARPis from other companies.

Third, we are engaging with the rapidly growing field of ‘wearable technologies’ and are currently pursuing two avenues. Prof Sara Faithfull has made an application to NHS Digital to use body-worn devices to measure long-term functional impairment in patients with chemotherapy-induced peripheral neuropathy; and Dr Gillian Prue has engaged with a wearable technology company Medopad to investigate the use of a modular technology platform to deliver and assess adherence to a complex lifestyle intervention in patients with metastatic colorectal cancer.

Finally, Dr Andrew Dickman is pursuing collaboration with the palliative care medicines pharmaceutical industry, with the possibility in sight of trials using a new model of syringe driver for continuous subcutaneous infusions for symptom control.

2. Structure of the Group

To address the overlapping areas of remit between NCRI Psychosocial Oncology and Survivorship (POS), Supportive and Palliative Care (S&PC) and Primary Care (PC) Groups, a restructure of these cross-cutting Groups has been agreed to ensure a more efficient and aligned approach moving forward. The work of the NCRI Cancer of Unknown Primary (CUP) and Acute Oncology Working Parties has also been encompassed into this new cross cutting structure.

In the new structure an Executive Group and Workstreams will be created, replacing the previous main Group and subgroups. The Executive Group will take a strategic role, providing oversight of the research landscape and proactively identifying opportunities for the work of the Group. The Workstreams will also identify new opportunities and develop new trials within their focus areas; reporting to the Executive Group regarding any changes in the research landscape relating to their area and providing reports on their progress.

Membership of the Executive Group will include:

- the Executive Group Chair
- the Chair of each of the five Workstreams (see below for further details)
- a consumer representative
- the relevant Research Delivery Manager
- funder representatives (as appropriate)

The following five Workstreams will be initiated, covering each of the listed topic areas:

MUO/CUP Workstream	Acute Care and Toxicities Workstream	Late Consequences Workstream	Advanced Disease and End of Life Care Workstream	Methodology Workstream
Acute Oncology Type I	Acute Treatment Toxicities	Late Toxicities	Palliative Care	PROMs
Primary Care Pathway	Acute Cancer Toxicities	Psychosocial Aspects	Hospice	Touch Screen/Apps
CUP Biology & Therapy	Psychosocial Impacts of Treatment	Primary Care follow-up	Bereavement Care	Quality of Life/ Health Economics
	Prehabilitation		Primary Care	Output Measures/ Trial Design
	Primary/Secondary Care Interface		Psychosocial Aspects	Qualitative Research
				Modelling
				Primary Care Data Linkage

3. Funding applications in last year

Table 2 Funding submissions in the reporting year

Committees					
Study	Committee & application type	CI	Outcome	Level of CSG input	Funding amount
EARLY STAGE DISEASE AND ACUTE TREATMENT TOXICITIES SUBGROUP					
ARTISTix' - A randomised trial of intravenous steroid therapy +/- infliximab for gastrointestinal side effects in cancer immune checkpoint therapy	NIHR HTA Commissioned Call	Prof Gareth Griffiths	REJECTED but invited to re-submit	Developed by subgroup. Gareth Griffiths and Annie Young lead applicants.	£2M
PRECISE: PancREatic Cancer: Individualised Supervised Exercise: a feasibility study.	Pancreatic Cancer UK and Yorkshire Cancer Research	Dr Gillian Prue	SUCCESSFUL	Developed by subgroup. Anthony Maraveyas main co-applicants. Adaptation of previous ovarian cancer study to focus on pancreatic cancer.	£330,000
CONFIRM-EXP: Patient and caregiver outcomes and EXPerience of the CONFIRM trial: a randomised double blinded placebo controlled trial of nivolumab for relapsed mesothelioma.	Bristol Myers Squibb (BMS)	Dr Gillian Prue with Prof Gareth Griffiths and Annie Young	REJECTED by BMS. Currently seeking alternative funding	Developed by subgroup with Gareth Griffiths and Annie Young.	£150,000
SURVIVORS AND LATE CONSEQUENCES SUBGROUP					
The efficacy of digital body-worn technology to quantify and predict long-term functional impairment	NIHR Digital Health	Prof Sara Faithfull	Awaiting stage 1 outcome	Subgroup collaboration with Gillian Prue and Theresa Young	£1.2 m

associated with chemotherapy-induced neuropathy in people with cancer					
PhD Funding: Developing a screening tool for the late effects of treatment for brain cancers	Marie Curie	Annmarie Nelson	SUCCESSFUL	No CSG input	£65,500
ADVANCED DISEASE AND END OF LIFE					
MICA. A phase II trial examining Bermekimab (anti-IL1 alpha) effects on muscle, physical function and appetite, in lung, pancreatic or ovarian cancer	MRC: Biomedical Catalyst – Developmental Pathway Funding Scheme Award 2018 with Industry Partner XBiotech	Barry J A Laird	SUCCESSFUL	Developed with Sam Ahmedzai (Advanced Disease Subgroup)	£962,000 + \$600,000 industry
Evaluation of the effectiveness and cost-effectiveness of a short-term integrated respiratory and palliative care intervention to OPTimise CARE for people with advanced respiratory disease (OPTCARE Breathe).	NIHR HS&DR stream	Bajwah S	SHORTLISTED	Matthew Maddock (Subgroup lead) co-investigator)	£1.3m
Improving health status and symptom experience for people living with advanced cancer.	Yorkshire Cancer Research	Bennett M.	SUCCESSFUL	Fliss Murtagh consulted in Advanced Disease Subgroup.	£1.37m
A parallel group, double-blind, randomised, placebo-controlled trial comparing the effectiveness and cost-consequence and cost effectiveness of low dose oral modified release morphine (MRM) versus placebo on	NIHR HTA	Johnson M	SUCCESSFUL	No CSG input	£1.23m

the intensity of worst breathlessness in people with chronic breathlessness.					
Understanding and supporting complex decision-making for people affected by head and neck cancer: the development of a decision support tool.		Catriona Mayland	SUBMITTED under review	Catriona Mayland and Michelle Collinson collaboration in Advanced Disease Subgroup	£75,091.00
Research Assessment Outcome Measures for Malignant Bowel Obstruction (RAMBO)	Marie Curie	Dr Jason Boland	SUCCESSFUL	Developed by Jason Boland and Annmarie Nelson (Advanced Disease subgroup members)	£218,403.87
Cancer caring coping at end of life: developing an end of life module for inclusion within an existing web-based carer resource	Marie Curie Cancer Care	Dr Olinda Santin	REJECTED But now re-submitted to NIHR HS&DR	Active CSG collaboration. Gillian Prue, Sam Ahmedzai and Jane Hopkinson are all co-investigators on the project	£150,000
Understanding and supporting complex decision-making for people affected by head and neck cancer: the development of a decision support tool.		Catriona Mayland	SUBMITTED Awaiting decision	Subgroup collaboration - Catriona Mayland and Michelle Collinson co-investigators	£75,091.00

4. Collaborative partnership studies with industry

In 2018-19 the Group has started to have success in **industry engagement**:

- Prof Sam Ahmedzai is co-applicant in a collaboration with US company Xbiotech, which is contributing \$600k to the MRC Biomedical Catalyst MICA trial of its interleukin-1 α antibody for management of cachexia in lung, pancreatic and ovarian cancers (main funder MRC Biomedical Catalyst – Developmental Pathway Funding Scheme)
- Prof Sam Ahmedzai is also working with the Gynaecology Cancer Group and a US company on a IIR application to design a ‘real world’ study of the longterm patient experience of their PARP inhibitor Niraparib
- Engaging with the rapidly growing field of ‘wearable technologies’ and currently pursuing two avenues.
 - Prof Sara Faithfull has made an application to recent NHS Digital call to use body-worn devices to measure long-term functional impairment in patients with chemotherapy-induced peripheral neuropathy. The proposal evaluates efficacy of a rapid digital clinical assessment using body-worn inertial sensor technology with the aim to guide more accurately dose reductions and rehabilitation as part of the practice pathway to subsequently reduce long term CIN symptoms and disability.
 - Dr Gillian Prue with Dr Vicky Coyle (former CSG member) have engaged with a wearable technology company Medopad to investigate the use of a modular technology platform to deliver and assess adherence to a complex lifestyle intervention in patients with metastatic colorectal cancer. The programme will aim to deliver physical activity and nutritional advice which aims to preserve muscle mass or attenuate the loss of muscle mass in patients with advanced colorectal cancer receiving palliative chemotherapy.
- Dr Andrew Dickman is pursuing collaboration with the palliative care medicines pharmaceutical industry, with the possibility of trials using a new model of syringe driver for continuous subcutaneous infusions for symptom control.
- Further discussions are taking place with companies producing immune-oncology drugs, as part of the new Immunotherapies Toxicities Working Group, in order to secure funding for future studies of late effects of IO drugs using NHS data linkages.

5. Appendices

Appendix 1 – Top 5 publications in reporting year

Appendix 2 – Recruitment to the NIHR portfolio in the reporting year

Professor Sam H Ahmedzai (Supportive & Palliative Care Group Chair)

Appendix 1

Top 5 publications in the reporting year

Trial name & publication reference	Impact of the trial	CSG involvement in the trial
<p>1. Young AM, Marshall A, Thirlwall J, Chapman O, Lokare A, Hill C, Hale D, Dunn JA, Lyman GH, Hutchinson C, MacCallum P, Kakkar A, Hobbs FDR1, Petrou S, Dale J, Poole CJ, Maraveyas A, Levine M.</p> <p>Comparison of an oral factor Xa Inhibitor with low molecular weight heparin in patients with cancer with venous thromboembolism: results of a randomised trial (SELECT-D). J Clin Oncol. 2018; 36(20): 2017 - 2023</p>	<p>This is a potentially practice-changing trial as it showed that an oral anticoagulant Rivaroxaban could be used as alternative to long term subcutaneous injections of Dalteparin to prevent venous thromboembolism (VTE) in cancer patients. However, Rivaroxaban was associated with higher risk of clinically relevant non-major bleeding, so the ideal management of VTE has still to be established.</p>	<p>Annie Young and Anthony Maraveyas led this from the Survivorship and Late Effects Subgroup</p>
<p>2. White C, Noble SIR, Watson M, Swan F, Allgar VL, Napier E, Nelson A, McAuley J, Doherty J, Lee B, Johnson MJ.</p> <p>Prevalence, symptom burden, and natural history of deep vein thrombosis in people with advanced cancer in specialist palliative care units (HIDDEN): a prospective longitudinal observational</p>	<p>This study – funded by NIHR RfPB - is likely to establish a standard of care in hospices, where there is a range of policies about anti-coagulating patients with advanced disease against the risk of VTE. This study showed that a third of such patients had femoral DVT and this was not associated with thromboprophylaxis. It shows that routine anti-coagulation is not needed, thus saving staff</p>	<p>Simon Noble and Miriam Johnson were members of the CSG/subgroup when this study was initiated.</p>

<p>study.Lancet Haematol. 2019 Feb;6(2):e79-e88.</p>	<p>time, costs and potential harm to some patients.</p>	
<p>3. Eerdeken MH, Kapanadze S, Koch ED, Kralidis G, Volkers G, Ahmedzai SH, Meissner W.</p> <p>Cancer-related chronic pain: Investigation of the novel analgesic drug candidate cebranopadol in a randomized, double-blind, noninferiority trial.</p> <p>Eur J Pain. 2019 Mar;23(3):577-588.</p>	<p>For over a decade there have been no new opioids to use for the management of moderate to severe cancer-related pain. This commercial study showed that cebranopadol – a new molecule with unique pharmacological profile including a specific action on the ORL-1 receptor – was non-inferior morphine, the current standard. It was also superior to morphine PR for the primary endpoint of daily rescue medication, which has not been shown with other recent synthetic opioids. With a tolerable safety profile, cebranopadol could become a new standard for longterm cancer pain management.</p>	<p>This international trial was industry-funded (Grunenthal) and was led by Prof Sam Ahmedzai who is chair of the CSG.</p>
<p>4. .Solheim TS, Laird BJA, Balstad TR, Bye A, Stene G, Baracos V, Strasser F, Griffiths G, Maddocks M, Fallon M, Kaasa S, Fearon K.</p> <p>Cancer cachexia: rationale for the MENAC (Multimodal-Exercise, Nutrition and Anti-inflammatory medication for Cachexia) trial.</p> <p>BMJ Support Palliat Care. 2018 Sep;8(3):258-265</p>	<p>This publication is the rationale for the portfolio MENAC trial, which is an international collaboration between the SPC CSG (Advanced Disease subgroup) and the European Palliative Care Research Network. It was led by the late Prof Ken Fearon, who was a member of the CSG and who died suddenly during the trial. This is the first large trial to use a comprehensive package of exercise, nutrition and anti-inflammatory medication. It has now been completed and results will be presented and published in 2019/2020.</p>	<p>This international study was led by current (Matthew Maddocks) and past (Ken Fearon) members of the Advanced Disease Subgroup.</p>

<p>5. Nanton V, Appleton R, Loew J, Ahmed N, Ahmedzai S, Dale J.</p> <p>Men don't talk about their health, but will they CHAT? The potential of online holistic needs assessment in prostate cancer. BJU Int. 2018 Apr;121(4):494-496.</p>	<p>This commentary and preliminary data publication arose from the ICARE-P trial, in which men with prostate cancer were invited to have holistic needs assessments online. Contrary to popular expectation, men of all ages were receptive to this technology. The study shows that older age and male gender is not a barrier to online support for cancer patients. The trial has now completed and is being written up.</p>	<p>This NIHR funded trial was developed by Dr Ronni Nanton and Prof Sam Ahmedzai who was chair of the CSG.</p>
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Additional publications by Group members, mostly but not all related to portfolio studies (CSG members in bold):

MENAC/ENERGY

Hall CC, Cook J, **Maddocks M**, Skipworth RJE, Fallon M, Laird BJ. Combined exercise and nutritional rehabilitation in outpatients with incurable cancer: a systematic review. Support Care Cancer. 2019 Apr 3. doi: 10.1007/s00520-019-04749-6.

BSS / Breathlessness services

Brighton LJ, Miller S, Farquhar M, Booth S, Yi D, Gao W, Bajwah S, Man WD, Higginson IJ, **Maddocks M**. Holistic services for people with advanced disease and chronic breathlessness: a systematic review and meta-analysis. Thorax. 2019 Mar;74(3):270-281.

Better-B

Lovell N, Wilcock A, Bajwah S, Etkind SN, Jolley CJ, **Maddocks M**, Higginson IJ. Mirtazapine for chronic breathlessness? A review of mechanistic insights and therapeutic potential. Expert Rev Respir Med. 2019 Feb;13(2):173-180.

Integrated rehabilitation for lung cancer

Bayly J, Edwards BM, Peat N, Warwick G, Hennig IM, Arora A, Wilcock A, Higginson IJ, **Maddocks M**. Developing an integrated rehabilitation model for thoracic cancer services: views of patients, informal carers and clinicians. *Pilot Feasibility Stud.* 2018 Oct 18;4:160.

C-Change

Pinto C, Bristowe K, Witt J, Davies JM, de Wolf-Linder S, Dawkins M, Guo P, Higginson IJ, Daveson B, **Murtagh FEM**. Perspectives of patients, family caregivers and health professionals on the use of outcome measures in palliative care and lessons for implementation: a multi-method qualitative study. *Ann Palliat Med.* 2018 Oct;7(Suppl 3):S137-S150.

Appendix 5

Recruitment to the NIHR portfolio in the reporting year

In the Supportive & Palliative Care Group portfolio, 10 trials closed to recruitment and 11 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	1336	498	1290	473	-	-
2015/2016	869	2261	706	2244	-	-
2016/2017	2510	1923	2250	1747	-	-
2017/2018	2132	3798	1875	3573	-	-
2018/2019	834	830	724	813	-	-