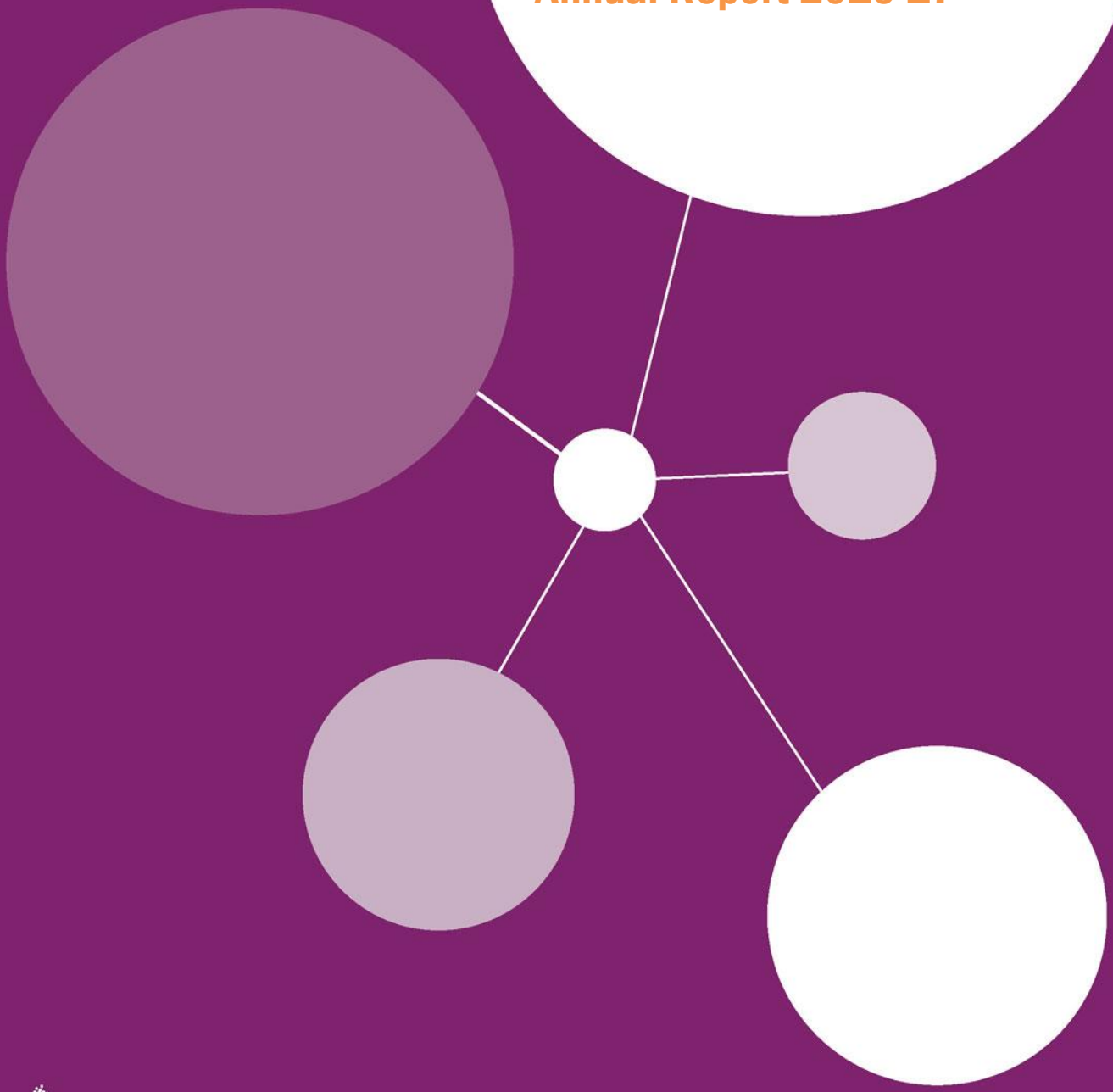
NCRI
National
Cancer
Research
Institute

NCRI Colorectal Cancer Clinical Studies Group

Annual Report 2016-17



Partners in cancer research

NCRI Colorectal Cancer
CSG Annual Report 2016-17

1. CSG & Subgroup strategies

Anorectal Subgroup (Chair, Professor Richard Adams)

The Anorectal Subgroup has been productive in reaching its stated strategic objectives in a number of areas and has updated and adapted these in a progressive fashion.

Significantly, in anal cancer we will shortly randomise our last patient into our expanded, international Rare Cancer Initiative (IRCI) randomised phase II study, with results hoped for late breaking at ASCO 2018. This study, led by the UK (Rao) and developed through the CSG, IRCI and the Subgroup, has been seen as an exemplar of international collaboration. We have already developed the proposal for the follow-on phase III international study and are in discussions internationally to seal this plan and seek funding. We have successfully developed, obtained funding and now opened the phase II/III umbrella trial PLATO, which has been seen as an exemplar by CTRad and is aiming to open internationally pending funding in Australia in late 2018. A sample collection and translational research project has been funded through CRUK; this proposal was developed in discussion with CTRad and other CSGs treating HPV-driven cancers and again has been seen as an exemplar of collaboration. In alignment with this, we will run a parallel phase Ib/II study in the ACT5 more locally advanced group of patients which will attempt to incorporate an immune check point inhibitor in combination with chemo-radiotherapy; this trial will recruit in Scandinavia as an international collaboration. There are significant PROMs components planned to be built in to the PLATO concept.

For the rectal cancer portfolio, the phase III RCT ARISTOTLE is due to complete in early 2018 and has an allied sample collection for translational research. Plans are also underway to evaluate data from the national radiotherapy quality assurance work within this trial.

A number of additional feasibility studies are still recruiting (TRIGGER, SAILOR) along with translational studies incorporating imaging and biology. The CSG is highly engaged with the S-CORT consortium, with samples being shared from historic trials.

Critically, we are keen to develop at least one platform study for rectal cancer and a number of options are under discussion including international collaborators. Most recently, with an international meeting in Chicago (Chair: Adams).

Screening & Prevention Subgroup (Chair, Professor Mark Hull)

The Subgroup has addressed all current strategic aims in 2016-17. Professor Colin Rees has replaced Professor Hull as Chair and will refresh the Subgroup strategy in due course.

- Increase the Subgroup membership to include more members of the CSG and a wider UK representation: The core membership has been refreshed to include expertise in translational medicine and epidemiology. There is also wide geographical representation. Several Investigators have joined the Subgroup in order to present a proposal, during which it is always made clear that attendance at future meetings is entirely open.
- Expand the trial portfolio to include more UK wide trials: There is still a dearth of truly national studies in this area. The Subgroup will play an important role in development of a national collaborative push for multi-modal S&P research at programme grant level in 2017-18 based on a consent to participate trial platform.
- Enhance research links with the four UK national bowel cancer screening programmes, the Primary Care CSG Screening Subgroup, the ECMC UK Therapeutic Cancer Prevention Network (UK-TCPN), the National Awareness & Early Diagnosis Initiative (NAEDI) and with the Screening, Prevention & Early Diagnosis Advisory Group (SPED): Links with these groups have strengthened with reciprocal representation with the Subgroup. Professor Brown strengthens the link with UK-TCPN and Professor Matt Rutter is now Chair of the English Bowel Cancer Screening Programme Research Advisory Committee, ensuring the strongest possible links and coordination with the Screening Programme in England. Several members were involved in the Bowel Cancer UK Critical Gaps exercise.

The relationship with SPED remains unclear, with some colorectal proposals being reviewed by that Group, thereby bypassing the Subgroup. The role of the Subgroup in support and peer-review of proposals for funders, including CRUK PRC, is also uncertain. These two issues continue to have a negative impact on engagement with existing and new members, as well as function of the Subgroup.

- Develop strategies to increase participation in screening and prevention studies and programmes, particularly from ‘hard to reach’ populations: This is likely to be an outcome from the national collaborative mentioned above.
- Develop more lifestyle studies in primary and secondary prevention of colorectal cancer.
- Develop more biology-based chemoprevention studies: Further phase II/III polyp prevention trials with biobanking and biomarker measurements are planned to follow on from the seAFOod Trial
- Encourage a seamless transition from screening to studies of novel treatment for early stage disease: The Subgroup has not had any proposals for studies on polyp cancer or other early stage lesions.
- Encourage and support studies of “generic” prevention agents including “re-purposed” drugs: See ‘chemoprevention studies’ above. Several interventions including nutraceuticals will be assessed. The close links with the UK-TCPN are critical for this pipeline.

Adjuvant & Advanced Disease Subgroup (Chair, Professor Anne Thomas)

In line with our strategy, key highlights this year include:

- The Subgroup has set up a Working Group chaired by Professor Gareth Griffiths of the Southampton Clinical Trials unit to lead in developing a study for the management of

colorectal liver metastases. A number of iterations of the complex proposal have been reviewed and a submission for funding is imminent.

- After significant negotiations and work by MRC Trials Unit, a new arm for FOCUS 4 will be is opening. Discussions with companies are ongoing to explore other innovative drugs for future arms.
- The membership of the Subgroup has been significantly revised.
- New member, Tony Dhillon, has successfully worked with Bristol Myers Squibb to set up a neo-adjuvant and adjuvant study using immunotherapy in MSI-High patients. The protocols are being finalised and the studies are expected to start recruiting in Q4 2017.
- Progress is being made developing a study using a comprehensive geriatric appraisal to deliver chemotherapy to our more frail patients. Engagement with a dynamic geriatrician has been difficult but a good team has now been established to take this forward.

Finally, pivotal studies led from the Subgroup were presented at ASCO this year: SCOT and FOXFIRE. These are practice changing which is the best metric to measure success of the Subgroup. We propose to build on this success with the portfolio of studies in development.

2. Patient recruitment summary for last 5 years

In the Colorectal Cancer CSG portfolio, 20 no. of trials closed to recruitment and 78 opened.

Table 1 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
2012/2013	4690	6416	3433	3151	8.5	7.8
2013/2014	3276	4432	1908	1924	4.7	4.8
2014/2015	4825	1081	4728	1020	11.7	2.5
2015/2016	4679	1765	4651	1213	11.52	3.00
2016/2017	2044	1772	2031	1544	5.03	3.82

3. 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**
May 2016			
Chemotherapy for Rectal cancer before or After local TrEatment. A UK led international phase III randomised trial comparing 12 weeks of chemotherapy either before or after standard local pelvic treatment in MRI defined operable cancer at high risk of metastatic relapse	Full application	Dr Simon Gollins, Professor David Sebag-Montefiore & Mr Simon Bach	Not funded
Screening for colo-rectal cancer using the volatile faecal metabolome and SIFT-MS	Full application	Dr Claire Turner & Professor John Hunter	Not funded
Validation of POLE proofreading domain mutation	Full application	Dr David Church	Not funded

as a biomarker in colorectal and uterine cancers			
Developing and validating prognostic and predictive biomarkers in high risk endometrial cancer	Full application	Professor Richard Edmondson	Not funded
November 2016			
Validation of Colorectal Cancer Molecular Subtype-specific Biomarker Assays to Predict Response to Anti-EGFR Therapeutic Agents	Full (Biomarker Project Award)	Dr Anguraj Sadanandam	Not Supported

4. Consumer involvement

Monica Jefford
Monica Jefford (MJ) is an integral member of the CSG and makes valid contributions to the main Group, the Anorectal Subgroup and several colorectal studies.

These are enhanced by other aspects in her eclectic PPI portfolio and likewise feed into the wider research picture. Underpinned by an ethos of "research for patient benefit", her provision of written or verbal comments ensures the CSG's documents are user friendly and support research delivery.

MJ is a member of TRACC (Tracking mutations in cell free DNA to Predict Relapse in eArly Colorectal Cancer) TMG and two others at the design stage. She also provides the patient view for the London Bowel Screening Programme Board, is a patient advisor to the London Research Design Service and a REC member. Volunteering with Bowel Cancer UK provides MJ with the opportunity to speak to varied community groups about colorectal cancer, the latest being to "Men in Sheds".

5. Appendices

Appendix 1 - Membership of main CSG and subgroups

Appendix 2 – CSG and Subgroup strategies
- A – Main CSG Strategy
- B – Advanced & Adjuvant Disease Subgroup Strategy
- C – Anorectal Subgroup Strategy
- D – Screening & Prevention Subgroup Strategy
- E – Surgical Subgroup Strategy

Appendix 3 - Portfolio Maps

Appendix 4 - Publications in previous year

Appendix 5 - Major international presentations in previous year

Professor Richard Wilson (Colorectal Cancer CSG Chair)

Appendix 1

Membership of the Colorectal Cancer CSG

Name	Specialism	Location
Professor Richard Adams	Clinical Oncologist	Cardiff
Professor David Sebag-Montefiore	Clinical Oncologist	Leeds
Dr Ricky Sharma	Clinical Oncologist	Oxford
Professor Richard Wilson (Chair)	Clinical Oncologist	Belfast
Dr Alexandra Irvine	Consumer	Belfast
Ms Monica Jefford	Consumer	Surrey
Professor Mark Hull	Gastroenterologist	Leeds
Dr Jane Winter	GI Cancer Nurse	Southampton
Dr Michael Braun	Medical Oncologist	Manchester
Dr Vicky Coyle	Medical Oncologist	Belfast
Dr Janet Graham	Medical Oncologist	Glasgow
Dr Sheela Rao	Medical Oncologist	London
Professor Anne Thomas	Medical Oncologist	Leicester
Dr Nick West	Pathologist	Leeds
Professor Manuel Salto-Téllez	Pathologist	Belfast
Professor Gina Brown	Radiologist	London
Dr Rohit Kochhar	Radiologist	Manchester
Dr Louise Brown	Statistician	London
Mr Simon Bach	Surgeon	Birmingham
Mr Stephen Fenwick	Surgeon	Liverpool
Mr James Hernon	Surgeon	Norwich
Mr James Hill	Surgeon	Manchester
Ms Susan Moug	Surgeon	Glasgow
Dr Alexandra Gilbert*	Clinical Oncologist	Leeds
Dr Chris Coyle*	?	?

* denotes trainee member

Membership of the Subgroups

Surgical Subgroup		
Name	**Specialism**	**Location**
Mr Angus McNair**	Clinical Lecturer in Academic Surgery	Bristol
Mrs Ann Russell	Consumer	St Neots
Mr Simon Bach (Chair)	Surgeon	Birmingham
Mr Aneel Bhangu*	Surgeon	Birmingham
Mrs Julie Cornish*	Surgeon	Oxford
Mr James Hernon	Surgeon	Norwich
Mr James Hill	Surgeon	Manchester
Miss Nicola Fearnhead	Surgeon	Cambridge
Professor Dion Morton**	Surgeon	Birmingham
Mr Tom Pinkney**	Surgeon	Birmingham
Mr Jared Torkington	Surgeon	Cardiff
Mr Dale Vimalachandran	Surgeon	Chester
Mr Paul Ziprin	Surgeon	London

Screening & Prevention Subgroup		
Name	**Specialism**	**Location**
Professor Diana Eccles**	Clinical Geneticist	Southampton
Mrs Lindy Berkman	Consumer	London
Dr Laura Neilson*	Trainee	South Tyneside
Professor Karen Brown	Scientist	Leicester
Professor Roger Blanks	Epidemiologist	Oxford
Professor John Burn	Epidemiologist	Newcastle
Dr Christian von Wagner	Epidemiologist	London
Professor Mark Hull (Chair)	Gastroenterologist	Leeds
Professor Colin Rees	Gastroenterologist	Newcastle
Professor Matt Rutter	Gastroenterologist	Stockton On Tees
Professor John Saxton	Physiologist	East Anglia
Mr Simon Bach**	Surgeon	Birmingham
Professor Linda Sharp	Epidemiologist	Newcastle

Anorectal Subgroup		
Name	**Specialism**	**Location**
Professor Richard Adams (Chair)	Clinical Oncologist	Cardiff
Dr Duncan Gilbert	Clinical Oncologist	Brighton
Dr Simon Gollins	Clinical Oncologist	Denbighshire
Dr Mark Harrison	Clinical Oncologist	Watford
Dr Leslie Samuel	Clinical Oncologist	Aberdeen
Professor David Sebag-Montefiore	Clinical Oncologist	Leeds
Ms Monica Jefford	Consumer	Surrey
Dr Sheela Rao	Medical Oncologist	London
Dr Gina Brown	Radiologist	London
Dr Susan Richman	Research Pathology Scientist	Leeds
Mr Andrew Renehan	Surgeon	Manchester

Adjuvant & Advanced Disease Subgroup		
Name	**Specialism**	**Location**
Dr Leslie Samuel	Clinical Oncologist	Aberdeen
Dr Mark Saunders	Clinical Oncologist	Manchester
Professor Richard Wilson	Clinical Oncologist	Belfast
Mrs Ann Russell	Consumer	St Neots
Dr John Bridgewater	Medical Oncologist	London
Dr Ian Chau	Medical Oncologist	London
Dr Janet Graham	Medical Oncologist	Glasgow
Dr Tim Iveson**	Medical Oncologist	Southampton
Professor Gary Middleton**	Medical Oncologist	Birmingham
Dr Paul Ross**	Medical Oncologist	London
Professor Anne Thomas (Chair)	Medical Oncologist	Leicester
Professor Phillip Quirke	Pathologist	Leeds
Professor John Primrose	Surgeon	Southampton

*denotes trainee member
**denotes non-core member

Appendix 2

CSG & Subgroup Strategies

B – Advanced & Adjuvant Disease Subgroup Strategy

- Continue to develop early phase studies to feed through to our future phase II and III RCTs.
- Extend our links with the ECMC network and with the pharmaceutical and biotechnology industries to increase the number of early phase trials in our portfolio.
- Ensure close working relationships with the Upper GI CSG with respect to CRC liver metastases, peritoneal malignancies and small bowel cancer studies.
- Collaborate with the Psychosocial Oncology and Survivorship, Supportive & Palliative Care and Primary Care CSGs to ensure appropriate input into our and their colorectal cancer studies and, where appropriate, develop joint studies.
- Standardise our approach to measuring late effects.
- Set up a post mortem tumour heterogeneity study.
- Explore the development of studies for different subgroups of patients and at different stages of the patient journey.
- Develop studies on biomarkers that will help us to define which patients do and do not benefit from therapy in the neo-adjuvant, adjuvant and advanced disease settings.
- Increase work in the field of survivorship (in particular as regards lifestyle issues) in both the adjuvant and advanced disease settings.
- Develop trials to cover all our disease settings, and in particular:
    - a large pragmatic adjuvant study (in addition to Add-Aspirin)
    - a large pragmatic 1st line study (in addition to FOCUS4)
    - studies in second-line, third-line and beyond third-line metastatic disease
    - studies on tissue/tumour heterogeneity
- Develop our biological research and trials in tumour immunology in CRC.

C – Anorectal Subgroup Strategy

- Develop a seamless portfolio of trials that allow timely follow-on with no significant gaps between.
- Use complex design in the delivery of future trials, e.g. MAMS design, umbrella trials.
- Develop and get funded an international phase III trial for metastatic anal cancer.
- Explore the options for trials in synchronous metastatic disease from rectal cancer.
- Develop studies which focus on improving toxicity and PROM assessment.
- Continue to develop combination trials of radiotherapy and novel agents.
- Link with other CSGs and international groups to develop studies to optimise outcomes for patients with rectal cancer including avoidance of surgery and improving survival.
- Link with pre-clinical and translational scientists to improve our understanding of biology to identify optimised prognostic and predictive markers.

D – Screening & Prevention Subgroup Strategy

- Increase the Subgroup membership to include more members of the CSG and a wider UK representation.
- Expand the trial portfolio to include more UK wide trials.
- Enhance research links with the four UK national bowel cancer screening programmes; the Screening and Prevention Sub-group of the Primary Care CSG; the ECMC UK Therapeutic Cancer Prevention Network (UK-TCPN); the National Awareness and Early

Diagnosis Initiative (NAEDI) and with the UK Screening, Prevention and Early Diagnosis Advisory Group (SPED).

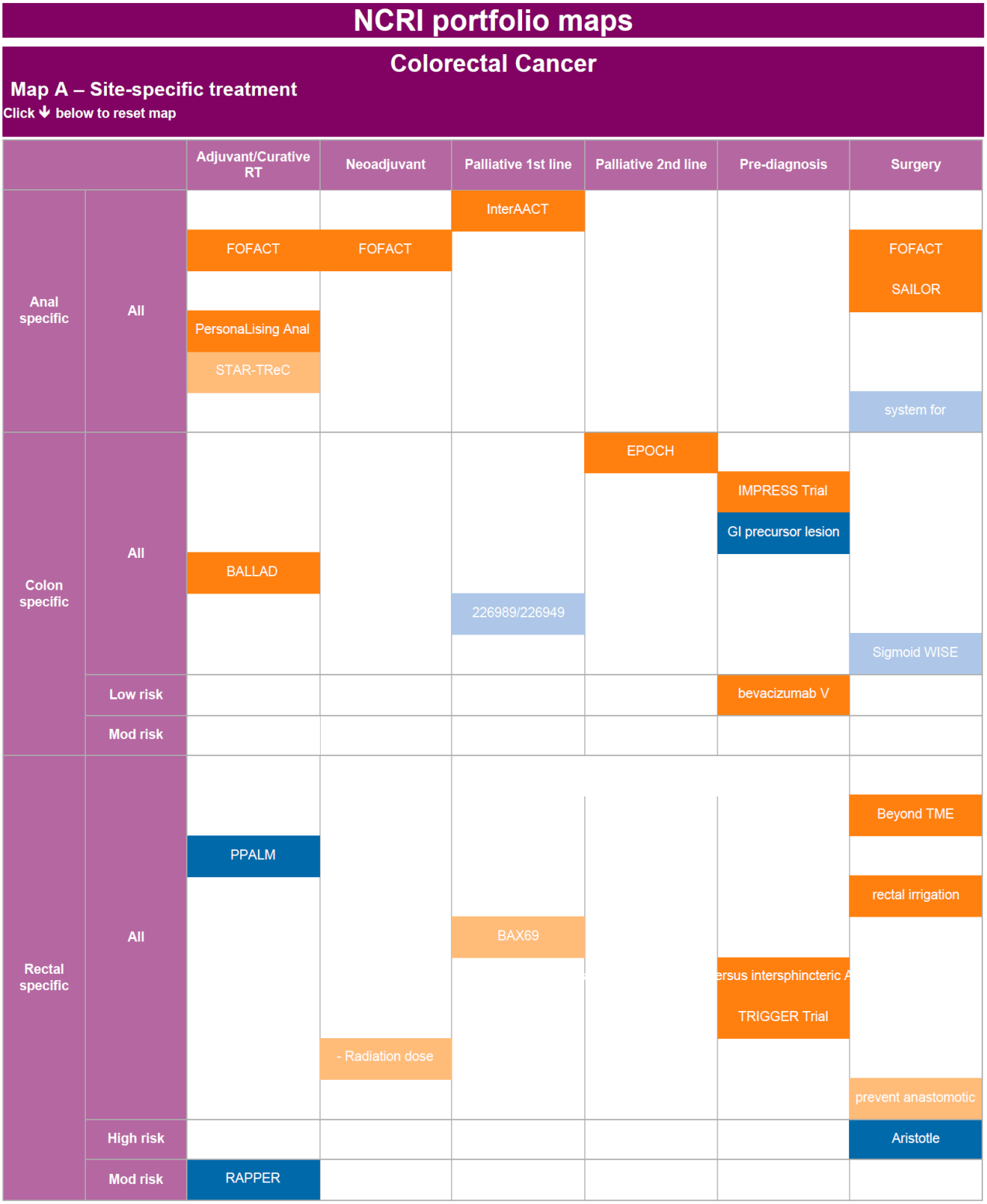
- Develop strategies to increase participation in screening and prevention studies and programmes, particularly from 'hard to reach' populations.
- Develop more lifestyle studies in primary and secondary prevention of CRC.
- Develop more biology-based chemoprevention studies.
- Encourage a seamless transition from screening to studies of novel treatment for early stage disease.
- Encourage and support studies of "generic" prevention agents including "re-purposed" drugs.

E – Surgical Subgroup Strategy

- Enhance the portfolio of surgical trials including the development of two new surgical trials by the end of 2015.
- Develop a study for patient optimisation prior to surgery.
- Develop a new study in organ preservation.
- Set up new studies on the role of surgery in advanced disease.
- Develop device studies.
- Include biomarker validation within our RCTs.
- Increase the number of surgical consultants across the UK involved in research.
- Integrate surgical trainees into the work of the Subgroup.

Appendix 3

Portfolio maps



NCRI portfolio maps

Colorectal Cancer

Map B – Non-specific treatment

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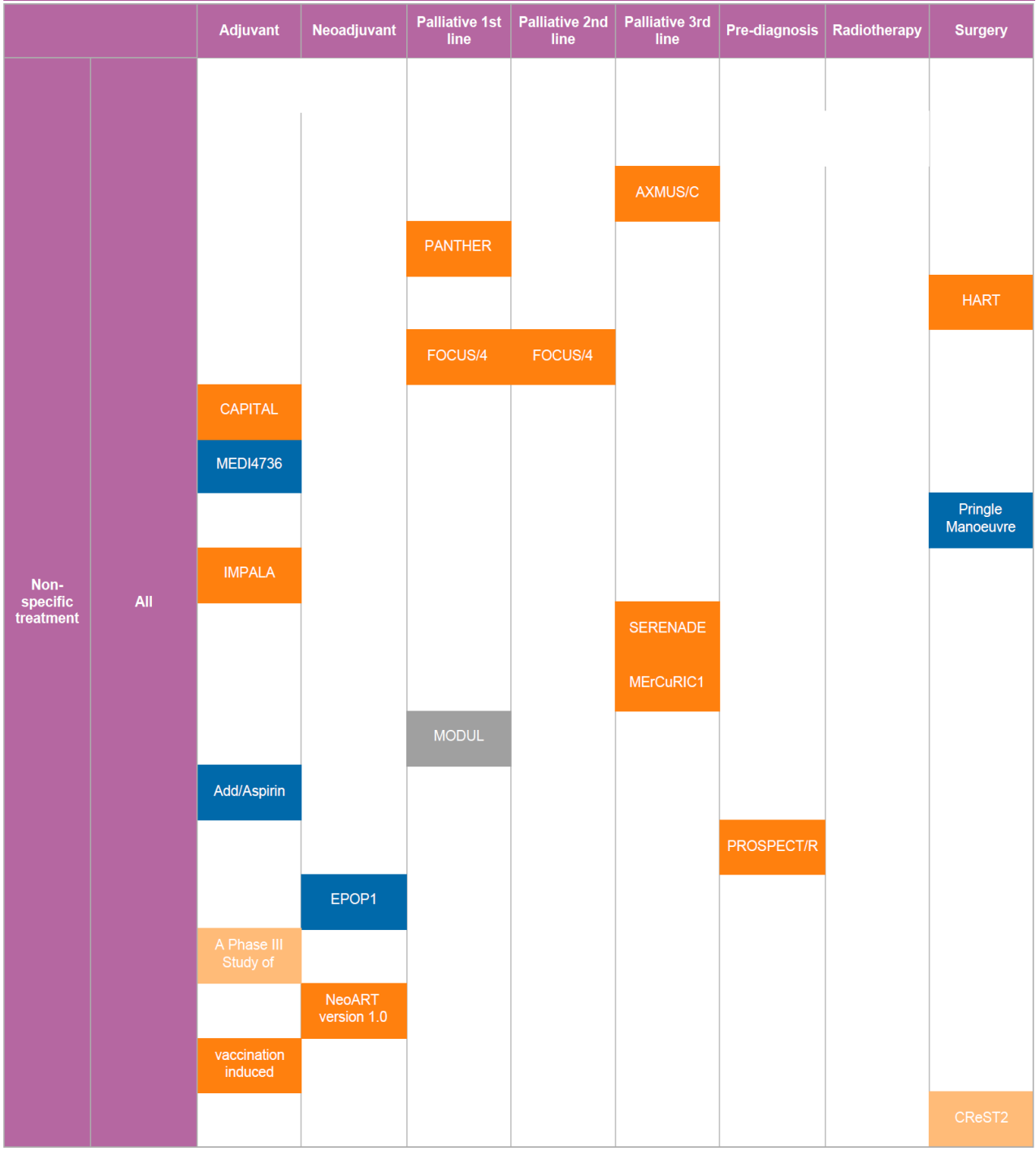

Filters Used:
Active Status: All, **CSG Involvement**: All, **Funding Type**: All, **Phase**: All

Open Multi CSG
Open Single CSG
Null
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In Setup, Waiting ..
Suspended Multi ..

NCRI portfolio maps

Colorectal Cancer

Map C – Non-treatment, translational

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		Adjuvant	Diagnosis / screening / prevention	Neoadjuvant	Palliative 1st line	Pre-diagnosis	Surgery	Therapeutic
Biomarkers	All	Functionality	Functionality	Functionality	Functionality	Functionality	Functionality	Functionality
		Tumour Angiogen	Tumour Angiogen	Tumour Angiogen	Tumour Angiogen	Tumour Angiogen	Tumour Angiogen	Tumour Angiogen
						Gut bacteria in colorectal cancer		
			ctDNA v6.0					
			TRACCr					
						nel lymph node biop		
			biomarkers of					
Diagnostics / imaging	All							
		Raman	Raman	Raman	Raman	Raman	Raman	Raman
			Lactate Imaging					
			CONSCOP					
						MAGENTA		
						MINSTREL		
			assisted					
							laparoscopic	
			AIM / AC					
			Detection of					
						PREDICT		
Genetics / mechanisms	All	NSCCG Functionality		NSCCG Functionality	NSCCG Functionality		NSCCG Functionality	NSCCG Functionality
		Molecular patho	Functionality	Molecular patho	Molecular patho	Functionality	Molecular patho	Molecular patho
						CORGI		
						COGS2		
		PRESENT	PRESENT	PRESENT	PRESENT	PRESENT	PRESENT	PRESENT
						Pop. DNA collxns		
						SOCCS3		
						Vitamin D and C		
						BRAFV600E immunoh		
								EpiMET
							system for	
						biomarker		

Filters Used:
Active Status: All, **CSG Involvement**: All, **Funding Type**: All, **Phase**: All

Open Multi CSG
Open Single CSG
Null
In Setup, Waiting ..

NCRI portfolio maps

Colorectal Cancer

Map D – Non-treatment, supportive care, primary care

Click ↓ below to reset map

		Diagnosis / screening / prevention	Neoadjuvant	Palliative 1st line	Pre-diagnosis	Surgery
Lifestyle / psychoso cial onc..	All	eRAPID feasibility pilot study in pelvic radiotherapy		eSMART: Randomi		The DISCLOSE st Prepare/ABC PARiS EPOP 2- Peri -Operative Isometric Exercise Programme
Primary care / data collection	All	The SCOTTY Study Uterine Protection in Lynch Syndrome (UP study) CORMAC: Core Outcome Research Measures in Anal Cancer phase 2	Anal Cancer Survival Analysis		Risk factors for colorectal precursor lesions	Physiological e IDEAL/PM

Filters Used:
Active Status: All, **CSG Involvement**: All, **Funding Type**: All, **Phase**: All

Open Multi CSG
Open Single CSG
In Setup, HRA Ap..

Appendix 4

Publications in the reporting year

Study	Reference
AFFIRM	Folprecht G, Pericay C, Saunders MP, Thomas A, Lopez Lopex R, Roh JK, Chistyakov V, Hohler T, Kim J-S, Hofheinz R-D, Ackland SP, Swinson D, Kppp M, Udovitsa D, Hall M, Iveson T, Vogel A, Zalcberg JR. Oxaliplatin and 5-FU/folinic acid (modified FOLFOX6) with or without aflibercept in first line treatment of patients with metastatic colorectal cancer – the AFFIRM study. Annals of Oncology 2016 first available online 18 April DOI 10.1093/annonc/mdw`76
BACCHUS	Glynne-Jones R, Hava N, Goh V, Bosompem S, Bridgewater J, Chau I, Gaya A, Wasan H, Moran B, Melcher L, MacDonald A, Osborne M, Beare S, Jitlal M, Lopes A, Hall M, West N, Quirke P, Wong WL, Harrison M; Bacchus investigators. Bevacizumab and Combination Chemotherapy in rectal cancer Until Surgery (BACCHUS): a phase II, multicentre, open-label, randomised study of neoadjuvant chemotherapy alone in patients with high-risk cancer of the rectum. BMC Cancer. 2015 Oct 23;15:764. doi: 10.1186/s12885-015-1764-1. PMID: 26493588
COIN	Grenader T, Nash S, Adams R, Kaplan R, Fisher D, Maughan T, Bridgewater J. Derived neutrophil lymphocyte ratio is predictive of survival from intermittent therapy in advanced colorectal cancer: a post hoc analysis of the MRC COIN study. Br J Cancer. 2016 Feb 18. doi: 10.1038/bjc.2016.23. PMID: 26889974
	Wood G, Grenader T, Nash S, Adams R, Kaplan R, Fisher D, Maughan T, Bridgewater J. Derived neutrophil to lymphocyte ratio as a prognostic factor in patients with advanced colorectal cancer according to RAS and BRAF status: a post-hoc analysis of the MRC COIN study. Anticancer Drugs. 2017 Mar 1. doi: 10.1097/CAD.0000000000000488. PMID:28252533
	Weber AM, Drobnitzky N, Devery AM, Bokobza S, Adams RA, Maughan TS and Ryan AJ. Phenotypic consequences of somatic mutations in the ataxia-telangiectasia mutated gene in non-small cell lung cancer. Oncotarget; Sept 2016 on line
	Renfro LA, Goldberg RM, Grothey A, Sobrero A, Adams R, Seymour MT, Heinemann V, Schmoll HJ, Douillard JY, Hurwitz H, Fuchs CS, Diaz-Rubio E, Porschen R, Tournigand C, Chibaudel B, Hoff PM, Kabbinavar FF, Falcone A, Tebbutt NC, Punt CJA, Hecht JR, Souglakos J, Bokemeyer C, Van Cutsem E, Saltz L, de Gramont A, Sargent DJ; ARCAD Clinical Trials Program. Clinical Calculator for Early Mortality in Metastatic

	Colorectal Cancer: An Analysis of Patients From 28 Clinical Trials in the Aide et Recherche en Cancérologie Digestive Database. J Clin Oncol. 2017 Apr 17:JCO2016715771. doi: 10.1200/JCO.2016.71.5771. [Epub ahead of print]
	Franko J, Shi Q, Meyers JP, Maughan TS, Adams RA, Seymour MT, Saltz L, Punt CJ, Koopman M, Tournigand C, Tebbutt NC, Diaz-Rubio E, Souglakos J, Falcone A, Chibaudel B, Heinemann V, Moen J, De Gramont A, Sargent DJ, Grothey A; Analysis and Research in Cancers of the Digestive System (ARCAD) Group. Prognosis of patients with peritoneal metastatic colorectal cancer given systemic therapy: an analysis of individual patient data from prospective randomised trials from the Analysis and Research in Cancers of the Digestive System (ARCAD) database. Lancet Oncol. 2016 Oct 12. pii: S1470-2045(16)30500-9. doi: 10.1016/S1470-2045(16)30500-9
	F. Bonnetain, C. Borg, R. Adams, J. A. Ajani, A. Benson, H. Bleiberg, B. Chibaudel, E. Diaz-Rubio, J. Y. Douillard, C. S. Fuchs, B. J. Giantonio, R. Goldberg, V. Heinemann, M. Koopman, R. Labianca, A. K. Larsen, T. Maughan, E. Mitchell, M. Peeters, C. J. A. Punt, H. J. Schmoll, C. Tournigand, A. de Gramont; How health-related quality of life assessment should be used in advanced colorectal cancer clinical trials. *Ann Oncol* 2017 mdx191. doi: 10.1093/annonc/mdx191
EPOCH	Pugh SA, Bowers M, Ball A, Falk S, Finch-Jones M, Valle JW, OReilly DA, Siriwardena AK, Hornbuckle J, Rees M, Rees C, Iveson T, Hickish T, Maishman T, Stanton L, Dixon E, Corkhill A, Radford M, Garden OJ, Cunningham D, Maughan TS, Bridgewater JA, Primrose JN. Patterns of progression, treatment of progressive disease and post-progression survival in the New EPOC study. Br J Cancer. 2016 Jul 19. doi: 10.1038/bjc.2016.208
FACS	Shinkins, B., Nicholson, B.D., Primrose, J., Perera, R., James, T., Pugh, S. & Mant, D. The diagnostic accuracy of a single CEA blood test in detecting colorectal cancer recurrence: Results from the FACS trial. PLoS One 2017 Mar 10; 12 (3)
LARRIS	Hughes, D.L., Cornish, J., Morris, C. Functional outcome following rectal surgery – predisposing factors for low anterior resection syndrome. Int J Colorectal Dis 2017
PLATO	Initial results from the Royal College of Radiologists UK National Audit of Anal Cancer Radiotherapy 2015 D Gilbert et al Clin Onc – in press.
	Biomarkers in Anal Cancer – from biological understanding to stratified treatment. D Gilbert, et al BJC Mini-review -submitted
	Treasure T, Macbeth F: Is there a survival benefit from increased intensity of CEA monitoring after primary resection

	of colorectal cancer? Eur J Surg Oncol 2016;42:312-313
PulMiCC	Treasure T, Macbeth F: Percutaneous Image Guided Thermal Ablation (IGTA) therapies are to be included in the interventional arm of the Pulmonary Metastasectomy in Colorectal Cancer (PulMiCC) trial to test if survival and quality of life are better than with intention to treat without intervention.Eur J Surg Oncol 2016;42:435-436.
	Treasure T, Macbeth F: The GILDA trial finds no survival benefit from intensified screening after primary resection of colorectal cancer: the PulMiCC trial tests the survival benefit of pulmonary metastasectomy for detected asymptomatic lung metastases. Ann Oncol 2016;27:745.
	Mokhles S, Macbeth F, Farewell V, Fiorentino F, Williams N, Younes RN TJ, Treasure T: Meta-analysis of colorectal cancer follow-up after potentially curative resection. Br J Surg 2016.
CRIB (Cardiac Rehabilitation In Bowel cancer)	Anika Maria Weber, Neele Drobnitzky, Aoife Maire Devery, Sivan Mili Bokobza, Richard A. Adams, Timothy S. Maughan, Anderson Joseph Ryan, Hubbard G, Munro J, O'Carroll R, Mutrie N, Kidd L, Haw S, Adams R, Watson AJM, Leslie SJ, Rauchaus P, Campbell A, Mason H, Manoukian S, Sweetman G, Treweek S The use of cardiac rehabilitation services to aid the recovery of patients with bowel cancer: a pilot randomised controlled trial with embedded feasibility study. Journal: Health Services and Delivery Research Volume: 4 Issue 24 August 2016

Appendix 5

Major international presentations in the reporting year

Study	Conference details
PLATO	The development of an umbrella trial (PLATO) to address radiotherapy dose questions in the loco-regional management of squamous cell carcinoma of the anus. D. Sebag-Montefiore et al IJROBP. 2016 Oct 1;96(2S):E164-E165
	Personalised Dose Escalation in Anal Cancer M Robinson et al IJROBP. 2016 Oct 1;96(2S):E198