

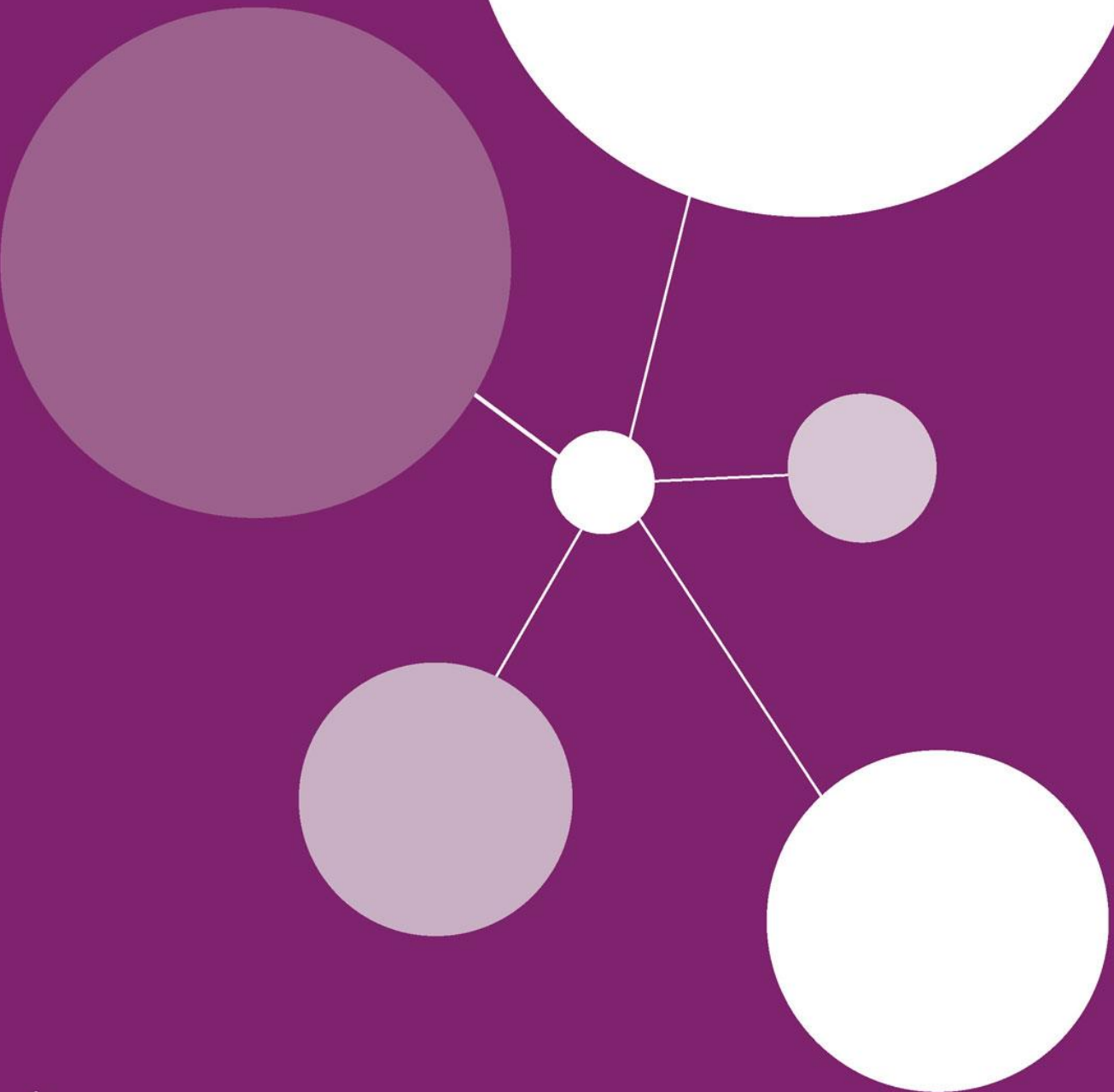


NCRI

National
Cancer
Research
Institute

NCRI Prostate Cancer Clinical Studies Group

Annual Report 2016-17



Partners in cancer research



NCRI Prostate Cancer CSG Annual Report 2016-17

1. Executive Summary (including top 3 achievements in the year)

The Prostate CSG has two main aims:

1. To develop biomarker-driven trials in advanced disease.
2. To reduce the overdiagnosis of localised disease.

Challenges

- Developing precision medicine trials: The lack of validated molecular targets has been a major challenge. DNA repair defects have been identified as the first such target, and trials of PARP inhibitors are now in development. Attempts to validate other putative targets, including PTEN loss and mismatch repair defects, are now underway.
- Clinical workload: Anecdotal evidence suggests that investigators are facing increased pressure of clinical work, leaving less time for clinical research activities.

Achievements

- ProtecT: This 1,600 patient phase III trial, led by Professor Hamdy, was the first to compare surgery, radiotherapy and observation for localised prostate cancer. It was reported in two back-to-back papers in the New England Journal. The results provide the best data available worldwide, both on efficacy and toxicity, to help men decide between these three treatment options.
- PROMIS: This 700 patient study, led by Professor Ahmed, tested the use of MRI as a triage test in the diagnostic pathway. The results were published in the Lancet and suggest that the number of men undergoing prostate biopsy could be safely reduced by 25%, thus reducing overdiagnosis of insignificant prostate cancer. The trial has already contributed to a change in practice, with increasing use of pre-biopsy MRI.
- STAMPEDE: the results of the abiraterone comparison, which will be presented at ASCO in June 2017 and published in the New England Journal, showed a substantial overall survival benefit. Subject to health economic analyses, the addition of abiraterone to androgen deprivation will become a new standard of care for men with newly diagnosed metastatic disease.

2. Structure of the Group

The current membership is listed in Appendix 1. Since the last report, the number of members on the Group has been reduced in accordance with NCRI policy. When making new appointments,

priority was given to strengthening surgical representation and encouraging new investigators.

3. CSG & Subgroup strategies

Main CSG

The CSG continues to focus on its two main strategic aims to develop biomarker-driven trials in advanced disease and address over-diagnosis of localised prostate cancer.

DNA repair defects have been recently identified as the first predictive biomarker in advanced prostate cancer. Several trials of PARP inhibitors are now open or in development for biomarker positive patients. TO-PARP B is testing olaparib in a randomised, dose-finding phase II trial. STAMPEDE will open a new comparison of rucaparib during 2017 for men with hormone-naive disease. TRITON, a commercial trial sponsored by Clovis, will test rucaparib in men with CRPC. These are the first biomarker driven trials in prostate cancer and represent an important new direction for the portfolio. Attempts to validate other putative targets, including PTEN loss and mismatch repair defects, are now underway.

The results of PROMIS, presented at ASCO 2016 (Ahmed et al. Lancet, 2016) are a major step towards reducing overdiagnosis. They suggest that the use of MRI in the diagnostic pathway can safely reduce the number of men undergoing biopsy by around 25%. Many UK centres have already changed practice to implement this approach. We hypothesise that the combination of MRI and the STHLM3 biomarker panel will be superior to either approach used alone, further reducing unnecessary biopsies and overdiagnosis. A proposal is in development to test this hypothesis.

Localised Disease Subgroup (Chair, Professor Hashim Ahmed)

The Localised Disease Subgroup has had an extremely productive year and we have met a number of our strategic aims.

Aims

1. To evaluate strategies to reduce the over-diagnosis burden in prostate cancer.
2. To evaluate strategies to improve current treatment options.
3. To evaluate minimally-invasive strategies within multi-centre studies.
4. To evaluate methodological strategies to improve accrual and success of comparative surgical research.
5. To encourage, nurture and enable young/new investigators to the field.

Broadly, our aims (described in detail in Appendix 2) centre on developing the next generation of research questions that aim to reduce the over-diagnosis, over-treatment and treatment-related harms of the current pathway. We aimed to either develop protocols within the Subgroup or work with research groups and investigators around the UK to do so. Whilst doing so, our other core activity of helping investigators with study design and peer review for CRUK and other NCRI affiliated organisations has remained, with it being carried out in a nurturing and supportive context albeit robust.

The Subgroup membership now includes core members of the main CSG, as well as invited other members, to enrich and enhance the skill-set for its strategic priorities. Further changes to the membership following a review of attendance and engagement will be necessary over the next few weeks.

Advanced Disease Subgroup (Chair, Professor Robert Jones)

Successful progress towards the introduction of the first genomically-guided intervention into the STAMPEDE trial

This was highlighted as a top priority in last year's report. Funding has been secured to introduce a new question within the trial at selected centres (during an initial feasibility phase) in which patients will be tested for a genomically based signature which predicts activity of the PARP inhibitor rucaparib. If positive, patients will be randomised to rucaparib or placebo. This builds on the UK group's pioneering research into PARP inhibitors in prostate cancer under the leadership of Professor De Bono. In addition to working with the MRC to develop the protocol, collaborative work with the STAMPEDE sites, Clovis (the drug company involved) and Foundation Medicine (the test provider), is ongoing to confirm the feasibility of signal detection in the trial population. Recruitment will begin during the coming year.

Development of a broader structure to develop a precision medicine platform STRATOSPHERE

Under the leadership of Dr Attard, a broad collaborative group has been brought together to build this platform to enable future precision medicine trials in advanced prostate cancer. Prostate Cancer UK has now funded the programme.

Imaging in advanced prostate cancer

The development of a study to better understand the role of different and emerging imaging modalities in advanced prostate cancer has now become a specific objective of the Subgroup. Discussions are ongoing and we hope to report next year on more concrete plans in this direction.

4. Task groups/Working parties

Not applicable.

5. Patient recruitment summary for last 5 years

In the Prostate Cancer CSG portfolio, 30 trials closed to recruitment and 25 opened. Recruitment to interventional trials over the last two years has increased compared with previous years.

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	2416	2475	2260	2363	5.6	5.8
2013/2014	3811	2826	3629	2826	9.0	7.0
2014/2015	4164	2836	4021	2786	9.9	6.9
2015/2016	3469	4025	3328	3892	8.23	9.62
2016/2017	6072	3317	4690	3260	11.59	8.06

6. Links to other CSGs, international groups and network subspecialty leads

We have close links with the Primary Care CSG and the SPED Advisory Group in our efforts to tackle overdiagnosis of prostate cancer. The proposal to test MRI and the STHLM3 biomarker

panel is being developed in collaboration with these Groups.

Two CSG members, Simon Crabb and Chris Parker, are members of the EORTC GU Group. Chris Parker also attended a meeting of the PEACE consortium, which aims to foster international collaboration in prostate cancer trials. Given that prostate cancer is so common, international collaboration has not been required for many 'one size fits all' trials in the past. However, now that the Group are developing biomarker driven trials, there is an increasing need for international collaboration for timely trial accrual.

Chris Parker took part in a meeting of the Urology CSG Chairs and the Urology network Subspecialty Leads (SSLs). Although attendance of the SSLs was limited, this was a useful forum for sharing details of ongoing and forthcoming trials. Three of the SSLs are now invited to each Prostate CSG meeting along with Kristina Duggleby, Senior Research Delivery Manager (RDM) for urology.

7. 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			
Systematic Therapy in Advancing or Metastatic Prostate Cancer: Evaluation of Drug Efficacy – Establishing a STAMPEDE Biorepository	Full application	Professor Nicholas James & Professor Malcolm Mason	Not funded
A phase III trial of prostate alone vs pelvic lymph node IMRT with or without prostate boost for intermediate and high risk localised prostate cancer	Full application	Dr Emma Hall & Dr Isabel Syndikus	Funded
Development of a detection method for multiple endogenous androgens for prostate cancer screening via molecular imprinting and comprehensive 4D gas chromatography	Full application	Dr Nicholas Turner	Not funded
November 2016			
PACE-C - Randomised phase III trial of image-guided conventional radiotherapy vs stereotactic radiotherapy for men with upper-intermediate or high risk localised prostate cancer.	Full application	Dr Nicholas van As	Not Supported
Development of a novel panel of genes as a prognostic biomarker for stratification of prostate cancer	Full (Biomarker Project Award)	Dr Yong-Jie Lu	Not Supported
Other committees			
Study	Committee & application type	CI	Outcome
Targeted Radiotherapy in Androgen-suppressed Patients (The TRAP trial)	Prostate Cancer UK, full application	Dr Alison Tree	Funded
STRATOSPHERE: STRatification for RAtional Treatment-Oncomarker pairings of STAMPEDE Patients starting long-term Hormone treatment	Prostate Cancer UK, full application	Dr Gerhard Attard	Funded

Transforming screening, diagnosis and treatment of localized prostate cancer	Wellcome Trust Senior Clinical Fellowship	Professor Hashim Ahmed	Funded (£2.1M)
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8. Collaborative partnership studies with industry

There are 12 open industry studies on the Prostate CSG portfolio.

STAMPEDE continues to provide an excellent example of collaboration with Industry. Janssen supported the abiraterone comparison, presented at ASCO 2017. The rucaparib comparison, due to open in 2017, has been supported by Clovis. Three other companies are also in detailed discussion with the STAMPEDE team about potential new comparisons. It has been interesting to note how the relationship between STAMPEDE and Industry has evolved: at the trial's inception, the TMG had to work hard to persuade companies to collaborate. Now, companies have seen the benefits of the STAMPEDE trial design and are approaching the TMG, keen to include their agents in the trial.

Further, a number of commercial companies are liaising with the PROMIS Translational Group to obtain access to the biobank and clinical data as well as evaluating machine learning of the MRI scans.

9. Impact of CSG activities

There have been several recent changes to routine clinical practice as a result of CSG trials:

- The addition of 'early' docetaxel to androgen deprivation has become standard of care for men with newly diagnosed advanced prostate cancer (STAMPEDE).
- Standard fractionation for radical prostate radiotherapy has changed from 74Gy in 37 fractions to 60Gy in 20 fractions (CHHIP).
- Pre-biopsy MRI has become a standard part of the diagnostic pathway (PROMIS).
- Abiraterone looks set to become a standard of care for men with newly diagnosed advanced prostate cancer (STAMPEDE).

During the last year, the CSG has advised NICE on the following technologies:

- A biodegradable spacer to reduce rectal toxicity from radiotherapy.
- Radium-223 for CRPC.
- Abiraterone for pre-docetaxel CRPC.
- Degarelix for hormone naïve disease.

The CSG has provided reviews of the funding applications submitted to CRUK listed above.

10. Consumer involvement

Sue Duncombe and Derek Price joined the CSG in 2016 and have now attended their first two main CSG meetings, the NCRI Conference in Liverpool and NCRI Consumer Forum meetings. They have taken part in Dragons' Den sessions where consumers provided feedback to researchers on research proposals. They both look forward to increasing their involvement in the CSG and are very keen to join the Subgroups.

Sue Duncombe

- NIHR Research Ambassador - radio interviews and press release on benefits of research for prostate cancer patients.
- CRUK Campaigns Ambassador:
 - Meetings with Prospective Parliamentary candidates to flag the importance of research in Brexit negotiations.
 - Campaigns for MPs and local government focused on addressing both childhood obesity and smoking rates.
- CRUK Science and Research Advisory group - feedback on potential messaging for Brexit campaigns.
- Oxford CRUK PPI group - feedback on research proposals and lay summaries.
- CRUK Strategy Review Workshop - feedback on communication of strategy progress.
- CRUK Catalyst Award Expert Review Group (consumer representative) - meetings to agree which proposal is awarded the £5m Catalyst Award.

Derek Price

- Involved with a range of awareness raising activities for Prostate Cancer UK including giving awareness talks and organising information stands.
- Lay-reviewed research grant applications as a member of the PCUK Grants Advisory Panel.
- Grants Advisory Panel representative on the PCUK Research Advisory Committee.
- Taken part in teleconferences as patient advocate on the CORE TMG.
- Appointed to the newly formed NCRI CT-PAG.

11. Open meetings/annual trials days/strategy days

Not applicable.

12. Priorities and challenges for the forthcoming year

Priorities

- Establishing biomarker-driven trials in advanced prostate cancer: We have made considerable progress in developing trials of PARP inhibition for patients with DNA repair defects. Our next priority is to validate other potential predictive biomarkers including PTEN loss and mismatch repair defects.
- Tackling overdiagnosis: Both MRI and the STHLM3 biomarker panel have been shown to reduce unnecessary biopsies and overdiagnosis of insignificant prostate cancer. Our priority now is to test whether the combination of both MRI and the biomarker panel is superior and cost-effective to either approach used alone.
- To maintain a portfolio of large, simple phase III trials: Until now, the CSG has been successful in running large, practice-changing phase III trials across the disease spectrum. With the increase in biomarker directed trials, this will become more challenging.

Challenges

- Surgical trials: Surgical trials are not well represented in the portfolio and those that are open often fail to meet their recruitment targets. The Localised Disease Subgroup is tackling this by encouraging new PIs and looking at novel trial designs for surgical

interventions such as multi-arm, multi-stage, stepped wedge RCT and cohort multiple RCT.

- International collaboration: There is no track record of international collaboration in academic prostate cancer trials. Although challenging, there will be new opportunities now that we are starting to design trials for specific subgroups of patients.
- Clinical workload: Anecdotal evidence suggests that investigators are facing increased pressure of clinical work, leaving less time for clinical research activities.

13. Appendices

Appendix 1 - Membership of main CSG and subgroups

Appendix 2 – CSG and Subgroup strategies

A – Main CSG Strategy

B – Localised Disease Subgroup Strategy

C – Advanced Disease Subgroup Strategy

Appendix 3 - Portfolio Maps

Appendix 4 - Publications in previous year

Appendix 5 - Major international presentations in previous year

Dr Chris Parker (Prostate Cancer CSG Chair)

Appendix 1

Membership of the Prostate Cancer CSG

Name	Specialism	Location
Dr Nicholas van As	Clinical Oncologist	London
Dr Chris Parker (Chair)	Clinical Oncologist	London
Professor John Staffurth	Clinical Oncologist	Cardiff
Dr Philip Turner*	Clinical Research Fellow	Belfast
Mrs Sue Duncombe	Consumer	Childrey
Mr Derek Price	Consumer	Solihull
Professor Ros Eeles	Geneticist	London
Professor Johann de Bono	Medical Oncologist	London
Dr Simon Chowdhury	Medical Oncologist	London
Dr Simon Crabb	Medical Oncologist	Southampton
Professor Robert Jones	Medical Oncologist	Glasgow
Dr Simon Pacey	Medical Oncologist	Cambridge
Mr Roger Wheelwright	Nurse	Poole
Mrs Vee Mapunde	Observer: NCRI Associate Consumer Lead	South Humberside
Professor Daniel Berney	Pathologist	London
Dr Tristan Barrett	Radiologist	Cambridge
Professor Gary Cook	Radiologist	London
Dr Suniel Jain	Radiologist	Belfast
Dr Emma Hall	Statistician	London
Dr Matthew Sydes	Statistician	London
Professor Hashim Ahmed	Surgeon	London
Mr Rakesh Heer	Surgeon	Newcastle
Mr Tom Leslie	Surgeon	Oxford
Mr Sanjeev Madaan	Surgeon	Kent
Mr Prasanna Sooriakumaran	Surgeon	Oxford
Mr Taimur Shah*	Urologist	London

* denotes trainee member

Membership of the Subgroups

Localised Disease Subgroup		
Name	Specialism	Location
Dr Ann Henry	Clinical Oncologist	Leeds
Dr Anita Mitra	Clinical Oncologist	London
Professor John Staffurth	Clinical Oncologist	Cardiff
Mr Christof Kastner	Consultant Urologist	Cambridge
Professor Daniel Berney	Pathologist	London
Dr Shonit Punwani	Radiologist	London
Dr Athene Lane	Senior Research Fellow	Bristol
Dr Rhian Gabe	Statistician	York
Professor Hashim Ahmed (Chair)	Surgeon	London
Mr Paul Cathcart	Surgeon	London
Professor Frank Chinegwundoh	Surgeon	London
Mr Rakesh Heer	Surgeon	Newcastle

Advanced Disease Subgroup		
Name	Specialism	Location
Dr Stefan Symeonides*	Clinical Fellow	Edinburgh
Dr Dan Ford	Clinical Oncologist	Birmingham
Dr Satinder Jagdev	Clinical Oncologist	Leeds
Dr Zafar Malik	Clinical Oncologist	Wirral
Professor David Waugh	Director, CCRCB	Belfast
Dr Simon Chowdhury	Medical Oncologist	London
Dr Simon Crabb	Medical Oncologist	Southampton
Professor Johann De Bono	Medical Oncologist	London
Professor Rob Jones (Chair)	Medical Oncologist	Glasgow
Dr Jonathan Shamash	Medical Oncologist	London
Dr Matthew Sydes	Statistician	London
Mr Prasanna Sooriakumaran	Surgeon	Oxford

*denotes trainee member

**denotes non-core member

Appendix 2

CSG & Subgroup Strategies

A – Main CSG Strategy

Overall goals

1. To minimise the harms from the investigation and treatment of localised prostate cancer.
2. To maximise the quality of life and overall survival of patients with advanced prostate cancer.

Aims

- To promote a clinical research culture within urology which encourages young urologists to develop an interest in clinical trials.
- To promote international collaborations on prostate cancer trials.
- To foster links with the British Uro-oncology Group (BUG) and the British Association of Urological Surgeons (BAUS) Section of Oncology.
- To work with the Bladder & Renal and TYA & GCT (the Testis CSG has merged with the TYA CSG) CSGs to encourage clinical research in the uro-oncology community.
- To foster a harmonised approach to tissue biomarker collection for future translational studies accompanying clinical trials.
- To support consumer involvement in clinical research and establishing links with the Prostate Cancer Support Federation.
- To strengthen links with Prostate Cancer UK.

B – Localised Disease Subgroup Strategy

Aims

1. To evaluate strategies to reduce the over-diagnosis burden in prostate cancer.

Project 1: Screening MRI in the community

The Subgroup discussed, developed and worked up (with the Chair as CI) to successfully gain funding from the Wellcome Trust (£2.1M; 2017-22) to develop and deliver a screening study using multi-parametric MRI (T2W and diffusion only) in the community with a primary focus on high risk men, e.g. African and African-Caribbean men, family history. The study will start in Q4 2017 and aims to recruit between 1,000-2,000 men.

Project 2: Validation of Stockholm-3 panel

The Subgroup has worked with the SPED Advisory Group and Primary Care CSG to develop a protocol and application for funding to conduct a validation study in the UK of the Stockholm-3 biomarker panel. The Chair, Rhian Gabe (York) and Fiona Walters (Cambridge) (both from NCRI Primary CSG, Walters and Ahmed from the NCRI SPED) will be co-leads of this project. At the time of writing, Prostate Cancer UK have shortlisted and interviewed our team as the preferred bidder and we are in further discussions about the next stages of changes prior to a final decision on funding. We expect this study to recruit 10,000-20,000 men in the community.

Project 3: re-IMAGINE proposal

We have worked with Professor Mark Emberton (UCL) to help the consortium he is leading for an MRC Stratified Medicine bid. This was shortlisted at the time of writing. It aims to recalibrate the current risk tools we have in localised prostate cancer which are based on Transrectal biopsy to one that is based on upfront multi-parametric MRI and targeted biopsies.

2. To evaluate strategies to improve current treatment options.

Project 1: Neurosafe technique to reduce surgical margins

We are working with a new PI, Greg Shaw (UCL), to develop a protocol to comparatively evaluate a new surgical technique which might improve nerve-sparing surgery during radical prostatectomy called Neurosafe. This is being worked up for a feasibility/pilot study.

Project 2: Strategies to minimize cardiovascular toxicity of hormones during radiotherapy

We are working with Ann Henry (Leeds) who is also working on funding for a comparative randomized study to evaluate strategies to minimized cardiovascular toxicity of hormones during radiotherapy.

Project 3: Using mpMRI after radiotherapy to predict long term failure

We are working with Anita Mitra (UCL) who has now obtained pilot funding to determine whether immediate post-radiotherapy mpMRI might predict long term outcomes.

3. To evaluate minimally-invasive strategies within multi-centre studies.

Project 1: Focal therapy Multi-arm Multi-Stage RCT

The role of ablative therapies is increasing and might be a strategy to reduce the harms of therapy in a select group of men who require treatment and would normally have surgery or radiotherapy. The Chair, Melissa Williams and Matt Sydes (MRC CTU), alongside the EORTC-GU group and one of the CSG trainee representatives (Taimur Shah), are all working on an MAMS RCT design to evaluate neoadjuvant and adjuvant strategies with focal ablative therapy. The EORTC-GU group, the Anticancer Fund and the EAU Research Foundation are all actively involved with commercial bodies to determine the best course and route towards funding. Discussions are ongoing with CRUK and commercial bodies as well as the Anticancer Fund about funding routes.

4. To evaluate methodological strategies to improve accrual and success of comparative surgical research.

This aim primarily concerns surgical research. We have seen countless RCTs of surgery in prostate cancer, but also in bladder and renal cancer, where RCTs evaluating strategies compared to surgery were proposed as the intervention arm. Novel trial designs and methods are needed. The Chair is working with members of the CSG such as Matt Sydes to evaluate novel trial designs such as the MAMS design (see above), as well as other designs such as the cohort-multiple RCT described by Jon Nicholls and Clare Relton from Sheffield.

5. To encourage, nurture and enable young/new investigators to the field.

We have started to help and encourage a number of new PIs in the field including Rhian Gabe, Anita Mitra, Ann Henry, Greg Shaw, Taimur Shah, Paul Cathcart and Declan Cahill in a robust but supportive manner. We hope those not part of the CSG will apply to become Localised Disease Subgroup members and, in time, some of the Subgroup members will apply to become main CSG members. This will be in tandem with working up their own ideas, protocols and grant submissions.

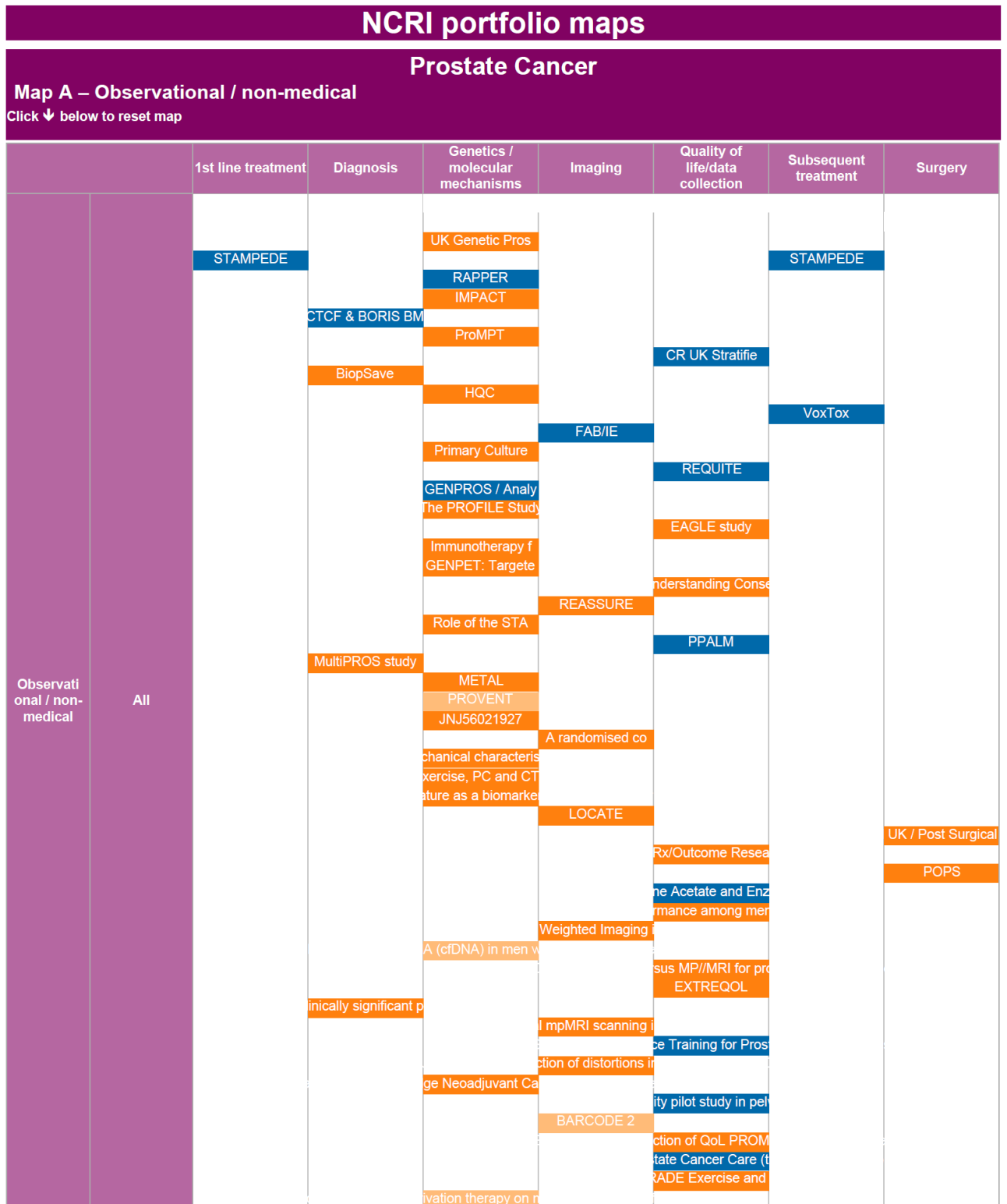
C – Advanced Disease Subgroup Strategy

- To build on the success of STAMPEDE, introducing new treatment comparisons into the trial.
- To identify intermediate endpoints to hasten clinical development of new agents.
- To collaborate with the Supportive and Palliative Care CSG.

- To focus on translational science with an overarching focus to progress the theme of personalized medicine in advanced prostate cancer.
- To engage with the ECMC network.

Appendix 3

Portfolio maps



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

- Open Multi CSG
- Open Single CSG
- In Setup, HRA Ap..
- In Setup, Waiting ..
- In Setup, Waiting ..
- Null

NCRI portfolio maps

Prostate Cancer

Map B – Metastatic

Click ↓ below to reset map

		1st line treatment	Diagnosis	Genetics / molecular mechanisms	Imaging	Quality of life/data collection	Subsequent treatment	Surgery
Refractory metastatic	All	STAMPEDE					STAMPEDE	
		PATCH					PATCH	
							CR UK Stratifie	
							AT13148 Phase I	
							TOPARP	
							MELCAP	
							ZD3965 in adv can	
							Medronic acid and IL	
		DCVAC	SWE					
							ProCAID	
		re Among Subjects					masit. V docet.	
							RE/AKT	
		MAdCaP						
		EASURE Radium/22					Add/Aspirin	
		VANCE						
PEACE III								
with Prostate Cancer								
Therapies in Metast								
						Talazoparib in Men		
ic Castration Resist								
with mCRPC and DN						Study for Participant		
						MedImCRPC		
POLERISE								
mab + Enzalutamid								
TRITON2								
TRITON3								
AZD5069 in combin						CAPRA		
Refractor..	All							
Sensitive metastatic	All	in mHSPC CANC /						
				INNOVATE				
		Plus AndrogenDepr						
		ARASENS						
		TRoMbone						
ty study of VAL201								
							CTC/STOP	

Filters Used:

Active Status: All, CSG Involvement: All, Funding Type: All, Phase: All

- Open Multi CSG
- Open Single CSG
- Null
- In Setup, HRA Ap..
- In Setup, NHS Per..
- In Setup, Waiting ..
- In Setup, Waiting ..
- In Setup, Waiting ..

NCRI portfolio maps

Prostate Cancer

Map C – Localised

Click ↓ below to reset map

		1st line treatment	Diagnosis	Genetics / molecular mechanisms	Imaging	Quality of life/data collection	Subsequent treatment	Surgery
Localised	All	ACT SURVEILL						
		INDEX						
		DELINEATE ProSpare II The PACE Study						
		ExAblateT 3641					SPARTAN	
		PART					Add/Aspirin	
		ENZARAD						
		JNJ/56021927 L/PC DIRMP				[18F] DIHYDRO/T ciclovine (18F) PET		
Locally advanced	All	STAMPEDE					STAMPEDE	
		PATCH					PATCH	
		ProSpare II					AdUP SPARTAN	
						FORECAST		
		ODM					Add/Aspirin	
		JNJ/56021927 L/PC				[18F] DIHYDRO/T	EMBARK	
		CORE Trial						
		combination of						
							Extension Study	
		safety study of						

Filters Used:

Active Status: All, CSG Involvement: All, Funding Type: All, Phase: All

Open Multi CSG

Open Single CSG

Null

In Setup, HRA Ap..

In Setup, Waiting ..

Appendix 4

Publications in the reporting year

Study	Reference
ProCAID	Crabb SJ, Birtle AJ, Martin K, Downs N, Ratcliffe I, Maishman T, Ellis M, Griffiths G, Thompson S, Ksiazek L, Khoo V, Jones RJ. ProCAID: A Phase I Clinical Trial to Combine the AKT Inhibitor AZD5363 with Docetaxel and Prednisolone Chemotherapy for Metastatic Castration Resistant Prostate Cancer. Invest New Drug 2017; doi: 10.1007/s10637-017-0433-4
SAKK08/11	Cathomas R, Crabb SJ, Mark M, Winterhalder R, Rothermundt C, Elliott T, von Burg P, Kenner H, Hayoz S, Vilei SB, Rauch D, Roggero E, Mohaupt MG, Bernhard J, Manetsch G, Gillissen S; Swiss Group for Clinical Cancer Research SAKK. Orteronel Switch Maintenance Therapy in Metastatic Castration Resistant Prostate Cancer After First-Line Docetaxel: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial (SAKK 08/11). Prostate 2016; 76(16):1519-1527
Review of systemic therapy for primary prostate cancer	Sanjeev Srinivas Kumar and Simon Pacey. The role of chemotherapy and new targeted agents in the management of primary prostate cancer. Journal of Clinical Urology 2017, Vol. 9(2S) 30–37
 ProtecT Trial	Johnston TJ, Shaw GL, Lamb AD, Parashar D, Greenberg D, Xiong T, Edwards AL, Gnanapragasam V, Holding P, Herbert P, Davis M, Mizieliński E, Lane JA, Oxley J, Robinson M, Mason M, Staffurth J, Bollina P, Catto J, Doble A, Doherty A, Gillatt D, Kockelbergh R, Kynaston H, Prescott S, Paul A, Powell P, Rosario D, Rowe E, Donovan JL, Hamdy FC, Neal DE; ProtecT study group. Mortality Among Men with Advanced Prostate Cancer Excluded from the ProtecT Trial Eur Urol. 2017 Mar;71(3):381-388. doi: 10.1016/j.eururo.2016.09.040.
	Lane A, Metcalfe C, Young GJ, Peters TJ, Blazeby J, Avery KN, Dedman D, Down L, Mason MD, Neal DE, Hamdy FC, Donovan JL; ProtecT Study group. Patient-reported outcomes in the ProtecT randomized trial of clinically localized prostate cancer treatments: study design, and baseline urinary, bowel and sexual function and quality of life. BJU Int. 2016 Dec;118(6):869-879. doi: 10.1111/bju.13582.
Improving the well-being of men by Evaluating and Addressing the Gastrointestinal Late Effects (EAGLE) of radical treatment for prostate cancer: study	Taylor S, Demeyin W, Muls A, Ferguson C, Farnell DJ, Cohen D, Andreyev J, Green J, Smith L, Ahmedzai S, Pickett S, Nelson A, Staffurth J. BMJ Open. 2016 Oct 3;6(10):e011773. doi: 10.1136/bmjopen-2016-011773.

protocol for a mixed-method implementation project	
10-Year Outcomes after Monitoring, Surgery, or Radiotherapy for Localized Prostate Cancer	Hamdy FC, Donovan JL, Lane JA, Mason M, Metcalfe C, Holding P, Davis M, Peters TJ, Turner EL, Martin RM, Oxley J, Robinson M, Staffurth J, Walsh E, Bollina P, Catto J, Doble A, Doherty A, Gillatt D, Kockelbergh R, Kynaston H, Paul A, Powell P, Prescott S, Rosario DJ, Rowe E, Neal DE; ProtecT Study Group. N Engl J Med. 2016 Oct 13;375(15):1415-1424.
ALERT-B	Taylor S, Byrne A, Adams R, Turner J, Hanna L, Staffurth J, Farnell D, Sivell S, Nelson A, Green J. The Three-item ALERT-B Questionnaire Provides a Validated Screening Tool to Detect Chronic Gastrointestinal Symptoms after Pelvic Radiotherapy in Cancer Survivors.
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<p>Post hoc Analysis for Detecting Individual Rare Variant Risk Associations Using Probit Regression Bayesian Variable Selection Methods in Case-Control Sequencing Studies</p>	<p>Larson NB, McDonnell S, Albright LC, Teerlink C, Stanford J, Ostrander EA, Isaacs WB, Xu J, Cooney KA, Lange E, Schleutker J, Carpten JD, Powell I, Bailey-Wilson J, Cussenot O, Cancel-Tassin G, Giles G, MacInnis R, Maier C, Whittemore AS, Hsieh CL, Wiklund F, Catolona WJ, Foulkes W, Mandal D, Eeles R, Kote-Jarai Z, Ackerman MJ, Olson TM, Klein CJ, Thibodeau SN, Schaid DJ. Genet Epidemiol. 2016;40(6):461-9</p>

Appendix 5

Major international presentations in the reporting year

Study	Conference details
PROMIS	A paired-cohort, blinded confirmatory study evaluating the accuracy of multi-parametric MRI and TRUS biopsy in men with an elevated PSA. Presenting Author: Hashim Uddin Ahmed, ASCO (2016)
STAMPEDE	Celecoxib with or without zoledronic acid for hormone-naïve prostate cancer: Survival results from STAMPEDE (NCT00268476). Presenting Author: Nicholas D. James, GU ASCO (2016)
 ProtecT	What ProtecT Tells Us About Active Surveillance. Presenter: Freddie Hamdy, GU ASCO 2017
STAMPEDE	Adding abiraterone for men with high-risk prostate cancer (PCa) starting long-term androgen deprivation therapy (ADT): Survival results from STAMPEDE (NCT00268476). Presenting Author: Nicholas D. James, ASCO (2017) J Clin Oncol 35, 2017 (suppl; abstr LBA5003)