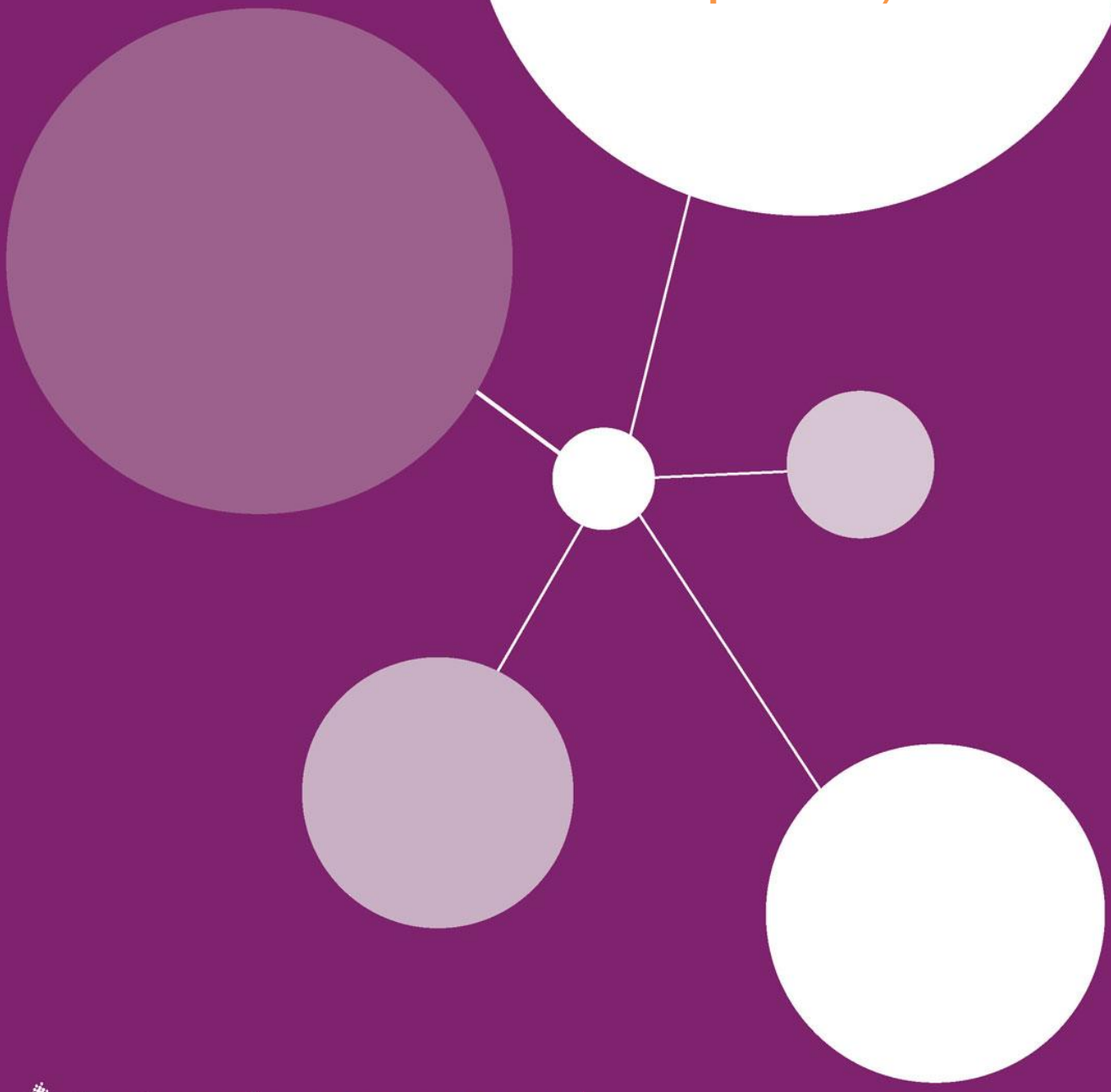
NCRI
National
Cancer
Research
Institute

NCRI Prostate Cancer Clinical Studies Group

Annual Report 2014/2015



Partners in cancer research

NCRI Prostate Cancer CSG
Annual Report 2014/15

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

Any report on 2014-15 must start with the first outcome report from the MRC STAMPEDE trial. This has shown a substantial survival benefit for the addition of docetaxel chemotherapy to androgen deprivation therapy, and being the largest such trial, it is set to definitively change medical practice for newly diagnosed metastatic disease, for the first time in over 60 years. As this report is written, members are preparing to present the results at ASCO. The final analysis of the other practice-changing trial, MRC PR07, has, in the last year, been published in the Journal of Clinical Oncology, and it's quality of life study is in press in the same journal. The STAMPEDE trial itself continues to recruit extraordinarily quickly, and now has nearly 7,000 patients. The last year has also seen the continued development of the PATCH study, with approval for its progression to a Phase III trial, and strong recruitment to the RADICALS trial, which is regarded internationally as a world-leading study (e.g. as cited at ASTRO 2014). We are also delighted to see the launch of the Add-aspirin study, with its prostate component.

One of the main challenges remains that of developing a strategic focus with such a broad portfolio, which of necessity covers almost every facet of the disease. The progress in the development of a strategy is described later, but some studies, notably TO-PARP, have made excellent progress in establishing the concept of biomarker-driven studies in this disease. We have also had some excellent basic science input to the strategy group, which has been invaluable. In terms of membership, we have welcomed a second consumer representative, Mr Paul Fryer, to the group, to add to the already superb input from Mr Allister Murphy, and it is pleasing to see our consumer representation now back up to strength.

One of our goals from last year's report was to establish closer links with the EORTC. We are fortunate that Dr Simon Pacey now represents the group on the EORTC Prostate DOG, and we still hope to be able to develop more overt participation in each other's studies. The situation has been somewhat complicated by the development of the PEACE initiative, which though separate from the EORTC, overlaps with it, and is another group that we must interact with.

2. Structure of the Group

The structure of the group is essentially unchanged compared to last year. The membership is as outlined in Appendix 1. We now have excellent pathology representation on the group, through Professor Dan Berney, we are moving towards expanding our basic science input, and our consumer representation is now back up to strength, having been previously severely diminished. We do still lack representation from the Allied Health professions, but this is likely to be resolved

in the near future. As with other groups, we are delighted to welcome our first trainee members, and see this as an excellent development. Professor Mason has now finished his term of office, and Dr Chris Parker has been appointed as the new Chair of the group. This report has been co-written by both.

3. CSG & Subgroup strategies

Main CSG

Our strategy, as agreed by the group in 2014, has two predominant arms. Firstly, we are moving to develop biomarker-driven trials, and, secondly, we are seeking to address the over diagnosis and over treatment which has characterised the management of early prostate cancer.

In addition, the group recognises other aims as suggested in last year's report feedback. These include the need to incorporate the many new agents into trial design (see below in relation to STRATOSPHERE), links with industry, and new health service studies, but the last of these does still require more work. Other aspects from last year's feedback are covered elsewhere.

Localised Disease Subgroup (Chair, Mr Vincent Gnanapragasam)

A key achievement has been the organisation of a national consensus meeting on clinical and research priorities in high-risk localised disease in November 2014. This meeting attracted 28 national opinion leaders from all the relevant disciplines. The meeting proceedings were captured in a report, which will be submitted for publication in 2015. This report describes the main areas of uncertainty in the current management of high-risk disease, and highlights key areas for future clinical research. The next step will be the detailed development of one, or possibly two, of the trial ideas with a view to grant applications. Over the last year, the Localised Subgroup has advised on the development of a range of studies that have entered the portfolio. However, efforts of the subgroup to design new studies from scratch have not come to fruition.

There remain several challenges. The subgroup does not have input to all studies that have entered the portfolio. As a result it lacks influence on competing studies. Another key challenge is the lack of opportunity for face-to-face meetings of the Subgroup. The membership is multi-disciplinary so there is no single event that serves as a natural forum to meet.

Advanced Disease Subgroup (Chair, Dr Rob Jones)

The Subgroup continues to focus on delivery of its core strategy. The main focus of this is a drive towards linking science and medicine to deliver personalized medicine trials for men with metastatic disease. There are fundamentally two components to the work overseen by the Subgroup. First, the development and delivery of proof of concept trials for novel targeted therapies. Much of this work continues in collaboration with industry. Among the highlights from this are the results of the first part of the TOPARP study of olaparib in heavily pre-treated patients. These results not only show a significant efficacy signal, but also go some way to identifying a molecularly-defined subgroup of patients who may benefit from this intervention. These results were presented at the ESMO meeting in Madrid in October 2014. The next stage of the trial is funded and will open to recruitment mid 2015. Second, the development of the STRATOSPHERE umbrella study. This is an ambitious project which, ultimately, will deliver novel drugs from early proof of concept through to practice-changing results in multiple molecularly-

defined cohorts at the time of initial diagnosis. This study is currently at the stage of advanced discussion, but the STRATOSPHERE team is now in close discussion with the STAMPEDE team to ensure optimal dovetailing of the two projects. As the Subgroup continues to develop these core themes, we hope to harness the powers of the Experimental Cancer Medicine Centres network in order to maximize impact for patients with advanced prostate cancer.

4. Task groups/Working parties

There are no task groups or working parties in the Prostate CSG.

5. Patient recruitment summary for last 5 years

We have maintained a good rate of recruitment despite the closure of 2 large RCTs – PATCH and CHHIP – which together accounted for a significant proportion of patients. In the case of PATCH, recruitment to the Phase III component is now opening. The particularly strong recruitment rate to STAMPEDE has already been commented on, and this raises an important point for the NCRI generally: the power of an adaptive trial 'platform' to mobilise the community, and to harness the power of UK clinicians to answer important questions quickly. We commend this as a model for other CSG strategies. In the Prostate CSG portfolio, 8 trials closed to recruitment and 20 opened.

Table 1 Summary of patient recruitment by RCT/Non-RCT

Year	All subjects		Cancer patients only		% of cancer patients relative to incidence	
	Non-RCT	RCT	Non-RCT	RCT	Non-RCT	RCT
2010/2011	2113	2293	1943	2095	5.9	6.4
2011/2012	2418	2140	2256	2044	6.9	6.2

Table 2 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

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

As before, the closest links have been to the other urological CSGs – bladder, testis and renal. However, in developing the STRATOSPHERE initiative, we have, through the MRC Clinical Trials Unit at UCL, been engaging with the Colorectal CSG, in view of their experience with the FOCUS-4 study. Internationally, our links have been via ongoing trials (SAKK, NCIC), but as described above we are seeking to establish closer links with the EORTC and the PEACE initiative. In the UK, as before, we maintain links with the BAUS section of oncology, BUG, and other specialist groups. Links with CRN subspecialty leads are in their infancy. We were represented by Dr Isabel

Syndikus at the recent meeting with CSGs, and these links will inevitably grow over the coming year.

7. Funding applications in last year

In addition to the summary in Table 3, the Group has had significant input to the MRC Add-aspirin study, and has been involved in discussions with other applications, including the RiskMan approach, submitted to the Population Research Committee.

Table 3 Funding submissions in the reporting year

Clinical Trials Advisory and Awards Committee (CTAAC)			
Study	**Application type**	**CI**	**Outcome**
July 2014			
HYPO-RT-PC trial: Randomised phase III study of hypo-fractionated radiotherapy in localised prostate cancer	Full application *Resubmission*	Dr Emma Hall and Professor David Dearnaley	Funded
November 2014			
Treatment Options for High-Risk Clinically Localised Prostate Cancer - A Feasibility Study	Feasibility Application	Mr Anthony Koupparis	Resubmission requested
March 2015			
PRONIM: A randomised phase II placebo-controlled trial in locally-advanced PROstate cancer of radical radiotherapy and androgen deprivation with NIMorazole	Outline application	Dr Ananya Choudhury	Revised outline requested
TO-PARP: Trial of Olaparib in Patients with Advanced Castration Resistant Prostate Cancer	Full application	Professor Johann de Bono	Funded

8. Collaborative partnership studies with industry

As before, the major industry collaboration is via the STAMPEDE trial, with both Janssen, and Astellas contributing to the ongoing abiraterone and enzalutamide arms. Major discussions are underway with pharma in relation to the STRATOSPHERE study, and it seems likely that an agreement will be reached.

9. Impact of CSG activities

The Prostate CSG has made an indelible impact on worldwide clinical practice in 2 areas:

The, now routine, addition of radiotherapy to ADT in the treatment of locally advanced prostate cancer (see earlier).

Ongoing, but already changing practice, is the establishment of ADT plus docetaxel as the new standard first line therapy for advanced disease. Further follow-up of STAMPEDE will determine whether the same is true of high-risk, non-metastatic disease.

In addition, it is likely that an analysis of the radiotherapy outcomes in STAMPEDE (manuscript in preparation) will further impact on worldwide practice.

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

- Enzalutamide for pre-docetaxel CRPC.
- Radium-223 for CRPC
- Sipuleucel-T for CRPC
- PCA3 in the diagnosis of prostate cancer.
- Prostate Health Index in diagnosis of prostate cancer.
- Cabazitaxel for CRPC (Comments on removal from the list).
- Suspected cancer draft guidelines

In addition to the reviews for CTAAC, the CSG has regularly provided comments for the Population Sciences Committee, as well as reviewing other ad-hoc proposals.

10. Consumer involvement

The Prostate CSG benefits from the input of their two highly involved consumers, Mr Allister Murphy and Mr Paul Fryer. Both are vocal in CSG meetings, as well as contributing well in between CSG meetings, where necessary. Their activities over the last year include, but are not limited to:

- Contributing to ongoing trials and drug debates e.g. Degarelix
- Met with the new N. Ireland Health Minister, Simon Hamilton and discussed the establishment of a cancer drugs fund for N. Ireland as well as the reform of the IFR process
- Attending the 2014 NCRI Cancer Conference
- Working as a volunteer with Prostate Cancer UK, promoting awareness with presentations to interested groups
- Joining NCRI AstraZeneca patient panel and am collaborating on the PROACT project
- Running local support groups
- NICE Quality Standard Stakeholder Engagement – Prostate Cancer
- Raising awareness through dissemination of relevant materials to GP surgeries and public places highlighting all symptoms of prostate cancer

11. Open meetings/annual trials days/strategy days

We have not held an open meeting this year. As before, we are planning a joint urological trials meeting with the other CSGs, which will probably be held early in 2016.

Following the main strategy day held in the last reporting year, we established a small strategy working group, which met in December 2014. The feedback from this group is described below in section 12.

12. Progress towards achieving the CSG's 3 year strategy

The strategy working group meeting was attended by Professors Mason, Robson, Clarke, Waugh and Berney; Drs Jones and Frame; and Messrs Gnanapragasam, Murphy, and Sydes. Agreed actions from this meeting are as follows:

- A task and finish multidisciplinary group, pathology led, and linking to ongoing work on minimum datasets, is reviewing all available and relevant biomarkers, with the aim of establishing a core set for all future translational studies accompanying clinical trials.

- The MRC meta-analysis group will review the output from this survey, and the potential for associated studies.
- A further group, focused on identifying important subgroups of patients with early, localised disease, will further develop the strategy for this area. Professor Max Parmar will be invited to join this group.

Meanwhile, good progress is being made in the development of the STRATOSPHERE study, with fruitful discussions with pharma, and further development of the study design. A meeting of the Trial Development group was held at the MRC Clinical Trials Unit, to which Professors Rick Kaplan and Max Parmar were invited, and which agreed that a MAMS-type design would allow for the maximal inclusion of novel agents in a timely fashion. The principles of stratification have been largely agreed, and further development aiming towards a submission jointly to CRUK and to PCUK is envisaged. It is proposed to use the Belfast gene signature for DNA damage repair deficiency, as a basis, but this is awaiting the outcome of a validation study which will be completed soon.

If STRATOSPHERE is established, it will provide the CSG with a platform for the future introduction of novel agents into the hormone-sensitive space. Now that the outcome of STAMPEDE in relation to docetaxel is known, the trial can further develop with ADT plus docetaxel as its control arm (and, as with STAMPEDE, further modifications may be needed in the future if other arms have a positive outcome).

13. Priorities and challenges for the forthcoming year

Priorities for the Prostate CSG are outlined below:

STRATOSPHERE

Biomarker-driven trials in advanced disease are a key part of the CSG strategy. The ongoing TO-PARP trial is the first example. We envisage that STRATOSPHERE will be the next. Within the year, we plan to refine the trial design and apply for funding. If successful, STRATOSPHERE could become a programmatic trial (like STAMPEDE). As we gain a better understanding of the molecular pathology of prostate cancer, so we will want to test a series of drugs in several different, biomarker-defined, subgroups. If STRATOSPHERE is established, it will provide the CSG with a platform for such trials in the hormone-sensitive space. The recent high risk meeting revealed a lot of interest in biomarkers driving not only CRPC therapy selection but also primary radical therapy selection (which need to be multimodal).

Tackling overdiagnosis

Tackling overdiagnosis and overtreatment of localised disease is the second theme of the CSG strategy. It is now a priority to make a clear plan for its implementation. The prostate cancer diagnostic pathway has not changed significantly in the last 20 years. New blood and urine markers, multi-parametric MRI and new biopsy techniques all offer real hope for progress. The results of the PROMIS trial, due at the end of 2015, might change practice and will certainly be highly relevant to the design of future studies in this setting.

The results of the STOCKHOLM-3 trial are expected during 2015 and may lead to a major shift in practice: the trial is expected to demonstrate that a risk prediction model based on multiple

serum biomarkers is superior to PSA alone for the detection of high-grade disease, while reducing unnecessary biopsies and overdiagnosis. If so, there will be a need for UK validation and optimisation of this approach.

Trial of surgery in high-risk non-metastatic disease

The role of radical prostatectomy for high risk non-metastatic disease is uncertain. Based to a large extent on the completed MRC PR07 trial, radiotherapy plus androgen deprivation is usually regarded as the standard of care. A previous CTAAC proposal (OPTIMALS) to test surgery in this setting was not funded. Building on the feedback from CTAAC, a revised application is being devised. The recent results of the ASCENDE-RT trial have provided new impetus. This randomised trial of a brachytherapy boost in addition to standard radiotherapy has shown that local recurrence after standard treatment is more common than previously appreciated.

Challenges for the Prostate CSG are outlined below:

International collaboration

With a few notable exceptions (e.g. MRC PR07/NCIC PR3, RADICALS), the CSG does not have a strong track record of successful international collaborations. New attempts are being made to reach out to the EORTC and the PEACE consortium with a view to establishing a closer working relationship.

Inter-disciplinary collaboration

Urologists and oncologists need to work together to support the CSG portfolio. While the culture and infrastructure in oncology tends to be conducive to clinical trials, that is often not the case in urology.

Impact of STAMPEDE results

The use of early docetaxel in men with hormone naïve disease is likely to have a huge impact on clinical practice. The greatly increased use of chemotherapy, if not accompanied by an increase in resources, could compromise the capacity of oncology services to deliver clinical trials.

14. Concluding remarks

The CSG would like to pay tribute to the outstanding support provided by the Secretariat, and in particular to acknowledge the enormous contribution of Dr Eileen Loucaides.

15. 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

Professor Malcolm Mason (Prostate CSG Chair to May 2015), and Dr Chris Parker (Prostate CSG Chair from May 2015)

Appendix 1

Membership of the Prostate CSG

Name	Specialism	Location
Mr Hashim Ahmed	Surgeon	London
Professor Daniel Berney	Pathologist	London
Dr Johann de Bono	Medical Oncologist	London
Dr Simon Chowdhury	Medical Oncologist	London
Professor Noel Clarke	Surgeon	Manchester
Professor Gary Cook	Radiologist	London
Dr Simon Crabb	Medical Oncologist	Southampton
Professor Ros Eeles	Geneticist	London
Mr Paul Fryer	Consumer	Liverpool
Mr Vincent Gnanapragasam	Surgeon	Cambridge
Dr Emma Hall	Statistician	London
Mr Rakesh Heer	Surgeon	Newcastle
Dr Suniel Jain	Radiologist	Belfast
Professor Nick James	Clinical Oncologist	Warwick
Dr Robert Jones	Medical Oncologist	Glasgow
Dr Vincent Khoo	Clinical Oncologist	London
Professor Malcolm Mason (Chair)	Clinical Oncologist	Cardiff
Mr Allister Murphy	Consumer	Belfast
Dr Chris Parker	Clinical Oncologist	London
Professor Craig Robson	Molecular Urologist	Newcastle
Mr Prasanna Sooriakumaran	Surgeon	Oxford
Dr John Staffurth	Clinical Oncologist	Cardiff
Mr Matthew Sydes	Statistician	London
Dr Isabel Syndikus	Clinical Oncologist	Wirral
Mr Roger Wheelwright	Nurse	Poole
Dr Stefan Symeonides*	Clinical Fellow	Edinburgh
Dr Mehran Afshar*	Medical Oncologist	Birmingham

* denotes trainee

Membership of the Subgroups

Localised Disease Subgroup		
Name	**Specialism**	**Location**
Dr Amit Bahl	Clinical Oncologist	Bristol
Dr John Staffurth	Clinical Oncologist	Cardiff
Dr John Graham	Clinical Oncologist	Taunton
Dr Isabel Syndikus	Clinical Oncologist	Wirral
Dr Anne Warren	Histopathologist	Cambridge
Professor Nandita de Souza	Radiologist	London
Dr Athene Lane	Senior Research Fellow	Bristol
Mr Matthew Sydes	Statistician	London
Mr Hashim Ahmed	Surgeon	London
Mr Vincent Gnanapragasam (Chair)	Surgeon	Cambridge
Professor Raj Persad	Surgeon	Bristol

Advanced Disease Subgroup		
Name	**Specialism**	**Location**
Dr Tony Elliott	Clinical Oncologist	Manchester
Dr Dan Ford	Clinical Oncologist	Birmingham
Dr Satinder Jagdev	Clinical Oncologist	Leeds
Zafar Malik	Clinical Oncologist	Wirral
Professor Malcolm Mason**	Clinical Oncologist	Cardiff
Dr John Staffurth	Clinical Oncologist	Cardiff
Dr Simon Chowdhury	Medical Oncologist	London
Dr Simon Crabb	Medical Oncologist	Southampton
Dr Johann De Bono	Medical Oncologist	London
Dr Rob Jones (Chair)	Medical Oncologist	Glasgow
Jonathan Shamash	Medical Oncologist	London
Mr Prasanna Sooriakumaran	Surgeon	Oxford

* denotes trainee

** 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: encouraging 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, testis and renal 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: establishing links with the Prostate Cancer Support Federation
- To strengthen links with Prostate Cancer UK

B – Localised Disease Subgroup Strategy

The main strategy of the Localised Disease Subgroup is to:

- Evaluate the use of individualised risk assessment models using multiplex tissue biomarkers in the diagnostic pathway. The aims of such an intervention are to reduce unnecessary biopsy, reduce the detection of low-grade disease while maintaining (or improving) the detection of high-grade disease.
- Minimise the morbidity of prostate biopsy, while improving the detection of high-grade disease.
- Evaluate the role of MRI in the diagnostic pathway
- Assess the role of radical prostatectomy in the treatment of high-risk localised disease

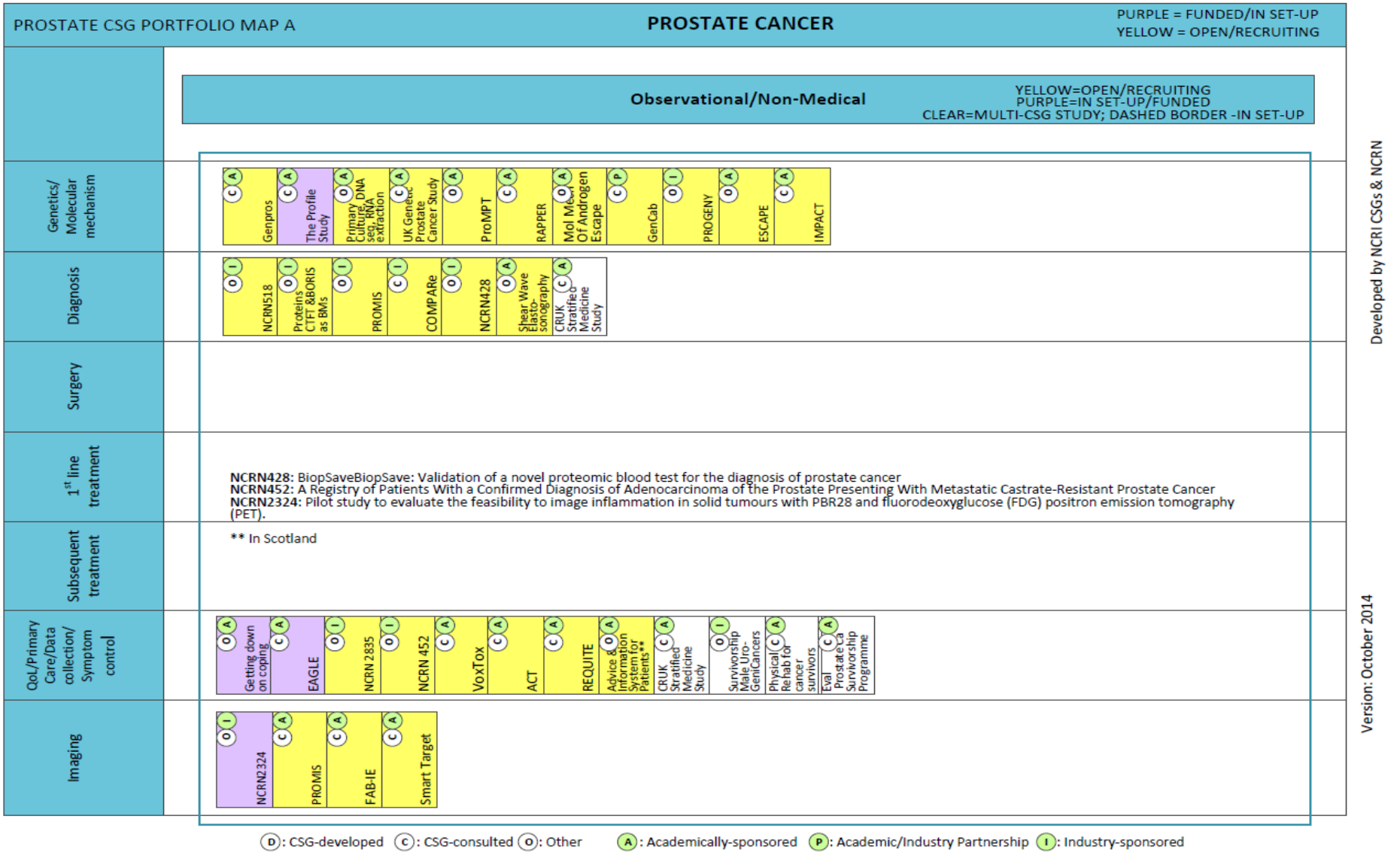
C – Advanced Disease Subgroup Strategy

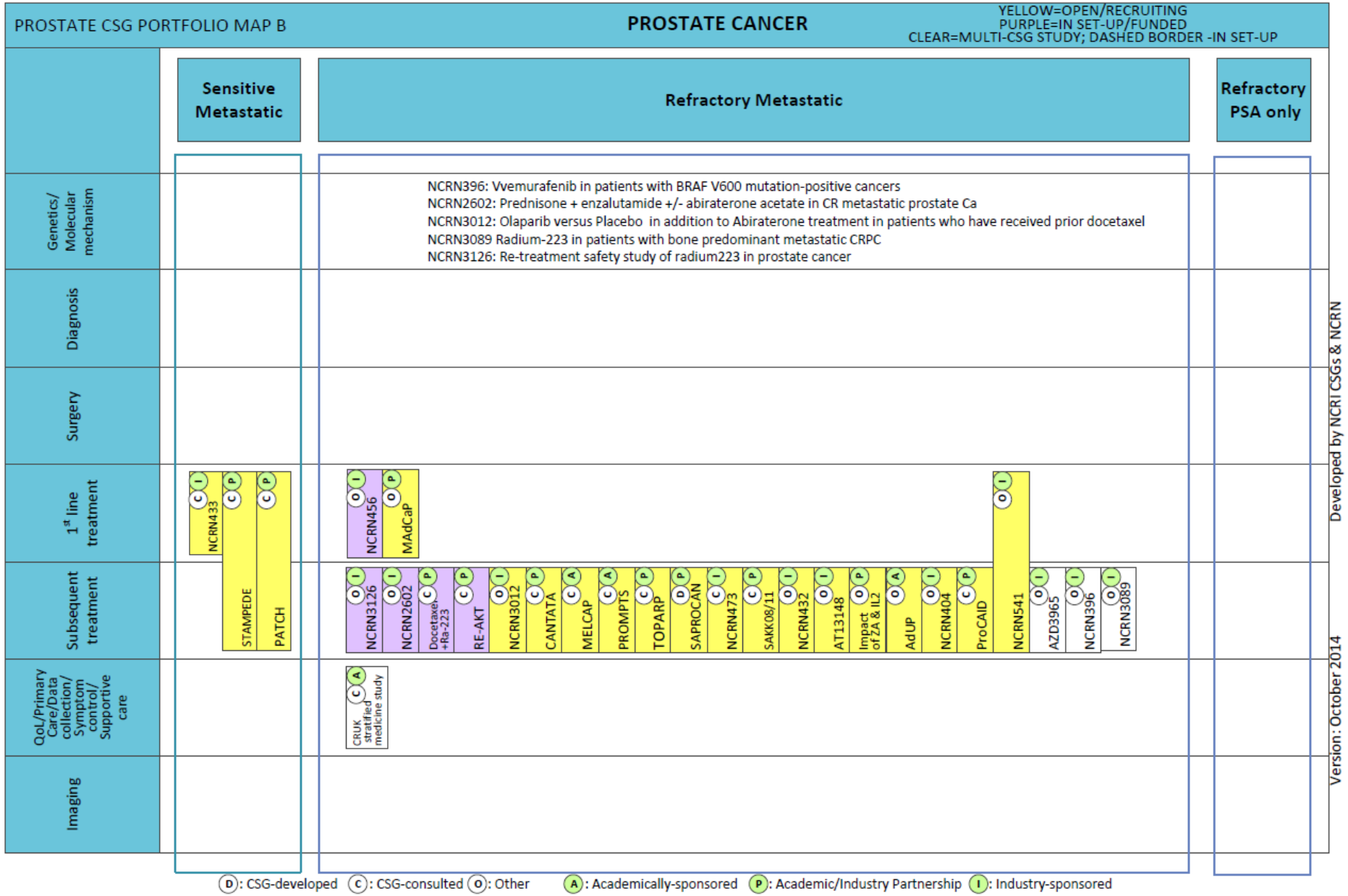
The main strategy of the Advanced Disease Subgroup is to:

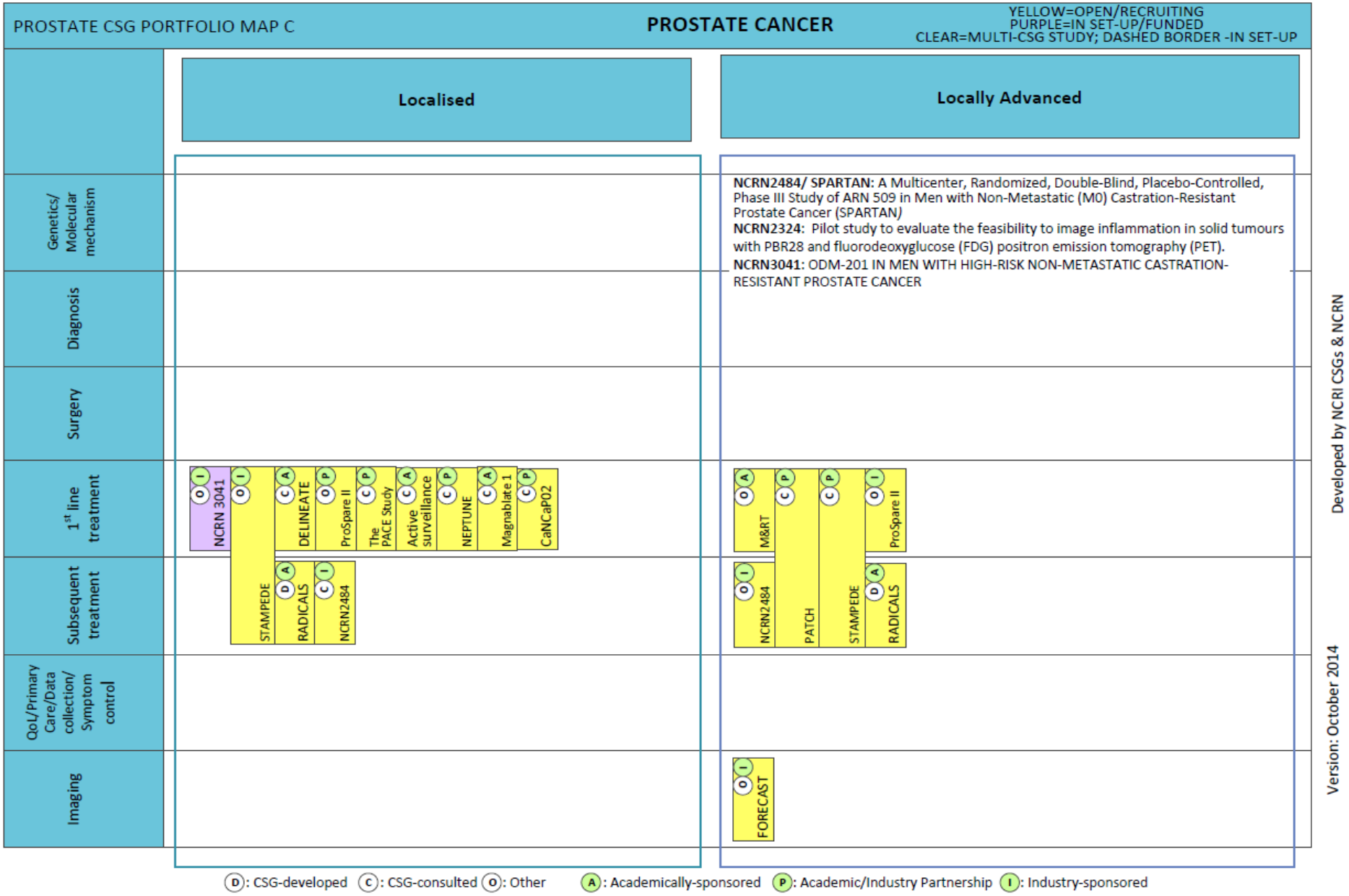
- To build on the success of STAMPEDE, introducing new treatment comparisons into the trial
- To identify intermediate endpoints to hasten clinical development of new agents
- To collaborate with the Palliative and Supportive Care CSG
- To focus on translational science with an overarching focus to progress the theme of personalized medicine in advanced prostate cancer.
- To engage with the ECMC network.

Appendix 3

Portfolio maps




PROSTATE CSG PORTFOLIO MAP B
PROSTATE CANCER
YELLOW=OPEN/RECRUITING
PURPLE=IN SET-UP/FUNDED
CLEAR=MULTI-CSG STUDY; DASHED BORDER -IN SET-UP
Sensitive Metastatic
Refractory Metastatic
Refractory PSA only
Genetics/ Molecular mechanism
Diagnosis
Surgery
1st line treatment
Subsequent treatment
QoL/Primary Care/Data collection/ Symptom control/ Supportive care
Imaging
NCRN396: Vvemurafenib in patients with BRAF V600 mutation-positive cancers
NCRN2602: Prednisone + enzalutamide +/- abiraterone acetate in CR metastatic prostate Ca
NCRN3012: Olaparib versus Placebo in addition to Abiraterone treatment in patients who have received prior docetaxel
NCRN3089 Radium-223 in patients with bone predominant metastatic CRPC
NCRN3126: Re-treatment safety study of radium223 in prostate cancer
NCRN433
STAMPEDE
PATCH
NCRN456
MAdCaP
NCRN3126
NCRN2602
Docetaxel, +Ra-223
RE-AKT
NCRN3012
CANTATA
MELCAP
PROMPTS
TOPARP
SAPROCAN
NCRN473
SAKK08/11
NCRN432
AT13148
Impact of ZA & IL2
AdUP
NCRN404
ProCAID
NCRN541
AZD3965
NCRN396
NCRN3089
CRUK stratified medicine study
Developed by NCRI CSGs & NCRN
Version : October 2014
(D): CSG-developed (C): CSG-consulted (O): Other (A): Academically-sponsored (P): Academic/Industry Partnership (I): Industry-sponsored


PROSTATE CSG PORTFOLIO MAP C
PROSTATE CANCER
YELLOW=OPEN/RECRUITING
PURPLE=IN SET-UP/FUNDED
CLEAR=MULTI-CSG STUDY; DASHED BORDER -IN SET-UP
Localised
Locally Advanced
Genetics/ Molecular mechanism
Diagnosis
Surgery
1st line treatment
Subsequent treatment
QoL/Primary Care/Data collection/ Symptom control
Imaging
NCRN2484/ SPARTAN: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Study of ARN 509 in Men with Non-Metastatic (M0) Castration-Resistant Prostate Cancer (SPARTAN)
NCRN2324: Pilot study to evaluate the feasibility to image inflammation in solid tumours with PBR28 and fluorodeoxyglucose (FDG) positron emission tomography (PET).
NCRN3041: ODM-201 IN MEN WITH HIGH-RISK NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER
NCRN 3041
STAMPEDE
DELINEATE
ProSpare II
The PACE Study
Active surveillance
NEPTUNE
Magnablate 1
CaNCaP02
RADICALS
NCRN2484
M&RT
PATCH
ProSpare II
FORECAST
Developed by NCRI CSGs & NCRN
Version: October 2014
(D): CSG-developed (C): CSG-consulted (O): Other (A): Academically-sponsored (P): Academic/Industry Partnership (I): Industry-sponsored

Appendix 4

Publications in the reporting year

CHHiP

Barnett GC, Thompson D, Fachal L, Kerns S, Talbot C, Elliott RM, Dorling L, Coles CE, Dearnaley DP, Rosenstein BS, Vega A, Symonds P, Yarnold J, Baynes C, Michailidou K, Dennis J, Tyrer JP, Wilkinson JS, Gomez-Caamano A, Tanteles GA, Platte R, Mayes R, Conroy D, Maranian M, Luccarini C, Gulliford SL, Sydes MR, Hall E, Haviland J, Misra V, Titley J, Bentzen SM, Pharoah PD, Burnet NG, Dunning AM, West CM (2014). A genome wide association study (GWAS) providing evidence of an association between common genetic variants and late radiotherapy toxicity. *Radiother Oncol* 111(2):178-85

Dearnaley D, Griffin C, Syndikus I, Scrase C, Thomas S, Naismith O, Mayles P, Staffurth J, Hall E, on behalf of the CHHiP Trial Management Group (2014). IGRT for prostate cancer - results from the CHHiP IGRT phase II sub-study. *Radiother Oncol* 111(Suppl 1):70 #OC-155

Fachal L, Gomez-Caamano A, Barnett GC, Peleteiro P, Carballo AM, Calvo-Crespo P, Kerns SL, Sanchez-Garcia M, Lobato-Busto R, Dorling L, Elliott RM, Dearnaley DP, Sydes MR, Hall E, Burnet NG, Carracedo A, Rosenstein BS, West CML, Dunning AM, Vega A (2014). A three-stage genome-wide association study identifies a susceptibility locus for late radiotherapy toxicity at 2q24.1. *Nat Genet* 46(8):891-4

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IMPACT

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PROFILE/IMPACT/UK Genetic Prostate Cancer Study

Eeles R, Goh C, Castro E, Bancroft E, Guy M, Al Olama A A, Easton D, Kote-Jarai Z. The genetic epidemiology of prostate cancer and its clinical implications. *Nat Rev Urol*. 2014;11(1):18-31. PMID: 24296704

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Others

Ahmed HU, Berge V, Bottomley D, Cross W, Heer R, Kaplan R, et al. Can we deliver randomized trials of focal therapy in prostate cancer? Nature Reviews Clinical Oncology. 2014

Appendix 5

Major international presentations in the reporting year

CHHiP

Dearnaley D, Griffin C, Syndikus I, Scrase C, Naismith O, Thomas S, Mayles P, Staffurth J, Cruickshank C, Murray J, Hall E (2014). Image guided radiotherapy (IGRT) for prostate cancer - results from the CHHiP IGRT phase II sub-study (CRUK/06/016). NCRI National Cancer Conference; 2014; Liverpool:#B298

PIVOTAL

Dearnaley D, Griffin C, Lewis R, Mayles P, Scrase C, Staffurth J, Syndikus I, Naismith O, Zarkar A, Ford D, Rimmer Y, Horan G, Sadozye A, Khoo V, Frew J, HALL E (2014). First toxicity results of PIVOTAL (CRUK 10/022): a phase II randomised trial of prostate and pelvis versus prostate alone radiotherapy. NCRI National Cancer Conference; 2014; Liverpool:#B299

STAMPEDE

James ND, Spears MR, Clarke NW, Sydes MR, Parker CC, Dearnaley DP, et al. Impact of Node Status and Radiotherapy on Failure-Free Survival in Patients With Newly–Diagnosed Non-Metastatic Prostate Cancer: Data From >690 Patients in the Control Arm of the STAMPEDE Trial. International Journal of Radiation Oncology *Biology* Physics. 2014;90(1, Supplement):S13, ATSRO, 2014

James N, Spears M, Clarke NW, Sydes M, Parker C, Dearnaley D, et al. Impact of node status and radiotherapy on failure-free survival in patients with newly diagnosed non-metastatic prostate cancer: data from >690 patients in the control arm of the STAMPEDE trial. Annals of Oncology. 2014;25(suppl 4):iv255, ESMO 2014

Sydes M, Carpenter J, Parmar MK, editors. The need for a cultural shift from two-arm to multi-arm randomised controlled trials (CPS 2A). Society for Clinical Trials 2014; 2014 May-2014; Philadelphia PA, USA,

PATCH

Langley RE et al. PATCH: A randomised controlled trial of transdermal oestrogen patches versus luteinising hormone releasing hormone agonists in locally advanced and metastatic prostate cancer. J Clin Oncol 2014; 32 (suppl 5; abstract TPS5099), ASCO 2014

Langley RE et al. Bone density in men receiving androgen deprivation therapy for prostate cancer, a randomised comparison between transdermal oestrogen and luteinising hormone-releasing hormone agonists. J Clin Oncol 2014; 32 (suppl 5; abstract 5067), ASCO 2014

Add-Aspirin

Langley RE, Wilson RH, Ring AE, Kynaston HG, Cameron DA, Coyle C, et al. Add-Aspirin trial: A phase III, double blind, placebo-controlled, randomized trial assessing the effects of aspirin on

disease recurrence and survival after primary therapy in common nonmetastatic solid tumors.. 2014;32(15_suppl):TPS1617, ASCO 2014

UK Genetic Prostate Cancer Study

Nora Pashayan Implications of polygenic risk-stratified screening for protate cancer on overdiagnosis, AACR Annual Meeting,5-9 April, San Diego, CA, USA

Zsofia Kote-Jarai Fine-mapping the HOXB region detects common variants tagging a rare coding allele: evidence for synthetic association in prostate cancer, AACR Annual Meeting,5-9 April, San Diego, CA, USA

Ying Han Generalizability of established prostate cancer risk variants in men of African ancestry, AACR Annual Meeting,5-9 April, San Diego, CA, USA

Ros Eeles Genetic predisposition to prostate cancer (PrCa) and its Clinical application, AACR Annual Meeting,5-9 April, San Diego, CA, USA

Ros Eeles, Integrating genomic data into risk modeling and other clinical applications. AACR Annual Meeting, San Diego, USA (NCI sponsored session) April 8, 2014.

Mahbubl Ahmed, Analysis of 76 prostate cancer risk SNPs in radiation toxicity suggests individuals can have standard radiation treatment, 6th Familial Cancer Conference, 5-6 June, Madrid, Spain

SK McDonnell et al & R Eeles. Quality control procedures for Whole Exome Sequencing Studies with application to a large family-based study: The International Consortium of Prostate Cancer Genetics (ICPCG) Study, ASHG, 18-22 October, San Diego, CA

D Schaid et al & R Eeles, Z Kote-Jarai. Statistical Genetics and Genetic Epidemiology, ASHG, 18-22 October, San Diego, CA

Dan Leongamornlert et all & R Eeles. HOXB13 G84E germline mutation and prostate cancer risk in the UK, ASHG, 18-22 October, San Diego, CA

Z Kote-Jarai et al & R Eeles. Fine-mapping of 67 prostate cancer GWAS regions identifies better and multiple association signals, ASHG, 18-22 October, San Diego, CA

M Luedeke et al & R Eeles. The prostate cancer risk mutation G84E in HOXB13 is associated with the subtype of ETS fusion negative adenocarcinoma with early age of diagnosis, ASHG, 18-22 October, San Diego, CA

Clara Cieza-Borrella et al & R Eeles. Longer Telomere length associates with Prostate Cancer, 10th NCRI Cancer Conference, 2-5th November, Liverpool

PROFILE

Ros Eeles The PROFILE feasibility study: genetic prostate cancer risk stratification for targeted screening, AACR Annual Meeting,5-9 April, San Diego, CA, USA

Christos Mikropoulos, The PROFILE feasibility study: genetic prostate cancer risk stratification for targeted screening, 6th Familial Cancer Conference, 5-6 June, Madrid, Spain

PROFILE/IMPACT/UK Genetic Prostate Cancer Study

Ros Eeles, Clinical translational application of germline genetic variation. AACR Annual Meeting,5-9 April, San Diego, CA, USA

Ros Eeles, Genetic predisposition to prostate cancer and its clinical implications. AACR Annual Meeting, San Diego, USA. April 5-9, 2014.

Ros Eeles, Genetic predisposition to prostate cancer and its clinical implications. Mount Sinai, April 10, 2014.

Ros Eeles, Familial prostate cancer genetics: clinical management & diagnostic biomarkers. 6th Familial Cancer Conference, CNIO, European School of Oncology. Madrid, June 5- 6, 2014

Ros Eeles, Genetic Profiling. 11 Biennial Prostate Cancer Forum, Baltimore, Maryland, USA. June 11-13, 2014.

Ros Eeles, Genetic risk and its implications for cancer surveillance: conclusions and clinical perspectives. ESMO Madrid, Spain. September 26-30, 2014. o Cancer Genetics & its relevance to the modern world. ICGCW Conference, Tata Memorial Centre, Navi Mumbai, India. November 01, 2014.

Ros Eeles, Inherited predisposition to prostate cancer. ICGCW Conferrence, Tata Memorial Centre, Navi Mumbai, India. November 01, 2014.

Ros Eeles, Genetic predisposition to prostate cancer and its clinical implications. CNIO Distinguished Seminars Series 2013-2014, Madrid, Spain. November 14, 2014.

Ros Eeles, Genetic predisposition to prostate cancer and its clinical applications. Irish Association for Cancer Research, Limerick, Ireland. Irish Cancer Society Lecture. 26-27 February 2015

IMPACT

Ros Eeles, The association of BRCA mutations with prostate cancer risk and implications for management". 29th Annual EAU Congress, Stockholm, Sweden April 12-14, 2014.

Ros Eeles, Making an IMPACT on prostate cancer in BRCA1/2 carriers. HBOC Symposium, Montreal, April 23 – 25, 2014.

Liz Bancroft et al & R Eeles. Identification of men with a genetic predisposition to prostate cancer: targeted screening of BRCA1/2 mutation carriers and controls. The IMPACT study Quality of Life Study, ASHG, 18-22 October, San Diego, CA

Ros Eeles, Patients with BRCA1/2 and other germline mutations. Advanced Prostate Cancer Consensus Conference, St Gallen, Switzerland. March 12 -14 2015

Others

Ed Saunders et al & R Eeles. Association between rare and common variants in DNA repair genes and prostate cancer using the iCOGS genotyping array. ASHG, 18-22 October, San Diego, CA