

NCRI Prostate Group

Annual Report 2020 - 2021



NCRI Partners

NCRI is a UK-wide partnership between research funders working together to maximise the value and benefits of cancer research for the benefit of patients and the public. A key strength of the NCRI is our broad membership with representation across both charity and government funders as well as across all four nations in the United Kingdom.



List of Appendices

Appendix 1	Membership of the Group, Subgroups and their specialty & location
Appendix 2	Group and Subgroup strategies
Appendix 3	Top 5 publications in reporting year
Appendix 4	Recruitment to the NIHR portfolio
Appendix 5	Annual report feedback 2019-20
Appendix 6	Quinquennial review feedback

NCRI Prostate Group

Annual Report 2020-21

1. Top achievements in the reporting year (up to three)

Achievement 1

The CADMUS Trial: comparison of multi-parametric ultrasound to multi-parametric MRI.

Presented at ASCO 2021 and featured in the NCRI Prostate ASCO webinar.

This study has shown that mpUSS is almost as accurate as mpMRI and therefore would allow healthcare settings which do not have ready access to MRI facilities to still offer highly accurate diagnostics to their populations at a fraction of the cost.

Achievement 2

The FORECAST Trial: a comparison of MRI targeted biopsy to transperineal mapping biopsy followed by focal ablation salvage therapy in patients with radiorecurrent prostate cancer.

Presented at ASCO 2021 and featured in the NCRI Prostate ASCO webinar.

This study has shown that mpMRI and targeted biopsy are accurate in localising recurrent prostate cancer and that ablation has reassuring functional and early cancer control outcomes. The former is practice changing whilst the latter provides justification for a larger RCT.

Achievement 3

Continued funding success for new studies over the last 12 months in both the localised and advanced disease settings from a variety of funding bodies, academic and commercial.

2. Structure of the Group

The Group continued to function with two Subgroups which have remained active right up to the last meeting of the current structure earlier this year. As before, the Localised Subgroup under the steady leadership of Rakesh Heer has built an enviable reputation for co-developing and supporting new studies to successful funding as can be seen in the summaries below. The Advanced Subgroup had a change in lead to Gert Attard and this has continued the strong and robust collaboration with the STAMPEDE RCT TMG in their efforts to develop the key new arms for the next few years. The Subgroup has responded to calls to support other trials in this space and it is reassuring to see a proposal in this area being submitted to the new Proposal Guidance meeting.

Our Consumer reps have been formidable in exercising their duties and are not only active in the NCRI but also in many other organisations as PPI representatives/leads and in specific studies as part of the Research Groups. Unfortunately, our trainees have not been as involved as they might have wanted given their redeployment to other duties over the last year.

We have agreed to transition over to the new structure forthwith and will be embracing this with as much energy as we can muster given what has been a tiring and trying year.

3. Prostate Group & Subgroup strategies

Prostate Group

Overall goals

- To minimise the harms from the investigation and treatment of localised prostate cancer.
- 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 support consumer involvement in clinical research and establishing links with the Prostate Cancer Support Federation.
- To strengthen links with Prostate Cancer UK (PCUK) and Prostate Cancer Research (PCR).

Our Group made the transition to the new structure in part holding our last meeting in April and then holding the first Proposal Guidance meeting with a morning and an afternoon spent reviewing a variety of study proposals that traversed detection through to metastatic treatment paradigms. Feedback has been provided to investigators and the secretariat have received feedback on the process itself which will be actioned for the next time. The Chair's personal opinion was that we may have lost some of our informality in the atmosphere created and because panel members were drawn from the wider expertise in the UK, the panel dynamic was perhaps adding to this.

Whilst commenting below on our successes, the impact of the pandemic on existing trials' set up, conduct and recruitment has, without exaggeration, been disastrous. Funders, sponsors, Trial Steering Committees and site PIs have been supportive in continuing on, but the impact may mean a minority of studies do not survive to completion. Our clinical members and investigators have also had much asked of them and I take this opportunity to thank them for all their effort and support to the greater cause of the pandemic whilst continuing on the fantastic work each of them do to improve outcomes for those at risk and diagnosed with prostate cancer. The resilience of researchers in prostate cancer during this year is to be applauded.

The Group's overall strategic aims were remarkably realised.

First, the Group continues its work in developing a screening study that fits the modern era and which builds on what has been learned from the existing and large body of screening studies so far reported. The IPI-PROSTAGRAM and BARCODE1 feasibility studies have provided evidence that patients will engage with screening invitations and both studies have shown that what processes in a future larger study might work or that should be dropped. BARCODE1 has launched its pre-planned 5000 patient cohort study evaluating polygenic risk score. The Prostagram approach – using a fast MRI to screen for prostate cancer in the community - has shown feasibility and possibly

improved diagnostic performance compared to PSA alone and a larger RCT is planned and under submission to a funder.

Second, our early diagnosis strategy has seen considerable success in developing and supporting ideas through to obtaining funding. The TRANSLATE RCT evaluating transperineal biopsy, the IP6-CHAIROS cohort study evaluating a histology AI tool to diagnose prostate cancer on H&E slides, the PRIME cohort study validating the role of biparametric MRI and the role of circulating tumour cells in risk stratification.

Third, we wanted to develop and nurture more studies in the surgical and localised disease space with examples of success with an RCT assessing the role of finasteride in active surveillance although others are being resubmitted (retzius sparing prostatectomy compared to conventional standard prostatectomy).

Fourth, we continue to proffer robust advice and support to the STAMPEDE RCT so that it continues its immense success whilst ensuring new arms are given the rigorous review that the NCRI and CRUK have asked of us. We also continue to welcome and support new studies in the hormone-sensitive metastatic prostate cancer space, something that was seen in the Proposal Guidance meeting on 24th May 2021.

Fifth, we have seen a whole cadre of young / new investigators come to fore. Our approach has been to offer a friendly critique and welcome investigators, experienced and inexperienced, to present their ideas and this has borne fruit.

Finally, we have also got regular engagement from key funders including CRUK, PCUK and PCR which has allowed our meetings and strategic aims to become more closely aligned and for the funders to complement the areas they will support through greater dialogue.

Advanced Disease Subgroup (Chair, Professor Gerhardt Attard)

Strategic aims

- To focus on translational science with an overarching focus to progress the theme of personalised medicine in advanced prostate cancer.
- 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 (this NCRI Group has now closed and now sits with the NCRI Living With & Beyond Cancer Group (LWBC) Group).
- To identify and address knowledge gaps where the UK has a unique opportunity to bring change and support new trials that meet these needs

The Advanced Disease Subgroup has focused its efforts in co-developing and supporting the STAMPEDE RCT group in new arms. A Lutetium PSMA theranostics arm and a precision-medicine arm using genetic testing of cancer tissue to guide therapy have both been proposed with the latter having commercial funding commitments. Further details will be forthcoming in the next year under the new structure of the Group.

The Proposal Guidance meeting under the new structure was able to review a number of proposals in the advanced disease space including a couple of notable ones in SABR for high volume metastatic disease and radiotherapy for oligo-recurrent pelvic disease.

Localised Disease Subgroup (Chair, Mr Rakesh Heer)

The Localised Disease Subgroup has been very much active and reviewed a number of proposals that were then successful in funding applications and some undergoing funder's review.

Strategic aims

- Evaluate strategies to reduce the over-diagnosis and over treatment burden in localised prostate cancer.

The TRANSLATE RCT (Bryant/Lamb) of transperineal biopsy versus transrectal biopsy was co-developed by the Subgroup and successfully awarded an NIHR HTA grant. Due to start 4Q 2021, and if successful, will lead to an international shift from transrectal biopsy to transperineal impacting on the sepsis rates that are often seen more commonly with the transrectal approach.

An RCT was funded by Yorkshire Cancer Research (YCR) to evaluate the role of finasteride in patients on active surveillance (Catto/Sasieni). The study was supported with advice and guidance after the initial funding decision was made and is due to start later this year.

The CHAIROS study was funded by the new NIHR AI funding stream (Ahmed/Brentnall) and is a validation study of a new AI tool that is reported to be able to detect and rule out prostate cancer on high resolution scanned pathology slides.

A new RCT developed in collaboration with the Subgroup was proposed to improve the manner in which robotic assisted radical prostatectomy is conducted in order to minimise side effects such as incontinence (Winkler/Bass). The study was initially turned down for funding, but the funder has specifically asked for a resubmission. If successful, the study will commence 3Q 2022.

A final funder decision by CRUK is pending on the proposed PACIFIC RCT which is a novel serial double randomisation design proposing to evaluate biparametric MRI and image fusion targeted biopsy.

The Subgroup continue to support the co-development of a screening study with members of the Primary Care group (part of the NCRI SPED Group) and PCUK. The latest iteration of a screening RCT, following on from the PROSTAGRAM pilot were presented and discussed last year and funding applications are currently in. If successful, this study will start 3Q 2022.

- Evaluate strategies to improve current treatments.

The Subgroup supported a successful application to PCUK to evaluate circulating tumour cells to risk stratify men with localised prostate cancer (Shaw/Lu). This study is due to start 4Q 2021. The Subgroup also helped with the development of a new study led by a young investigator (Shah, a previous trainee member) to evaluate the feasibility of an RCT in patients with radiorecurrent prostate cancer. Currently, the options for this group of patients is limited with little prospective research being undertaken. Funding applications have been submitted in 2Q 2021 and if successful the study will commence 4Q 2021/1Q 2022.

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

Several previously funded studies were actively trying to recruit over the last year but were impacted by the COVID-19 pandemic. We look forward to hearing of their success over the next year.

- Encouraging trials with value added secondary themes of biobanking and health service research.

The CHAIROS AI validation study will databank all imaging and scanned H&E slides for future development and validation of other AI tools. The PART and CHRONOS studies have in-built qualitative components to determine acceptability to randomisation in surgical RCTs and improvements that could be made therein.

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

Several new investigators have been supported including Dr Julia Murray, Mr Taimur Shah, Mr Edward Bass, Mr Mathias Winkler, Mr Richard Bryant and Mr Alastair Lamb.

4. Cross-cutting research

Over the next year, the Group has identified 3 areas which will fit closely with our strategic aims and form the core of the task-and-finish groups. Some of work has already been laid down and will be continued in the new Group structure. These include:

- a) Screening: Build on the existing discussions and plans to develop and deliver a practice-changing study of screening for prostate cancer. This will be in collaboration with PCUK, experts in epidemiology, primary care, health economics, and qualitative health services research.
- b) Novel imaging and AI tools in imaging: To evaluate the role of PSMA PET in the staging of high risk and/or recurrent prostate cancer and its role in follow-up after therapy; to evaluate the role of AI Imaging tools to reduce radiology burden and improve diagnosis of clinically significant prostate cancer. This will be in collaboration with nuclear medicine and computing scientists/mathematicians.
- c) Metastatic disease: a specific standing group will continue the pivotal role played by the Advanced Disease Subgroup in helping to shape, develop and review proposed new arms to the STAMPEDE RCT.

5. Funding applications in last year

Table 1 Funding submissions in the reporting year

Study	Committee & application type	CI	Outcome	Level of Group input	Funding amount
Cancer Research UK*					
March 2021					
Electrochemical detection of prostate cancer RNA transcripts using specific aptamers	Biomarker Project Award	Professor Paul Millner	Not Supported		
December 2020					
Prostate Adenocarcinoma TransCutaneous Hormones (PATCH) MRC PR09	Clinical Trial Award - Extension (May 2020)	Professor Ruth Langley	Supported		
Other committees**					
Study	Committee & application type	CI	Outcome	Level of Group input	Funding amount
A randomised controlled trial of TRANSrectal biopsy versus Local Anaesthetic Transperineal biopsy Evaluation (TRANSLATE) of potential clinically significant prostate cancer	NIHR HTA	Bryant/Lamb (Oxford)	Successful	Presented and co-developed. Bryant is a NCRI Group member.	£1.07M
Increasing compliance with Active surveillance: A randomised trial evaluating the role of Finasteride	Yorkshire Cancer Research	Sasieni/Catto (Kings/Sheffield)	Successful	Input post-award	£1.6M
Circulating tumour cells as biomarkers for treatment stratification of localised prostate cancer	Prostate Cancer UK & Movember 2020/21 Major Awards call in Curative Treatments	Lu/Shaw (QMUL)	Successful	Presented and provided feedback. Shaw is a NCRI Group member	£600K
A validation study of a Histology AI tool for detecting and ruling-out prostate cancer on biopsy slides	NIHR AI	Ahmed/Brentnall (Imperial/QMUL)	Successful	Co-developed. Presented and provided feedback.	£600K

				Ahmed is a NCRI Group member	
Evaluating the role of fast MRI and image-fusion for detection of prostate cancer	NIHR HTA	Ahmed/Gabe (Imperial/QMUL)	Unsuccessful	Developed and worked up by NCRI Group.	£2.2M
A randomised controlled trial to assess the role of retzius sparing prostatectomy in treating localised prostate cancer	Prostate Cancer UK & Movember 2020/21 Major Awards call in Curative Treatments	Winkler/Bass (Imperial)	Unsuccessful	Developed and worked up via NCRI Group.	£600K

**CRUK CRC applications for table 1 completed by NCRI Executive.*

***Other applications in the table to be completed by Group Chair*

6. Consumer involvement

Sue Duncombe and Derek Price have attended all meetings of the Prostate Group and Consumer Forum during the year. Sue has continued to serve on the Advanced Disease Subgroup and Derek on the Localised Disease Subgroup in addition to their membership of the main Group. As a result of this they have both been involved in commenting on research proposals presented to the groups.

They regularly communicate with each other concerning activities or materials relevant to prostate cancer research. Communication with other members of the Prostate Group, particularly the Prostate Chair, Subgroup Chairs and mentors are excellent, with queries being responded to rapidly and contributions always acknowledged.

The transition to online meetings has allowed both Sue and Derek to increase their knowledge of prostate cancer research and broader aspects of the disease. They have participated in Zoom/Teams meetings including the ASCO virtual conference and webinars organised by NCRI, PCUK, CRUK, useMYdata and ReIMAGINE.

Derek Price

Derek has provided feedback to researchers, on several developing research proposals, by means of Zoom, emails and at Dragons' Den. He has also reviewed patient-facing materials including web pages for CRUK, a draft patient survey for a trial and a fact sheet on "Diet and Physical Activity" for PCUK.

He continues to be a member of a number of TMGs - ATLANTA, PACIFIC, CORE, PACE and PROSPECT. These trials study a range of prostate clinical issues ranging from initial diagnosis to treatment of advanced disease. Derek has recently joined the TRANSLATE Trial Steering Committee.

The completed phase II screening trial IPI-PROSTAGRAM, the TMG of which Derek was a member, published a paper in JAMA Oncology in February 2020 and the trial presented an abstract at the 2020 ASCO annual meeting.

Derek has continued in his role as a member of the National Prostate Cancer Audit (NPCA) group and has been actively involved in feeding back on the annual reports and commenting on aspects of the audit. He has presented and discussed the results of the audit at a local Support Group Meeting.

He was invited to contribute to the NIHR CED collection on "improving men's health outcomes alerts" (on urological research), and his comments are now part of the online commentary. In addition, he contributed to the NIHR Evaluation, Trials and Studies Coordination Centre (NETSCC) after being asked to provide a patient's viewpoint for a potential Research Brief currently under consideration.

Sue Duncombe

Sue's activities, outside the Prostate Group, support more general areas of oncology and research. These roles allow her to bring a wider perspective and experience to her consumer role in the Prostate Group.

She is very engaged with CRUK activities, particularly in campaigning. In the last year she has met with her MP and communicated with government ministers to try to ensure that the Brexit negotiations created a positive environment for research. She has also been involved in a

campaign to encourage the government to provide financial support to medical charities whose funding and hence research budgets were affected by COVID-19.

Sue is on the TMG of a study presented to the Prostate Group and currently awaiting funding. Her contributions to the TMG have included proposing ways of disseminating results to participants and suggesting changes to the lay summary to explain risk. These ideas were incorporated into the funding submission.

Sue is on the Steering Group for a prostate cancer trial on "Integrating genetic testing into the prostate cancer pathway" (NIHR201620). Her suggestion to look at patient barriers to screening, to assess if there was a risk of widening health inequalities, was reviewed for incorporation into one of the work packages and taken to the PPI Advisory Group for discussion.

Sue has worked with Oxford BRC to develop the PPIE strategy for the next 5 years. This has meant that best practice PPI discussed in the Consumer Forum has been incorporated. She has facilitated workshop sessions of a new PPI group in Oxford BRC, composed of representatives from underserved communities. Her increased awareness of challenges faced by a more diverse population allows her to input these into research proposals.

7. Collaborative partnership studies with industry

Screening: the new task-and-finish group in screening will place a call out to all interested biomarker companies to get involved so that either validation or testing of utility can be incorporated into new study designs, possibly with co-funding.

PSMA: active discussions are in place with the key manufacturers and suppliers of the radioactive tracer for evaluating the role of PSMA PET in staging and guiding treatment decisions.

Localised treatment: The PART RCT funded by NIHR HTA has a large commitment from the vascular targeted photodynamic agent manufacturer (Steba Biotech). The RCT has been delayed to the end of 2021 when it would be expected to commence.

CHAIROS: NIHR AI funded study has an active collaboration with Ibex Medical, the developer of the Galen Histology AI system.

8. Priorities and challenges for the forthcoming year

Priority

To have a screening study funded which would form the basis of addressing an evidential gap which might, if successful, lead to a change in National Screening Committee guidance for prostate cancer screening. There are now some interesting early pilot data that are described above which will guide this process.

Challenge

Lack of consensus currently on what key elements of such a study are required. We will establish a broad group of experts from the UK and beyond if necessary, in partnership with PCUK and other funders and stakeholders. Discussions are already in place about what such a task-and-finish group will look like and we plan to potentially hold this in 4Q 2021.

Professor Hashim Ahmed (Prostate Group Chair)

Appendix 1

Membership of the Prostate Group

Name	Specialism	Location
Dr Aravindhan Sundaramurthy	Clinical Oncologist	Glasgow
Dr Hannah Tharmalingam*	Clinical Oncologist	London
Dr Alison Tree	Clinical Oncologist	London
Dr Nicholas van As	Clinical Oncologist	London
Dr Mohini Varughese	Clinical Oncologist	Somerset
Ms Sue Duncombe	Consumer	Childrey, Oxfordshire
Mr Derek Price	Consumer	Solihull
Dr Simon Pacey	Medical Oncologist	Cambridge
Dr Gerhardt Attard	Medical Oncologist	London
Dr Simon Crabb	Medical Oncologist	Southampton
Professor Daniel Berney	Pathologist	London
Dr Athene Lane	Reader in Trials Research	Bristol
Dr Tristan Barrett	Radiologist	Cambridge
Dr Athar Haroon	Radiologist	London
Dr Hayley Whitaker	Scientist	London
Dr Richard Wagland	Senior Research Fellow	Southampton
Dr Fay Cafferty	Statistician	London
Professor Hashim Ahmed (Chair)	Surgeon	London
Mr Rakesh Heer	Surgeon	Newcastle
Mr Tom Leslie	Surgeon	Oxford
Mr Greg Shaw	Surgeon	London
Professor Richard Bryant	Surgeon	Oxford
Professor Rob Bristow	Urologist	Manchester
Mr Alex Hoyle*	Urology Registrar	Manchester

Consumer Representation

Name	Location
Mr Derek Price	Solihull
Ms Sue Duncombe	Childrey, Oxfordshire

Trainee Members

Name	Specialism	Location
Dr Hannah Tharmalingam*	Clinical Oncologist	London
Mr Alex Hoyle*	Urology Registrar	Manchester

Membership of the Subgroups

Advanced Disease Subgroup		
Name	Specialism	Location
Dr Zafar Malik	Clinical Oncologist	Liverpool
Dr Alison Tree	Clinical Oncologist	London
Dr Mohini Varughese	Clinical Oncologist	Somerset
Professor Joe O'Sullivan	Clinical Oncologist	Belfast
Professor Sobhan Vinjamuri	Consultant in Nuclear Medicine	Liverpool
Ms Sue Duncombe	Consumer	Childrey
Dr Gerhardt Attard (Chair)	Medical Oncologist	London
Professor Silke Gillessen	Medical Oncologist	Manchester
Dr Simon Crabb	Medical Oncologist	Southampton
Dr Satinder Jagdev	Medical Oncologist	Leeds
Professor Janet Brown	Medical Oncologist	Sheffield
Dr Nuria Porta	Statistician	London
Dr Matthew Sydes	Statistician	London
Dr Prabhakar Rajan	Surgeon	London
Mr Prasanna Sooriakumaran	Surgeon	Oxford

Localised Disease Subgroup		
Name	Specialism	Location
Dr Ann Henry	Clinical Oncologist	Leeds
Dr Anita Mitra	Clinical Oncologist	London
Dr Suneil Jain	Clinical Oncologist	Belfast
Dr Hannah Tharmalingam*	Clinical Oncologist	London
Mr Christof Kastner	Consultant Urologist	Cambridge
Mr Derek Price	Consumer	Solihull
Dr Mehran Afshar**	Medical Oncologist	London
Professor Daniel Berney	Pathologist	London
Dr Shonit Punwani	Radiologist	London
Dr Hayley Whitaker	Scientist	London
Dr Athene Lane	Senior Research Fellow	Bristol
Dr Rhian Gabe	Statistician	York
Dr Fay Cafferty	Statistician	London
Professor Emma Hall	Statistician	London
Professor Hashim Ahmed	Surgeon	London
Mr Paul Cathcart	Surgeon	London
Professor Frank Chinegwundoh	Surgeon	London
Mr Greg Shaw	Surgeon	London
Mr Rakesh Heer (Chair)	Surgeon	Newcastle

* denotes trainee member

**denotes non-core member

Appendix 2

Prostate Group & Subgroup Strategies – 2020-2021

A – Prostate Group Strategy

Overall goals

- To minimise the harms from the investigation and treatment of localised prostate cancer.
- 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 support consumer involvement in clinical research and establishing links with the Prostate Cancer Support Federation.
- To strengthen links with Prostate Cancer UK and Prostate Cancer Research

B – Advanced Disease Subgroup Strategy

Aims

- To focus on translational science with an overarching focus to progress the theme of personalised medicine in advanced prostate cancer.
- 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 identify and address knowledge gaps where the UK has a unique opportunity to bring change and support new trials that meet these needs

C – Localised Disease Subgroup Strategy

Aims

- Evaluate strategies to reduce the over-diagnosis and over treatment burden in localised prostate cancer
- Evaluate strategies to improve current treatments
- To evaluate methodological strategies to improve accrual and success of comparative surgical research.
- Encouraging trials with value added secondary themes of biobanking and health service research
- To encourage, nurture and enable young/new investigators to the field.

Appendix 3

Top 5 publications in the reporting year

Trial name & publication reference	Impact of the trial	CSG involvement in the trial
<p>1. Parker CC, Clarke NW, Cook AD, Kynaston HG, Petersen PM, Catton C, Cross W, Logue J, Parulekar W, Payne H, Persad R, Pickering H, Saad F, Anderson J, Bahl A, Bottomley D, Brasso K, Chahal R, Cooke PW, Eddy B, Gibbs S, Goh C, Gujral S, Heath C, Henderson A, Jaganathan R, Jakobsen H, James ND, Kanaga Sundaram S, Lees K, Lester J, Lindberg H, Money-Kyrle J, Morris S, O'Sullivan J, Ostler P, Owen L, Patel P, Pope A, Popert R, Raman R, Røder MA, Sayers I, Simms M, Wilson J, Zarkar A, Parmar MKB, Sydes MR. Timing of radiotherapy after radical prostatectomy (RADICALS-RT): a randomised, controlled phase 3 trial. <i>Lancet</i>. 2020 Oct 31;396(10260):1413-1421. doi: 10.1016/S0140-6736(20)31553-1. Epub 2020 Sep 28. PMID: 33002429.</p> <p>2. Vale CL, Fisher D, Kneebone A, Parker C, Pearse M, Richaud P, Sargos P, Sydes MR, Brawley C, Brihoum M, Brown C, Chabaud S, Cook A, Forcat S, Fraser-Browne C, Latorzeff I, Parmar MKB, Tierney JF; ARTISTIC Meta-analysis Group. Adjuvant or early salvage radiotherapy for the treatment of localised and locally advanced prostate cancer: a prospectively planned systematic review and meta-analysis of aggregate data. <i>Lancet</i>. 2020 Oct</p>	<p>Change in practice to salvage radiotherapy strategy following radical prostatectomy</p>	<p>Development and design from inception</p>

<p>31;396(10260):1422-1431. doi: 10.1016/S0140-6736(20)31952-8. Epub 2020 Sep 28. PMID: 33002431.</p>		
<p>3. Eldred-Evans D, Burak P, Connor MJ, Day E, Evans M, Fiorentino F, Gammon M, Hosking-Jervis F, Klimowska-Nassar N, McGuire W, Padhani AR, Prevost AT, Price D, Sokhi H, Tam H, Winkler M, Ahmed HU. Population-Based Prostate Cancer Screening With Magnetic Resonance Imaging or Ultrasonography: The IPI-PROSTAGRAM Study. JAMA Oncol. 2021 Mar 1;7(3):395-402. doi: 10.1001/jamaoncol.2020.7456. PMID: 33570542; PMCID: PMC7879388.</p>	<p>Justification for a larger RCT in screening</p>	<p>Development and design from inception</p>
<p>4. Benafif S, Ni Raghallaigh H, McGrowder E, Saunders EJ, Brook MN, Saya S, Rageevakumar R, Wakerell S, James D, Chamberlain A, Taylor N, Hogben M, Benton B, D'Mello L, Myhill K, Mikropoulos C, Bowen-Perkins H, Rafi I, Ferris M, Beattie A, Kuganolipava S, Sevenoaks T, Bower J, Kumar P, Hazell S, deSouza NM, Antoniou A, Bancroft E, Kote-Jarai Z, Eeles R. The BARCODE1 Pilot: a feasibility study of using germline SNPs to target prostate cancer screening. BJU Int. 2021 Jul 2. doi: 10.1111/bju.15535. Epub ahead of print. PMID: 34214236.</p>	<p>Justification and refinement of a larger prospective 5,000 participant study</p>	<p>Review and feedback</p>

Appendix 4

Recruitment to the NIHR portfolio

Summary of patient recruitment by Interventional/Non-interventional and number of studies opened/closed.

Year	All participants		Cancer patients only*		Number of studies	
	Non-interventional	Interventional	Non-interventional	Interventional	Opened	Closed
2016/17	6301	5756	6301	5756	28	31
2017/18	3164	5155	3164	5155	24	28
2018/19	3756	5311	3756	5311	29	23
2019/20	3540	3811	3319	3811	29	29
2020/21	1170	1339	877	1339	16	8

*This data is based on a proxy from CPMS (the NIHR database used to collect patient recruitment data) and includes diagnostics, screening and prevention patients

Appendix 5

Annual report feedback 2019-20

06 November 2020

Dear Hashim

Re: NCRI Prostate Group Annual Report 2019-20

Thank you for submitting an annual report for the Prostate Group for 2019/20, especially given the challenges with the ongoing COVID-19 pandemic which will have impacted on both the Group and the report itself.

All the Group's annual reports were reviewed at a two-day meeting on the 12th and 13th October 2020 by a panel consisting of some former NCRI Group Chairs, NCRI CMPath Chair, former NCRI CTRad and the current NCRI Strategic Advisory Group (SAG) Chair, NCRI Head of Research Groups and representatives from the NIHR Cancer Coordinator Centre, NHS Cancer Alliances, epidemiology, CTU/basic science, allied health profession, NCRI Consumer Forum and the Canadian Cancer Clinical Trials Network.

We are writing to you now with a summary of the feedback which is based on the information provided in the report. It was noted that there is likely to be more activity taking place within the Group than is documented.

Please share the contents of this letter with your members for discussion at the next Group meeting.

Generic feedback for all the Groups

Strategic objectives and the impact of COVID 19

- Due to the research funding challenges and restrictions on NHS resources resulting from COVID 19, the Panel recommended the Groups evaluate their strategic objectives and focus on the most important priorities or questions that need to be answered as it would not be feasible for the Groups to be doing everything they planned or continue to "plug in the gaps." Additionally, the Panel suggested looking for more cost-efficient methods of working where they can.
- The Panel felt that the strategic objectives for most Groups were too broad especially in the current climate. The Groups were asked to provide specific, measurable aims for their strategic objective and attach timelines/metrics to them.

Multidisciplinary approach to research and membership

- The Panel noted the importance of collaborative and multidisciplinary working, especially in the current climate, and would encourage all Groups to continue to reach out to other relevant NCRI Groups and consider the NCRI strategic priorities where appropriate.

National Cancer Research Institute, 2 Redman Place, London, E20 1JQ

T: +44 (0)20 3469 8798 **W:** www.ncri.org.uk

NCRI is a Charitable incorporated Organisation registered in England and Wales (charity number 1160609)

Linking with the wider research community

- The Groups were asked to link with the wider research community and engage with relevant networks, in particular, with researchers who are developing or are running large national platform studies when there is one available in the disease site e.g. PrecisionPanc (Upper GI Group) and TRACERx (Lung Group). The NCRI recognised that there is a role for them to play in promoting collaboration and will be working with the partners to encourage greater interaction between the Groups and the networks in future.

Funding opportunities

- Given the potential decrease in funding opportunities, the Groups are encouraged to explore alternative funding sources and collaborations e.g. with industry, government funders, NHS Cancer Alliances etc.

Consumers involvement:

- The Panel encouraged Groups to integrate public and patient involvement (PPI) in all aspects of the Group's activities e.g. study design, proposal development, prioritisation of strategic areas etc.
- The Panel wanted to ensure that the consumer activity was captured throughout the report and not just in the consumer section, especially where the consumer reports are missing.

Specific feedback for the Prostate Group

Areas of strength:

- The Panel noted that the report demonstrated a well matured Group and reflected the breadth of their work.
- The Panel recognised the Group's impact through the publication of RADICAL-RT as well as the Group's breadth of trials in development, in particular the screening trials. Additionally, the Panel felt the development of a community-based MRI screening trial PROSTAGRAMP, and the pilot project looking at genetic profiling in BARCODE 1 were successful outcomes for year.
- High success rate with funding application submissions.
- Excellent links and engagement with industry was shown by the Group, and the Panel welcomed engagement with the NIHR Clinical Research Networks (CRNs) to strengthen this partnership approach.

Areas which the Group need to consider:

- The Panel commended the Groups ambitious priorities in screening, capturing longitudinal survival data in early disease and stratified approaches to molecular diagnostics in the STAMPEDE trial. The Panel agreed that more definitive timelines and outcomes for completion were required, as well as working more closely with local cancer alliances to aid implementation and delivery.

Areas requiring further clarity due to limited information provided as a result of COVID 19:

- Positive and active consumer involvement on the Group was recognised by the Panel, however, the report failed to demonstrate wider consumer involvement.
- The Panel would appreciate greater clarity about the Group's completed work, plans in progress and the direction of their future work. It was noted that this may have been less well defined in the report due to the impact of COVID-19.

National Cancer Research Institute, 2 Redman Place, London, E20 1JQ

T: +44 (0)20 3469 8798 **W:** www.ncri.org.uk

NCRI is a Charitable incorporated Organisation registered in England and Wales (charity number 1160609)

Congratulations to you and your members for all your hard work and achievements in 2019/20.

If you have any comments on this year's process, please send them to Nanita Dalal (Nanita.Dalal@ncri.org.uk) for collation.

Best wishes,



Professor Meriel Jenney
Annual Reports Review Committee Chair, NCRI
Consultant Paediatric Oncologist,
University Hospital of Wales



Dr Gillian Rosenberg
Head of Research Groups,
NCRI

National Cancer Research Institute, 2 Redman Place, London, E20 1JQ

T: +44 (0)20 3469 8798 **W:** www.ncri.org.uk

NCRI is a Charitable incorporated Organisation registered in England and Wales (charity number 1160609)

Appendix 6

Quinquennial review feedback - 2018

1. Comments and recommendations

The Panel thanked the Prostate Cancer CSG for the documentation provided and the openness with which they had engaged in discussions.

The Panel identified a number of strengths of the Group and issues that the CSG need to consider:

Strengths

- The Panel commended the work of the CSG in developing a broad portfolio.
- The Group were commended on their outstanding international profile and work being done particularly in reference to STAMPEDE, ProtecT and PROMIS. It was acknowledged that the CSG has a track records of delivering world practice changing trials, with an impact that is inspiration to other CSG's.
- Commended the Localised Subgroup in bringing new ideas and new researchers into the Group.

Issues for the CSG to consider

- It was highlighted that local therapy is primarily a UK-led line of research and is currently challenged internationally. The Panel recommended that the Group gives further consideration to how they plan to preserve the theme of treatment reduction going forward with research to determine who will and who will not benefit from treatment.
- It was highlighted that the majority of the Groups portfolio of trials was concentrated in early and advanced disease, and that further effort is required to identify populations where there is currently gaps in research (i.e. management of locally-advanced disease and those who progress from STAMPEDE).
- Whilst the Panel supported continued perpetuation of STAMPEDE, it also recommended that the Group consider parallel research efforts to validate the changes in practice established from the platform, as not all findings are being accepted as standard of care globally.
- The Panel felt that the portfolio is currently dominated by a few senior internationally renowned individuals. The Group were encouraged to integrate new investigators and encourage new trial ideas across the spectrum of disease, from both within and outside of the CSG.
- The Panel encouraged the Group to actively build upon relationships with funding partners and identify areas where funding partners can help to support and develop their studies.
- The Panel recommended that the Groups should strengthen its basic scientist membership to encourage development of translational research. The Group were encouraged to hold a workshop bringing together clinicians, translational research experts and basic researchers (similar to the colorectal 'Mind the Gap' workshop).
- Further to previous recommendation from the NCRI, the Panel continued to stress the need for the CSG to actively engage with the Psychosocial Oncology & Survivorship (POS) and Supportive & Palliative Care CSGs to progress work in this area. The Panel also encouraged the Group to refer to the recent priorities published by the LWBC initiative.

Issues for the NCRI/NIHR CRN to consider

- The NIHR and NCRI Executive Team will arrange an annual meeting between all the SSLs and the CSG to promote better collaboration.

In concluding the Review, Professor Seymour thanked everybody for participating and the NCRI CSG Team for preparing the paperwork and organising the Review. The business of the meeting took four hours. **The Group will be reviewed in five years' time.**



National Cancer Research Institute
2 Redman Place,
London, E20 1JQ

T: +44 (0)20 3469 8460
F: +44 (0)20 3014 7658

info@ncri.org.uk