NCRI
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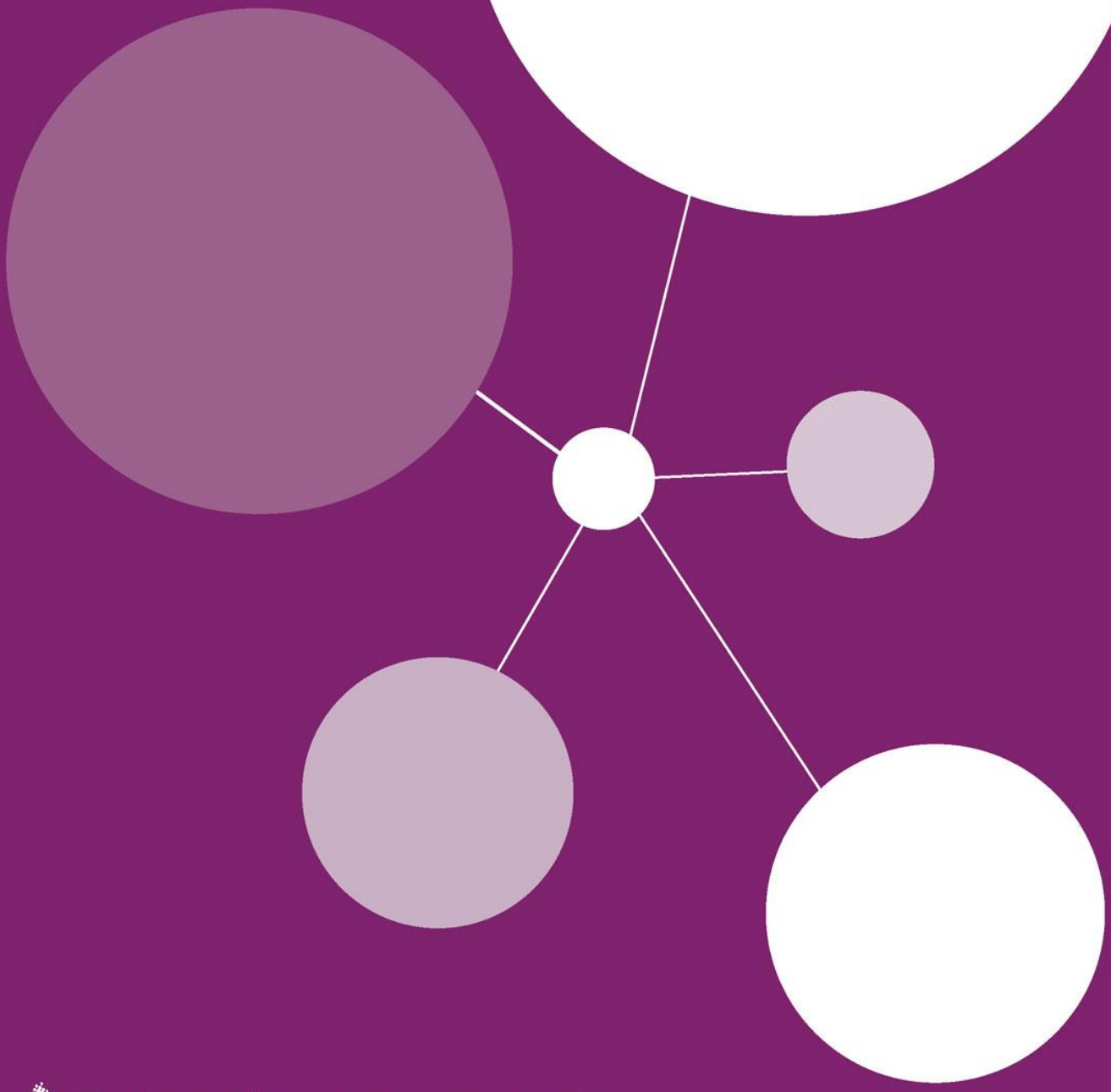
NCRI Bladder & Renal Clinical Studies Group

Annual Report 2016-17



Partners in cancer research

NCRI Bladder & Renal Cancer CSG
Annual Report 2016-17

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

Full integration of the merged Bladder and Renal CSGs has now occurred. The Group increasingly draws on experience from all members in project development and we have established a non-tumour specific working party exploring opportunities in combination immunotherapy and radiotherapy. Subgroups have met more frequently to succession plan and develop protocols. The Systemic Therapies Renal Working Party meets monthly and hosts teleconferences with open access for new investigators. The aims remain to develop internationally competitive practice changing studies that offer ***a trial for every patient***, use the biobank resource for translational work for the next generation of portfolio trials, and continue to engage with the surgical urological community.

The challenges we face include:

- The CSG faces unprecedented interest from Industry, leading to academic studies being in direct competition with Industry trials for target trial populations.
- Although there is an established and successful network of engaged urologists on trials in Non-muscle invasive bladder cancer (NMIBC), these are concentrated in certain CRNs.
- Increasing NHS pressures have led to CSG members, including the TABS Subgroup Chair, having to step down from the Group.

The top five achievements:

- Full integration of the Group enabling seamless cross-fertilising protocols and allowing greater input into funding submissions and NICE review. The CSG has provided expert input into eight reviews for NICE in the reporting year and liaises closely with the Urology SSLs via newsletters after CSG meetings and a first face-to-face meeting.
- Portfolio trial publications and presentations reflecting the activity of the Group and delivery of practice changing trials including 10 year follow up from the BC2001 trial.
- Trainee CSG members have developed successful portfolio trials and related publications: Sally Appleyard has worked on the QoL Trial and Sebastian Trainor wrote a collaborative paper on behalf of the CSG and BUG.
- Substantial increase of the renal portfolio (e.g. RAMPART, PRISM and TRIBE) and the use of biomarker material from the LAMB trial to develop the biomarker for its successor study ATLANTIS.

- Robust consumer engagement, including the patient champion project in renal cancer and training of regional research representatives in bladder cancer.

2. Structure of the Group

The Group is composed of 22 members, with two trainee members appointed for an 18 month term. There are seven medical oncologists, six clinical oncologists, four urological surgeons, one statistician, two radiologists and two consumer members. One consumer member, Christy Watson, has stepped down from the Group during this reporting year. The urological membership has been strengthened via advert for a surgeon with specialist interest in renal cancer.

The membership of each of the Subgroups has been refreshed and the Surgical Subgroup expanded. The TABS Subgroup is now co-Chaired by an urologist and a clinical oncologist to reflect the need for maintaining surgical engagement.

3. CSG & Subgroup strategies

Main CSG

- Significant progress has been made to utilise the biobank resources from recent portfolio trials in muscle invasive and advanced bladder cancer. Sample set data from Subgroups in the published LaMB study are being currently used to develop the biomarker for the rucaparib arm in the newly opened MAMS style ATLANTIS trial. Current biomarker validation of subsets in the radio-sensitiser studies BCON and BC2001 is ongoing to inform a successor trial of biomarker directed radical treatment in MIBC.
- Recruitment into the industry partnership first line systemic therapy studies (ToTEM, FIESTA) has completed and there are multiple ongoing trials of immunotherapy in the adjuvant, first line metastatic and second line metastatic settings.
- Areas of unmet need remain a priority. Recruitment to the potentially practice changing POUT study of adjuvant therapy in upper tract TCC is on target. In penile cancer, the UK led international InPACT study has begun recruitment after a lengthy set up period due to the complexity of international governance agreements.
- Studies in NMIBC continue to deliver strongly, e.g. DETECT 1 has recruited beyond target six fold allowing amendments to the protocol to increase the power of the study. However, recruitment remains centred on certain CRNs and this requires close working with the SSLs.
- Development of an increased academic portfolio of high quality interventional systemic treatment studies in RCC facilitated by a Systemic Treatments Working Party that nurtures talented young investigators. Significant progress has been made over the last year with the development of RAMPART, PRISM and TARGET.
- Development of a highly functional Surgical Subgroup that can deliver surgical studies in RCC and address the failings of previous surgical studies in this area. Significant progress has been made with the development of NAXIVA and there is continuing effort to establish a small renal mass study.
- Assessment of the feasibility of a screening programme for early RCC in higher risk individuals.

- Consumers that not only provide essential perspective on studies in development but lead and facilitate the engagement of the consumer community within the clinical research environment.

Penile Subgroup (Bladder) (Chair, Dr Amit Bahl)

The Subgroup has incorporated consumer representatives and also trainee urologists with special interest in penile cancer. The strategic aim is to keep the momentum for developing and delivering on trials in this rare cancer.

The Subgroup has supported the development of the InpacT trial which has now opened in its first UK centre with other centres are to follow shortly. The VinCaP study is close to completing recruitment and the JAVA-P study has now completed. The Subgroup has also been part of the new staging of penile cancer and disseminated this information nationally.

The strategic aim for the future is now to enable and promote recruitment into InpacT and to develop further trials, particularly addressing the issue of molecular markers and response and evaluating the benefit of novel therapies in advanced disease, which is chemo-resistant to initial chemotherapy.

T2 & Below Subgroup (Bladder) (Chair, Professor Robert Huddart; Deputy Chair, Mr Mark Johnson)

The Subgroup has had a change of chairmanship this year with Robert Huddart taking over from Jo Cresswell at the end of 2016. Mark Johnson was appointed as deputy Chair to synergise working between surgeons and oncologists on this Subgroup.

The year saw good progress in NMIBC with completion of HIVEC 2 and good progress in the PHOTO and CALIBER trials. BRAVO pilot study in pT1G3 disease has been launched in pilot phase. The Subgroup has had extended discussions about successor systemic trials that are ongoing. Diagnostic trials based on advanced genomics have been successful with rapid recruitment to the DETECT trials and agreement to support the SURVEY in London and the AmSeq study in Birmingham.

The Subgroup's advanced radiotherapy phase II study HYBRID successfully completed recruitment in August 2016 and was presented at GU ASCO; and RAIDER has continued expand to include most UK radiotherapy sites. Successor trials are under discussion including study of immunotherapy/radiotherapy combinations with a multi-arm design under consideration.

We continue to explore issues of Quality of Life (QoL) after treatment of bladder cancer with launch of testing a new QoL tool in Yorkshire (CI: Jim Catto), publication/presentation of data from the SPARE and BC2001 trials and a prospective comparison study is in development.

Advanced Bladder Cancer Subgroup (Chair, Dr Simon Crabb)

Our overriding objective is to increase cure rates by improving systemic therapy as a component of multimodality therapy. The strategy to achieve this is to develop a pipeline of new drug hypotheses in a precision medicine environment, for eventual evaluation in the neo-adjuvant setting. Central to this, ATLANTIS, an umbrella, precision medicine trial of advanced disease maintenance therapy, builds on successful delivery of the LaMB trial. ATLANTIS commenced recruitment in 2017. The comprehensive LaMB tissue set is enabling rapid exploration of putative predictive biomarkers for assimilation into new ATLANTIS arms.

In the neoadjuvant setting, NeoBLADE explores addition of nintedanib to standard chemotherapy, whist ABACUS is an early mechanistic immunotherapy trial. POUT is the first randomised phase III trial in upper tract TCC. The phase Ib/IIa Combinations Alliance SPIRE study combining SGI-110 with cisplatin/gemcitabine opened in 2016.

The Subgroup published final results from two of its first randomized trials in advanced disease (PLUTO second line, LaMB maintenance) and has presented data from a third (TOUCAN). Of note, LaMB was a world first randomized phase III precision medicine trial in urothelial cancer and PLUTO is the only randomized second line trial with paclitaxel as the comparator, strongly suggesting greater activity than was previously thought.

Surgical Subgroup (Renal) (Chair, Mr Grant Stewart)

Following on from the reformation of the renal cancer Surgical Subgroup and the evaluation of the key questions that renal cancer surgeons feel are important, we are now in the process of trial development and delivery. In order to facilitate the shift in focus from idea development to delivery, we have changed the Subgroup structure. The Subgroup has recruited several young consultants (Ravi Barod, Maxine Tran and Satish Maddineni) and senior trainees (Alex Laird, Tom Mitchell) to provide energy for study development and delivery. The Subgroup meets every 6-8 weeks by teleconference to ensure progress. As well as clinical trial development, we are ensuring all translational research opportunities are explored and we have expertise to execute this aim via Maxine Tran, Grant Stewart and Tom Mitchell who are all academic clinicians. The Subgroup aims to have all members 'attached' to one of the studies in our portfolio.

The key studies and their current stage of development are:

- A-PREDICT (upfront axitinib in patients not suitable for cytoreductive nephrectomy) - study complete. Presented at Late Breaking Abstract session AUA and BAUS Best Academic Abstract session.
- NAXIVA (neoadjuvant axitinib in IVC tumour thrombus patient) - CRUK endorsed, Pfizer funded and IRAS submitted.
- RAMPART (adjuvant immune-oncology study) - Kidney Cancer UK endorsed, AZ funded and IRAS in progress.
- EASE and UK small renal mass study (observational study of small renal cancer natural history) - IRAS submission imminent.
- RaSP: Renal Cancer Screening Pilot - feasibility study of screening for renal cancer to start in Cambridge in Q1/2 2018.

4. Task groups/Working parties

Systemic Treatments Working Party (Renal) (Chair, Professor Thomas Powles)

The renal Systemic Treatments Working Party (WP) meets by teleconference every month and is an environment which has successfully generated novel academic studies that are now approved and will be opening in this calendar year.

- PRISM (CI: Naveen Vasudev) - Combination ipilimumab + nivolumab standard vs dose light schedules - Funded and IRAS submitted.
- TRIBE (CI: Fiona Thistlethwaite) - A biomarker study in patients receiving immunotherapy after TKI – Funding has been secured.

The WP also has other projects in development which are likely to feed through to the CSG portfolio over the next year. Members have been closely involved in the development of RAMPART and Tom Powles and Paul Nathan are on the TMG for the study.

Combination Radiotherapy/Drug Working Party (Chair, Dr Vincent Khoo)

This Working Party (WP) was formed in early 2017 and had its first meeting by teleconference in February 2017. The main remit was to explore opportunities of Combined modality therapy particularly Immunotherapy in combination with RadioTherapy (CIRT). The WP aimed to enhance collaboration between centres undertaking individual CIRT studies to identify areas of common interest and gaps for new research and potential national/international studies. A review of current studies was undertaken. There is considerable interest in both bladder and renal cancer for immunotherapy studies but there are relatively few studies of CIRT.

In bladder cancer, there are currently two single institutional specific phase I CIRT studies based at the Christie Hospital (CI: A Choudhury) and at the Royal Marsden Hospital (CI: R Huddart). Both were initiated in 2016 and are still recruiting. These two studies have been developed in collaboration with pharma (Durvalumab from AZ and Pembrolizumab from Merck, respectively).

The strategy was to encourage collaboration with both centres as well as to involve other investigators active in this field namely Nick James, Peter Hoskin, Maria De Santis by invitation to participate in subsequent meetings with the hope of developing an appropriate national study. Suggestions included adding immunotherapy agents for the follow-on studies to either BC2001, BCON or RAIDER trials.

5. Patient recruitment summary for last 5 years

In the Bladder & Renal CSG portfolio, 21 trials closed to recruitment (15 Bladder and 6 Renal) and 37 opened (31 Bladder and 6 Renal).

Table 1 Summary of patient recruitment by Interventional/Non-interventional

Bladder

Year	All participants		Cancer patients only		% of cancer patients relative to incidence	
	Non-interventional	Interventional	Non-interventional	Interventional	Non-interventional	Interventional
2012/2013	0	324	0	324	0.0	3.1
2013/2014	648	287	648	287	6.2	2.7
2014/2015	69	262	69	262	0.7	2.5
2015/2016	763	604	649	604	6.20	5.77
2016/2017	5827	948	5624	948	53.70	9.05

Renal

Year	All participants		Cancer patients only		% of cancer patients relative to incidence	
	Non-interventional	Interventional	Non-interventional	Interventional	Non-interventional	Interventional
2012/2013	434	833	329	696	4.0	8.6

2013/2014	596	345	497	322	6.1	4.0
2014/2015	154	255	130	255	1.6	3.1
2015/2016	61	399	61	378	0.75	4.64
2016/2017	148	315	148	315	1.82	3.87

Bladder cancer recruitment remains healthy with 28 new bladder cancer studies being initialised in the reporting year showing a year on year trend (Cf 9 in FY 13/14, 17 in FY 14/15). There has been a sharp increase in both the number of commercial and interventional studies. Whilst expanding the opportunities for patients, this does provide challenges for the CSG where significant time may be spent developing an academic trial only for an Industry study to be adopted onto portfolio at short notice and in direct competition for a niche patient group.

Observational studies provide excellent recruitment opportunities and it is unclear why some CRN are unable to support these trials. The DETECT 1 study in NMIBC has significantly over recruited allowing a greater power calculation to be achieved. The two Industry CSG developed trials in systemic therapy FIESTA and ToTEM have successfully completed recruitment.

Recruitment to the renal portfolio has been in decline since 2012/13 reflecting the closure of our high recruiting adjuvant study SORCE. In the metastatic setting STAR has continued to recruit strongly, however other academic studies were far smaller in scale and had a limited impact on network recruitment. This issue was identified by the CSG and noted at last year's review. The addition of RAMPART, PRISM and TRIBE to the portfolio is expected to have a significant impact on recruitment to renal studies and there is increased activity in commercially adopted studies.

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

The CSG has a number of productive links with other groups, detailed below:

- The CSG is represented at the SPED Advisory Group by Chris Blick.
- A newsletter regularly updates the SSLs following CSG meetings highlighting key trials and potential barriers to recruitment. A successful joint meeting with the urology SSLs was held on 23 March 2017.
- The EORTC GU Group has been revitalised and the CSG is represented by Simon Crabb.
- There is close collaboration with the British Uro-Oncology Group (BUG) and joint representation of the CSG and BUG at NICE evaluations.
- The Renal Cross Channel Group (RCCG), led by Grant Stewart, links the CSG with the French and Italian co-operative groups and is resulting in development of collaborative cross-territory studies.
- CSG members are involved in the 100,000 genome project with Simon Crabb leading the bladder cancer module.
- Liaison with BAUS and BAUS Oncology remains robust with portfolio trials being publicised at their annual meetings. Jo Cresswell, the former TABS Subgroup Chair, is now Chair of BAUS Oncology.
- An initiative with the BURST (British Urology Registrars in Surgical Training) Research Collaborative brings in young investigators onto established trial management groups to develop their research skills.
- The RAIDER study has sites open in Australia and New Zealand.

7. Funding applications in last year

A number of unsuccessful applications to CRUK have been unsuccessful despite ranking highly by the CSG, reflecting the ever increasing competitive nature of funding and changes in CRUK priorities. The Group sought an alternative route for portfolio adoption and RAMPART has been successfully adopted onto the portfolio. The CSG offers input into any funding submission/protocol in development to ensure that submissions are as robust as possible. It is therefore disappointing that highly ranked studies with potential significant impact upon patient care have been unsuccessful.

Both the bladder and renal cancer research community benefit from significant commercial study activity and adoption of commercial studies onto the portfolio. However, these studies can compete with CSG developed academic studies and entry onto the portfolio is more demanding for academic studies rather than adopted commercial studies.

It is also disappointing that funding was withdrawn prematurely from the POUT–T study collecting translational samples from patients in the main POUT Trial in Upper Tract TCC (see section 12).

Table 2 Funding submissions in the reporting year

Cancer Research UK Clinical Research Committee (CRUK CRC)			
Study	**Application type**	**CI**	**Outcome**
May 2016			
RAMPART: Renal Adjuvant MultiPle Arm Randomised Trial: A multi-arm, multi-stage trial of adjuvant therapy in patients with resected primary renal cell carcinoma (RCC) at high or intermediate risk of relapse	Full application	Professor Max Parmar & Dr Angela Meade	Not funded
November 2016			
NAXIVA: Phase II neoadjuvant study of axitinib for reducing extent of venous tumour thrombus in clear cell renal renal cell cancer with venous invasion	Full (Endorsement)	Dr Grant Stewart	Supported
HYBRID pIII: A multicentre randomised phase III study of HYpofractionated Bladder Radiotherapy with or without Image guided aDaptive planning	Full application	Dr Emma Hall	Not Supported
Sample collection co-ordination and pre-storage processing of serial samples collected for PHOTO-T (a trial associated bladder cancer sample biorepository)	Sample Collection	Dr Rakesh Heer	Not Supported
AmpseqUr: Amplicon deep sequencing of Urinary DNA for the detection of bladder cancer	Full (Biomarker Project Award)	Dr Richard Bryan	Supported
Other committees			
Study	**Committee & application type**	**CI**	**Outcome**
Quality of life after Bladder cancer (Q/ABC) - quantitative study	RfPB	Ashok Nikapota & Sally Appleyard	Not supported
Quality of life after Bladder cancer (Q/ABC) - qualitative study	Sussex Cancer fund and PELICAN	Ashok Nikapota & Sally Appleyard	Supported

Life and Bladder cancer: the Yorkshire Cancer research patient reported outcomes study	Yorkshire Cancer	James Catto	Supported
BRAVO: high risk bladder cancer, a randomised controlled feasibility study of cystectomy versus intravesical immunotherapy	Yorkshire Cancer	James Catto	Supported
IROC A Phase III multicentre randomised controlled trial to compare the efficacy of robotically assisted radical cystectomy (RACR) and intracorporeal urinary diversion with open radical cystectomy (ORC) in patients with bladder cancer	The Urology Foundation	James Catto	Supported
Developing the evidence for risk stratified screening for renal cell carcinoma, using focused renal ultrasound: a systematic review of risk prediction models and feasibility study investigating the potential for technician-performed ultrasound	The Urology Foundation	Sabrina Rossi and Grant Stewart	Supported
RAMPART: Renal Adjuvant MultiPle Arm Randomised Trial: A multi-arm, multi-stage trial of adjuvant therapy in patients with resected primary renal cell carcinoma (RCC) at high or intermediate risk of relapse	Kidney Cancer UK	Professor Max Parmar & Dr Angela Meade	Supported

8. Collaborative partnership studies with industry

The CSG has continued to take advantage of the AZ initiative with partnerships on new technologies such as hyperthermia and chemo/immunotherapy studies in the neoadjuvant, adjuvant, and first and second line metastatic settings. The adjuvant study of atezolizumab post-cystectomy has recruited behind target in the UK and discussions with the sponsor have been held to optimise recruitment.

There are currently 15 industry studies in the portfolio, including both Industry-sponsored Investigator-led alliance and fully commercial trials. The ATLANTIS trial, which has newly opened, combines a number of Industry Partners in a MAMS style study.

RCC has always attracted significant commercial interest and this continues. We have commercially adopted studies in the adjuvant, first, second and third line metastatic settings. CSG members are international leaders and have strong relationships with pharma, resulting in the UK still being valued as an attractive place for commercial activity in RCC. The collaboration with AZ that underpins RAMPART demonstrates how successful partnerships can be.

9. Impact of CSG activities

In 2017, the updated BC2001 data demonstrated a survival advantage for patients treated with chemoradiation, rather than the previously published local control alone rate. BC2001, together with the BCON trial, both of which look at different methods of radiosensitisiation, had already changed international practice but it is likely this will encourage sceptics to update their practice. The PLUTO trial provided second line chemotherapy data in advanced bladder cancer for the first time in a randomized study. Completion of phase III immunotherapy studies in the portfolio and the unprecedented interest of Pharma in bladder cancer has led to the proposed UK licensing for a number of Immune Oncology (IO) agents which may cause a field shift in the management of

metastatic disease. Given the current uncertainty regarding the use of adjuvant TKIs for RCC, SORCE will have a profound influence on the standard of care internationally.

The CSG has provided expert opinion on four IO agents in bladder cancer and four in renal cancer in the current year, at scoping and consultation exercises and the NICE Appraisal Committee. The CSG response jointly represents BUG and ACP specialist opinion on these committees, highlighting collaborative working.

The Group provides twice yearly feedback to CRUK, and on funding applications to Wellcome, HTA and RfPB on the full spectrum of translational, observational, diagnostic and interventional submissions.

10. Consumer involvement

The CSG benefits from extensive consumer engagement. Fight Bladder Cancer (Andrew Winterbottom as Chair and Alison Birtle as mentor) ensures robust PPI input into all bladder portfolio trials at every stage. Rose Woodward and Christy Watson, in collaboration with the Kidney Cancer Support Network, have led two highly successful clinical trial workshops as part of the patient champion project.

Rose Woodward
In addition to contributing to discussions about renal cancer during meetings, via emails and teleconference calls, I was pleased to provide a patient perspective as a member of the Surgical Subgroup. I have also been able to offer patient insights into patient information sheets and recommend a renal cancer patient with relevant experience to join the NAXIVA study group.

A major focus this year has been the ongoing Patient Champion Project: a collaboration between the former Renal CSG and KCSN charity. We have put on two hugely successful clinical trial training workshops co-hosted by my CSG mentor Dr Fiona Thistlethwaite in Manchester and Dr James Larkin in London. The patient champion volunteer teams are in place and the aim of the Patient Champion Project is to ultimately provide a more equitable spread of renal cancer trials across the UK and to disseminate information throughout the patient community to increase recruitment and retention into renal trials.

Andrew Winterbottom
I have been a member of the former Bladder CSG since late 2014 and continue to be impressed by the way the clinicians and researchers involve the consumer representatives and value our input. In addition, I am also a member of the ABC and TABS Subgroups where I feel equally valued.

As a result of my involvement with the CSG, I am able to talk knowledgeably with the large bladder cancer community the Fight Bladder Cancer charity supports across the UK. This enables patients to become pro-active in seeking participation in trials and thus aids recruitment. FBC is also now recruiting, training and mentoring a panel of patients and carers to be involved in trials from an early scoping stage, through development and then onto being members of trial management boards.

A key focus has been the Bladder Cancer Patient Reported Outcomes (PROMs) Survey using

patients recruited by FBC to review the details of the questionnaires that will be used in this study.

11. Open meetings/annual trials days/strategy days

As a strategy day was held shortly before the time of last reporting, no further formal strategy meeting has been held. However, a joint meeting with the Urology CSGS and the SSLs was held on 21 March 2017 at which a SWOT analysis of bladder and renal cancer was undertaken.

Local barriers to recruitment were highlighted and good practice shared. The need to balance observational "easy win" pragmatic trials with more challenging interventional studies to maximise recruitment was highlighted as a priority.

12. Priorities and challenges for the forthcoming year

Trial development and recruitment
To publicise and deliver recruitment into portfolio studies, continue to highlight the recently opened ATLANTIS biomarker-directed maintenance therapy study and encourage new investigators to come forward with future arms for this MAMS trial. The InPACT study in penile cancer has now opened after the formal period for this CSG report and recruitment to this International Rare Cancer Initiatives study will be key. Falling recruitment has been the main issue for RCC. We have now successfully secured support for a number of studies but it is essential that the CSG a) ensures delivery of patients into these studies and b) continues to develop additional studies on the portfolio. The work of the Systemic Treatments WP continues to be a key element of this activity and maximising the potential from the RCCG collaboration and encouraging new investigators to develop their ideas through the CSG are a priority. The challenge is to develop studies in an environment where funding is increasingly limited and commercial activity is significant.

Tissue collection represents both a challenge and a priority
The use of biorepository material was highlighted in our external review and subsequent annual review. Work for the LAMB data set continues to inform the biomarker directed arms of ATLANTIS and implementation of this translational work is vital. The premature withdrawal of funding for the accompanying biospecimen collection for POUT (POUT-T, CRUK: C16909/A16781) in UTUC has meant that the translational potential of this unique trial has been significantly hampered. There is now limited ability to use the AmpseqUr approach currently being developed in bladder cancer, itself ironically funded by a CRUK biomarker project award. Furthermore, POUT-T would have provided an excellent platform through which to develop liquid biopsy/ctDNA based personalised genomic biomarkers, as has recently been demonstrated in lung cancer, and for which the POUT-T CI already has a working partnership with the appropriate industry partner. In addition, it is noted that two translational funding applications for tissue collection in recruiting interventional portfolio trials were not supported. The funded NAXIVA study will provide a valuable tissue resource for translational work in RCC.

Interaction with SSL is a challenge and a priority
The utilisation of the SSL at each stage, from concept of trial to establish any potential barriers to recruitment, through to trial opening, is vital. The Group must work with SSLs to engage with those CRNs where recruitment into surgically-led trials is poor and to continue to utilise research active urologists, e.g. Jo Creswell to publicise the importance of engagement with the portfolio.

There is also a need to re-work the current clinical pathway of patients with NMIBC to allow us to develop studies of novel agents in this disease setting. This will require patients to be seen in oncology rather than surgical clinics and it is likely that there will be significant barriers, especially relating to oncology workload and capacity. However, we are at a time of unprecedented demand on clinical time and many SSLs and CSG members report constraints being placed upon their ability to attend both CSG activities and SSL events by host NHS organisations.

13. Appendices

Appendix 1 - Membership of main CSG and subgroups

Appendix 2 – CSG and Subgroup strategies

- A – Main CSG Strategy
- B – Penile Subgroup Strategy
- C – T2 & Below Subgroup Strategy
- D – Advanced Bladder Cancer Subgroup Strategy
- E – Surgical Renal Cancer Subgroup Strategy
- F – Systemic Treatments Renal Cancer Working Party Strategy
- G - Combination Radiotherapy/Drug Working Party Strategy

Appendix 3 - Portfolio Maps

Appendix 4 - Publications in previous year

Appendix 5 - Major international presentations in previous year

Dr Alison Birtle and Dr Paul Nathan (Bladder & Renal Cancer CSG Co-Chairs)

Appendix 1

Membership of the Bladder & Renal Cancer CSG

Name	Specialism	Location
Dr Amit Bahl	Clinical Oncologist	Bristol
Dr Alison Birtle (Co Chair)	Clinical Oncologist	Preston
Dr Ananya Choudhury	Clinical Oncologist	Manchester
Professor Robert Huddart	Clinical Oncologist	London
Dr Vincent Khoo	Clinical Oncologist	London
Dr Sally Appleyard*	Clinical Research Fellow	Brighton
Dr Henry Däbritz*	Clinical Research Scientist	Glasgow
Dr Yvonne Rimmer	Clinical Oncologist	West Suffolk
Mr Andrew Winterbottom	Consumer	High Wycombe
Mrs Rose Woodward	Consumer	Truro
Professor Janet Brown	Medical Oncologist	Sheffield
Dr Simon Crabb	Medical Oncologist	Southampton
Professor Robert Jones	Medical Oncologist	Glasgow
Dr Paul Nathan (Co Chair)	Medical Oncologist	Middlesex
Professor Thomas Powles	Medical Oncologist	London
Dr Fiona Thistlethwaite	Medical Oncologist	Manchester
Dr Naveen Vasudev	Medical Oncologist	Leeds
Dr Jane Belfield	Radiologist	Liverpool
Professor Vicky Goh	Radiologist	London
Professor Emma Hall	Statistician	London
Mr Christopher Blick	Surgeon	Oxford
Mr Mark Johnson	Surgeon	Newcastle
Mr Param Mariappan	Surgeon	Edinburgh
Mr Grant Stewart	Surgeon	Cambridge

* denotes trainee member

Membership of the Subgroups

Advanced Bladder Cancer Subgroup		
Name	**Specialism**	**Location**
Dr Maria de Santis	Associate Clinical Professor	Warwick
Dr Alison Birtle	Clinical Oncologist	Preston
Dr Ananya Choudhury	Clinical Oncologist	Manchester
Professor Robert Huddart	Clinical Oncologist	London
Dr Sundar Santhanam	Clinical Oncologist	Nottingham
Mr Andrew Winterbottom	Consumer	High Wycombe
Professor John Chester	Medical Oncologist	Cardiff
Dr Simon Crabb (Chair)	Medical Oncologist	Southampton
Dr Syed Hussain	Medical Oncologist	Liverpool
Professor Robert Jones	Medical Oncologist	Glasgow
Professor Tom Powles	Medical Oncologist	London
Professor Maggie Knowles**	Pathologist	Leeds
Mr Gareth Griffiths	Statistician	Southampton

Penile (Bladder) Subgroup		
Name	**Specialism**	**Location**
Dr Amit Bahl (Chair)	Clinical Oncologist	Bristol
Dr Jim Barber	Clinical Oncologist	Cardiff
Dr Tony Elliot	Clinical Oncologist	Manchester
Dr Vincent Khoo	Clinical Oncologist	London
Mr Neil Walker	Consumer	Bristol
Dr Mark Callaway	Radiologist	Bristol
Professor Emma Hall	Statistician	London
Mr Asif Muneer	Surgeon	London
Mr Vijay Sangar	Surgeon	Manchester
Mr Duncan Summerton	Urological Surgeon	Leicester

T2 & Below (Bladder) Subgroup		
Name	**Specialism**	**Location**
Dr Alison Birtle	Clinical Oncologist	Preston
Professor Robert Huddart (Chair)	Clinical Oncologist	London
Dr Ashok Nikapota	Clinical Oncologist	Brighton
Dr Sally Appleyard*	Clinical Research Fellow	Brighton
Mr Andrew Winterbottom	Consumer	High Wycombe
Professor Robert Jones	Medical Oncologist	Glasgow
Dr Rik Bryan	Senior Research Fellow	Birmingham
Professor Emma Hall	Statistician	London
Mr Mark Johnson (Deputy Chair)	Surgeon	Newcastle
Mr Param Mariappan	Surgeon	Edinburgh
Professor James Catto	Urological Surgeon	Sheffield

Surgical (Renal) Subgroup		
Name	**Specialism**	**Location**
Mrs Rose Woodward	Consumer	Truro
Mr Ravi Barod	Surgeon	London
Mr Christopher Blick	Surgeon	Oxford
Mr Steve Bromage	Surgeon	Manchester
Mr Jon Cartleidge	Surgeon	Leeds
Mr Anurag Golash	Surgeon	Stafford
Mr Alex Laird*	Surgeon	Edinburgh
Mr Satish Maddineni	Surgeon	Manchester
Mr Tom Mitchell*	Surgeon	Cambridge
Mr David Nicol	Surgeon	London
Mr Pieter Le Roux	Surgeon	London
Mr Grant Stewart (Chair)	Surgeon	Cambridge
Mr Mark Sullivan	Surgeon	Oxford
Mr Grenville Oades	Surgeon	Glasgow
Miss Maxine Tran	Surgeon	London
Mr Nikil Vasdev	Surgeon	Stevenage
Mr Simon Williams	Surgeon	Derby

Systemic Treatments Working Party		
Name	**Specialism**	**Location**
Dr Henry Däbritz*	Clinical Research Scientist	Glasgow
Professor Janet Brown	Medical Oncologist	Sheffield
Dr Syed Hussain	Medical Oncologist	Liverpool
Dr James Larkin	Medical Oncologist	London
Dr Paul Nathan	Medical Oncologist	Middlesex
Professor Tom Powles (Chair)	Medical Oncologist	London
Dr Fiona Thistlethwaite	Medical Oncologist	Manchester
Dr Naveen Vasudev	Medical Oncologist	Leeds

Combination Radiotherapy/Drug Working Party		
Name	**Specialism**	**Location**
Dr Amit Bahl	Clinical Oncologist	Bristol
Dr Alison Birtle	Clinical Oncologist	Preston
Dr Ananya Choudhury	Clinical Oncologist	Manchester
Professor Robert Huddart	Clinical Oncologist	London
Dr Vincent Khoo (Chair)	Clinical Oncologist	London
Dr Yvonne Rimmer	Clinical Oncologist	West Suffolk
Dr Paul Nathan	Medical Oncologist	Middlesex

*denotes trainee member **denotes non-core member

Appendix 2

CSG & Subgroup Strategies

A – Main CSG Strategy

The main CSG strategy remains to offer as broad a research portfolio as possible, ideally to develop a high quality competitive trial suitable for every patient. This requires a combination of pragmatic trials allowing smaller units to actively participate in bladder and renal trials, balanced with more complex interventional studies.

To do this, an optimal skill mix is required on the CSG and to succession plan. Whilst the CSG membership and that of the Subgroups has been refreshed, it is important to highlight that the pool of research active clinicians in these tumour types is significantly smaller than, e.g. breast cancer, and thus it is important to retain as well as refresh membership, particularly where members continue to make a significant contribution to the Group and portfolio activities.

Immunotherapies have an increasing role in the management of both bladder and renal cancer and have become a standard of care in both diseases. The CSG membership contains international leaders in this area and the Subgroups aim to use their experience to maximal effect. We therefore aim to develop immunotherapy studies in both diseases that explore novel combinations and clinical settings.

The role of patients as research champions is paramount and both consumers, together with KCSN and FBC, continue to work with the CSG to train patient representatives as research experts to liaise with other patients and to exert pressure on research inactive clinicians. All current portfolio interventional trials collect quality of life data and there are a number of studies with a primary qualitative endpoint to allow us to better inform patients on the optimum choice of radical treatment. The CSG has particularly strong consumer input and there is an opportunity to build upon their already excellent work and to consider opportunities in PROM research.

The use of and challenges in expanding the translational work of the CSG has been highlighted already, with withdrawal of funding from POUT-T prematurely and unsuccessful applications for tissue collection for two other portfolio interventional trials. Given the already successful work from LAMB in informing the biomarker directed Rucaparib and Enzalutamide arms of ATLANTIS, the CSG will need to consider other funding sources to continue this component of its portfolio. NAXIVA and A-PREDICT both have rich translational components and information from these studies will inform the development of future studies.

Several years ago, the Bladder CSG conducted a national audit of surgical barriers on recruitment into bladder trials and has attempted to act on the feedback. One key message to develop pragmatic trials deliverable in smaller units has been rectified, yet some CRNs and urologists continue to fail to engage. Working with the SSLs, together with a direct approach from the CSG Co Chairs and BAUS Oncology, the Group will continue to try to overcome this issue. The work of the Surgical Subgroup directly addresses the barriers to engagement of the renal surgical community and it is of strategic importance to us that this issue is addressed.

There is an unmet need for patients with node positive bladder cancer; previous attempts to design a study for this patient group have been unsuccessful but there is now momentum to achieve this. In addition, the interface between systemic therapies and radiotherapy has been identified as a key research area.

B – Penile Subgroup Strategy

The Penile Subgroup strategy is to:

- Hold regular six monthly meetings with the opportunity of joining in person or by teleconference.
- Provide opportunities for advice and support of applications for grants.
- Increase engagement in clinical trials through promotion of clinical trials and regular engagement with supraregional teams.
- Regularly review Subgroup membership and widening of the membership base to increase contribution to future trials development.
- Ensure consumer involvement in all projects.
- Ensure trainee involvement in the Subgroup to promote development of future researchers.

C – T2 & Below Subgroup Strategy

The Subgroup aims to develop and support studies aiming to enhance the care of patients with non-metastatic bladder cancer. We will seek to improve the patient experience through enhancing cancer control and maximising quality of life. Key targets areas of the Subgroup include:

- To enhance the outcomes of patients with high risk NMIBC through
    - Improved diagnostics utilising developments and knowledge in genomics and gene profiling.
    - Optimised adjuvant therapies both intravesical and systemic.
    - Exploration of the optimal approach to the use of radical surgery.
- To develop improved bladder sparing approaches in muscle invasive bladder disease.
- To work with the Systemic Treatments Renal Cancer Working Party Strategy to improve neo-adjuvant, concomitant and adjuvant therapies for patients with MIBC.
- To seek to understand better, and then improve, factors that impact on patient quality of life and experience of bladder cancer treatment.

We will seek to achieve these goals by utilising improved knowledge of tumour biology from translational research projects and through advances in drug development leading to enhanced treatment personalisation.

D – Advanced Bladder Cancer Subgroup Strategy

The Subgroup strategy works towards our central objective to ‘increase cure rates by improving systemic therapy as a component of multimodality therapy’ in the following ways:

- Optimising systemic therapy by developing new drug hypotheses to test in MIBC
    - Efficient delivery of proof of concept studies in advanced disease exemplified by the development of the ATLANTIS precision medicine platform in the maintenance therapy setting.
    - Working towards options for practice changing trials of neoadjuvant therapy through initiation of studies in this clinical setting. Current examples of recruiting trials include NeoBLADE, ABACUS and SPIRE.
    - Working in collaboration with industry to deliver high quality trials of novel agents in areas of unmet need. In addition to the multiple examples on which we have recently published (e.g., LaMB, PLUTO), current examples of trials in recruitment

include ATLANTIS, SPIRE, ABACUS, NeoBLADE. We have further emerging trials in development involving collaborations with AstraZeneca and Roche

- Delivery of potentially practice changing studies
    - Implementing POUT, the first ever randomised phase III trial of adjuvant therapy in upper tract TCC.
- Development of a larger translational research programme
    - Utilisation of the LaMB sample set to allow generation of data on biomarker rates to facilitate hypotheses for testing in ATLANTIS.
    - Entry of bladder cancer into the 100,000 Genomes Project.
    - Coordination of a collaborative approach to utilisation of samples sets from the Subgroup's prior and ongoing studies.

E – Surgical Renal Cancer Subgroup Strategy

The Surgical Subgroup strategy is:

- Regular teleconference meetings every 6-8 weeks to facilitate rapid development of trial ideas to design and delivery.
- Involvement of each member of the Subgroup with a specific study within our portfolio.
- Use the Subgroup as a proving ground for members of the main CSG and also new trial CIs.
- Engagement with BAUS and BAUS Oncology (current Chair is Miss Jo Creswell, former Bladder CSG member) on promotion of new trials at their annual meetings and in Presidential newsletters.
- Regular review of Subgroup membership to ensure all members are contributing.
- Ensure strong background information (literature review, BAUS database analysis, canvassing urologist opinion) before new trial plans developed more formally.
- Delivery and completion of feasibility studies in contentious areas to prove recruitment can be achieved, i.e. NAXIVA in IVC tumour thrombus.
- Close liaison with oncologists for neoadjuvant and adjuvant trials, with greater engagement of urologists in the TDG/TMG of these studies and also providing information to the urological community during development phase.

F – Systemic Treatments Renal Cancer Working Party Strategy

The Working Party strategy is as detailed below:

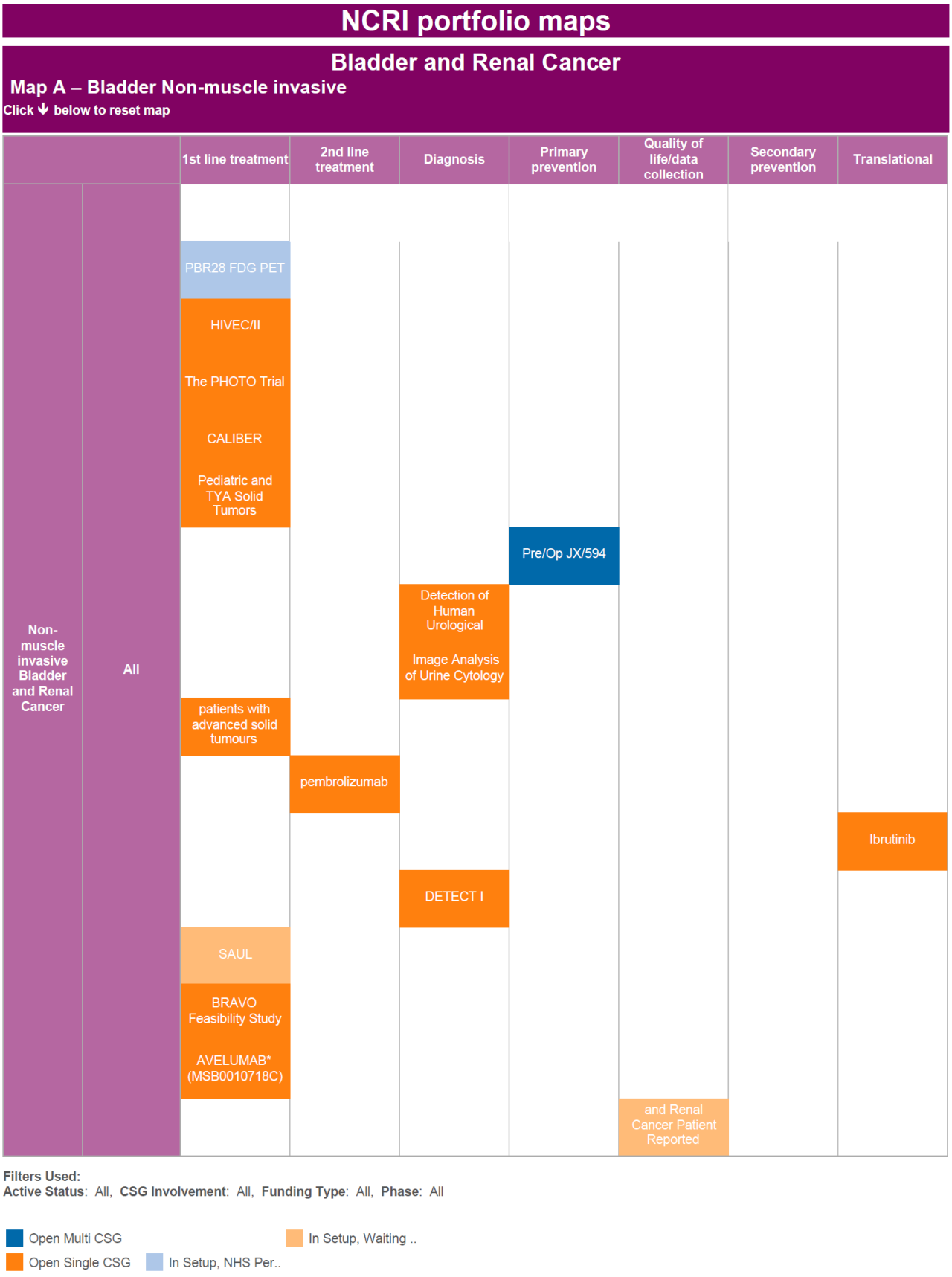
- Monthly meetings by teleconference.
- Explicit expectation that members are expected to start developing a study within a year of membership.
- Permissive attitude to WP membership and an environment that nurtures young investigators.
- Study development in novel agents/combinations, translational endpoints and novel schedules.

G - Combination Radiotherapy/Drug Working Party Strategy

The strategy of the Radiotherapy/Systemic Therapy Working Party is currently in development and will not be formally confirmed until the next Bladder & Renal CSG meeting in December.

Appendix 3

Portfolio maps

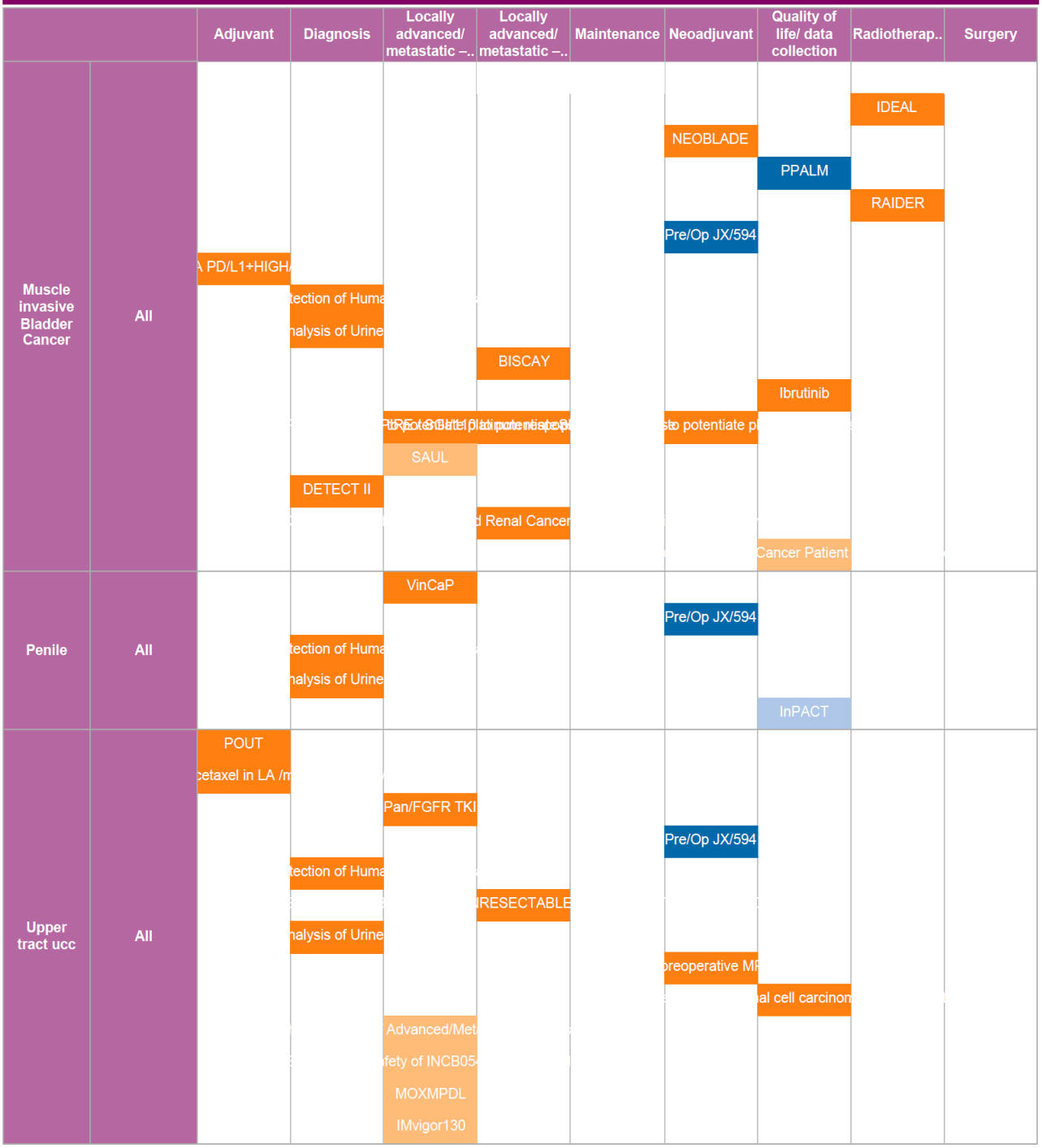


NCRI portfolio maps

Bladder and Renal Cancer

Map B – Bladder Muscle invasive, urothelial cell carcinoma, penile

Click ↓ below to reset map



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, HRA Ap..
In Setup, Waiting ..
In Setup, NHS Per..

NCRI portfolio maps

Bladder and Renal Cancer

Map C – Renal clear cell, non-clear cell, adrenal

Click ↓ below to reset map

		1st line metastatic	2nd line metastatic	3rd line metastatic	Adjuvant	Neoadjuvant	Non-interventio..	Surgery
Adrenal	All							
Clear cell	All	STAR Standard v CREATE MEDI4736 (MSB0010718C)			MLN0128	CALYPSO IM/201 IMmotion010 DETECT II	Genetics of Pap SCOTRRCC	Pre/Op JX/594
Non-clear cell	Null							Tivozanib to
	All	MEDI4736 (MSB0010718C) KEYNOTE-426 Keynote/427 E7080-G000-307 (CLEAR)	levels of E7080			The REMAP study	SCOTRRCC PORUS-aRCC TRACERx Renal	
Other	All						and Renal	

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 ..

Appendix 4

Publications in the reporting year

Study	Reference
BC2001 trial	A Choudhury, CM West, E Hall, N Porta, H Denley, C Hendron, R Lewis, SA Hussain, R Huddart, N James on behalf of the BC2001 investigators. The predictive and prognostic value of tumour necrosis in muscle invasive bladder cancer patients receiving radiotherapy with or without chemotherapy in the BC2001 trial (CRUK/01/004) Br J Cancer. 2017 Feb 28;116(5):649-657. doi: 10.1038/bjc.2017.2. Epub 2017 Jan 26.
	Choudhury A, West C, Porta N, HALL E, Denley H, Hendron C, Lewis R, Hussain S, Huddart R, James N, on behalf of the BC2001 Investigators (2017). The predictive and prognostic value of tumour necrosis in muscle invasive bladder cancer patients receiving radiotherapy with or without chemotherapy in the BC2001 trial (CRUK/01/004). Peer-reviewed Article: BJC 116:649-57
	HALL E, Hussain S, Porta N, Crundwell M, Jenkins A, Rawlings C, Tremlett J, Friend C, Stubbs C, Lewis R, James N, Huddart R, on behalf of the BC2001 Investigators (2017). BC2001 long term outcomes: A phase III randomised trial of chemo-radiotherapy versus radiotherapy (RT) alone and standard RT versus reduced high-dose volume RT in muscle invasive bladder cancer. Oral Presentation & Meeting Abstract : J Clin Oncol 35(Suppl 6S):#280
	Huddart R, HALL E, Miranda M, Crundwell M, Jenkins P, Rawlings C, Tremlett J, Hendron C, Lewis R, Porta N, Hussain S, James N, on behalf of the BC2001 Investigators (2017). Quality of life (QL) of patients (pts) treated for muscle invasive bladder cancer (MIBC) with radiotherapy (RT) +/- chemotherapy (CT) in the BC2001 trial (CRUK/01/004): Analysis of impact of treatment at an individual level. Meeting Abstract: J Clin Oncol 35(Suppl 6S):#292
	Hussain S, HALL E, Porta N, Crundwell M, Jenkins P, Rawlings C, Tremlett J, Hendron C, Lewis R, Huddart R, James N, on behalf of the BC2001 Investigators (2017). Outcome of BC2001 patients (CRUK/01/004) who received neoadjuvant chemotherapy prior to randomisation to chemo-radiotherapy (cRT) vs radiotherapy (RT). Meeting Abstract: J Clin Oncol 35(Suppl 6S):#298
	Porta N, Calle ML, Huddart R, Hussain S, Lewis R, Newton M, Hendron C, James N, HALL E (2016). Dynamic predictions of metastasis free survival in bladder cancer. Meeting Abstract: Proceeds of ISCB Conference, Birmingham #P.084

GemX/GEMTrans study	C Thompson, N Joseph, B Sanderson, J Logue, J Wylie, T Elliott, J Lyons, C Anandadas, A Choudhury. Tolerability of Concurrent Chemoradiotherapy with Gemcitabine (GemX), with and without prior Neoadjuvant Chemotherapy in Muscle Invasive Bladder Cancer. DOI: http://dx.doi.org/10.1016/j.ijrobp.2016.11.040. In Press Accepted Manuscript. November 26, 2016
	O Caffo, C Thompson, M De Santis, B Kragelj, DA Hamstra, D Azria, G Fellin, GL Pappagallo, E Galligioni, A Choudhury. Concurrent gemcitabine and radiotherapy for the treatment of muscle-invasive bladder cancer: A pooled individual data analysis of eight phase I–II trials. Radiotherapy and Oncology, Volume 121, Issue 2, November 2016, Pages 193–198
BCON study	JJ Irlam-Jones, A Eustace, H Denley, A Choudhury, AL Harris, PJ Hoskin, CM West. Expression of miR-210 in relation to other measures of hypoxia and prediction of benefit from hypoxia modification in patients with bladder cancer. Br J Cancer. 2016 Jul 21. doi: 10.1038/bjc.2016.218
SCOTRRCC	C. Van Neste, A. Laird, F. O'Mahony, W. Van Criekinge, D. Deforce, F. Van Nieuwerburgh, T. Powles, D.J. Harrison, G.D. Stewart (joint senior author), T. De Meyer. Epigenetic sampling effects: nephrectomy modifies the clear cell renal cell cancer methylome. Cellular Oncology (IF=3.6). In press.
	U. Capitanio, G.D. Stewart, T. Klatte, B. Akdogan, M. Roscigno, M. Marszalek, P. Dell'Oglio, E. Zaffuto, O.R. Faba, M. Salagierski, J. Lingard, M. Carini, I. Ouzaid, M.C. Mir, F. Montorsi, L. Filippo Da Pozzo, C. Stief, A. Minervini, S.D. Brookman-May. Does an unexpected presence of non-organ disease at final pathology undermine cancer control in clinically T1N0M0 renal cell carcinoma patients who underwent partial nephrectomy? European Urology Focus (IF=N/A). In press.
	G. Gremel, D. Djureinovic, M. Niinivirta, A. Laird, O. Ljungqvist, H. Johannesson, J. Bergman, P-H. Edqvist, S. Navani, N. Khan, T. Patil, Å. Sivertsson, M. Uhlén, D.J. Harrison, G.J. Ullenhag, G.D. Stewart, F. Pontén. A systematic search strategy identifies cubilin as independent prognostic marker for renal cell carcinoma. BMC Cancer (IF=3.4). In press.
	G.D. Stewart, T. Powles, C. Van Neste, A. Meynert, F. O'Mahony, A. Laird, D. Deforce, F. Van Nieuwerburgh, G. Trooskens, W. Van Criekinge, T. De Meyer, D.J. Harrison. Dynamic epigenetic changes to VHL occur with sunitinib in metastatic clear cell renal cancer. Oncotarget (IF=6.3). 2016. 7(18):25241-50
SURTIME & CARMENA	G.D. Stewart, M. Aitchison, A. Bex, J. Larkin, C. Lawless, A. Méjean, P. Nathan, G. Oades, J.-J. Patard, J. Paul, A. Ravaud,

	B. Escudier, on behalf of the Renal Cross Channel Group. Cytoreductive nephrectomy in the tyrosine kinase inhibitor era: a question that may never be answered. European Urology (IF=14.9). In press
PLUTO	Jones RJ, Hussain SA, Protheroe AS, Birtle A, Chakraborti P, Huddart RA, Jagdev S, Bahl A, Stockdale A, Sundar S, Crabb SJ, Dixon-Hughes J, Alexander L, Morris A, Kelly C, Stobo J, Paul J, Powles T. A Randomised Phase II study investigating pazopanib vs. weekly paclitaxel in relapsed or progressive Transitional Cell Carcinoma (TCC) of the urothelium. J Clin Oncol 2017; in press
CALIBER Trial	Lewis R, Maynard L, Catto J, Cresswell J, Feber A, Griffiths L, Kelly JD, Knight A, Knowles M, McGrath J, Penegar S, HALL E, Mostafid A, on behalf of CALIBER Trial Management Group (2016). Recruitment aids for a phase II randomised trial in low risk bladder cancer. Meeting Abstract: NCRI Cancer Conference 2016:#149
PANTHER	Powles T, Sarwar N, Stockdale A, Sarker SJ, Boleti E, Protheroe A, Jones R, Chowdhury S, Peters J, Oades G, O'Brien T, Sullivan M, Aitchison M, Beltran L, Worth D, Smith K, Michel C, Trevisan G, Harvey-Jones E, Wimalasingham A, Sahdev A, Ackerman C, Crabb S. Safety and Efficacy of Pazopanib Therapy Prior to Planned Nephrectomy in Metastatic Clear Cell Renal Cancer. JAMA Oncol. 2016; 2(10):1303-1309
LaMB	Powles T, Huddart RA, Elliott T, Sarker SJ, Ackerman C, Jones R, Hussain S, Crabb S, Jagdev S, Chester J, Hilman S, Beresford M, Macdonald G, Santhanam S, Frew JA, Stockdale A, Hughes S, Berney D, Chowdhury S. Phase III, Double-Blind, Randomized Trial That Compared Maintenance Lapatinib Versus Placebo After First-Line Chemotherapy in Patients With Human Epidermal Growth Factor Receptor 1/2–Positive Metastatic Bladder Cancer. J Clin Oncol 2017; 35(1):48-55
COSAK	Powles T, Brown J, Larkin J, Jones R, Ralph C, Hawkins R, Chowdhury S, Boleti E, Bhal A, Fife K, Webb A, Crabb S, Geldart T, Hill R, Dunlop J, Hall PE, McLaren D, Ackerman C, Beltran L, Nathan P. A randomised, double-blind phase II study evaluating cediranib vs cediranib and saracatinib in patients with relapsed metastatic clear cell renal cancer (COSAK). Ann Oncol. 2016; 27(5):880-6
POUT Trial	Birtle A, Maynard L, Johnson M, Kockelbergh R, Jones R, Chester J, Catto J, Blacker A, HALL E, on behalf of the POUT Trial Management Group (2016). Acute toxicity data from POUT: a phase III randomised trial of peri-operative chemotherapy versus surveillance in upper tract urothelial cancer. Meeting Abstract: J Clin Oncol 34(Suppl 15):#e16138
	Birtle A, Maynard L, Johnson M, Kockelbergh R, Jones R,

	Chester J, Catto J, Blacker A, HALL E on behalf of the POUT trial management group (2016). Acute toxicity data from POUT: a phase III randomised trial of peri-operative chemotherapy versus surveillance in upper tract urothelial cancer. Meeting Abstract: Proceeds of BAUS 2016, Liverpool 49:#P6-10
	Birtle A, Lewis R, Maynard L, Johnson M, Kockelbergh R, Newton M, Jones R, Chester J, Catto J, Blacker A, HALL E, on behalf of POUT Trial Management Group (2016). Acute toxicity data from POUT: a phase III randomised trial of peri-operative chemotherapy versus surveillance in upper tract urothelial cancer (UTUC). Meeting Abstract: British Association of Urological Nurses Liverpool 2016
HYBRID Trial	Huddart R, Henry A, Khoo V, Staffurth J, Syndikus I, Hansen V, McNair H, Hafeez S, Lewis R, Parsons E, Baker A, Vassallo-Bonner C, Moinuddin S, Mossop H, A B, Horan G, Rimmer Y, Venkitaraman R, Mitra A, HALL E, on behalf of the HYBRID PIs (2017). Results of a randomised phase II study of hypofractionated bladder radiotherapy (RT) with or without image guided adaptive planning (HYBRID - CRUK/12/055). Meeting Abstract: J Clin Oncol 35(Suppl 6S):#283
	Lewis R, J I, Henry A, Moinuddin S, Mossop H, HALL E, Huddart R, on behalf of the HYBRID Trial Management Group (2016). Current UK practice in palliative treatment of muscle invasive bladder cancer (MIBC) and impact on design of the phase III HYBRID adaptive image guided radiotherapy (IGRT) trial. Meeting Abstract: NCRI Cancer Conference 2016, Liverpool:#203
AZURE	Westbrook JA, Cairns DA, Peng J, Speirs V, Hanby AM, Holen I, Wood SL, Ottewell PD, Marshall H, Banks RE et al. CAPG and gipc1: Breast cancer biomarkers for bone metastasis development and treatment. Journal of the National Cancer Institute 108(4) 01 Jan 2016
CSG work by Trainee on National compliance with NICE guidance in Bladder cancer, in collaboration with British Urology Group	The National Institute for Health and Care Excellence (NICE) guidance on bladder cancer; a step in the right direction? Sebastian Trainor,Ananya Choudhury; Robert Huddart; Anne E Kiltie; Roger Kockelbergh; William Turner; Alison Birtle; Simon J Crabb. Clinical Oncology (R Coll Radiol) 2017 Jun 29(6):344-347 Epub 2017 Feb 9 doi: 10.1016/j.clon.2017.01.040

Appendix 5

Major international presentations in the reporting year

Study	Conference details
POUT	Birtle A, Maynard L, Johnson M, Kockelbergh R, Jones R, Chester J, Catto J, Blacker A, HALL E on behalf of the POUT trial management group (2016). Acute toxicity data from POUT: a phase III randomised trial of peri-operative chemotherapy versus surveillance in upper tract urothelial cancer. Moderated poster presentation – BAUS, June 2016, Liverpool
BC2001	HALL E, Hussain S, Porta N, Crundwell M, Jenkins A, Rawlings C, Tremlett J, Friend C, Stubbs C, Lewis R, James N, Huddart R, on behalf of the BC2001 Investigators (2017). BC2001 long term outcomes: A phase III randomised trial of chemo-radiotherapy versus radiotherapy (RT) alone and standard RT versus reduced high-dose volume RT in muscle invasive bladder cancer - Oral Presentation: ASCO GU, February 2017
	Huddart R, HALL E, Miranda M, Crundwell M, Jenkins P, Rawlings C, Tremlett J, Hendron C, Lewis R, Porta N, Hussain S, James N, on behalf of the BC2001 Investigators (2017). Quality of life (QL) of patients (pts) treated for muscle invasive bladder cancer (MIBC) with radiotherapy (RT) +/- chemotherapy (CT) in the BC2001 trial (CRUK/01/004): Analysis of impact of treatment at an individual level - February 2017, ASCO GU
	Hussain S, HALL E, Porta N, Crundwell M, Jenkins P, Rawlings C, Tremlett J, Hendron C, Lewis R, Huddart R, James N, on behalf of the BC2001 Investigators (2017). Outcome of BC2001 patients (CRUK/01/004) who received neoadjuvant chemotherapy prior to randomisation to chemo-radiotherapy (cRT) vs radiotherapy (RT) - ASCO GU Meeting, February 2017
	Porta N, Calle ML, Huddart R, Hussain S, Lewis R, Newton M, Hendron C, James N, HALL E (2016). Dynamic predictions of metastasis free survival in bladder cancer - ISCB Conference, August 2016, Birmingham
CALIBER	Lewis R, Maynard L, Catto J, Cresswell J, Feber A, Griffiths L, Kelly JD, Knight A, Knowles M, McGrath J, Penegar S, HALL E, Mostafid A, on behalf of CALIBER Trial Management Group (2016). Recruitment aids for a phase II randomised trial in low risk bladder cancer - Nov 2016, NCRI Cancer Conference
	Huddart R, Henry A, Khoo V, Staffurth J, Syndikus I, Hansen V, McNair H, Hafeez S, Lewis R, Parsons E, Baker A, Vassallo-Bonner C, Moinuddin S, Mossop H, A B, Horan G, Rimmer Y, Venkitaraman R, Mitra A, HALL E, on behalf of the HYBRID PIs (2017). Results of a randomised phase II study of

HYBRID	hypofractionated bladder radiotherapy (RT) with or without image guided adaptive planning (HYBRID - CRUK/12/055) - February 2017, ASCO GU
	Lewis R, J I, Henry A, Moinuddin S, Mossop H, HALL E, Huddart R, on behalf of the HYBRID Trial Management Group (2016). Current UK practice in palliative treatment of muscle invasive bladder cancer (MIBC) and impact on design of the phase III HYBRID adaptive image guided radiotherapy (IGRT) trial - NCRI Cancer Conference Nov 2016, Liverpool