NCRI Gynaecological 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

NCRI Gynaecological Group

Annual Report 2020-21

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

Achievement 1

Impact on patient care

The Group has made significant contributions to patient care, in terms of survivorship, treatment personalisation and also the availability of novel therapeutic options to women with gynaecological cancers.
The PRIMA trial demonstrated the benefit of PARP inhibitors beyond BRCA1/2 mutation carriers and led to the approvals of maintenance Niraparib therapy in women with newly diagnosed advanced ovarian cancer. The Group also supported the approval process for the combination of olaparib and bevacizumab for women with homologous recombinant deficient newly diagnosed ovarian cancer – further expanding choice and personalisation for this group of women with advanced disease. The Ovpsych2 trial, highlights the importance of psychological interventions in ovarian cancer and will aid the development of a more holistic approach to patient care and survivorship.
Endometrial cancer: the PETALS study, published in September 2020, was the first UK study of unselected Lynch syndrome testing in endometrial cancer and demonstrated that 3% of endometrial tumours are caused by Lynch syndrome, and that widespread testing was acceptable to women and cost effective for the NHS. This study informed new NICE guidance (DG42, October 2020) that all endometrial cancer patients be screened for Lynch syndrome and has changed clinical practice. Group members were also integral to the recent international consensus guideline publication on management of gynaecological cancers in Lynch Syndrome further supporting the NICE guidance, and also potentially opens up new treatment options with immunotherapy (e.g Dostarlimab –GARNET trial, NCRI –International collaboration) for this group of women.

Achievement 2

Breadth of portfolio

In addition to developing and leading a wide range of interventional trials in gynaecological cancer, the Group has continued to expand its expertise in the early diagnostic and prevention arena. Building from the UK Led largest international screening trial in ovarian cancer, UKCTOCs, the Group is also leading projects such as the PROTECTOR trial, targeting high risk women who are BRCA1/2 mutation carriers and offering early surgical intervention to reduce mortality and there are plans to offer genomic screening to women beyond this group in the PROTECT trial.
The Endometrial Workstream has also been at the forefront of trials of early detection. The DETECT study reported its preliminary findings in Nature Communications (February 2021), showing that endometrial cancer can be detected in urine and vaginal fluid by cytology. This study has now informed a larger portfolio study of 2,000 women. The Group's involvement in the GRAIL trial could also potentially lead to earlier diagnosis of gynaecological cancers.
The Group have also led in the development of trials for rare gynaecological cancers with specific trials such as Peacocc, ATARI, and RANGO that have recruited well despite the challenges from COVID19. We also have an active cervical trials portfolio of NCRI

developed trials such as INTERLACE, COMICE and NOVEL. All trials developed by the group continue to have strong translational research embedded within them.
Achievement 3 International Collaboration The NCRI Gynaecological Group continues to maintain strong links with its international groups: European Network of Gynaecological Oncology Trials Groups and GCIG (Gynecologic Cancer InterGroup) and is leading major studies through both– ICON8B, ICON9, ATARI and ATHENA in ovarian cancer, INTERLACE in cervix cancer. The Group will continue to have a strong influence in the development of future international trials in gynaecological cancer as the current chair will join the ENGOT Strategy Group this year and previous Chair of the NCRI Gynaecological Group has been appointed as the Co-Chair of the GCIG Ovarian Cancer Group. Gynaecological Group members were integral to a recent international consensus guideline publication on management of gynaecological cancers in Lynch Syndrome patients and members will also represent the NCRI at the International Ovarian Cancer Consensus Statement meeting in October 2021, which was postponed from Oct 2020 due to COVID-19.

2. Structure of the Group

The Group structure has remained largely unchanged following a restructure in March 2018: with a small executive group consisting of the Chair, the Workstream Chairs (Ovary, Endometrial, Cervix/Vulva), a Consumer member as well as the National Institute for Health Research (NIHR) Clinical Research Network (CRN) Research Delivery Manager (RDM). A new Chair, Dr Shibani Nicum was appointed in February 2020 and took over from Professor Iain McNeish in June 2020 and Dr Rebecca Bowen, new Ovarian Workstream Chair, was also appointed June 2020. The Endometrial (Professor Emma Crosbie) and Cervical/Vulval (Dr Emma Hudson) Workstream Chairs are unchanged. This structure has worked well for the Group, driving focused clinical trials design and decision making, and will be retained following the planned central NCRI restructuring in 2021.

Trainee members: we currently have two trainee members, Dr Michael-John Devlin, Dr Vanitha Sivalingam, appointed in late 2018 for a two-year term. They have had important training opportunities as they were appointed to the Trial Management Group of one of our portfolio trials and developed specific research proposals with their mentors. Overall, the Gynaecological Group remains an enthusiastic supporter of the trainee member programme and we will be advertising for new members this year, and feedback from the current members will be sought to ensure that we continue to meet training needs.

Consumer members: The Group was particularly pleased to welcome our new consumer members, appointed in February 2021, who will join Dr Hilary Morrison, who has supported the group tirelessly since her appointment. Ms Helen White, will join the Executive Group and will also represent the Endometrial Workstream together with Hilary, and will also act as liaison with the NCRI Consumer Forum. The Group also welcomes, Ms Joanne Nunn, Ms Lesley Sage to the Ovarian Workstream and Ms Laura Reynolds to the Cervix and Vulval Workstream. All our Consumer members have named mentors in addition to working closely with the Chairs to ensure that they will be appropriately supported

NIHR: RDM – the Group would like to welcome our newly appointed Gynae Research Delivery Manager, Helen Graham and thank the outgoing manager, Penny Williams for her work with the team.

3. Gynaecological Executive Group & Workstream strategies

Gynaecological Executive Group

The overall strategic aim of the Group remains to lead innovative clinical trials in all gynaecological cancers that allow widespread patient enrolment and involvement of investigators across the whole of the UK and that have potential to change clinical practice in the UK and worldwide.
There are four named strategic targets:

Aim 1: The Group should aim to have a first line trial in all three common gynaecological cancers: endometrium, ovary, cervix

Aim 1 Progress:
Endometrial cancer – RAINBO is an international molecularly-stratified trial in newly diagnosed disease, that is under development with the European trials group, ENGOT. The NCRI will lead one arm on this targeted therapy trial and gives us the opportunity to imbed UK translational science into this important trial. Funding is currently being sought in the UK and has the potential to be impacted by COVID-19.

Ovarian Cancer – the Group has led and been involved in a number of the important practice changing first line trials: ATHENA (developed/led) and PRIMA (participated) that have led to changes in practice with the access of PARP inhibitors for women with newly diagnosed ovarian cancer. New standards of care are being investigated in the ATHENA trial with a combination of a PARP inhibitor, immunotherapy and an anti angiogenic agent. Both completed UK recruitment prior to COVID-19. A key priority for the Group is to develop the next front line trial, particularly for the group of women who have been identified within these trials as having limited benefit for a PARP inhibitors/ combination maintenance therapy.
All our trials have been developed and run with strong consumer input within the appropriate Workstreams.

Cervical Cancer **-** the NCRI developed and led INTERLACE trial, evaluating the role of neoadjuvant chemotherapy locally advanced cervical cancer has recruited 446 of the 500 patients required to answer this important question. This trial has been a success of international collaboration through ENGOT and GCIG and has run successfully in countries including India, Brazil and Mexico.

Aim 2: Group-led studies that identify high-risk patients prior to diagnosis of cancer and/or studies addressing prevention of gynaecological cancer in an unselected population

Aim 2 Progress:
The Group has made significant progress in this arena - the Group has an expanding portfolio of studies in prevention/risk stratification (e.g. OBITEC, PROTECTOR, FORECEE), imaging (MROC) and early and rapid diagnosis (DETECT, CLOCS, ROCKeTS) as well as supportive care (ENDOMd). The NOVEL trial falls mainly into the risk/prevention category and studies the effect of nonavalent HPV vaccination following conservative management of CIN-2/3, a pre invasive phase in the development of cervical cancer, and recruitment continues but has been impacted by COVID-19. The absence of effective screening for ovarian cancer means that there is great need for primary prevention approaches. The Group are supporting strategies such as the Population based germline testing for early detection and cancer prevention (PROTECT) trial, which will involve germline testing of a panel of breast, ovarian, endometrial and bowel cancer susceptibility genes in an unselected population. This follows from earlier work in a high-risk Ashkenazi population showing that this approach was acceptable in unselected general populations.

Aim 3: To develop a trial/protocol early detection of ovarian cancer-cross collaborations e.g with the NCRI Primary Care Group

Aim 3 Progress:

The National Grail early detection programme (NIHR funded and NCRI Gynae Group supported) will be run in Oxford July – September 2021. This trial will initially include 6000 patients, approximately 1700 patients who present to their GP with gynaecological symptoms and will assess the accuracy of the Grail Galleri MCED screening blood test to detect cancer. Subset analysis of the gynaecological group of patients will be aided by input from the NCRI Gynaecological team and will be a cross-cutting collaboration with other NCRI Groups, including the Primary Care Group. COVID-19 trials have highlighted the importance of routinely collected data and this trial will additionally aim to evaluate the accuracy of local vs nationally collected data, which could be beneficial for protocols going forward.

Aim 4: RECIST has multiple flaws as a reporting tool, particularly in ovarian cancer. Action to incorporate novel endpoints into future phase III trials, including novel imaging endpoints.

Aim 4 Progress: ongoing - Novel endpoints continue to be evaluated and are added to new Group trials as appropriate.

Impacts of COVID-19
Since March 2020, due to the COVID-19 pandemic all meetings have been held virtually, and this has interestingly widened access and engagement across the UK, with a significant increase in the number of participants at the meeting now averaging over 40 people. The NCRI Executive Group have taken opportunities at national congress such as the UK GOM and BGCS to promote the work of the NCRI and to increase regional engagement in clinical trials.

Group Changes Addressing Annual Report Feedback 2019/20
Since February 2020, the Group had already looked to widen access to novel agents by reaching out to biotech and larger pharma, who have presented novel agent pipelines to the group. The Group has had a strong translational base and this has been widened by combining the NCRI meetings with scientific talks to the Group from members of the wider UK scientific community. Despite the virtual format, this has worked very well for the Group with positive feedback from attendees.

The Executive Group support the use of virtual open meetings combined with smaller in person strategic/ brainstorming meetings as a useful model going forward, and that this will ensure wide geographic and multidisciplinary representation. In line with the proposed NCRI Group strategy changes the development of new proposals, including from young investigators will be further facilitated outside of the meetings by the Chair and Workstream Chairs and with the formation of a New Trial Proposal Group, and a key aim will be to ensure that appropriate translational elements are be built into clinical trial protocols. This Group may have a fluid membership beyond a core team to ensure that we have the most appropriate input to new trial proposals and this will promote collaborations that harness the scientific expertise in the UK Gynaecology Community and closer working with the ECMC and industry.

Cervix/Vulva Workstream (Chair, Dr Emma Hudson)

COVID-19 had a dramatic impact on trials in cervical cancer with all trials halting to recruitment either at a national or local level during the pandemic. The investigators have worked tirelessly since the trials have reopened to lessen the impact on trial recruitment.

The use of virtual meetings has facilitated increased attendance and a very successful meeting of the Cervical/Vulval Workstream took place virtually in December 2020 in conjunction with the Endometrial Workstream with more than 40 attendees. In addition to updates on open trials we supported trials in difficulty and heard new trial concepts. Since the BGCS meeting where the

Workstream meetings were advertised we have had contact from new investigators to attend and present their ideas at the forthcoming meeting next month.

The Workstream remains committed to develop trials in all settings. In prevention, two trials have been developed in cervical cancer screening- urine HPV testing and the validation of HPV test systems using self-collected test samples. These are two important trials because if successful, these strategies have the potential to increase screening uptake, particularly in groups where previously this has been low. EDuCATE aims to increase early detection of vulval cancer in high-risk patients using self-examination. The NOVEL trial falls into the risk/prevention category and studies the effect of nonavalent HPV vaccination following conservative management of CIN-2/3. This is recruiting more slowly in the UK than with its Scandinavian counterparts. PREVENT is a trial developed within the Gynae Group but crosses into the Colorectal Group. It is a randomised trial of the Gardasil Vaccine in patients treated for anogenital intraepithelial neoplasia which has been submitted to the NIHR. Work is ongoing to secure funding to progress the RT3 trial in the treatment of VIN with two biomarkers having been validated as predictors to response.

In the definitive treatment of locally advanced cervical cancer the role of neoadjuvant chemotherapy is being evaluated in the INTERLACE trial. This trial has recruited 446 of the 500 patients required to answer this important question. This trial has been a success of international collaboration opening in several other countries including India, Brazil and Mexico.

The CX11 trial looking at the addition of pembrolizumab to standard of care in locally advanced cervical cancer opened late in the UK due to COVID-19 and is yet to recruit its first patient.

In relapsed disease, the COMICE trial investigates olaparib and cediranib in recurrent or metastatic cervical cancer. It is open in 19 sites in the UK and has recruited 46/108 patients despite recruitment halting last year.

The development of another radiotherapy trial in addition to the EMBRACE trial remains a key strategy for the Workstream. Although this work is in progress one of our workstream members is a member of NCRI Clinical and Translational Radiotherapy Group (CTRad) and attends their meetings regularly to increases collaboration between the Groups.

Endometrial Workstream (Chair, Professor Emma Crosbie)

A virtual joint Endometrial and Cervix and Vulval Workstream meeting was held in November 2020 and was attended by over 40 people. COVID-19 closed our trials for several months and recovery to full recruitment capacity was slow, however, we are making good progress again now.
The PETALS study was published in September 2020, which was the first UK study of unselected Lynch syndrome testing in endometrial cancer. The study showed that 3% of endometrial tumours are caused by Lynch syndrome, how to test for them, that women want to be tested and that it is cost-effective for the NHS to test everyone, irrespective of clinical predictors. This study informed new NICE guidance (DG42, October 2020) that all endometrial cancer patients be screened for Lynch syndrome and has changed clinical practice.

The TransPORTEC consortium showed for the first time that molecular workstream predicts benefit from adjuvant chemotherapy in high risk endometrial cancer patients. This work was published in the Journal of Clinical Oncology (September 2020) and will enable the rationalisation of adjuvant treatment decisions to maximise benefit and minimise the harms of overtreatment. This work inspired the RAINBO programme, an international umbrella study of four linked trials of adjuvant treatment in endometrial cancer, led by the Netherlands, UK, France and Canada. The UK (NCRI) will lead the Orange trial, an RCT of hormone therapy in no specific molecular profile (NSMP) endometrial tumours, sponsored through the UCL CTU. This trial is currently under consideration for funding via CRUK.

The DETECT study reported its preliminary findings in Nature Communications (February 2021), showing that endometrial cancer can be detected in urine and vaginal fluid by cytology. This study has now informed a larger portfolio study of 2,000 women with postmenopausal bleeding, to establish the diagnostic accuracy of this new detection tool in endometrial cancer.

Recruitment to our systemic therapy trials in endometrial cancer was severely impacted by COVID-19, but trials have re-opened now. COPELIA, AtTEnd and RUBY are all open and recruiting, albeit at lower rates than pre-COVID, and ENGOT-11 should open soon.

Ovarian Workstream (Chair, Dr Rebecca Bowen)

Recruitment to ovarian cancer studies has been heavily impacted by the COVID-19 pandemic due to temporary closure of the majority of trials, prioritisation of COVID studies by the NIHR, and associated paucity of resource such as staffing (medical and trials) and radiology (imaging and research biopsies). Several members of the Workstream contributed the BGCS COVID-19 working group, developing the BGCS Framework of Care for patients with Gynaecological Cancers during the COVID-19 pandemic. However, all studies have now reopened and are actively recruiting, and many have not drifted too far from their planned completion date. We have also recruited well to CovidSurg_Cancer_Gynae and to the UKCOvid and Gynaecological Cancer Study (UKCOG).

We successfully hosted the first virtual NCRI Ovarian Workstream meeting on 11th September 2020 with 57 attendees and this increased to 87 attendees for the virtual joint NCRI/SGCTG on 5th February 2021. We welcome all interested researchers to this inclusive meeting to promote and develop ovarian cancer research and were delighted to see an increase in attendance. We were able to address issues relating to trials in difficulty and in February 9 new study proposals were discussed with the group.

We have academic studies in all settings, except the first line, following the completion of ICON8B, FIRST and ATHENA in 2020. MONITOR-UK, a Phase IV observational study of maintenance niraparib is, however, recruiting well in the 1st line and relapse settings. ICON9 (>6 months relapse) continues to recruit and DICE (<6 months relapse) is nearing its recruitment target. We now have new trials e.g. MIRASOL, EPIK-O and PROMPT in the platinum resistant setting. A key priority is the development of the next first line ovarian cancer study.

We continue have a strong rare tumour portfolio with RANGO, PEACOCC, ATARI open and recruiting while NiCCC has completed and was presented at ESGO 2020. In screening, prevention and early diagnosis, CLoCs (Cancer Loyalty Card Study), FORCEE, ROCKETS and PROTECTOR are open and actively recruiting. The Feasibility of Frailty Assessment and Interventions in women over 70 years (FAIR-O) trial opened in January 2021, following development through the Elderly Workstream. The translational prospective tumour biopsy collection study BriTROC-2 set-up was impacted by the pandemic but now aims to open in 2021. The imaging study MROC has now completed recruitment.

The Workstream continue to collaborate with international groups and contribute to ENGOT and EORTC trials. NCRI have representation through our members at ENGOT, GCIG and EORTC allowing for cross-collaboration and enhanced trial development and recruitment.

4. Cross-cutting research

The NCRI Gynaecological Group has continued its close working with the BGCS (through the Chair and Workstream Chairs) and the Gynaecological Charities, and this has been particularly important during the COVID-19 pandemic, where members have supported a number of initiatives to develop patient guidelines and support clinical trial activity across the country. There have been 2 new multidisciplinary trials initiated with particular focus on the COVID-19 pandemic

and the impacts on clinical care and patient outcomes: CovidSurg_Cancer_Gynae and to the UKCOvid and Gynaecological Cancer Study (UKCOG)

The Group currently does not have any working parties/finish groups.

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*					
December 2020					
ICON8B: A phase III randomised trial investigating the combination of dose-fractionated CT + bev compared to either strategy alone for the first-line treatment of women with ovarian cancer	Clinical Trial Award - Extension New	Dr Andrew Clamp	Supported	Developed and supported	
Treatment Rare Tumours of Gynaecological Origin (TRaNGO)	Clinical Trial Award - Outline New	Professor Marcia Hall	Full application not invited - Resubmission welcome	Developed and supported	
March 2021					
CRAIN: A phase 1b clinical trial with dose escalation and dose expansion phases of ASTX660 in combination with standard radical radiotherapy in cervical cancer with chemoradiation.	Clinical Trial Award	Professor Peter Hoskin	Conditionally Supported	Supported	
ASTEROID – A Phase I proof of concept study of ASTX660 in combination with PEmbROlizumab: utilizing triple IAP blockade as a strategy to maximize Immunogenic cell Death and the generation of a efficient adaptive immune response.	Clinical Trial Award	Dr Juanita Lopez	Conditionally Supported	Supported	
Other committees**					
Study	**Committee & application type**	**CI**	**Outcome**	**Level of Group input**	**Funding amount**
FAIR-O Study	Wellbeing of Women	Dr.Susana Banerjee	Supported	Developed and supported	-

ATARI	Astrazeneca educational research grant and Lady Garden Charity	Dr.Susana Banerjee	Supported	Developed/Supported	-
MONITOR-UK Study	GSK educational research grant	Dr.Susanna Banerjee	Supported	Developed/Supported	-

**CRUK CRC applications for table 1 completed by NCRI Executive.*
***Other applications in the table to be completed by Group Chair*

6. Consumer involvement

Hilary Morrison

Since March 2020 both Gynaecology Executive Group meetings, all Workstream meetings and NCRI Consumer meetings have been held virtually due to the COVID-19 pandemic, but this has not impacted negatively on the quality or inclusiveness of the meetings. It has been impressive how much the Group has managed to achieve in terms of new trials and research this year despite COVID-19, but also very concerning for all members of the Group regarding delayed recruitment of patients into new trials and on-going cancer care. It is heartening to see trials now reopening and recruitment rising in new and on-going trials.

Outside of her role within the NCRI, Hilary has continued to work as an 'expert' patient /ovarian cancer advocate in various roles.

She is a member of the TMGs for the CEBOC and VALTIVE 1 trials and has helped with a press release for the launch of the VALTIVE 1 trial. She was involved in the finalising policy document meetings with clinicians and NHS England for the adoption of bevacizumab in September 2020 and completed the patient impact form prior to the review. She has continued to attend quarterly meeting of the GP Advisory Board for Ovarian Cancer run by the charity Target Ovarian Cancer, where there has been much work looking into how to try to improve early diagnosis of ovarian cancer within primary care with the challenge of the recent COVID-19 induced rapid rise in electronic rather than face to face GP appointments.

She also attended a virtual All Party Parliamentary Group for Ovarian Cancer meeting in February looking at the findings of the Ovarian Cancer Feasibility Pilot Steering Group audit. This audit revealed a significant postcode lottery in access to ovarian cancer treatment, particularly availability of surgery across England. Possible next steps to help improve the geographical inequality were discussed.

She still runs a small local support group for women with ovarian cancer, and this group has now successfully been sponsored and supported by the charity Ovacome with the hope of reaching out to more women in the North Staffordshire area.
The NCRI and the Gynaecological Executive Group have addressed the lack of other consumer members within the Gynae Executive and Workstreams this year with a very successful recruitment drive in December and 4 excellent candidates were appointed to posts in 2021. Hilary would like to extend a warm welcome to the new consumer members in the Gynaecological Group:

The following have recently been appointed to the NCRI Consumer Forum and have joined Hilary Morrison as members of the Gynaecological Group:

- Jo Nunn and Lesley Sage – Ovarian Workstream
- Laura Reynolds – Cervix/Vulva Workstream
- Helen White – Endometrial Workstream
- Helen has also joined Hilary in the Gynaecological Executive Group

Due to their recent appointment to the Groups/Workstreams, they have not been asked to submit a report this year. However, below is a list of the new members additional involvement activities/standing appointments (outside of NCRI):

Jo Nunn

- Member of the ILAP Patient Reference Group.
- Participant in a patient focus group for Cambridge University BRCA EMBRACE Study.
- Research Advocate for Target Ovarian Cancer Research.

Lesley Sage

- Trustee of Ovacome
- Patient Participant and member of the management team for a PhD on Chemotherapy-induced Peripheral Neuropathy (CIPN), Guys/St. Thomas's.
- Patient representative for CRUK-UCL Cancer Trials Centre on gynaecological and lung cancer trials
- Member of Trial Management Group for PEACOCC trial and the Trials Steering Committee.
- Patient Representative for the NHS Highlands Lymphoedema Steering Committee.

Helen White

- Member of Genomic England's Participant Panel
- Patient representative for the Endometrial Cancer Genomics England Clinical Interpretation Partnership (GeCIP) domain
- Member of the CRUK Cambridge Centre Ovarian Cancer Patient Group
- Member of the CanGene-CanVar Patient Reference Panel
- Lay co-author:
  a) Njoku K, O'Flynn H, Jones E, Ramchander NC, White H, Macey R, Crosbie EJ. Screening tests for endometrial cancer in the general population (Protocol). Cochrane Database of Systematic Reviews 2021, Issue 1. Art. No.: CD013859. DOI: 10.1002/14651858.CD013859.
  b) Morotti, M., Albukhari, A., Alsaadi, A. et al. Promises and challenges of adoptive T-cell therapies for solid tumours. Br J Cancer 124, 1759–1776 (2021). https://doi-org.manchester.idm.oclc.org/10.1038/s41416-021-01353-6

Laura Reynolds

- Assisted the Eve appeal to produce a leaflet on vulval cancer symptoms leaflet for GPs.

7. Collaborative partnership studies with industry

The Gynaecological Group has good partnership with industry, particularly in ovarian cancer, and this has rapidly expanded within endometrial and cervical cancer. COMICE and COPELIA (AstraZeneca) are open and recruiting well nationally. In collaboration with ENGOT we have been involved in several industry-led studies in the UK, including LEAP, RUBY, Attend and KEYNOTE-775. There have been a number of proposed trials in vulval and vaginal cancer but currently there is limited interest from the pharmaceutical industry in this setting and we may require broader umbrella-type studies.

As detailed previously the ATHENA trial is funded by Clovis Oncology, and is led by the NCRI Gynaecological Group in Europe (the NRG group leads in the US), with Dr Rebecca Kristeleit as co-Chief Investigator. Other ovarian cancer studies with industry funding and/or collaboration include OCTOVA, ATARI, ICON9 (all AstraZeneca), OCTOPUS, PEACOCC (Merck), PROMPT (Merck, Sharpe and Dohme) CENTURION (Clovis Oncology) and NiCCC (Boehringer Ingelheim), the first randomised trial in relapsed ovarian clear cell carcinoma.

8. Priorities and challenges for the forthcoming year

Priority 1 Once again, the first priority is to maintain recruitment to time and target in all our trials. This is particularly important for the flagship studies. Our strategy for maintaining recruitment includes ensuring that trials are available in as many centres as possible, regular meetings with investigators to identify barriers to recruitment and encouraging Chief Investigators to interact with recruiting sites.
Priority 2 Molecularly targeted trial – Endometrial Cancer RAINBO is an international molecularly-stratified trial in newly diagnosed disease, that is under development with the European trials group, ENGOT. The NCRI will lead one arm on this targeted therapy trial and gives us the opportunity to imbed UK translational science into this important trial.
Priority 3 Ovarian cancer: A key priority for the Group is to develop the next front-line trial, particularly for the group of women who have been identified within these trials as having limited benefit from a PARP inhibitor. Innovative trial designs e.g. umbrella designs, with translational endpoints are being considered as this will help to rapidly evaluate the efficacy and on target effects of novel agents in this setting.
Priority 4 Cervical Cancer: a key priority for the Group is to ensure timely recruitment within the NOVEL trial which falls into the risk/prevention category and studies the effect of nonavalent HPV vaccination following conservative management of CIN-2/3.
Challenge 1 Following challenges during the COVID-19 period where trial recruitment was on hold for the majority of sites, most of our trials we are now recruiting to extended timelines and meeting targets. This has required intensive efforts from the Chief Investigators and Trials Unit, as well as the Group but trials such as ATARI and ICON9 are recruiting well in the UK and internationally and INTERLACE has almost completed international recruitment.
Challenge 2 Ensuring that funding for the RAINBO trial can be secured in a timely manner to ensure that all arms of the trial run in harmony. This is important to ensure the relevance of the trial outcomes and also in the ability of the UK to take part and lead trials particularly in the post BREXIT era.
Challenge 3 Suitable agents in this setting are not clearly defined and with Brexit and COVID-19 impacting our ability to fund and run trials in an efficient manner – developing this trial is likely to be a challenge in the short term. This is a medium-term goal for the Group and is a key area where we are focusing our energy by strengthening our links with small biotech and larger pharma and the ECMC. The national innovative licensing and access pathway ILAP may help to strengthen our access to novel agents and their rapid evaluation.

Challenge 4 This is recruiting more slowly in the UK than with its Scandinavian counterparts and COVID-19 has had a significant impact on timely trial set up at many sites. We will be supporting the trial team to ensure delivery of this trial.

Dr Shibani Nicum (Gynaecological Group Chair)

Appendix 1

Membership of the Gynaecological Executive Group

Name	Specialism	Location
Dr Emma Hudson	Clinical Oncologist	Cardiff
Dr Hilary Morrison	Consumer	Staffordshire
Ms Helen White	Consumer	Leicestershire
Dr Shibani Nicum (Chair)	Medical Oncologist	Oxford
Dr Rebecca Bowen	Medical Oncologist	Bath
Ms Penny Williams	Research Delivery Manager	Cumbria
Professor Emma Crosbie	Surgeon	Manchester

Consumer Representation

Name	Location
Dr Hilary Morrison	Staffordshire
Ms Helen White	Leicestershire

Membership of the Workstreams

Cervix/Vulva Workstream		
Name	**Specialism**	**Location**
Dr Vanitha Sivalingam*	Clinical Lecturer in Gynaecological Oncology	Manchester
Dr Jackie Martin	Clinical Oncologist	Sheffield
Ms Emma Hudson (Chair)	Clinical Oncologist	Cardiff
Dr Alexandra Taylor	Clinical Oncologist	London
Dr Jessica Mason**	Clinical Oncologist	Somerset
Dr Susan Lalondrelle	Clinical Oncologist	London
Dr Emma de Winton**	Clinical Oncologist	Bath
Dr Jackie Martin	Clinical Oncologist	Sheffield
Dr Tara Barwick	Consultant Radiologist	London
Ms Laura Reynolds	Consumer	Manchester
Dr Jenny Forrest	Gynaecological Oncologist	Devon
Professor John Tidy	Gynaecological Oncologist	Sheffield
Dr Susana Banerjee**	Medical Oncologist	London
Dr Rosemary Lord**	Medical Oncologist	Merseyside
Dr Emma Cattell**	Medical Oncologist	Somerset
Dr Asma Faruqi	Pathologist	London
Dr Lynn Hirschowitz	Pathologist	Birmingham
Dr Pinias Mukonoweshuro	Pathologist	Bath

Endometrial Workstream		
Name	**Specialism**	**Location**
Dr Melanie Powell	Clinical Oncologist	London
Dr Gemma Eminowicz	Clinical Oncologist	London

Dr Azmat Sadozye	Clinical Oncologist	Glasgow
Ms Helen White	Consumer	Leicestershire
Professor Emma Crosbie (Chair)	Gynaecological Oncologist	Manchester
Dr Jo Morrison	Gynaecological Oncologist	Taunton
Dr Maria Kyrgiou	Gynaecological Oncologist	London
Dr Esther Moss	Gynaecological Oncologist	Leicester
Dr Andrew Clamp	Medical Oncologist	Manchester
Dr Rosemary Lord	Medical Oncologist	Merseyside
Dr Christine Parkinson**	Medical Oncologist	Cambridge
Dr Axel Walther	Medical Oncologist	Bristol
Dr Naveena Singh	Pathologist	London
Dr Pinias Mukonoweshuro	Pathologist	Bath

Ovarian Workstream		
Name	**Specialism**	**Location**
Dr Michael-John Devlin*	Clinical Research Fellow	London
Mrs Lesley Sage	Consumer	Ross-Shire
Mrs Joanne Nunn	Consumer	Northallerton
Professor Christina Fotopoulou	Gynaecological Oncologist	London
Dr Sadaf Ghaem-Maghami (Mentor - LS)	Gynaecological Oncologist	London
Mrs Sudha Sundar	Gynaecological Oncologist	Birmingham
Dr Mona El-Bahrawy	Histopathologist	London
Dr Susana Banerjee	Medical Oncologist	London
Dr Rosalind Glasspool**	Medical Oncologist	Glasgow
Professor Jonathan Ledermann**	Medical Oncologist	London
Dr Rosemary Lord	Medical Oncologist	Merseyside
Professor Iain McNeish**	Medical Oncologist	London
Dr Shibani Nicum (Gynae Group Chair)	Medical Oncologist	Oxford
Dr Rebecca Bowen (Ovarian Chair)	Medical Oncologist	Bath
Dr Sarah Williams (Mentor – JN)	Medical Oncologist	Birmingham
Dr Nafisa Wilkinson	Pathologist	London
Ms Rachel O'Donnell	Surgeon	Newcastle

* denotes trainee member
**denotes non-core member

Appendix 2

Gynaecological Group & Workstream Strategies

Strategic objective	Action	CSG Lead	Date	Outcomes
1. Current CSG membership 1a – to widen diversity of specialties	Active encouragement of applications from clinical oncology, nursing, virology and epidemiology. Not possible to restrict geographical applications but active encouragement of applications from all of UK	IMcN	Dec 2019	Two more clinical oncology members; one more nurse member
1b – Re-organisation	Given the diverse nature of gynae cancers, aim to discuss with NCRI Central possibility of reducing overall CSG membership (e.g. to 10) to make the main CSG a strategic/oversight body, with much greater delegated to the subgroups as the decision-making forum for the CSG. This would allow an increase in the number of core sub-group members (e.g. 14 per subgroup) and increase the input from consumers.	IMcN	By time of next formal CSG review	Reduction in CSG membership; increased membership of subgroups

Strategic objective	Action	CSG Lead	Date	Outcomes
2. Subgroups 2a - Subgroup numbers	Subgroup meetings to remain the critical forum for trial and protocol development. To continue with three subgroups (ovary, endometrial, cervix/vulva)	EC, EH, RG, IMcN	On-going	CSG to continue to have three subgroups
2b - Subgroup meetings	Joint endometrial and cervix/vulva meetings to take place twice per year	EC, EH,	Mar 2019	Two face-to-face meetings of endometrial and cervix/vulva subgroups to have taken place by April 2019
2c - Subgroup chairs	Time as subgroup chair not to count in 3+3 year membership of CSG – vital to gain necessary experience prior to becoming subgroup chair.	IMcN	Dec 2018	Subgroup chairs to be allowed to continue beyond 3+3 year membership of CSG

Strategic objective	Action	CSG Lead	Date	Outcomes
2d - Subgroup membership	To widen membership, especially if numbers of subgroup members can increase. Increased participation/membership from basic scientists and charity representatives, especially in cervix/vulva subgroup	EC, EH, RG, IMcN	Mar 2019	At least one charity representative to be invited to cervix/vulva subgroup; invitation for basic scientists with interest in translational research to attend subgroup meetings

Strategic objective	Action	CSG Lead	Date	Outcomes
3.Subspecialty leads interactions 3a - Full list of SSL	NIHR central to provide accurate and up to date list of Gynae SSL	PW	Jul 2018	Accurate and up to date SSL list
3b - Improved dialogue between SSL and CSG	Subgroup chairs to liaise with SSL rather than individual sites for site selection	EC, EH, RG	On-going	Site identification to be devolved to SSL

Strategic objective	Action	CSG Lead	Date	Outcomes
4. Consumers and charity partners 4a - Consumer role	Consumer members to be embedded within subgroups rather than main CSG	EC, EH, RG, IMcN	Dec 2018	Consumer members to attend subgroup meetings rather than main CSG meetings
4b - Charity partners	Patient organisation/charities to be regularly invited to attend endometrial and cervix/vulva subgroup meetings – already attending ovarian subgroup meetings	EC, EH	Mar 2019	Eve Appeal, Jo's Trust,

Strategic objective	Action	CSG Lead	Date	Outcomes
5. Overall trials strategy 5a - First line intervention trials	The CSG should aim to have a first line trial in all three common gynaecological cancers – endometrium, ovary, cervix – and aim to have future trials in planning at time of opening of current trial	All	On-going	A major phase III first-line intervention trial open at all times for all three common gynaecological cancers
5b - Risk/prevention studies	To expand CSG-led studies that address identification of high risk patients prior to diagnosis of cancer and/or studies addressing prevention of gynaecological cancer	All	Jun 2019	One national risk/prevention study led by the CSG funded/ approved
5c - Early diagnosis/ rapid diagnosis	Develop a trial/protocol with primary care CSG to improve speed of diagnosis in ovarian cancer	All	Jun 2020	

Strategic objective	Action	CSG Lead	Date	Outcomes
5d - Imaging studies	RECIST has multiple flaws as a reporting tool, particularly in ovarian cancer. Action to incorporate novel imaging endpoints into future phase III trials	All	Jun 2021	Incorporation of novel imaging analysis as co-primary or secondary endpoint in phase II or phase III trial.

Strategic objective	Action	CSG Lead	Date	Outcomes
6.1.Disease-specific research: Vulva Cancer 6.1a - First line trial in locally advanced vulval cancer	Develop a first line trial in locally advanced/recurrent vulval cancer – combination of radiotherapy and immune checkpoint inhibition deemed most likely to be funded. Consider IRCI badging given the rarity of vulval cancer	EH, SL	Jun 2020	Funding or industry support for trial
6.1b - Joint HPV-positive study	Aim to develop joint protocols for HPV-positive cancers within gynae tumours and to include anal cancer subgroup +/- head and neck CSG	EH, IMcN	Jun 2020	Joint protocol for HPV positive gynae/ anal malignancies funded/supported by industry
6.2 Disease-specific research: Ovarian cancer 6.2a - Ovarian cancer in the frail/elderly	Development of trial evaluating geriatric assessment tool and chemotherapy treatment in the frail/elderly	AM, SB, RMG IMcN	Jun 2020	One new trial in which geriatric assessment tool is utilised and/or that evaluates chemotherapy specifically in the frail/elderly

Strategic objective	Action	CSG Lead	Date	Outcomes
6.2b - Molecular stratification	Urgent need to develop trial in which patients with newly diagnosed ovarian cancer are stratified according to molecular classifiers	All	Jun 2020	First line trial in which molecular stratification is an integral component to be
6.2c -Surgical trial	There is still robust debate as to which patients gain benefit from primary surgery vs interval debulking, and which patients may not benefit from surgery at all. Action to develop study in which surgical decision algorithm is integral to study design	All	Jun 2021	First line trial in which surgical decision algorithm is integral to stratification and/or treatment allocation

Strategic objective	Action	CSG Lead	Date	Outcomes
6.2c Screening	Following failure of UKCTOCS, there remains a need to screening study in ovarian cancer, both for high risk populations and unselected population. Such a study would have to incorporate molecular markers and improved imaging.	All	Jun 2022	Development of pilot protocol for screening study with stage shift as primary endpoint.
6.2d - Platinum-resistant trials	Outcomes for women with platinum-resistant disease remain very poor. CSG needs to have a portfolio of trials for women with resistant disease, including those who have had multiple prior lines of therapy	All	On-going	At least two trials open at all times for women with platinum-resistant disease
6.3 Disease-specific research: Endometrial cancer 6.3a - Prevention	Significant strength in endometrial cancer prevention within CSG. National primary prevention study women at high risk of developing endometrial cancer required	EC	Jun 2020	National primary prevention study in high risk women to be funded/supported by industry

Strategic objective	Action	CSG Lead	Date	Outcomes
6.3b Survivorship	Outcome for women with endometrial cancer is good. Need to develop protocols to minimise hospital visits and maximise QoL for women treated for endometrial cancer	KB	Jun 2020	Multi-centre study investigating survivorship in early stage endometrial cancer
6.3c- Recurrent endometrial cancer	Although overall prognosis for endometrial cancer is good, prognosis for those with relapsed disease is very poor with no licensed new drugs. CSG needs to develop portfolio of trials in relapsed endometrial cancer	All	Jun 2019	At least one national trial open in relapsed endometrial cancer
6.3d Molecular stratification	Recent advances in the understanding of endometrial cancer biology means that stratification by molecular subtype should be incorporated into first line endometrial cancer trials	All	Jun 2020	Molecular stratification to be incorporated into next first line intervention trial in newly-diagnosed endometrial cancer

Strategic objective	Action	CSG Lead	Date	Outcomes
6.4 Disease-specific research: Cervical cancer 6.4a - Screening	Uptake of cervical cancer screening remains low. Studies required to assess methods to increase screening uptake in partnership with primary care CSG	All	Jun 2020	Study addressing interventions to increase cervical screening uptake funded
6.4b Recurrent disease	Prognosis for recurrent cervix cancer is very poor. CSG needs to ensure that there are studies open for women with recurrent disease	All	Jun 2019	At least one multi-centre study open in recurrent cervical cancer.

Appendix 3

Top 5 publications in the reporting year

Trial name & publication reference	Impact of the trial	CSG involvement in the trial
1. O'Flynn H, Ryan NAJ, Narine N, Shelton D, Rana D, Crosbie EJ. Diagnostic accuracy of cytology for the detection of endometrial cancer in urine and vaginal samples. **Nat Commun. 2021 Feb 11;12(1):952.**	This paper shows proof-of-principle that non-invasive urogenital sampling can enable the detection of endometrial cancer by cytology. This could provide a simple, patient-friendly 'rule out' test for women with postmenopausal bleeding, to facilitate the urgent referral of women with suspected endometrial cancer for invasive testing, whilst safely reassuring healthy women. It could also serve as a screening tool for high risk women (eg Lynch syndrome, women with obesity)	Developed and participated.

2. Ovarian cancer population screening and mortality after long-term follow-up in the UK Collaborative Trial of Ovarian Cancer Screening (UKCTOCS): a randomised controlled trial	UK Collaborative Trial of Ovarian Cancer Screening (UKCTOCS) evaluated population screening and impact on mortality. This report is of ovarian cancer mortality after long-term follow-up. The reduction in stage III or IV disease incidence in the MMS group was not sufficient to translate into lives saved. This important trial illustrated the importance of specifying cancer mortality as the primary outcome in screening trials. As screening did not significantly reduce ovarian and tubal cancer deaths, general population screening cannot be recommended.	Supported.
3. León-Castillo A, de Boer SM, Powell ME, Mileshkin LR, Mackay HJ, Leary A, Nijman HW, Singh N, Pollock PM, Bessette P, Fyles A, Haie-Meder C, Smit VTHBM, Edmondson RJ, Putter H, Kitchener HC, Crosbie EJ, de Bruyn M, Nout RA, Horeweg N, Creutzberg CL, Bosse T; TransPORTEC consortium. Molecular Classification of the PORTEC-3 Trial for High-Risk Endometrial Cancer: Impact on Prognosis and Benefit From Adjuvant Therapy. **J Clin Oncol. 2020 Oct 10;38(29):3388-3397.**	A TransPORTEC collaborative study (UK, Netherlands, France, Canada). Showed for the first time that molecular Workstream predicts response to adjuvant chemotherapy in high risk endometrial cancer. Informed the RAINBO trial design, currently under review for funding at CRUK.	Developed and participated.

4. Ryan NAJ, McMahon R, Tobi S, Snowsill T, Esquibel S, Wallace AJ, Bunstone S, Bowers N, Mosneag IE, Kitson SJ, O'Flynn H, Ramchander NC, Sivalingam VN, Frayling IM, Bolton J, McVey RJ, Evans DG, Crosbie EJ. The proportion of endometrial tumours associated with Lynch syndrome (PETALS): A prospective cross-sectional study. **PLoS Med. 2020 Sep 17;17(9):e1003263.**	First UK prospective study of universal Lynch syndrome testing in endometrial cancer. Showed 3% endometrial cancers are associated with Lynch syndrome and how best to identify them. Informed new NICE guidance (DG42, October 2020), that all endometrial cancer patients should be screened for Lynch syndrome, which has transformed clinical care in the UK.	Developed and participated.
5. OVPSYCH2: A randomized study of psychological support versus standard of care following chemotherapy for ovarian cancer Dr Sarah Patricia Blagden; Elena Frangou; Gianfilippo Bertelli; Sharon Love; Melanie J Mackean; Ros Glasspool; Christina Fotopoulou; Audrey Cook; Shibani Nicum; Rosemary Lord; Michelle Ferguson; Rene L Roux; Maria Martinez; Nicholas Hulbert-Williams, PhD; Chrissie Butcher; Lesley Howells **Accepted Gynecologic Oncology May 2021**	This is the first study to look at an intervention to address FoR in Ovarian Cancer patients and ran in collaboration with Maggies Centres. It was a randomised trial of cognitive behavioural therapy (CBT) based counselling (versus no counselling) delivered to ovarian cancer patients who had just finished chemotherapy.The trial demonstrated that fear of relapse was a significant problem and in the CBT arm, the levels of fear dropped significantly for up to 6 months. We are collaborating with the ovarian charities and the BGCS for professionals to learn more about Fear of Relapse/Progression (FOP)	Developed and participated.
6. A phase II randomised, placebo-controlled trial of low dose (metronomic) cyclophosphamide and nintedanib (BIBF1120) in advanced ovarian, fallopian tube or primary peritoneal cancer**.** Hall MR, Debhi H-M, Banerjee S, Lord R, Clamp A, Lederman JA, Nicum S, Lilleywhite R , Bowen R et al.	This was an important assessment of a novel treatment combination in women with multiply relapsed difficult to treat ovarian cancer –a key priority area for the Group. The METRO BIBF trial was the largest reported cohort of patients with relapsed ovarian cancer treated with oral cyclophosphamide. Nintedanib did not improve outcomes when added to oral	Developed and participated.

Gynecol Oncol 2020. 159(3):692-698.	cyclophosphamide. Although not significant, more patients than expected remained on treatment for ≥6 months. This may reflect a higher proportion of patients with more indolent disease or the higher dose of cyclophosphamide used.	
7. A randomised phase II study of nintedanib (BIBF1120) compared to chemotherapy in patients with recurrent clear cell carcinoma of the ovary or endometrium. (NICCC/ENGOT-OV36) Glasspool R, Mcneish I, Westermann A, et al; International **Journal of Gynecologic Cancer 2020;30:A127-A128.**	This was a NCRI – ENGOT collaboration and was the first randomised trial in relapsed clear cell cancer. It gave important information on the efficacy and toxicity of both nintedanib and chemotherapy. These are the results of the ovarian cancer cohort.	Developed and participated.

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	1327	3136	1327	3136	21	19
2017/18	900	3257	900	3154	20	22
2018/19	2834	3026	643	1779	29	18
2019/20	2409	5085	740	1282	15	23
2020/21	1290	2445	562	739	13	11

*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 Shibani

Re: NCRI Gynaecological Group Annual Report 2019-20

Thank you for submitting an annual report for the Gynaecological 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.

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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 Gynaecological Group

Areas of strength:

- The Group showed good evidence of international and industry collaboration in their work. It was recognised by the Panel the ambition the Group had in the successful delivery of an international combination trial for patients with high risk endometrial cancer. In addition, the Group successfully delivered a commercially sponsored international registration trial.
- The Panel recognised that the Group had produced high impact outcomes from their work over the last year; in particular the publication of the ICON8 trial.
- The Groups commitment to transforming clinical practice through their engagement with NICE was applauded by the review Panel.
- The Panel commended the high success rate with funding application submissions.
- The Group's strategic approach and objectives were clear and provided great value to understand the future vison. The Panel were particularly impressed with the Group's approach to expand their portfolio of work into prevention, early diagnosis, biomarkers and survivorship research.
- The Group's active consumer member was applauded for their direct involvement in trials development, this was evidenced through her representation on the Trial Management Group for CEBOC trial.
- The Group's chairs were praised by Panel, this was testament to the joint compilation of the annual report and is an exemplar for succession planning within the Group.
- The Group's recognition of the upcoming challenges of Brexit for data sharing agreements in future trial plans was also acknowledged. This provides notable recognition of how successfully the Group are working with their UK counterparts and EU consortiums in the delivery of trials.

Areas which the Group need to consider:

- The Panel suggested the Group needed to rework the strategy timelines for delivering their objectives to ensure these are reflective of the current climate and funding shortages. Although, the Panel felt the group were well equipped to address the challenges ahead.
- The translational science in the development of their work had been prioritised although they provided limited evidence of wider translational developments, with the exception of novel agent work. The Panel encouraged the Group to demonstrate evidence of genuine experimental medicine studies across the portfolio.
- The Panel acknowledged the Group's aspiration to appoint consumer representatives across all workstreams and noted the commitment to encourage a supportive environment for consumer integration into all aspects of trial development.

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,
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Appendix 6

Quinquennial review feedback - 2020

1. Comments and recommendations

The panel concluded the discussion and thanked the group for their efforts in presenting and creating the report. They then provided a summary of feedback for the group to take forward.

Areas of strengths;

- The panel felt overall, the group was very effective. The QQR report and discussions with the panel highlighted the impact of the Group in the form of high impact publications and examples of practice changing trials.
- The new structure appeared to be working very well and the leadership across the executive and workstreams was commended as having enabled the Gynaecological Research Group and wider community to be highly active and effective. Plans for another strategy meeting in 2021 will hopefully reinforce this activity.
- The trainee involvement is working well and there seems to be high levels of engagement across the Workstreams and a supportive environment created by the Chairs.
- A wide trials portfolio, particularly in ovarian has highlighted the importance of the international contributions and the increased links with radiology, pathology and scientists.
- The group demonstrates an open and inclusive processes, with wide geographical engagement and training involvement. It was positive to see attempts in other disease areas, including rare diseases. The improvement in translational work is significant compared to 5 years prior.

Areas for the group to consider;

- The panel felt the engagement across the country and recruitment was a challenge, including variable engagement with NIHR Sub-Specialty Leads (SSLs). It was suggested that the Group make contact with the NIHR CRN: Cancer coordinating centre to help address this.
- Radiotherapy is a weak link despite best efforts. The panel recommended development of a strong link with CTRad, in the hope of some improvement here. The RadNet centres are being encouraged to collaborate further. The group should feedback to NIHR if trials are not supported where lack of resource and funding is cited as the reason.
- The balance of academic and non academic studies needs to be considered as well as the development of further surgical studies.
- In setting up prospective registries, it is important for all centres to engage e.g. CTU input, QOL researches etc. rather than relying on retrospective work. Some of this may come

from interaction from other NCRI Groups. The Group and Workstreams may benefit from a additional statistician involvement since the retirement of Mr Jim Paul when it comes to input on novel trials designs.

- The Group are asked to further pursue studies for vulval cancer, although the panel acknowledged that the group are already trying hard in this difficult area.

Issues for the NCRI to consider;

- With regard the consumer input, this will be further discussed within the NCRI, as the Group feel they have struggled in this area due to issues outside of their control.
- The links with clinical oncologists are not particularly strong, which may be aided by CTRad. NCRI can help facilitate these links, if required.

Concluding the Review, Professor Wadsley thanked the Panel and Group members for their participation. The business of the meeting took four hours.
The Group will be reviewed in five years' time.

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