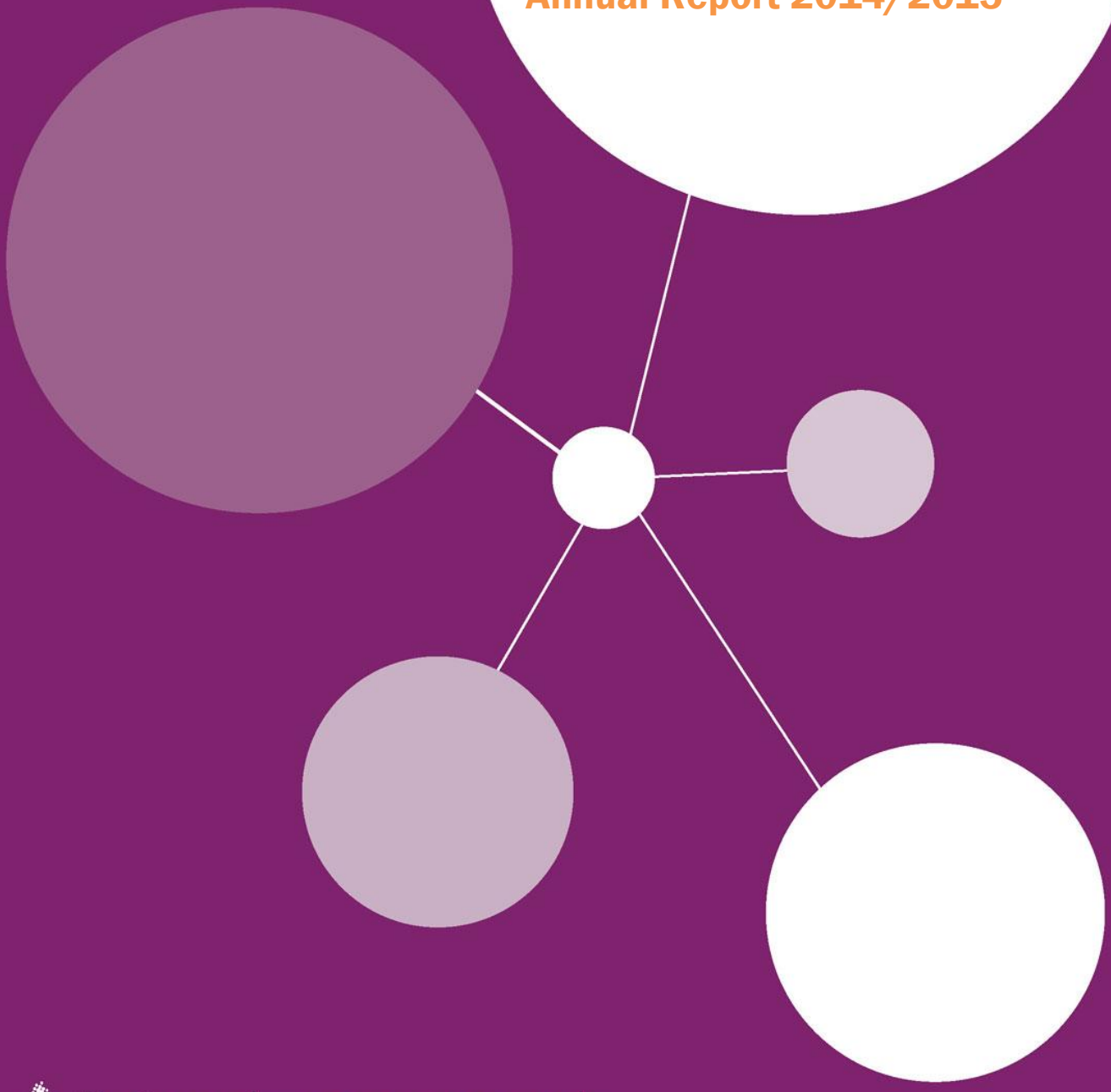
NCRI
National
Cancer
Research
Institute

NCRI
Head & Neck Cancer
Clinical Studies Group

Annual Report 2014/2015



Partners in cancer research

NCRI Head & Neck Cancer CSG Annual Report 2014/15

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

The NCRI Head & Neck CSG has continued to grow from strength to strength. Our main challenges have been to manage the set up of many new studies at the same time, and the over subscription of trials within the oropharyngeal cancer space. Our top 3 achievements have been to work together to achieve a streamlined RTQA process between studies to reduce the RTQA requirements on individual units, resulting in a more rapid set up of studies. We have also reached an agreement on the management of the portfolio with limiting studies in oropharyngeal cancer and encouraging studies in other areas. We have also expanded the clinical trials felllowships with now approval and funding for a pathologist and a clinical oncologist trainee, in addition to an ENT and maxillofacial surgeon trainee.

2. Structure of the Group

The Group has appointed Mr Stuart Winter, ENT Surgeon, Oxford, and Dr Max Robinson, Pathologist, Newcastle, as new members. The Group has also appointed Dr Wai Lup Wong who rejoins the group as a Radiologist. The Group has also appointed Professor Jim McCaul as Chair of the Surgery and Localised Therapies Subgroup to succeed Professor Richard Shaw, who has provided excellent leadership to the subgroup for the past four years, and has now demitted.

3. CSG & Subgroup strategies

Main CSG

The CSG strategy this year has been concentrating on three areas:

1. Successful set up and initiation of the large number of randomised trials, for which the CSG members received funding. An important aspect of that has been the co-ordination and harmonisation of RTQA processes between four studies that required RTQA input, and which were being set up at the same time. Through negotiation and collaboration, the CSG along with the NCRI RTQA group, has managed to develop a streamlined RTQA process with unified guidelines for oropharyngeal planning and outlining. This has decreased the amount of work required for the centres to set up the studies as well as the amount of resource required by the NCRI RTQA group. This innovative solution has only come about due to the close cooperation and collaboration of the CIs of the different studies and by the coordination of the Head and Neck CSG.

2. The CSG has also continued to work on managing the over subscription of studies in the oropharyngeal area and has agreed a formal strategy for that which stipulates that further Phase III studies will be discouraged in the field for the time being.
3. Concentration on developing studies in the areas that are undersubscribed, such as laryngeal cancer and premalignancy, is also being encouraged.

Thyroid Subgroup (Chair, Dr Laura Moss)

Achievements

Following the publication of the first NCRI phase 3 study, HiLo, in the NEJM in 2012, the results have changed UK standard practice and have been incorporated into the 2014 British Thyroid Association thyroid cancer guidelines.

A submission to the AZ NCRN alliance in 2013 was successful and CTAAC funding has now been secured for the SELIMETRY study looking at the MEK inhibitor, selumetinib, in radioiodine refractory thyroid cancer.

A subgroup research meeting was held in London in October 2014 to discuss potential new studies and encourage new researchers to put forward ideas. Consumer and CNS representation and input was strong. Four studies were selected for further development, covering the following clinical areas: ctDNA: low iodine diet use prior to radioiodine treatment; quality of life in sporadic and inherited medullary thyroid cancer; radioiodine use and dosimetry in high risk thyroid cancer.

Aims

We would like to be in a position to have studies available for patients with all subtypes of thyroid cancer and at all stages in their cancer journey. This is challenging particularly with regard to interventional studies in anaplastic thyroid cancer due to the combination of its rarity and poor prognosis. To date there has not been a surgery focused study in the portfolio so we are keen to try and address this facet of patient management.

Challenges

Following the publication of several NCRI adopted international phase 3 industry studies assessing tyrosine kinase inhibitors (TKIs) in metastatic medullary and differentiated thyroid cancer, new drugs have been licensed for these indications. Funding constraints however are limiting access to these agents in routine clinical practice as well as limiting opportunities for UK centres to participate in further studies of new TKIs, multiple TKIs or sequential TKI use.

Surgery & Localised Therapy Subgroup (Chair, Professor Jim McCaul)

Following the elevation of Professor Richard Shaw to Lead for Surgical Oncology, Professor Jim McCaul took over the role of Subgroup Chair in January.

The committee continues to have two trainee members and we plan for this to continue. In the interim period Mr Paul Nankivell (ENT) and Mr Andrew Schache (Maxillofacial) remain part of the committee.

A current area of strength in the head and neck trials portfolio involving surgery is oropharyngeal cancer. Two surgical trials (PATHOS and comPARE) are to open in the very near future. Given

some concerns expressed regarding recruitment from this patient population some units have adopted a pragmatic approach to ensure that both PATHOS and De-ESCALATE (non surgical trial) recruit successfully.

Open trials in the oral cavity category currently address the complication of osteoradionecrosis (ORN) following combined therapy for oral cavity and chemoradiotherapy for oropharynx cancer. HOPON for ORN prevention remains open and DAHANCA 21 is open in one centre (Liverpool) with a second to open in the near future (Northwick Park Hospital). The LIHNCS randomized controlled trial recruited to time and target 419 oral cavity cancer patients in 24 centres and continues in follow up phase. Early outcome data will be presented in Brazil (IAOO Sao Paolo) and Liverpool (BAOMS) this year. The SEND trial has very recently ceased recruitment and data is anticipated to be available in the very near future.

New surgical trials supported by the group include NODES (sentinel node vs selective neck dissection for primary oral cavity cancer) and LISTER (Lugol's iodine in surgical treatment of epithelial dysplasia of the oral cavity and oropharynx). These have recently been submitted to funders and not achieved awards. Both are in work up for further submission with further modification under discussion.

Systemic Therapy & Radiotherapy Subgroup (Chair, Professor Kevin Harrington)

The Subgroup supports a broad-ranging and highly active research portfolio – these protocols can be subdivided according to treatment intent and will be considered under the following subheadings:

(i) Improving curative treatment

A number of protocols address the issue of using altered radiotherapy dose/fractionation or the addition of targeted drugs in an attempt to improve loco-regional and/or systemic disease control.

The randomised phase III trial of IMRT as a means of delivering dose-escalated radiotherapy in laryngo-hypopharyngeal cancers (ART-DECO) was supported by a large number of radiotherapy centres and has nearly completed recruitment.

A number of early phase clinical trials of novel radiosensitisers that target the DNA damage response are underway or in trial set-up. The PATRIOT trial of the novel ATR inhibitor (AZD6738) is actively recruiting patients and a study amendment will open to recruitment in late 2015. The ORCA-2 trial is currently in set-up and will open to recruitment early in 2016. In addition, the WISTERIA trial has been recommended for funding and will open in 2016.

There are two ongoing phase III trials in the curative setting. Data from the De-Escalate study will be added to data from the RTOG-1016 trial to provide a robust evidence-base for treatment selection in this group of patients. The second study (NIMRAD) is testing the role of the hypoxic cell sensitiser nimorazole in patients who are not suitable for cisplatin-based chemoradiotherapy.

(ii) Improving palliative treatment

The CHECKMATE-141 study (recruitment now completed) involved testing the anti-PD1 monoclonal antibody (nivolumab) versus physician's choice chemotherapy in the second-line setting in relapsed/metastatic head and neck cancer.

A phase Ib study of cisplatin/carboplatin, cetuximab and the anti-HER3 monoclonal antibody (patritumab) has completed recruitment. In light of the initial tolerability and efficacy data, a randomised phase II protocol will open to recruitment in late 2015. This European study will be led from the UK.

(iii) Developing adjuvant treatment

The UK has the leading recruiter in a randomised phase III trial of adjuvant afatinib (a pan-HER tyrosine kinase inhibitor) in patients who have achieved a complete remission following radical chemoradiotherapy. This study seeks to test the hypothesis that adjuvant therapy can prolong progression-free and overall survival.

(iv) Biological studies in head and neck cancer

A number of studies are evaluating the biology of head and neck cancers with a view to enhancing our ability to treat disease and cause few side effects. These include imaging studies (INSIGHT study) and radiogenomics analyses (RAPPER study).

Survivorship Subgroup (Chair, Professor Steven Thomas)

The remit of the Subgroup is the development of studies to enhance the quality of life of patients undergoing therapy for H&N cancers, and additionally the development of studies, which assist wider understanding of H&N cancer through epidemiology or population, based research.

Major achievements include the completion of recruitment with 5511 participants in the benchmark NIHR clinical cohort HeadandNeck5000. The first data release is due mid 2015. The study includes a wide range of patient centred outcomes and contributes as a well-annotated bio resource. It is already part of a large IARC collaborative study to improved understanding of the germ line variants and somatic alterations that drive oral cavity and oropharyngeal carcinogenesis and how they affect disease risk and outcome and the development of effective and more personalized prevention as well as diagnostic and treatment strategies. The resource is also a key component of the recently awarded £4 million CRUK Programme. The cohort will be used to assess systemic metabolic and epigenetic biomarkers to predict head and neck squamous cell cancer progression.

The Subgroup has project level funding from a variety of agencies including NIHR RfPB, HTA and CRUK for a diverse range of studies from reducing radiotherapy induced ototoxicity to improving the appeal of food for head and neck cancer survivors. Of particular note is the award of 3 NIHR and 1 MRC Doctoral Research Fellowships focusing core disclosure and outcome sets, decision-making and quality of life.

The Subgroup plans to extend the follow-up of the HeadandNeck5000 cohort to 3 years. The CARE study of Personalised interventions for the alleviation of symptoms and disability of survivors of head and neck cancer is under development. The success of the HeadandNeck5000 in establishing a clinical research network has led to calls for an ongoing population based resource for head and neck cancer and precancer linking the understanding of the molecular and epigenetic profiles with patient centred outcomes and predict development of cancer from precancer, time to metastases or death and may lead to the identification of clinically useful predictive biomarkers for head and neck cancer progression or fatality.

4. Task groups/Working parties

There are no task group or working groups in the CSG.

5. Patient recruitment summary for last 5 years

Overall patient recruitment this year has dropped mainly due to the closure of HeadandNeck5000, a large observational study that was recruiting approximately 1000 patients a year. With that in mind, the current recruitment rate has been very reasonable.

Recruitment into interventional trials (both cancer and all categories) trials has increased from last year, despite the difficulties in setting up several randomised trials at the same time requiring RTQA, which delayed the set-up of these studies.

In the Head & Neck CSG portfolio, 5 trials closed to recruitment and 10 opened.

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

Year	All subjects		Cancer patients only		% of cancer patients relative to incidence	
	Non-RCT	RCT	Non-RCT	RCT	Non-RCT	RCT
2010/2011	1216	672	1182	672	15.8	9.0
2011/2012	2053	617	1860	617	24.9	8.2

Table 2 Summary of patient recruitment by Interventional/Non-interventional

Year	All participants		Cancer patients only		% of cancer patients relative to incidence	
	Non-interventional	Interventional	Non-interventional	Interventional	Non-interventional	Interventional
2012/2013	2414	773	2374	681	24.9	7.2
2013/2014	2445	658	2415	602	25.4	6.3
2014/2015	1894	699	1888	654	19.8	6.9

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

We are currently working with the EORTC Head and Neck Group to find mechanisms to open two studies, one from the UK [Pathos] and one from the EORTC [Best of]. One of the main issues is finding funding support for both, especially in Europe.

We are also participating as founding members in the set up of the Head and Neck InterGroup, which is a collaborative of clinical trials co-operative groups from around the world with the hope of harmonisation and collaboration in the running of studies.

The CSG has also originated, and is leading, the application to set up the EuroHNC COST Action, which aims to improve harmonisation of clinical trials processes across Europe.

7. Funding applications in last year

Despite the fact that the CSG has been concentrating mainly on the set up and delivery of several large studies funded last year, there have been several new applications, including: PACIFIC, LISTER, WISTERIA for the ECMC, Elation for HTA (thyroid), Sel-i-PET and the application to Wellcome for head and neck 10,000as well as extensions for the LIHNS and COAST trials which have been successful.

Table 3 Funding submissions in the reporting year

Clinical Trials Advisory and Awards Committee (CTAAC)			
Study	**Application type**	**CI**	**Outcome**
July 2014			
PARLAY: Partial laryngectomy versus radiation therapy for intermediate stage laryngeal cancer: a feasibility randomised controlled trial	Feasibility application	Mr Vinidh Paleri and Mr Terry Jones	Not funded
COAST: Cisplatin Ototoxicity attenuated by ASpirin Trial. A Phase II randomised controlled trial of aspirin in the preventative role of Cisplatin induced ototoxicity.	Full application *Extension*	Dr Emma King	Funded
November 2014			
SEL-I-METRY: Investigating the potential clinical benefit of selumetinib in resensitising advanced iodine refractory differentiated thyroid cancer to radioiodine therapy	Full Application	Dr Jon Wadsley	Funded
LIHNCS Extension	Full Application *Extension*	Professor James McCaul	Funded
March 2015			
Pathos-T: A Bioresource Collection associated with PATHOS, a Phase II/III trial of risk-stratified, reduced intensity adjuvant treatment in patients undergoing transoral surgery for Human papillomavirus (HPV)-positive oropharyngeal cancer	Sample collection application	Professor Terry Jones	
Other committees			
Study	**Committee & application type**	**CI**	**Outcome**
HeadandNeck 10,000	Wellcome Trust	Professor Andy Ness	Not funded
Wisteria	NAC, Outline application	Professor Hisham Mehanna	Full application invited
PAcific	Commercial	Professor Hisham Mehanna	funded

8. Collaborative partnership studies with industry

The Head & Neck CSG's partnership with industry continues to prosper. We already have a well-established relationship with Astra Zeneca and we have developed this further with the Wisteria Study through the ECMC Alliance. Funding for a new study using Prembrimazab [sic] has been developed with Merck. There has also been funding from Silence PLC for the PACIFIC study.

9. Impact of CSG activities

The PET Neck study, a multicentre randomised controlled study on the management of advanced nodal disease was presented as an oral presentation at ASCO and has had very favourable feedback. The study has changed and continues to change practice in the UK. The study results have now been incorporated into UK head and neck guidelines for head neck cancer.

The CSG has also participated in the NICE Clinical Guidelines Meeting, as well as commented on several NICE guidelines.

10. Consumer involvement

Malcolm Babb

The past twelve months have seen continued progress in developing studies that successfully secure funding and further growth in numbers of patients taking part. I believe consumer members of the Group have played a full part in this success.

Head and Neck 5000, which had strong consumer involvement and support from its inception, did remarkably well in meeting its ambitious recruitment target and will provide a valuable resource for years ahead.

Future consumer involvement may benefit from wider involvement in the Subgroups. In contrast with many other CSGs this has been quite limited to date and it would provide the opportunity for consumer impact at the earliest stage in the development of studies.

11. Open meetings/annual trials days/strategy days

We have had one scientific meeting involving the CSG, this was held in Harrogate and was organised by Dr Mehmet Sen. We also had a joint CompARE launch and De-ESCALaTE update meeting in October which was attended by approximately 100 clinicians and researchers from around the country.

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

We have achieved all of our three year strategy objectives ahead of time including setting up studies in low-activity areas, especially post-operative setting and the recurrence – metastatic setting. We have also set up the clinical trials fellowship, which has now been adopted across the other CSGs. We have now started to work on developing a new three-year strategy which is currently in development.

13. Priorities and challenges for the forthcoming year

Challenges for the Head & Neck CSG include:

- Develop a successor for Head and Neck 5000 – the large cohort study that helped secure much needed infrastructure support.
- Develop studies in areas of need e.g. laryngeal cancer and thyroid cancer
- Identify new members for the CSG to inject new blood as several of the established members have come to the end of their tenure.
- Counteract the threat from the development of the NRG group in the USA as their size and rapid recruitment rates into head and neck may result in the UK losing out on leadership in phase 3 trials especially that are industry supported

Key priorities for the Head & Neck CSG in 2015/16 are:

- We will continue to encourage the development of new studies in priority areas, especially in early laryngeal cancer, premalignancy and image guided studies. In particular, we wish to set up a new cohort study.
- We will continue to manage the oversubscription in the oropharyngeal cancer space, and encourage recruitment into existing trials.
- We will expand the Clinical Trials Fellowships to include trainees from Oncology and Radiology.
- Select and integrate a new cohort of members onto the CSG
- Development of a phase 1 network in head and neck

14. Concluding remarks

The Head & Neck CSG continues to work remarkably successfully. We have opened a record number of studies, especially interventional ones, which are either recruiting or in the process of set up. We have also led the way in training a new generation of researchers to ensure a pipeline. Due to the immense efforts of the CSG members, we have achieved our 3 year strategy ahead of time, and we are now working on developing a new 3 year strategy.

15. Appendices

Appendix 1 - Membership of main CSG and subgroups

Appendix 2 – CSG and Subgroup strategies

A – Main CSG Strategy
B – Thyroid Subgroup Strategy
C – Surgery & Localised Therapy Subgroup Strategy
D – Systemic Therapy & Radiotherapy Subgroup Strategy
E – Survivorship Subgroup Strategy

Appendix 3 - Portfolio Maps

Appendix 4 - Publications in previous year

Appendix 5 - Major international presentations in previous year

Professor Hisham Mehanna (Head & Neck CSG Chair)

Appendix 1

Membership of the Head & Neck CSG

Name	Specialism	Location
Dr Mererid Evans	Clinical Oncologist	Cardiff
Dr Stefano Fedele	Clinical Oncologist	London
Dr Teresa Guerrero-Urbano	Clinical Oncologist	London
Professor Kevin Harrington	Clinical Oncologist	London
Dr Laura Moss	Clinical Oncologist	Cardiff
Dr Mehmet Sen	Clinical Oncologist	Leeds
Mr Malcolm Babb (CLG)	Consumer	Chesterfield
Professor John Chester	Medical Oncologist	Cardiff
Dr Martin Forster	Medical Oncologist	London
Dr Max Robinson	Pathologist	Newcastle
Professor Gareth Thomas	Pathologist	Southampton
Dr Wai Lup Wong	Radiologist	Middlesex
Ms Jo Haviland	Statistician	Southampton
Dr Emma King	Surgeon	Southampton
Professor Jim McCaul	Surgeon	London
Professor Hisham Mehanna (Chair)	Surgeon	Birmingham
Mr Vinidh Paleri	Surgeon	Newcastle
Professor Steven Thomas	Surgeon	Bristol
Mr Stuart Winter	Surgeon	Oxford
Professor Stephen Porter		London

Membership of the Subgroups

Thyroid Subgroup		
Name	**Specialism**	**Location**
Dr Clive Harmer	Clinical Oncologist	London
Dr Ujjal Mallick	Clinical Oncologist	Newcastle
Dr Laura Moss (Chair)	Clinical Oncologist	Cardiff
Dr Kate Newbold	Clinical Oncologist	London
Dr Jon Wadsley	Clinical Oncologist	Sheffield
Dr Carol Evans	Endocrinologist	Cardiff
Professor Mark Strachan	Endocrinologist	Edinburgh
Professor Allan Hackshaw	Epidemiologist	London
Dr Sarah Johnson	Pathologist	Newcastle
Professor Valerie Lewington	Radiologist	London
Mr Radu Mihai	Surgeon	London
Mr John Watkinson	Surgeon	Birmingham

Systemic Therapy & Radiotherapy Subgroup		
Name	**Specialism**	**Location**
Dr Caroline Brammer	Clinical Oncologist	Liverpool
Professor Kevin Harrington (Chair)	Clinical Oncologist	London
Dr Andrew Hartley	Clinical Oncologist	Birmingham
Dr Liz Junor	Clinical Oncologist	Edinburgh
Dr Mehmet Sen	Clinical Oncologist	Leeds
Dr Nick Slevin	Clinical Oncologist	Manchester
Mrs Christine Allmark	Consumer	West Yorks.
Professor Chris Boshoff	Medical Oncologist	London
Professor John Chester	Medical Oncologist	Cardiff
Dr Martin Forster	Medical Oncologist	London
Professor Hisham Mehanna	Surgeon	Birmingham

Surgery & Localised Therapy Subgroup		
Name	**Specialism**	**Location**
Dr Mereid Evans	Clinical Oncologist	Cardiff
Mr Max Robinson	Pathologist	Newcastle
Dr Catrin Tudur-Smith	Statistician	Liverpool
Professor Terry Jones	Surgeon	Liverpool
Mr Tas Kanatas	Surgeon	Leeds
Mr Dae Kim	Surgeon	Portsmouth
Dr Emma King	Surgeon	Southampton
Mr Jim Mccaul (Chair)	Surgeon	London
Professor Hisham Mehanna	Surgeon	Birmingham
Mr Vin Paleri	Surgeon	Newcastle
Professor Richard Shaw	Surgeon	Liverpool
Paul Nankivell*		Birmingham
Andrew Schache*		Liverpool

Survivorship Subgroup		
Name	**Specialism**	**Location**
Dr Cherith Semple	CNS	Ulster
Dr Charles Kelly	Clinical Oncologist	Newcastle
Mrs Christine Allmark	Consumer	West Yorks.
Professor Gerry Humphris	Psychologist	St Andrews
Dr Sheila Fisher	Surgeon	Leeds
Professor Hisham Mehanna	Surgeon	Birmingham
Professor Simon Rogers	Surgeon	Liverpool
Professor Steven Thomas (Chair)	Surgeon	Bristol

*denotes trainee

Appendix 2

CSG & Subgroup Strategies

A – Main CSG Strategy

1. Strategic outlook and planning

1.1 Focused Portfolio development

To date HN CSG has developed studies opportunistically. There is a need to become more directed and more focused on the gaps in the portfolio. These include:

a) HPV negative patients
b) Elderly patients
c) Metastatic and recurrent patients, and end of life care
d) Biomarker led studies
e) Development of novel radiosensitisers
f) Studies for rarer cancers – anaplastic, salivary

1.2. Actively engage funders and commercial companies in this difficult funding environment

This will include inviting CRUK and HTA and MRC representatives to discuss their funding priorities and funding mechanisms at the CSG meetings. Importantly I would like to engage commercial companies more closely, and invite them to discuss their priorities and current pipelines and explore ways of working more closely.

We will also explore having a pharma representative on the CSG, as we previously had.

We will also hold an annual strategy group meeting with pharmaceutical and commercial companies. We will also consider closed meetings with companies alongside annual meetings.

2. Maintaining and Increasing Recruitment into Trials

We would aim to assess national recruitment into head and neck studies, so that we identify the regional and local variances and identify networks who are recruiting poorly to studies.

I propose that HN CSG ambassadors be appointed to each of six regions nationwide. The ambassadors' function will be: A. Present the head and neck portfolio studies available for recruitment to the network members in that region. B. The ambassadors will also visit network leads and research network leads to examine specific reasons for non recruitment and to develop specific plans to help improve recruitment. C. The ambassadors will act as the focal point for that region's clinicians who wish to develop new studies. They will then liaise with the CSG Chair to identify the appropriate expertise to help the person develop the study further. This may include expertise from outside the CSGs. D. Ambassadors may also select members from subgroups to assist them in dissemination. The ambassadors will be publicised in the Newsletter, on the Website and in the HN CSG presentation pack.

3. Increasing Collaborations and Networking

We will aim to increase the local and national profile of the head and neck CSG. This will include an annual meeting which may alternate between translational focus and a general studies focus. 2012 will be a translational focus and therefore 2013 may be a general focus.

We will also develop a newsletter specific to head and neck. This may have three sections. The first consisting of a short summary of the main studies open to recruitment. The second being a specific focus of one or two studies in detail. The third - an information section on roadshows and contact details for regional ambassadors. The newsletter will be developed by the CSG members and formatted by the CSGs Secretariat.

We will also develop a set of slides for the roadshows to help the ambassadors when talking to the networks and presenting.

We will also aim to increase the collaboration internationally. This will include collaborations with the EORTC and the Rare Cancers Initiative as well as possibly the RTOG. We will engage with the NCI as well as possibly the RTOG. We will engage with the EORTC liaison officer and with the EORTC head and neck group through the direct link of Mehmet Sen. The Rare Cancers Initiative has already been engaged through Kevin Harrington and Laura Moss. Hisham Mehanna and Richard Shaw are exploring contacts with the RTOG.

4. CSG Meetings

I propose that we change the format of the meeting to include less of the 'for your information' type material and concentrate more on the poorly recruiting trials and trials in development as well as focussed sessions to develop new trials or new areas. The briefing documents for the meeting would have a large component with 'for your information' briefing documents including the reports of the trials.

Subgroup chairs will be asked to summarise the progress of the studies in their subgroup and highlight only the ones that are struggling and the reasons for this. It would be recommended that subgroups have their subgroup meetings one month before the full CSG so that they are up to date with all of the studies in their portfolio.

A large part of the meeting would be dedicated to discussing the study ideas in development in detail, and developing studies in the areas of focus (such as the elderly), and in translational studies as well. Meeting with funders, pharma companies and other CSGs may also be included.

Leads would be appointed for the following:

Portfolio management, NICE reviews, newsletters and publicity, 6 regional ambassadors

5. Clinical Trials Fellowship for Trainees

We will develop a mentorship scheme for trainees; one from each of ENT, Maxillofacial, Clinical Oncology and thyroid and possibly one for Medical Oncology as well if viewed appropriate. These trainees will be offered a one year fellowship in which they attend clinical studies group and the relevant subgroup meetings. They will also be attached to a PI who is currently developing an application and/or a protocol. They will help the PI develop the applications, thereby gaining experience. The Fellowship will be for one year but may be extended for people who show

exceptional talent. Funding for these Fellowships will come from the relevant professional body. The ENT UK president and the BAHNO president have already indicated provisional interest. The funds would cover the travel expenses and would be claimed directly from the professional bodies or given to the NCRI and claimed by the trainees by the NCRI.

B – Thyroid Subgroup Strategy

UK Participation

We have established a strong network of thyroid cancer clinicians across the UK and are now strengthening our links with nuclear medicine teams and physicists in order to investigate and develop dosimetry for use in radioiodine treatment.

Patient inclusion

As thyroid cancer occurs in children, teenagers and young adults we would like to be able to approach and include younger patients in future studies.

Long term follow up and survivorship

As long term survival for many thyroid cancer patients is excellent we need to address long term quality of life as well as treatment morbidity in future studies.

Research Themes

Continue to conduct existing trials successfully and develop new studies addressing important unanswered questions and unmet needs.

Aim to incorporate emerging biomarkers as translational aspects of future interventional studies and investigate the use of molecular markers to aid preoperative diagnosis of thyroid cancer.

International Collaboration

With representation on the EORTC Endocrine Taskforce and International Thyroid Oncology Group (ITOG) we hope to be able to collaborate on international academic studies as well as industry studies in the future.

C – Surgery & Localised Therapy Subgroup Strategy

Future strategy for the Surgery & Localised Therapy Subgroup aims to further strengthen the committee with the appointment of a new member and to maintain two trainee places. Areas of identified need within our disease site and stage remit include precancer and early disease identification and management and treatment trials for oral cavity cancer.

D – Systemic Therapy & Radiotherapy Subgroup Strategy

The Systemic Therapy & Radiotherapy Subgroup strategy is currently under review.

E – Survivorship Subgroup Strategy

The Survivorship Subgroup strategy is to develop cohort studies, follow up existing cohorts and develop new ones for both pre malignant and malignant disease. We will use them to examine frequency of follow up and to develop links already established with metabolomics and epigentic studies. We will examine the profile of survival at all levels from 'omics' to clinical and patient centred outcomes and identify what is important for follow up and survival.

We want to build on the success we have had with MRC and NIHR Doctoral Research Fellowships and develop a research network for survivorship researchers. The Doctoral Research Fellows will be encouraged to link with the NCRI CSG Specialist Fellows in head and neck cancer and extend this network amongst the NIHR ACFs and ACLs and specialist trainees.

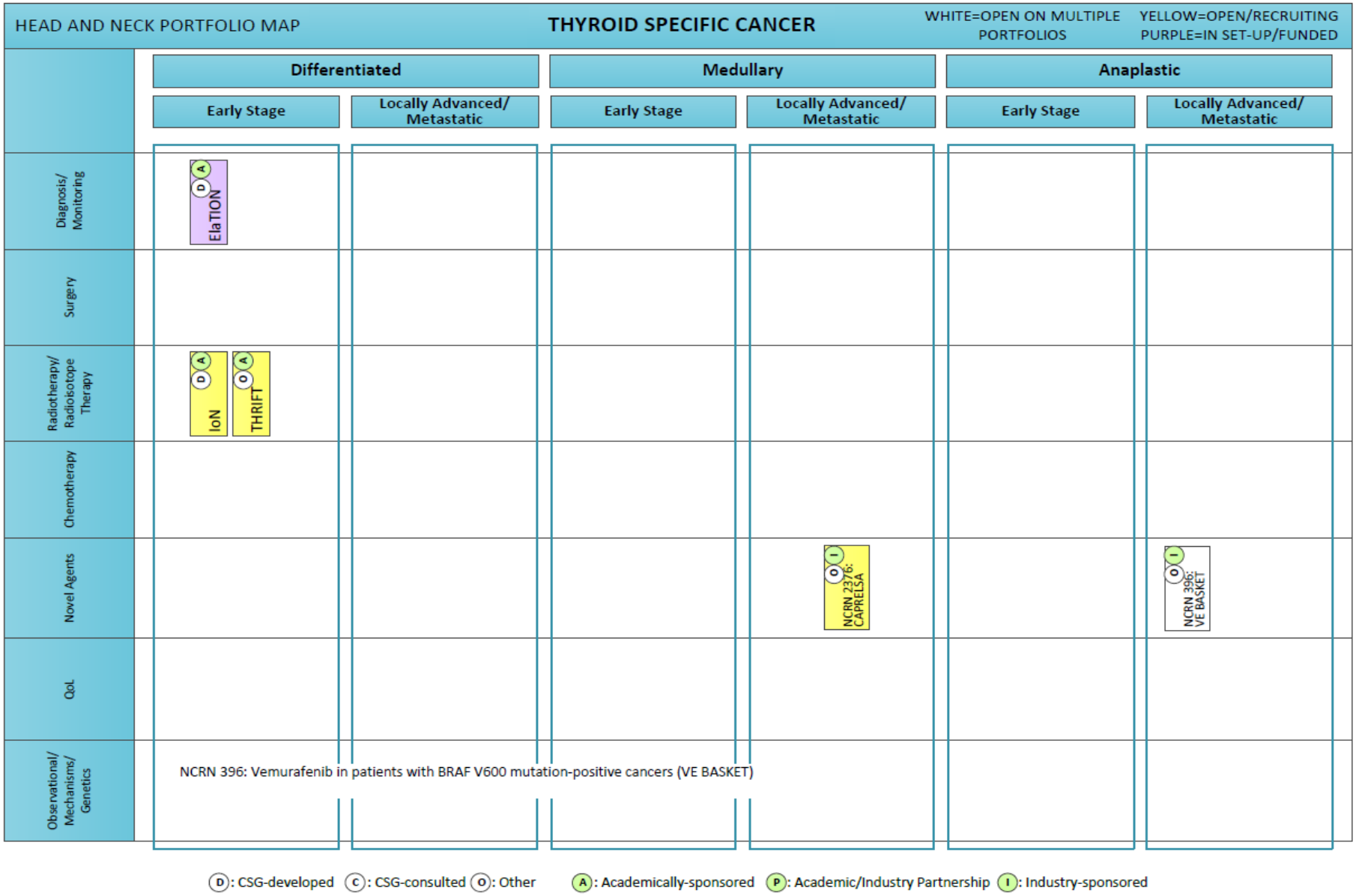
Specifically, the Survivorship Subgroup plans to extend the follow-up of the Head and Neck 5000 cohort from 1 year to 3 years.

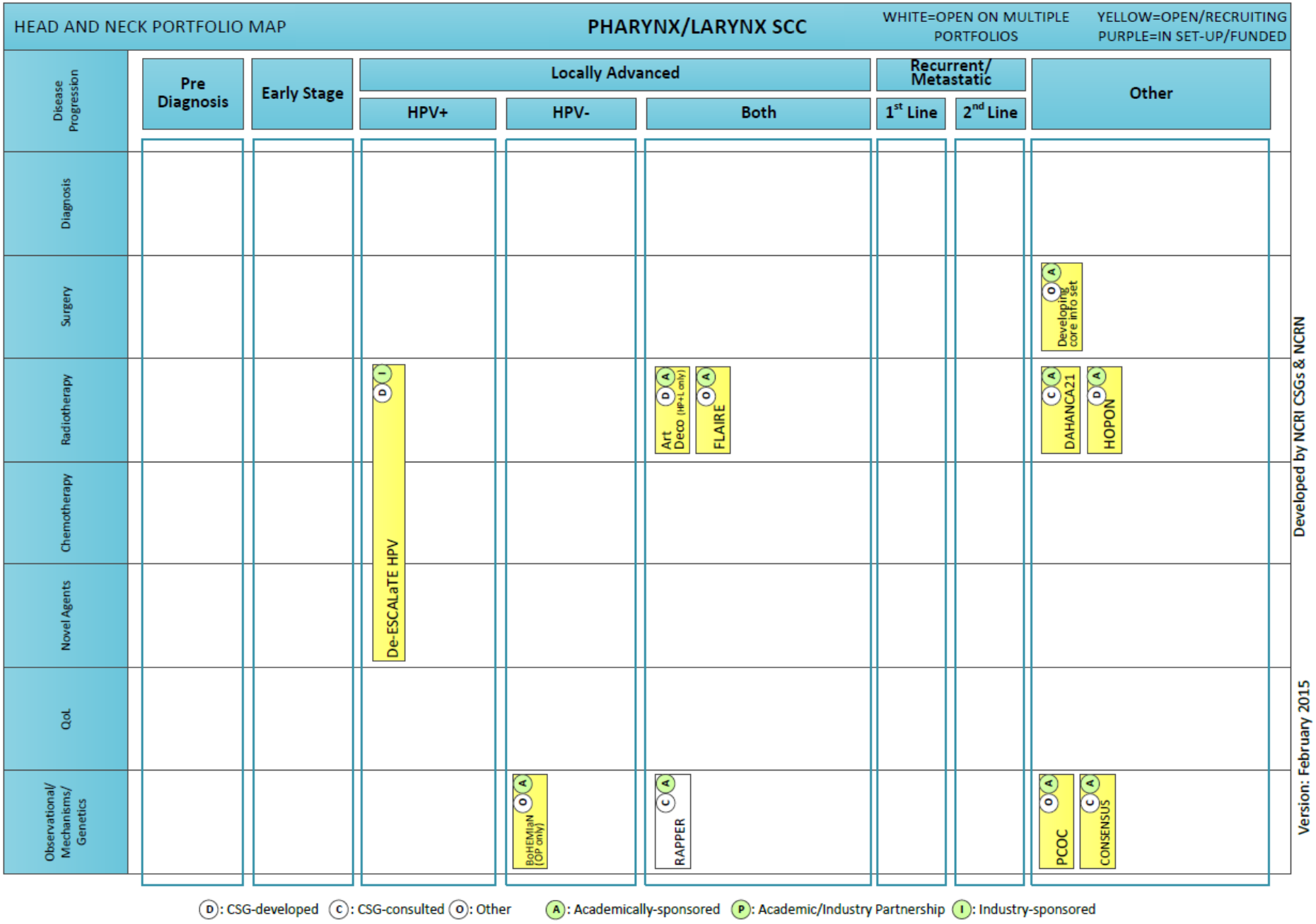
The CARE study of Personalised interventions for the alleviation of symptoms and disability of survivors of head and neck cancer is under development.

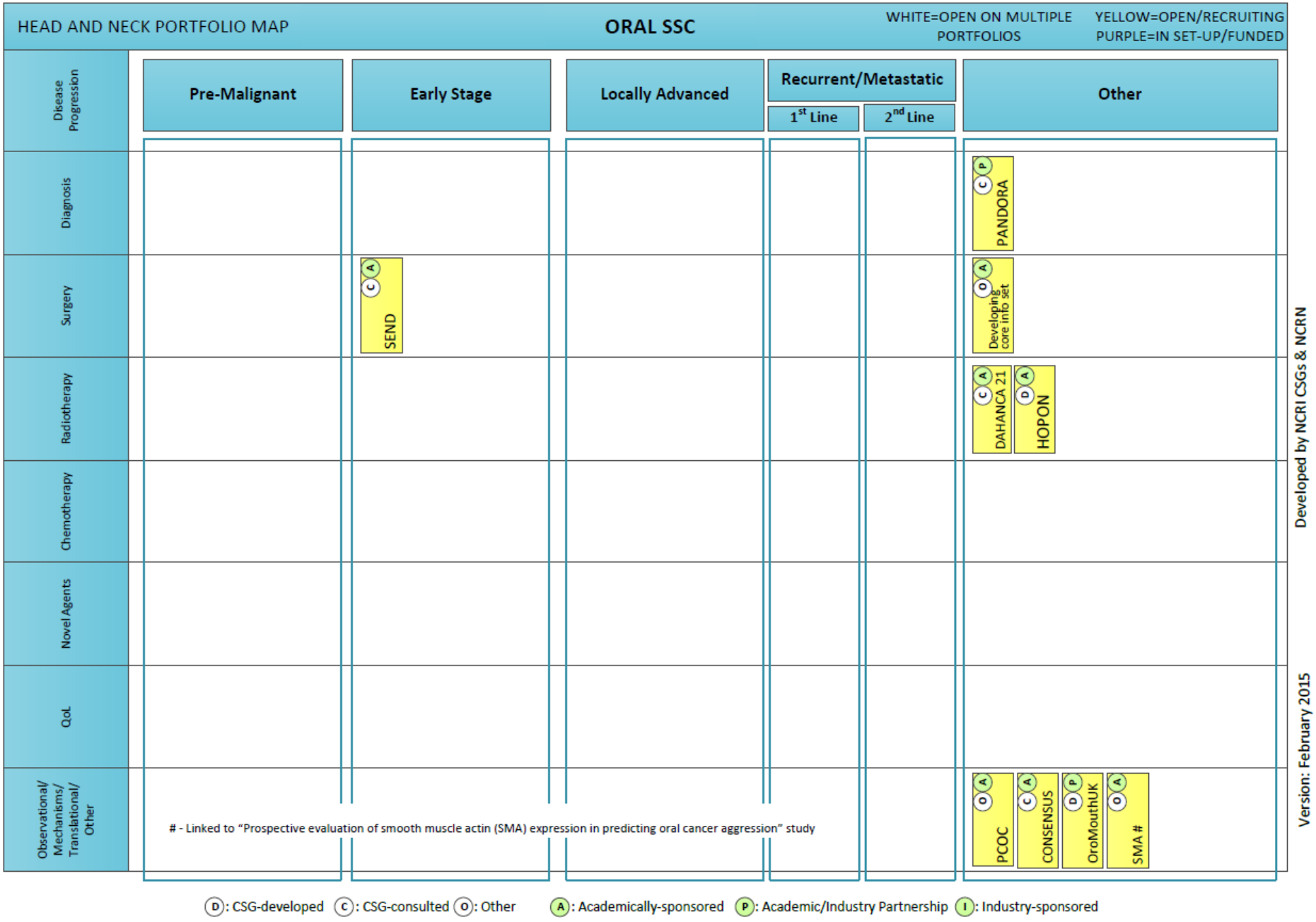
The success of the H&N5000 in establishing a clinical research network, recruiting in 78 UK centres, has led to calls for an ongoing population based resource for head and neck cancer and precancer. This will link the understanding of the molecular and epigenetic profiles with patient centred outcomes and predict development of cancer from precancer, time to metastases or death and may lead to the identification of clinically useful predictive biomarkers for head and neck cancer progression or fatality.

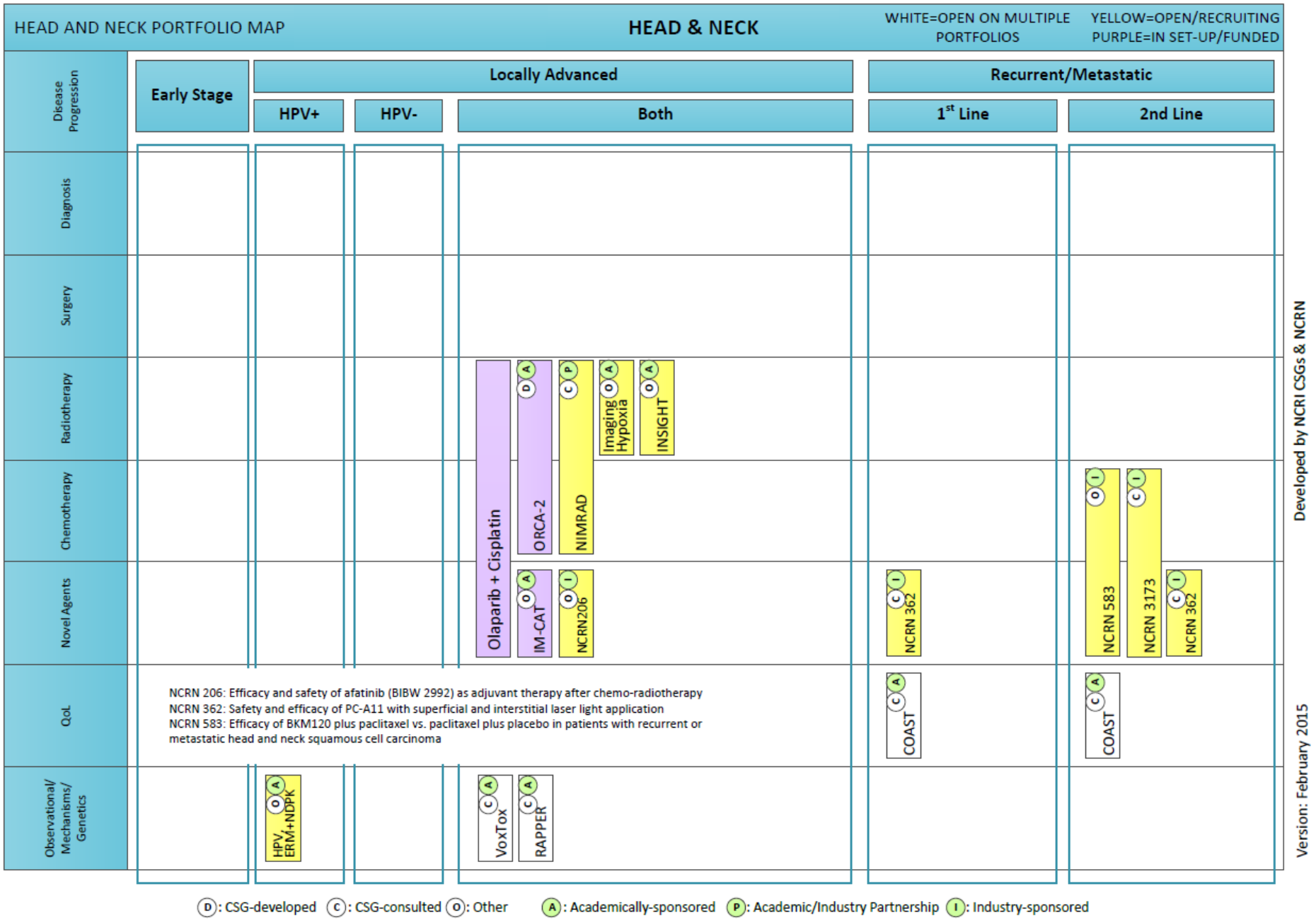
Appendix 3

Portfolio maps




HEAD AND NECK PORTFOLIO MAP
PHARYNX/LARYNX SCC
WHITE=OPEN ON MULTIPLE PORTFOLIOS
YELLOW=OPEN/RECRUITING
PURPLE=IN SET-UP/FUNDED
Disease Progression
Pre Diagnosis
Early Stage
Locally Advanced
HPV+
HPV-
Both
Recurrent/ Metastatic
1st Line
2nd Line
Other
Diagnosis
Surgery
Radiotherapy
Chemotherapy
Novel Agents
QoL
Observational/ Mechanisms/ Genetics
De-ESCALaTE HPV
Art Deco (HP+L only)
FLAIRE
BoHEMIaN (OP only)
RAPPER
Developing core info set
DAHANCA21
HOPON
PCOC
CONSENSUS
Developed by NCRI CSGs & NCRN
Version: February 2015
(D): CSG-developed (C): CSG-consulted (O): Other
(A): Academically-sponsored (P): Academic/Industry Partnership (I): Industry-sponsored


HEAD AND NECK PORTFOLIO MAP
ORAL SSC
WHITE=OPEN ON MULTIPLE PORTFOLIOS
YELLOW=OPEN/RECRUITING
PURPLE=IN SET-UP/FUNDED
Disease Progression
Pre-Malignant
Early Stage
Locally Advanced
Recurrent/Metastatic
1st Line
2nd Line
Other
Diagnosis
Surgery
Radiotherapy
Chemotherapy
Novel Agents
QoL
Observational/ Mechanisms/ Translational/ Other
C A SEND
C P PANDORA
O A Developing core info set
C A DAHANCA 21
D A HOPON
O A PCOC
C A CONSENSUS
D P OroMouthUK
O A SMA #
- Linked to "Prospective evaluation of smooth muscle actin (SMA) expression in predicting oral cancer aggression" study
Developed by NCRI CSGs & NCRN
Version: February 2015
(D): CSG-developed (C): CSG-consulted (O): Other (A): Academically-sponsored (P): Academic/Industry Partnership (I): Industry-sponsored


HEAD AND NECK PORTFOLIO MAP
HEAD & NECK
WHITE=OPEN ON MULTIPLE PORTFOLIOS
YELLOW=OPEN/RECRUITING
PURPLE=IN SET-UP/FUNDED
Disease Progression
Early Stage
Locally Advanced
HPV+
HPV-
Both
Recurrent/Metastatic
1st Line
2nd Line
Diagnosis
Surgery
Radiotherapy
Chemotherapy
Novel Agents
QoL
Observational/ Mechanisms/ Genetics
Olaparib + Cisplatin
ORCA-2
NIMRAD
Imaging Hypoxia
INSIGHT
IM-CAT
NCRN206
NCRN 362
NCRN 583
NCRN 3173
NCRN 362
COAST
COAST
HPV ERM+NDPK
VoxTox
RAPPER
NCRN 206: Efficacy and safety of afatinib (BIBW 2992) as adjuvant therapy after chemo-radiotherapy
NCRN 362: Safety and efficacy of PC-A11 with superficial and interstitial laser light application
NCRN 583: Efficacy of BKM120 plus paclitaxel vs. paclitaxel plus placebo in patients with recurrent or metastatic head and neck squamous cell carcinoma
Developed by NCRI CSGs & NCRN
Version: February 2015
(D): CSG-developed (C): CSG-consulted (O): Other (A): Academically-sponsored (P): Academic/Industry Partnership (I): Industry-sponsored

HEAD AND NECK PORTFOLIO MAP
HEAD & NECK
WHITE=OPEN ON MULTIPLE PORTFOLIOS
YELLOW=OPEN/RECRUITING
PURPLE=IN SET-UP/FUNDED
Disease Progression
Diagnosis
Surgery
Radiotherapy
Chemotherapy
Novel Agents
QoL
Observational/ Mechanisms/ Genetics
Other
PANDORA
HOPON
DAHANCA 21
MVAEBNA1/ LMP2 Vaccine (NPC only)
NCRN - 2888
PACiFiC
TUBE Trial
OPEN WIDE
SIP SMART
CB-EST
PATRIOT
R4L pilot
Talking about HPV-rel cancer
Secondary Data Analysis
Value of PFS to patients
Head & Neck Skin Malignancy
BoHEMIaN
Genetic factors in eyelid mBCC and SGC
Investigating underlying mechanisms – Part I
Investigating underlying mechanisms – Part II
TRAC
Developed by NCRI CSGs & NCRN
Version: February 2015
(D): CSG-developed (C): CSG-consulted (O): Other
(A): Academically-sponsored (P): Academic/Industry Partnership (I): Industry-sponsored

Appendix 4

Publications in the reporting year

HeadandNeck5000

Ness AR, Waylen A, Hurley K, Jeffreys M, Penfold C, Pring M, Leary S, Allmark C, Toms S, Ring S, Peters TJ, Hollingworth W, Worthington H, Nutting C, Fisher S, Rogers SN, Thomas SJ; Head and Neck 5000 Study Team, Establishing a large prospective clinical cohort in people with head and neck cancer as a biomedical resource: head and neck 5000. *BMC Cancer*. 2014 Dec 17;14:973. doi: 10.1186/1471-2407-14-973.

Appendix 5

Major international presentations in the reporting year

There were no presentations at major international meetings in the reporting year.