NCRI
National
Cancer
Research
Institute

NCRI Head & Neck Cancer Clinical Studies Group

Annual Report 2015-16

Partners in cancer research

NCRI Head & Neck Cancer CSG Annual Report 2015-16

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

The Group has been undergone a rejuvenation of its membership with the recruitment of seven new members from a range of disciplines, as well as two new Subgroup Chairs to lead a rejuvenation of the membership.

The Group has been successful in securing funding and setting up several new studies. It has also been able to secure funding for four more clinical trials fellows, thereby increasing their number to seven – from ENT, maxillofacial surgery, clinical oncology, medical oncology, plastics surgery and pathology.

The Group has also had a very successful Strategy Day, which has identified areas of development and priority topics. These are now being worked upon by the Group and Subgroups to develop the relevant studies. In addition, the Group aims to establish several new trials including an observational trial to provide new opportunities for recruitment for the head and neck community.

Induction and integration of the new membership to establish an effective and harmonious Group will be a challenge for the coming year.

2. Structure of the Group

The Group has been very successful in setting up several trials over the last three years. This has meant that almost all the CSG members are now heavily committed, either running their own trials or participating as major co-investigators in these trials. It is therefore felt that the CSG membership required renewal needing younger, less committed, members to join the group to provide capacity for developing new studies. Therefore in the last six months, seven CSG members have demitted and seven new members have joined. The Group now comprises seven clinical oncologists, one medical oncologist and eight head and neck surgeons (both maxillofacial and ear, nose and throat surgeons). We also have one radiologist, two pathologists and one clinical trial specialist.

3. CSG & Subgroup strategies

Main CSG

The Group has identified the following priority areas in the coming three years. These include:

- An interventional trial for laryngeal and hypopharyngeal cancer.

- Post-operative trials in oral cancer.
- A large observational trial for pre-malignancy.
- Trials in thyroid disease, especially in immunotherapy, diagnosis and follow up.
- Trials in oral health, especially in mucositis and oral fibrosis.

The plan to achieve the above includes the following:

- Directed management of trial development process by the CSG Chair and Subgroup Chairs to ensure that leads are allocated and workgroups are set up to develop specific trials in those areas.
- Active mentorship of the new (less experienced) CSG members by the more experienced, longer serving members of the group. This is being undertaken by specific allocation of mentorship and buddying up of group members.
- Regular workgroup meetings which will be undertaken in conjunction with the subgroup meetings with the subgroups and regular review of the strategy output and outcomes of the workgroups at the main CSG meetings to ensure that progress is being made.

The Group has also identified the following as important areas for development:

1. Setting up a phase I network.
2. Strengthening relations with the CRN leads for head and neck.
3. Continuing to engender international collaborations especially with the Head Neck Intergroup.

Thyroid Subgroup (Chair, Dr Kate Newbold)

Links with nuclear medicine and medical physics to develop national protocols and expertise in radioiodine dosimetry have progressed significantly over the last year alongside the soon to open SEL-I-METRY study (CI Jon Wadsley, Sheffield). This is a major achievement involving training and quality assurance across multiple centres. This should lay the foundation for further studies involving dosimetry in future.

Building on aims to develop diagnostic, predictive and prognostic biomarkers in thyroid cancer, David Poller (consultant pathologist, Portsmouth) has joined the Subgroup for his expertise and interest in molecular biomarkers.

International research collaborations have been developed through the EORTC endocrine tumour taskforce and the International Oncology Group (ITOG). As a result of participation in these groups, we have open the EORTC nintedanib study and have been selected as one of four European countries to run an immunotherapy study developed through ITOG.

Collaboration with Industry continues to build with Astra Zeneca 104 study investigating effect of RET mutation on response to vandetanib in medullary thyroid cancer and two studies in set-up with Eisai, one phase II assessing efficacy of lower starting dose of lenvatinib in iodine refractory differentiated thyroid cancer and a phase II study of lenvatinib in anaplastic thyroid cancer.

IoN study continues to recruit in early stage differentiated thyroid cancer having recruited 280/550. iNATT (anaplastic thyroid cancer tissue bank) has samples from 41 patients and collaborations with international sites are in progress. QALM (quality of life in patients with medullary thyroid cancer) is being set up in 21 centres with five currently open. ElaTION (elastography in thyroid nodules) has recruited 209/925 with more centres in setup.

Surgery & Localised Therapies Subgroup (Chair, Dr Jim Mccaul)

The H&N Surgery and Localised Therapies Subgroup continues to thrive.

Our contribution toward the strategic aims of the Head & Neck CSG specifically include interventional trials for laryngeal and hypopharyngeal cancer, premalignancy trials, post-operative trials in oral cancer and mucositis and oral health trials.

We have made significant progress in the following areas:

- Premalignancy – LISTER trial (Lugols iodine visualisation for excision vs control) has achieved feasibility funding and opening in four centres. SAVER trial of sodium valproate vs placebo for patients not suitable for surgical management has achieved funding from the Efficacy and Mechanism Evaluation programme. Plans for a large observational cohort study of patients with dysplasia are underway with the Bristol team who ran the head and neck 5000 trial.
- Post-op trials in oral cancer – The Liteform trial (low level laser light therapy for patients with oral mucositis following adjuvant chemoradiotherapy or radiotherapy) has secured HTA funding. MediaTOr and RaPTOR trials for medical therapy for osteoradionecrosis are in work up
- The Subgroup also has ongoing success with trials such as AMG-319 (TKI inhibitor vs control for all head and neck sites), PATHOS, ComPARE. We have also successfully competed for a new international commercial trial (INSPIRE – IRX therapeutics) soon to open in UK.

Systemic Therapy & Radiotherapy Subgroup (Chair, Dr Martin Forster)

The portfolio of studies run within the Systemic Therapy & Radiotherapy Subgroup has a healthy mix of early and late phase trials, with recognition of current / upcoming gaps in the portfolio that require focus over the upcoming 12 months. A series of large phase II/III studies have been the backbone of successful recruitment over recent years. In HPV-driven oropharyngeal cancer, De-ESCALaTE is due to complete recruitment by the end of 2016, with PATHOS continuing beyond 2017. ART DECO recently closed following an interim analysis, and is replaced by CompARE, which has recently opened, for patients with high risk orophayngeal disease and a consortium is focusing on the development of a large phase III study in high risk hypopharnygeal/laryngeal cancer. NIMRAD continues to recruit in patients not suitable for dual modality therapy.

Early phase studies currently recruiting include ORCA2 and BoHEMIaN, both looking at novel methods of intensification for primary chemo-radiotherapy (CRT) in high risk disease, with Wisteria currently in set up, looking at potentiation of post-operative CRT for oral cancer, with a second biological 'windows' arm to better under mechanisms of chemo-potentiation. A second 'windows' study to open in 2016 explores the impact of PI3K-delta inhibition on the tumour immune environment and the safety of the addition of pembrolizumab to radical CRT will be explored in a new phase I/II study also opening in 2016-17. A further pembrolizumab study due to open in 2016-17 will evaluate the safety and activity in patients with recurrent / metastatic disease and a performance status of two. Further consideration will be given to randomised studies in high risk oral cavity and first line recurrent / metastatic disease.

Survivorship Subgroup (Chair, Professor Steven Thomas)

We recruited 5,511 people with head and neck cancer to our clinical cohort Head Neck 5000 and we have now completed four and 12 month follow up (completed 31/12/15). We have collected

data on diagnostic and pathological parameters, clinical care and outcomes, as well as quality of life and toxicity providing a comprehensive dataset across all aspects of care and management. We are working with collaborators across the UK and internationally to analyse data from these resources. For example, we have contributed over a 1,000 cases to a genome wide association study led by the International Agency for Research into cancer that has identified novel genetic variants associated with risk of oral and oropharyngeal cancer. We have approval for three year follow-up and have applied for a funded extension of the grant.

The Subgroup studies have attracted substantial funding via NIHR at programme and project level as well as Charities. The projects range from innovative approaches to improve quality of life such as assisting survivors in the expression of their concerns, and fundamental studies of swallowing as well as improving the palatability of food. We have five NIHR/MRC doctoral research fellows working on survivorship topics such as outcomes, decision making and consent – a critical area of investment in the future of survivorship research.

The importance of prognosis research has been highlighted by HN 5000. We plan to extend this approach to preclinical/premalignant disease using existing cohorts such as UK Biobank to identify novel epigenetic signatures before clinical diagnosis, which may have significant diagnostic utility in head and neck cancer. In addition, we plan to develop of a core outcome set for oral dysplasia, a survey of current practice for management and the feasibility for a clinical cohort of people with dysplasia. This approach will work across subgroups.

4. Task groups/Working parties

There are no specific task groups.

5. Patient recruitment summary for last 5 years

The CSG aimed to maintain and increase recruitment into clinical trials. This has been undertaken through opening a large number of diverse head and neck trials. It has also involved CSG members promoting the Head & Neck CSG portfolio in local meetings and at their centres. This has been successful and we have been recruiting large numbers of patients. The closure of the Head and Neck 5000 observational trial has, of course, decreased the number of patients recruited in headline figures. However, the follow up observational study is now about to start and those numbers should increase again. Recruitment to interventional trials have dropped this year due to several trials closing, e.g. Art Deco, LINCHS, and COAST, and several new trials only recently opening, e.g. Compare and Pathos.

In the Head & Neck Cancer CSG portfolio, 15 are currently open to recruitment and 13 trials are closed.

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
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
2015/2016	527	641	527	631	5.54	6.63

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

We have worked hard to improve our international links, we now have good links with the DAHANCA group where we are running one of their studies and they are running one of ours. We have also developed a good collaboration with the EORTC head and neck group, despite the EORTC declining to adopt two of our studies, we persisted and we are now collaborating on mutual adoption of two trials, one from the UK and one from the EORTC on low risk HPV positive for surgical disease.

We have also been a founding member of the Head and Neck Cancer InterGroup which is an international collaboration of over 20 national head and neck study groups looking to improve harmonisation of clinical trials methodology and processes amongst the different countries.

7. Funding applications in last year

Table 3 Funding submissions in the reporting year

Cancer Research UK Clinical Research Committee (CRUK CRC)			
Study	**Application type**	**CI**	**Outcome**
July 2015 (CTAAC)			
CompARE: Phase III randomised controlled trial Comparing Alternative Regimens for escalating treatment of intermediate and high-risk oropharyngeal cancer	Full application *Amendment*	Professor Hisham Mehanna	Approved (no cost)
ELATION – Collect: The Efficacy and cost effectiveness of real time ultrasound Elastography in the investigation of Thyroid Nodules and the diagnosis of thyroid cancer	Sample collection application	Professor Hisham Mehanna	Not funded
December 2015			
Biological sample collection for translational research within the Head and Neck cancer DARS and ART DECO radiotherapy trials	Sample Collection	Dr Sheerang Bhide	Scored as Preliminary - invited to resubmit
May 2016			
IoN: Is ablative radioiodine Necessary for low risk differentiated thyroid cancer patients	Full application	Dr Ujjal Mallick	Funded
Biological sample collection for translational research within the Head and Neck cancer DARS and ART DECO radiotherapy trials	Sample collection application	Dr Sheerang Bhide & Dr Mike Hubank	Not funded

Other committees			
Study	**Committee & application type**	**CI**	**Outcome**
SAVER: Sodium Valproate for Epigenetic Reprogramming in the Management of High Risk Oral Epithelial Dysplasia	EME	Professor Richard Shaw	Funded
JetPROX: use of a jejunal flap transfer to treat severe xerostomia resistant to other treatments.	EME	Professor Vinidh Paleri	Successful at outline – invited for full application
PIT-STOP: PentoxIfylline and Tocopherol for the treatment of poST radiotherapy fibrOsis in head and neck cancer Patients: a feasibility study	EME	Dr Stefano Fedele	Submitted
LISTER: lugol iodine to help resection of oral dysplasia	HTA	Professor Jim McCaul	Funded
LiteForm: low level laser light for mucositis	HTA	Mr Michael Nugent	Funded

8. Collaborative partnership studies with industry

The CSG identified that we needed to actively engage funders and commercial companies due to the difficult funding environment. This has been undertaken through bilateral meetings. The strategy has been successful, as evidenced by the fact that we now have more commercial studies than has ever been the case in head and neck cancer portfolio in the UK, and that we have strong collaborations with BMS, AstraZeneca and Merck.

9. Impact of CSG activities

One of the Group's trials, the PET NECK study, was published in the New England Journal of Medicine this year. It was covered by the National news and has change in the National Head and Neck Guidelines. The study results have been adopted by the new National head and neck Guidelines as the standard of care.

The Group has also provided a strong mechanism of peer review to CRUK's CRC, providing advice on a large number of applications this year. The Group's feedback has been very timely, and often done at very short turnaround times. In addition the group provides peer review support for the Commercial Portfolio Adoption team providing review and feedback at short notice on the large number of commercial studies applying to enter the portfolio.

10. Consumer involvement

The consumer members of the CSG have played a full role in the work of the group. This has included involvement in the development of new studies, contributing to the CSG's review of proposals seeking funding from CTAAC and elsewhere, review and development of patient information material and membership of management groups. The consumer members also input into the future strategy of the CSG, attending planning days and providing feedback on the proposed direction of research.

Malcolm Babb has been a member of the CSG since 2010 and is currently a member of the TSC and TMG of several studies in head and neck cancer and lung cancer. In his work with NALC, a

nationwide head and neck support group, he assists in the recruitment of patients to small studies, and gives formal support on request to researchers seeking funding for relevant projects.

He was a member of the team that planned the first UK Clinical Trials Conference for Supportive Care in Cancer Research which was held in Sheffield in 2015 and chaired one of the sessions.

Emma Kinloch has been a member of the CSG since 2015 and is also a member of the patient and public advisory panel for radiotherapy research in cancer of the head and neck at Guy's and St Thomas's Hospital.

Through her work running a head and neck support group in London and attendance at other groups, current key patient feedback is fed into the work of the CSG. The scientific mentoring relationship within the CSG that Emma has been part of has allowed the opportunity for support with, and insight into, CSG work when needed.

11. Open meetings/annual trials days/strategy days

We set up a national research meeting to precede the first Controversies meeting, but there was little interest, so it was cancelled. It was not clear whether this was due to lack of interest, lack of time of the delegates, or poor advertisement of the meeting.

However, we have held several other meetings that have utilised existing meetings. This appears to be a better strategy in view of the fact that funding and leave time is becoming more difficult to obtain for NHS consultants. Therefore, we are utilising the fact that people are already attending another meeting for us to update them. Importantly we have secured an annual slot in the well-attended British Association of Head and Neck Oncologists Annual Meeting and the Annual York Update Meeting. Most consultants attend one or the other of these two meetings. This way we are able to reach a very large part of the head and neck clinicians in the UK.

12. Priorities and challenges for the forthcoming year

Our priorities for the next year are to:

- Integrate the new members into the CSG, including the new clinical trials fellows.
- Set up and recruit into the studies that have recently opened, e.g. Pathos and Compare.
- Apply and secure funding for two new interventional /observational studies.

13. 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 Therapies 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 Cancer CSG Chair)

Appendix 1

Membership of the Head & Neck Cancer CSG

Name	Specialism	Location
Ms Clare Schilling*	Clinical Fellow	
Dr Stefano Fedele	Clinical Oncologist	London
Dr Bernie Foran	Clinical Oncologist	Sheffield
Dr Teresa Guerrero-Urbano	Clinical Oncologist	London
Professor Kevin Harrington	Clinical Oncologist	London
Dr Ioanna Nixon	Clinical Oncologist	Edinburgh
Dr Stefano Schipani	Clinical Oncologist	Glasgow
Mr Malcolm Babb	Consumer	Chesterfield
Ms Emma Kinloch	Consumer	
Dr Martin Forster	Medical Oncologist	London
Dr Max Robinson	Pathologist	Newcastle
Dr Karwan Moutasim*	Pathologist	Southampton
Professor Gareth Thomas	Pathologist	Southampton
Professor Stephen Porter	Professor of Oral Medicine	London
Dr Wai Lup Wong	Radiologist	Middlesex
Ms Jo Haviland	Statistician	Southampton
Mr Jagtar Dhanda*	Surgeon	Staffordshire
Dr Emma King	Surgeon	Southampton
Mr Navin Mani*	Surgeon	Manchester
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
Dr Kate Newbold	Clinical Oncologist	London

*denotes trainee member

Membership of the Subgroups

Thyroid Subgroup		
Name	**Specialism**	**Location**
Dr Clive Harmer	Clinical Oncologist	London
Dr Ujjal Mallick	Clinical Oncologist	Newcastle
Dr Laura Moss	Clinical Oncologist	Cardiff
Dr Kate Newbold (Chair)	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

Surgery & Localised Therapy Subgroup		
Name	**Specialism**	**Location**
Mr Paul Nankivell*	Clinical Fellow	Birmingham
Mr Andrew Schache*	Clinical Fellow	Liverpool
Dr Mereid Evans	Clinical Oncologist	Cardiff
Mr Max Robinson	Pathologist	Newcastle
Professor Terry Jones	Surgeon	Liverpool
Mr Tas Kanatas	Surgeon	Leeds
Mr Mike Nugent	Surgeon	Sunderland
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

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

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
Professor Hisham Mehanna	Surgeon	Birmingham
Professor Simon Rogers	Surgeon	Liverpool
Professor Steven Thomas (Chair)	Surgeon	Bristol

*denotes trainee member

**denotes non-core member

Appendix 2

CSG & Subgroup Strategies

CSG strategy

The Group has identified the following priority areas in the coming three years. These include:

- An interventional trial for laryngeal and hypopharyngeal cancer.
- Post-operative trials in oral cancer.
- A large observational trial for pre-malignancy.
- Trials in thyroid disease, especially in immunotherapy, diagnosis and follow up.
- Trials in oral health, especially in mucositis and oral fibrosis.

The plan to achieve the above includes the following:

- Directed management of trial development process by the CSG Chair and subgroup Chairs to ensure that leads are allocated and workgroups are set up to develop specific trials in those areas.
- Active mentorship of the new (less experienced) CSG members by the more experienced, longer serving members of the Group. This is being undertaken by specific allocation of mentorship and buddying up of CSG members.
- Regular workgroup meetings which will be undertaken in conjunction with the subgroup meetings with the sub groups and regular review of the strategy output and outcomes of the workgroups at the main CSG meetings to ensure that progress is being made.

The Group has also identified the following as important areas for development:

1. Setting up a phase I network.
2. Strengthening relations with the CRN leads for head and neck.
3. Continuing to engender international collaborations especially with the Head Neck Intergroup.

Survivorship subgroup strategy

The importance of prognosis research has been highlighted. Clinical cohorts have advantages over other study designs, including the recruitment of a broad and representative sample with limited exclusion criteria; participants with a shared clinical starting point; the measurement of prognostic factors not used in clinical practice; the inclusion of outcomes not routinely collected in existing sources and the collection of biological samples that can be analysed later. Many studies of disease prognosis have been small and not been clearly described or reported. We have developed a large UK based well-phenotyped clinical cohort called Head and Neck 5000 that will provide a biomedical resource for translational and prognostic research.

We plan to extend this approach to preclinical/premalignant disease using existing cohorts such as UK Biobank to identify novel epigenetic signatures before clinical diagnosis, which may have significant diagnostic utility in head and neck cancer. In addition, we plan to develop of a core outcome set for oral dysplasia, a survey of current practice for management and the feasibility for a clinical cohort of people with dysplasia. This approach will work across subgroups.

Surgery and localised therapies subgroup strategy

Our contribution toward the strategic aims of the Head & Neck CSG specifically include interventional trials for laryngeal and hypopharyngeal cancer, premalignancy trials, post-operative

trials in oral cancer and mucositis and oral health trials. We are currently working on planning and/or implementing these proposals and studies.

Thyroid Subgroup strategy

The Thyroid Subgroup aims to develop diagnostic, predictive and prognostic biomarkers studies in thyroid cancer. With that aim in mind, David Poller (consultant pathologist, Portsmouth) has joined the group for his expertise and interest in molecular biomarkers.

We wish to continue to build on our International research collaborations to increase recruitment into our studies. We also aim to develop and run an immunotherapy study and that may in conjunction with EORTC.

Finally we aim to develop studies on follow up and detection of recurrence and develop tissue collections to support these.

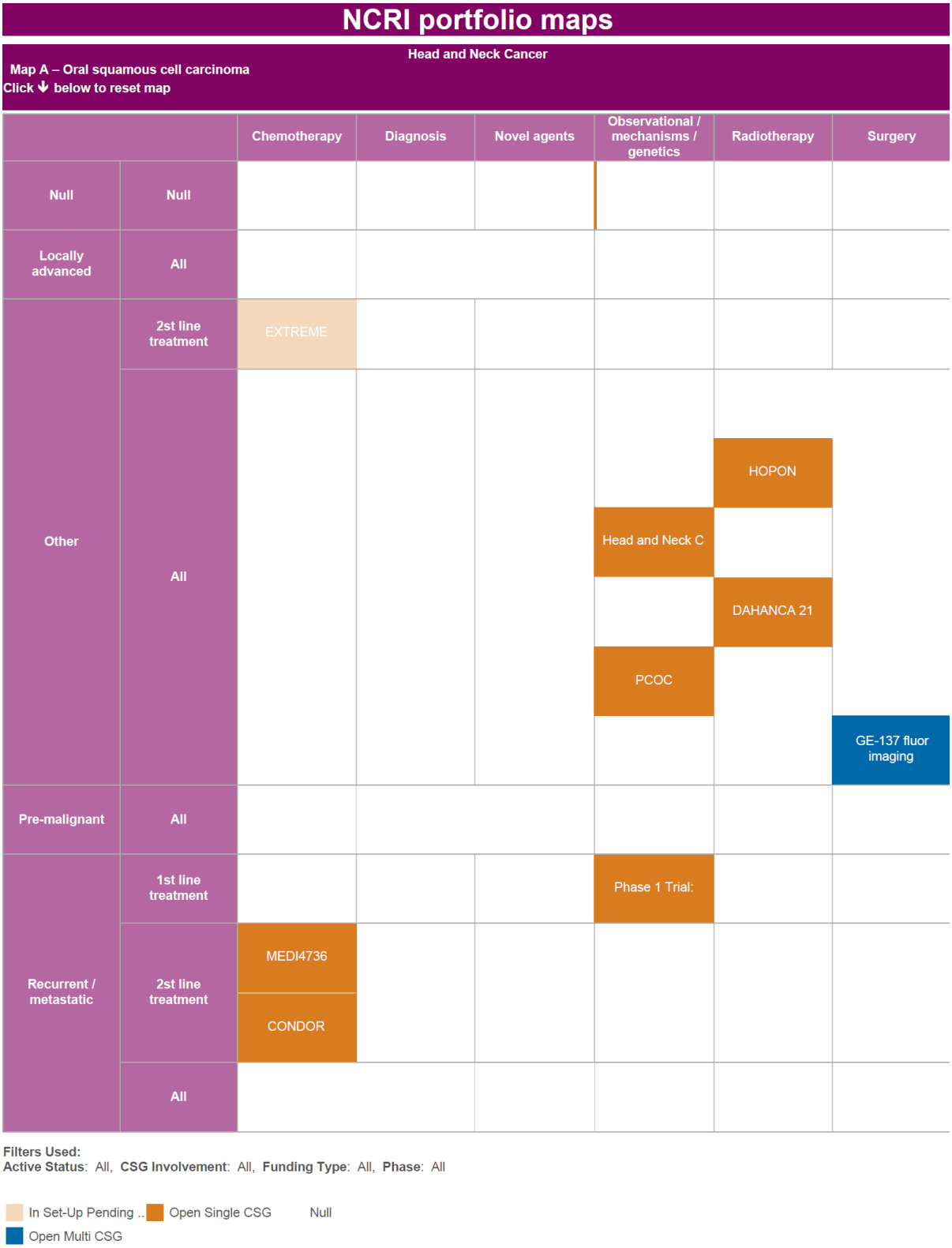
Surgery and localised therapies subgroup strategy

The strategy of Systemic Therapy & Radiotherapy Subgroup is to attempt to address the upcoming gaps in the portfolio that require focus over the upcoming 12 months. Therefore, a consortium is focusing on the development of a large phase III study in high risk hypopharnygeal/laryngeal cancer. Further consideration will be given to randomised studies in high risk oral cavity and first line recurrent/metastatic disease.

We also wish to continue to develop our phase I and phase II trials, especially in the window of opportunity setting. We are strongly supportive of the setting up of a phase I trials network and are working to help establish it.

Appendix 3

Portfolio maps



NCRI portfolio maps

Head and Neck Cancer

Map B – Pharynx-larynx squamous cell carcinoma
Click ↓ below to reset map

		Chemotherapy	Diagnosis	Novel agents	Observational / mechanisms / genetics	Quality of life	Radiotherapy	Surgery
Early stage	All						EaStER	
Locally advanced	1st line treatment	MEDI4736 CONDOR						
	2st line treatment							
	HPV-				PROMPTS			
	HPV+	De-ESCALaTE		De-ESCALaTE Nivolumab A Cancer Resear			De-ESCALaTE	
	HPV+/-	EXTREME			RAPPER Phase 1 Trial:			
Other	Other				PCOC Phase 1 Trial:		HOPON OCTiLarynx (Opt DAHANCA 21	
Pre-diagnosis	All							

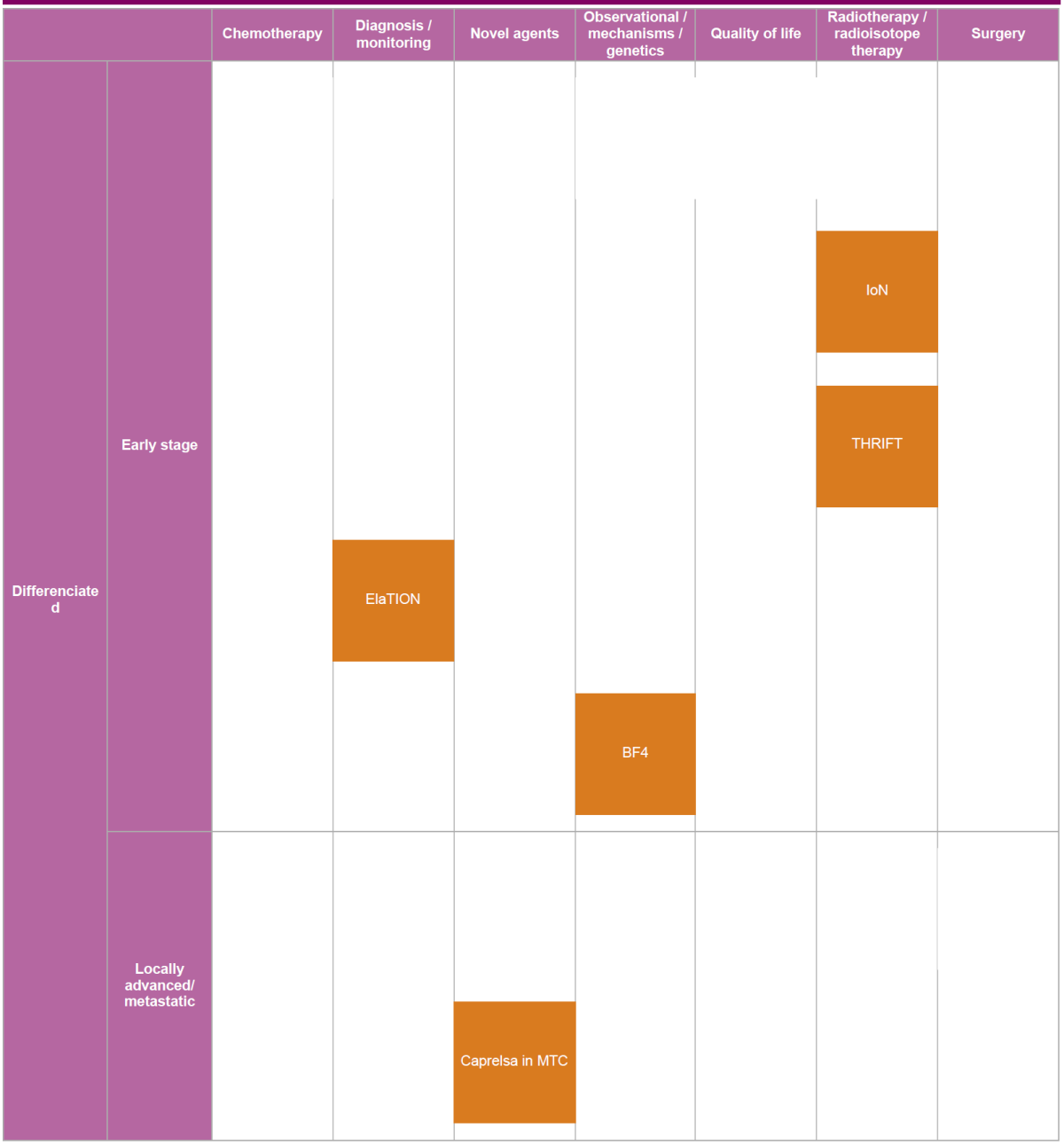
Filters Used:
Active Status: All, **CSG Involvement**: All, **Funding Type**: All, **Phase**: All

In Set-Up Pending .. Open Single CSG Null
Open Multi CSG Suspended Single ..

NCRI portfolio maps

Head and Neck Cancer

Map C – Thyroid-specific cancer
Click ↓ below to reset map

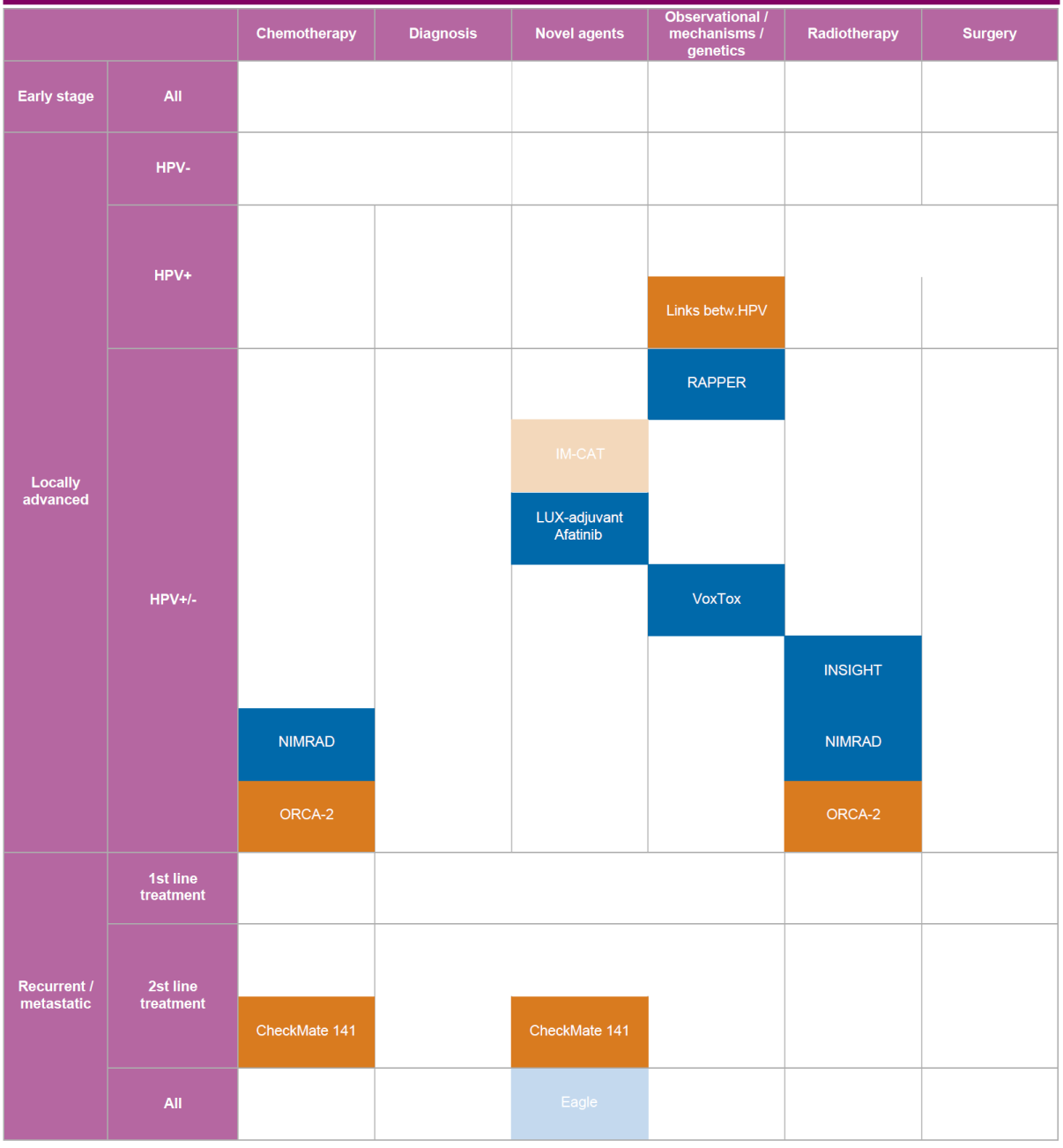


Filters Used:
Active Status: All, **CSG Involvement**: All, **Funding Type**: All, **Phase**: All

Open Single CSG

NCRI portfolio maps

Head and Neck Cancer
Map D – Cross-cutting: early stage, locally advanced, recurrent / metastatic
Click ↓ below to reset map



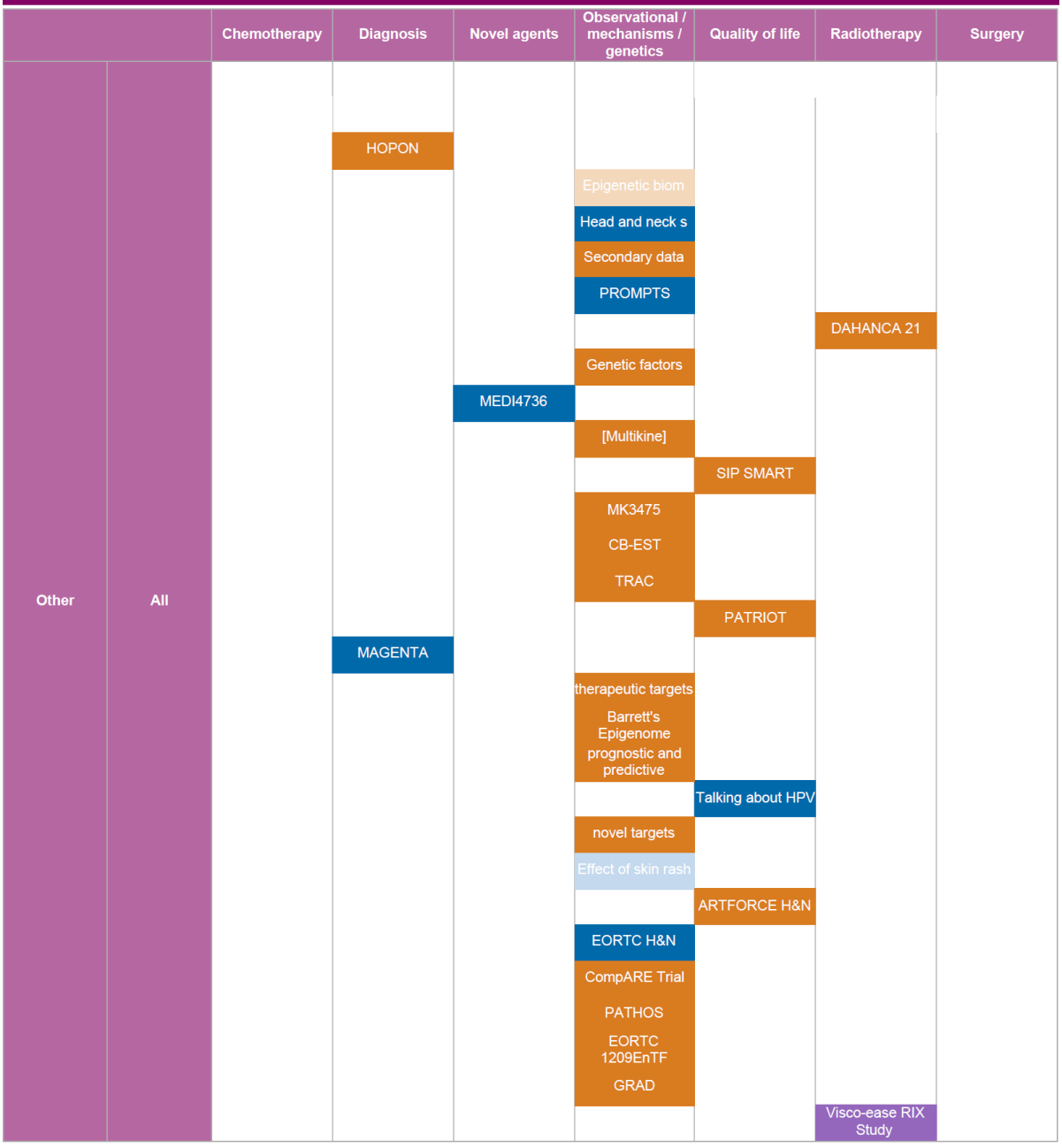
Filters Used:
Active Status: All, **CSG Involvement**: All, **Funding Type**: All, **Phase**: All

Open Multi CSG
Open Single CSG
Null
In Set-Up NHS Per..
In Set-Up Pending ..

NCRI portfolio maps

Head and Neck Cancer

Map E – Cross-cutting: other
Click ↓ below to reset map



Filters Used:
Active Status: All, **CSG Involvement**: All, **Funding Type**: All, **Phase**: All

Open Multi CSG
Open Single CSG
Null
In Set-Up NHS Per..
In Set-Up Pending ..
In Set-Up Pending ..

Appendix 4

Publications in the reporting year

PANDORA Trial

Graham KA, Mulhall HJ, Labeed FH, Lewis MP, Hoettges KF, Kalavrezos N, McCaul J, Liew C, Porter S, Fedele S, Hughes MP. A dielectrophoretic method of discrimination between normal oral epithelium, and oral and oropharyngeal cancer in a clinical setting. Analyst. 2015 Aug 7;140(15):5198-204. doi: 10.1039/c5an00796h. PubMed PMID: 26086875.

Appendix 5

Major international presentations in the reporting year

PET-NECK study results

Hisham Mohamed Mehanna, et al. PET-NECK: A multi-centre, randomized, phase III, controlled trial (RCT) comparing PETCT guided active surveillance with planned neck dissection (ND) for locally advanced (N2/N3) nodal metastases (LANM) in patients with head and neck squamous cell cancer (HNSCC) treated with primary radical chemoradiotherapy (CRT). J Clin Oncol 33, 2015 (suppl; abstr 6009) - ASCO June 2015

Quality of life of HPV+ versus HPV negative patients

H. Mehanna, W.L. Wong, C.C. McConkey, J.K. Rahman, M. Robinson, A. Hartley, C. Nutting, N. Powell, H. Al-Booz, M. Robinson, E. Junor, C. Hulme, A.F. Smith, P. Hall, J.A. Dunn. Differences in the quality of life (QoL) and functional outcomes of treatment between HPV associated (HPV+) and HPV - patients receiving primary chemoradiotherapy in PET-NECK - a multi-centre randomized phase III controlled trial (RCT) comparing PETCT guided active surveillance with planned neck dissection (ND) for locally advanced (N2/N3) nodal metastases (LANM) in patients with head and neck squamous cell cancer (HNC) treated with primary radical chemoradiotherapy (CRT) – ESMO 2015