

Head and Neck International Group
Baseline Questionnaire: Year 2014-2015
SUMMARY REPORT

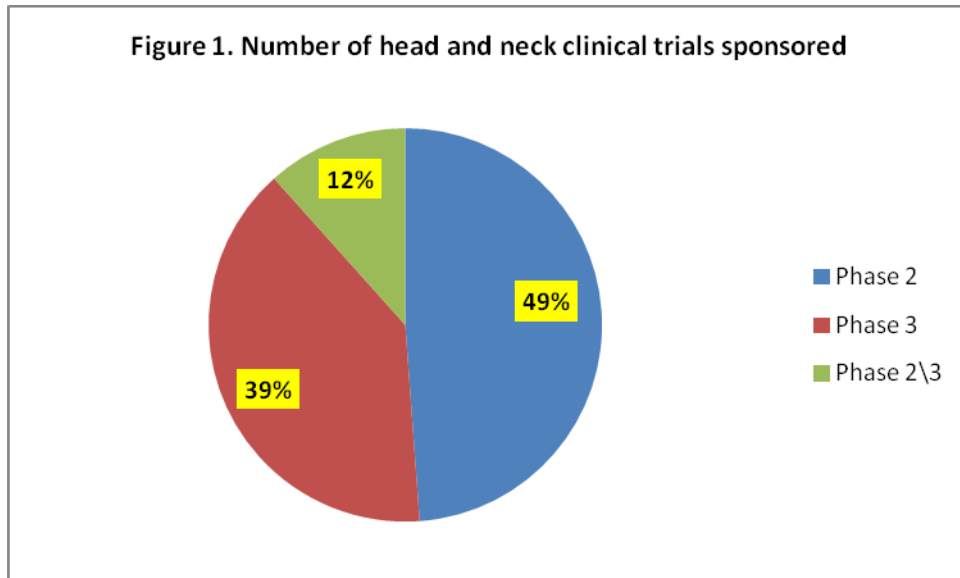
- A total of 17 Head and Neck Cancer Investigators were invited to complete the questionnaire, of those, 13 (68%), completed their responses. The following international head and neck cancer groups were represented in the baseline questionnaire:
 1. ECOG-ACRIN (USA)
 2. EORTC (Europe)
 3. Fudan University (China)
 4. GORTEC (France)
 5. Hellenic HN Group (HHNG) (Greece)
 6. Japan Clinical Oncology Group (JCOG) (Japan)
 7. National Cancer Center Singapore (NCCS) (Singapore)
 8. National Cancer Institute Canada Clinical Trials Group (NCIC) (Canada)
 9. NCRI (United Kingdom)
 10. NRG (USA)
 11. NWHHT (Netherlands)
 12. Taiwan COG (Taiwan)
 13. Tata Memorial Hospital (TMH) (India)
 14. Trans Tasman Radiation Oncology Group Limited (TROG) (Australia)

- Table 1 shows the number of all the Phase 2 and 3 head and neck clinical trials (surgical, radiation, therapeutic) currently sponsored by the groups mentioned above by HNIG. Only approved, active and ongoing studies are included in the table below (Please refer to Table 3 for a detailed list).

Table 1. Number of Phase 2 and 3 Head and Neck Clinical Trials by HNIG.

HNIG	Phase 2	Phase 3	Phase 2\3
ECOG-ACRIN	3	0	0
EORTC	2	1	0
Fudan University	0	0	0
GORTEC	0	0	0
HHNG	0	0	0
JCOG	2	0	1
NCCS	1	1	1
NCIC	0	1	0
NCRI	1	2	0
NRG	5	1	1
NWHHT	1	2	1
TCOG	0	0	1
TMH	4	7	0
TROG	2	2	0

- A total of 43 head and neck clinical trials were reported as being sponsored at each at the groups; of those, 49% were Phase 2, 40% were Phase 3, and 12% were Phase 2\3 clinical trials (Figure 1).



- In the last past years, a total of 43 were opened, 4 were closed, and 21 were closed early as per protocol (Table 2).

Table 2. Number of Phase 3 clinical trials open for enrollment in last 5 years.

Phase 3 Trials	n
Opened?	43
Closed early?	4
Closed per protocol (including after pre-planned interim analysis)?	21

- Currently, a total of 29 Phase 3 head and neck clinical trials are opened for enrollment among the groups that responded the baseline questionnaire (data not shown).
- The majority (n=9) reported having a collaboration formal policy. Also, having an informal collaboration policy to conduct head and neck clinical trials was reported by 4 groups. The number of HN groups that decide separately for each HN trial was five. Among the types of collaborations reported, it is worth noting that one group reported having 2 types of collaboration policies and two groups reported having 3 types of collaboration policies.
- Among those groups reporting having a collaboration, 9 of them expressed several opinions, as noted below:
 - *Yes, Collaboration in progress with EORTC*
 - *Yes in future depending on protocol*
 - *I would like to establish a collaboration between the UK's National Cancer Institute's Head and Neck Group, which I chair and the HNIG to harmonize clinical trials processes and procedures.*
 - *Norms, regular communication, the flow of information and resource sharing.*
 - *Yes, in inviting participation from other centers in clinical trials designed and initiated by the TMCHNWG & participating in ongoing studies within the HNIG.*

- *Yes! Each group conducts the trial according to the same protocol. Finally, the combined analysis will be performed.*
- *Yes I believe that international collaboration will make feasible the execution of large randomize trials in HNSCC.*
- The responders provided a brief description of their organization's policies related to international bio-banking of tissue samples, as follow:
 - *Not applicable*
 - *Dictated by local institutions willingness to release samples*
 - *According to EORTC guidelines*
 - *International bio-banking of tissue samples is possible but is a complex procedure. Many of the centres in our collaboration will approve international bio-banking provided the appropriate governance and ethics approvals are in place.*
 - *It will done according government policy*
 - *Our organization has a in-house biospecimen bank. International bio-banking of tissue is subject to IRB approval of individual studies.*
 - *We follow the Indian Regulations for the same*
 - *EORTC has an established and recognized policy for collection and storage of Human Biological Material in order to ensure preservation and maintain traceability.*
 - *There is no policy of the DHNS concerning international bio-banking*
 - *No policies related to international bio-banking of tissue samples. Only domestic.*
 - *Local bio-bank allowed.*
- The following NCI-CTEP agents were of interest for a head and neck clinical trial:
 - *Agents targeting: stem cell pathways PI3K/AKT/mTOR Ras/Raf/Mek/Erk agents for Epigenetic priming*
- The partnerships with pharmaceutical companies were noted:
 - *Astra Zeneca, BMS, and with several smaller pharmaceutical companies.*
 - *Pfizer (palbociclib) Astra Zeneca (PD1,PDL1)*
 - *We are currently developing a WEE1 inhibitor to be used in trials along with Cisplatin*
- Expectations as member of the HNIG
 - *We would like more collaboration and the introduction of more phase III clinical trials in Australia.*
 - *To collaborate in future studies through participation or leadership*
 - *Excellent initiative, we look forward to see what can be done with other groups*
 - *As a member of HNIG I would hope that we would increase collaborations on: 1. The harmonization of clinical trial processes between groups. 2. Improving and increasing the number of studies that can be done internationally.*
 - *International collaborations to answer clinically important questions which might be impossible on single centre/country setting. 1. Enhance knowledge sharing in cancer research. 2. Advice on approach and direction for H&N cancer research*
 - *We would like to be an active group, collaborating with other members in the design, participation and implementation of clinical, translational and basic science research in Head and Neck cancers. We would be keen in being involved in networking with interested partners in the region and globally, making useful contributions towards all aspects of Head and Neck Cancer, from treatment, education to research.*
 - *Share strategic developments, designing and participate in global trials*

- *Collaboration to conduct the clinical trial for rare cancer.*
- *I am very enthusiastic with the potential of this intergroup effort HNSCC is a rare disease and this collaboration will make feasible the execution of practice changing studies*
- *Take the first step towards international collaboration of head and neck cancer trials.*

TABLE 3. HEAD AND NECK PHASE 2 AND 3 CLINICAL TRIALS by HNIG.

NCT number	Local Protocol Number	Phase	Title
ECOG-ACRIN			
01824823	E1311	2	Afatinib after Chemoradiation & surgery in Treating patients with Stg III-IV at high risk of recurrence
01898494	E311	2	Transoral surgery followed by Low dose or standard dose radiation with or without chemotherapy in treating patients with HPV positive Stage III -IV
00588770	E1305	2	Chemotherapy with or without Bevacizumab in oropharyngeal cancer without Bevacizumab in treating patients with recurring or metastatic HNC
EORTC			
NCT01538381	90111 - 24111	2	Neoadjuvant Afatinib Window Study in Squamous Cell Carcinoma of the Head and Neck
NCT01969578	1206 - HNCG	2	Androgen Deprivation Therapy in Advanced Salivary Gland Cancer
NCT01880359	1219 - ROG-HNCG	3	AF CRT +/- Nimorazole in HPV/p16 NEG HNSCC
Fudan University			
-	-	-	-
GORTEC			
-	-	-	-
HHNG			
-	-	-	-
JCOG			
UMIN000009125	JCOG1008	2\3	Phase II/III Trial of Postoperative Chemoradiotherapy Comparing 3-Weekly Cisplatin with Weekly Cisplatin in High-risk Patients with Squamous Cell Carcinoma of the Head and Neck
UMIN000001272	JCOG0706	2	Phase II trial of chemoradiotherapy concurrent with S-1 plus cisplatin in patients with unresectable locally advanced squamous cell carcinoma of the head and neck (JCOG0706)
UMIN000013706	JCOG1212	2	Dose finding and confirmatory trial of super selective intra-arterial infusion of cisplatin and concomitant radiotherapy for patients with locally advanced maxillary sinus cancer (JCOG1212, RADPLAT-MS)

TABLE 3. (continued)

NCT number	Local Protocol Number	Phase	Title
NCCS			
NCT00957086	IHN01	3	Phase III, Double-Blind, Placebo-Controlled Study of Post-Operative Adjuvant Concurrent Chemo-Radiotherapy With or Without Nimotuzumab for Stage III/IV Head & Neck Squamous Cell Cancer
NCT00690872	-	2	Phase II Trial Evaluating Efficacy of a Strategy Employing Combination Gemcitabine and Carboplatin Chemotherapy Followed by EBV-Specific Cytotoxic T-Lymphocytes in Patients With Metastatic or Locally Recurrent EBVPositive Nasopharyngeal Carcinoma
NCIC			
NCT00820248	-	3	Radiation Therapy and Cisplatin or Panitumumab in Treating Patients With Locally Advanced Stage III or Stage IV Head and Neck Cancer
NCRI			
NCT02040207	AM-101-CL-12-04	3	AM-101 in the Treatment of Post-Acute Tinnitus 2 (AMPACT2)
NCT02040194	AM-101-CL-12-02	3	AM-101 in the Treatment of Acute Tinnitus 3 (TACTT3)
NCT02207530	D4193C0001	2	Phase II Study of MEDI4736 Monotherapy in the Treatment of Patients With Recurrent or Metastatic SCCHN
NRG			
-	RTOG 0912	2	A Randomized Phase II Study of Concurrent Intensity Modulated Radiation Therapy (IMRT), Paclitaxel, and Pazopanib (NSC 737754)/Placebo for the Treatment of Anaplastic Thyroid Cancer
-	RTOG 0920	3	A Phase III Study of Postoperative Radiation Therapy (IMRT) +/- Cetuximab for Locally-Advanced Resected Head and Neck Cancer
-	RTOG 1008	2	A Randomized Phase II Study of Adjuvant Concurrent Chemotherapy and Radiation in Resected High Risk Malignant Salivary Gland Tumors
-	RTOG 1216	2/3	Randomized Phase II/III Trial of Surgery and Postoperative Radiation Delivered with Concurrent Cisplatin Versus Docetaxel Versus Cetuximab and Docetaxel for High-Risk Squamous Cell Cancer of the Head and Neck

TABLE 3. (continued)

NCT number	Local Protocol Number	Phase	Title
-	RTOG 1221	2	Randomized Phase II Trial of Transoral Endoscopic Head and Neck Surgery followed by Risk-Based IMRT and Weekly Cisplatin versus IMRT and Weekly Cisplatin for HPV Negative Oropharynx Cancer
-	NRG-HN001	2\3	Randomized Phase II and Phase III Studies of Individualized Treatment for Nasopharyngeal Carcinoma Based on Biomarker Epstein Barr Virus (EBV) Deoxyribonucleic Acid (DNA)
-	NRG-HN002	2	A randomized Phase II Trial for Patients with p16 positive, Non-Smoking Associated, Locoregionally Advanced Oropharyngeal Cancer
-	RTOG Foundation 3501	2	TryHard: A Phase II, Randomized, Double Blind, Placebo-Controlled Study of Lapatinib (Tykerb®) for Non-HPV Locally Advanced Head and Neck Cancer with Concurrent Chemoradiation
NWHHT			
NWHHT 2014-01	-	3	Uniform FDG-PET guided GRAdient Dose prEscription to reduce late Radiation Toxicity (UPGRADE RT study)
NWHHT 2015-01	-	3	Dutch randomized multicenter trial COmparing twO Palliative RAdiaTION schemes for incurable head and neck cancer (COOPERATION study)
NWHHT 2013-01	-	2	A phase Ib-II study of the combination of cetuximab and methotrexate in recurrent or metastatic squamous cell carcinoma of the head and neck (COMMENCE study)
NWHHT 2011-01	-	2\3	Efficacy and Cost Efficacy of Prophylactic treatment with Antibiotics during concomitant chemoradiotherapy in patients with locally advanced head and neck cancer to prevent Aspiration Pneumonia (PANTAP study)
TCOG			
NCT01744587	T2312	2\3	Study of Epstein-Barr Virus Reactivation and the Effect of Dietary Supplement Epigallocatechin Gallate (EGCG) on Virus Reactivation in Remission Patients with Nasopharyngeal Carcinoma – A Randomized Trial.
Tata Memorial Hospital			
NCT00193765	CTRI/2013/04/003568	3	Elective versus Therapeutic Neck Dissection in the treatment of early node negative squamous cell carcinoma of the oral cavity

TABLE 3. (continued)

NCT number	Local Protocol Number	Phase	Title
NCT00193843	-	3	Phase III trial of surgery followed by conventional radiotherapy (5 fractions/week) vs concurrent chemoradiotherapy vs accelerated radiotherapy (6 Fractions/week) in high risk, locally advanced stage III & iva, resectable, squamous cell carcinoma of oral cavity
-	-	2	A randomized trial comparing intensity modulated external beam radiation alone vs intensity modulated radiation and brachytherapy for reduction in xerostomia in patients with early staged oropharyngeal cancers
-	-	2	A prospective randomized phase II Study comparing metronomic chemotherapy with chemotherapy (single agent cisplatin), in patients with metastatic, relapsed or inoperable squamous cell carcinoma of Head and Neck
-	CTRI/2014/09/00498 0	3	An Open label, Randomized, Investigator Initiated Multicentric, Phase III Study of Nimotuzumab in combination with Concurrent Radiotherapy and Cisplatin versus Radiotherapy and Cisplatin alone, in Subjects with Locally advanced Squamous Cell Carcinoma of the Head and Neck (LASCCHN)
-	2012/10/00/3062	3	Phase III non-inferiority randomized trial comparing three-weekly Cisplatin versus weekly Cisplatin in combination with radiation therapy in patients with advanced carcinoma of the head and neck
-	REF/2014/08/00750 0	3	Randomised controlled trial assessing addition of neoadjuvant and maintenance oral Metronomic chemotherapy to standard surgery and adjuvant therapy in Stage III/IV Operable Oral cancers
-	-	2	Phase II Randomised Controlled Trial Of Postoperative Intensity Modulated Radiotherapy (IMRT) in Locally Advanced Thyroid Cancers
-	-	2	Protocol No. CABAZL06500- A phase II controlled clinical trial comparing efficacy of Cabazitaxel versus Docetaxel in recurrent head and neck cancer in India
-	-	3	Prophylactic antibiotics in operable oral cancer: one versus five days – a randomized control trial

TABLE 3. (continued)

NCT number	Local Protocol Number	Phase	Title
-	-	3	A randomized multicentre trial of accelerated hypo –vs. normo-fractionated radiotherapy for head and neck squamous cell carcinoma (IAEAHYPNO trial)
TROG			
-	TROG 12.03	2	An RCT of psychological training for dieticians to reduce malnutrition and depression in head and neck cancer patients undergoing radiotherapy (Eating As Treatment: EAT)
01855451	TROG 12.01	2\3	A randomised trial of weekly cetuximab and radiation versus weekly cisplatin and radiation in good prognosis locoregionally advanced HPV-associated oropharyngeal squamous cell carcinoma (HPV OROPHARYNX)
00704639	TROG 07.04	1\2	A Phase I/II trial of Cetuximab, Carboplatin and Radiotherapy for patients with locally advanced Head and Neck Squamous Cell Carcinoma.
01917942	TROG 07.03	3	Radiotherapy with humidification in head and neck cancer. A randomized phase III trial of the Trans Tasman Radiation Oncology Group in collaboration with Fisher and Paykel Healthcare