

# HEAD AND NECK CANCER INTERNATIONAL GROUP (HNCIG)

25 SEPTEMBER 2015

VIENNA, AUSTRIA

## MINUTES

Present: Ethan Argiris (HeCOG, Hellenic Oncology Research Group), Pierre Blanchard (NACH-NC/NARCH), Jean Bourhis (GORTEC), Ezra Cohen (NCI-HNSC), Chaosu Hu (Fudan University and the Chinese Anti-Cancer Association, HN), Denis Lacombe (EORTC), Hisham Mehanna (UK NCRI HNCSSG), Marco C. Merlano (G.O.N.O., Northwest Oncology Group, Italy), Jens Overgaard (DAHANCA), Amanda Psyrri (Hellenic Cooperative Oncology Group), Makoto Tahara (Japanese Clinical Oncology Group), Ulrich Keilholz (IAG-KHT Germany), Jan Vermorken (Advisor), Jack Welch (U.S. NCI, Center for Global Health).

Regrets (in some cases, represented by proxies, above): Vincent Grégoire (EORTC), Yoke-Lim Soon, Melvin Chua (NCC, Singapore), Danny Rischin, Sandro Porceddu (TROG), Sarbani Laskar (TMH), Jorgen Johansen, Claus Kirstensen (DAHANCA), Andreas Dietz (IAG-KHT Germany), Dora Kwong, Brigitte Ma (HKNPCSG), Randal Weber, John Waldron (NCIC-CTG),

Dialed-In: Bob Ferris (ECOG), Quynh Le (NRG), John Waldron (NCIC-CTG)

1. Introductions: Those present and on the phone introduced themselves and their groups.
2. Administrative update: The Elisabeth Dupont of the U.S. Center for Global Health had been the primary administrative coordinator for this group, but she left NCI in August. Dr. Jack Welch is now functioning as group administrator; please copy him in all correspondence. His email is [jack.welch@nih.gov](mailto:jack.welch@nih.gov).
3. Review of previous minutes: There was a request for more detail in meeting minutes. Minutes were otherwise approved.
4. Statutes: Members were asked to comment on the version of the statutes circulated immediately prior to this meeting. Comments to be integrated into the next version of the statutes included:

- Remove references to gynecology carried over from the template document
- Amend the type of studies within the scope of the HNCIG groups to include meta-analyses
- In more than one place in the statutes, member groups are defined as “has...participated in...studies”; amend to reflect that this may be ongoing, i.e., “has participated or is participating in...”
- There were two concerns regarding special provisions for the U.S. NCI that appear in the statutes:
  - “NCI Center for Global health will have an ex-officio, but non-voting seat on the Board of Directors” – In discussion, the rationale was put forward that whatever organization is functioning as the secretariat would benefit from having some non-voting presence on the board level. There was agreement that the statutes could be amended this way, tying the role not to NCI, but to whatever organization assumes this function.
  - “The NCI HNSC will have an ex-officio, but non-voting seat on the Board of Directors” – This was a more contentious issue as it treats this network differently than others. Given the size and potential contribution of the US cooperative group system and desire to reach its various sections through a central contact, it was agreed to compromise that a representative of the NCI Head and Neck Scientific Steering Committee, who is privy to discussion across the U.S. National Clinical Trial Network across cooperative groups, could have a place on the Board, but that this person will not have a vote in that capacity.
- Clarification is needed about HNCIG organization: membership, board, executive board, etc.
  - The secretariat will produce an organogram and include it in the statutes
  - Generally, people present agreed to this structure, which will be elaborated in the statutes:
    - General Assemblies – Large meetings for general discussion; up to three members present per group. Ideally, these three would represent different H&N subspecialties: surgical, medical and radiation. The HNCIG may invite non-members to contribute informationally to these meetings.
    - Board of Directors – Decision-making body; one vote per group. A specific person has that vote but may delegate to other members of that group with notice. To assure that there is no uncertainty about which person officially represents a given group, group chairs will be asked to identify their official representative on letterhead. To designate a proxy for a specific meeting, the representative should communicate that intention before the meeting to the HNCIG secretariat, e.g., by email.
    - Executive Committee – Group officers who are responsible for implementing the decisions of the Board of Directors on a day-to-

day basis. Specific officer positions and means of appointment will be described in the statutes.

- Election of officers
  - Statutes will clarify that officer positions are specific to individuals, not groups.
  - Before officers can be elected, the existing groups need to identify their official representative. A deadline will be set for this, and after that deadline, these representatives will be asked to submit nominations for the executive committee officers. These officers do not have to be drawn from members of the board of directors. Voting will occur electronically. In case a person is nominated for more than one position, voting results will be resolved from highest to lowest position.
  - The past-chair position will initially be unfilled.

5. Intergroup name and logo: After much discussion, there was consensus to go with “Head and Neck Cancer International Group”, abbreviated HNCIG, as the official name of this organization. Groups are asked to submit logo ideas, or if they are feeling artistic, designs.

#### 6. Group membership

- According to the statutes, member groups must demonstrate that they are actively involved in head and neck cancer clinical research. The founding member groups for the intergroup are defined in the statutes as those that were present at the 2014 HNCIG kickoff meeting in Nice, France.
- A request was made and generally accepted to add ICORG (the Irish Cooperative Oncology Research Group) to the HNCIG on par with founding groups.
- There needs to be some review of existing and future groups to assure compliance with the group membership requirements. After group representatives have been identified, a membership subcommittee can be formed at a future board meeting. In preparation for that, the secretariat will ask existing groups to provide their evidence of their activity.

7. Database: There was agreement that an important central function of the intergroup would be maintenance of a head and neck cancer database to track projects by member groups. The database would include group projects regardless of whether these projects are badged as HNCIG projects. To keep the database current and spread the load, it was recommended that an implementation be adopted that facilitates distributed editing, e.g., a wiki, with each group responsible for its own portfolio. Jean Bourhis indicated that he would look into the possibility of hosting this service on the GORTEC website.

8. Group updates: Groups provided updates about their current portfolios and opportunities for collaboration.

- DAHANCA.
  - Current portfolio consists of 31 protocols. Most trials are related to radiation therapy: hypoxic modification, accelerated fractionation, EGFR inhibitors, dose modification. Currently, there is a focus on HPV negative patients.
  - Phase II: Increased radiation dose with weekly cisplatin and hyperfractionation.
  - Phase II: Dose escalation based on imaging
  - Non-inferiority study in glottis cancer: laser-based therapy.
  - DAHANCA29 – in collaboration with EORTC (EORTC 1219) – experimental arm is the standard arm in Denmark. Hypoxia gene classifier being investigated as a predictive marker. Now accrued about 75/640 patients, running at 7 institutions in EU; discussion with Canada and TROG.
  
- GONO
  - GONO has published late phase head and neck clinical trials in high-impact journals such as NEJM since the 1990s.
  - Current trial: INTERCEPTOR
  - Recurrent / metastatic HNC: randomized phase II: cisplatin + cetuximab vs. cisplatin + cetuximab + taxol
  
- GORTEC
  - Francophone group created 15 years ago.
  - Has completed more than 15 randomized trials; about 4000 patients randomized in most recent studies.
  - Current
    - Locally advanced: +/- SMAC inhibitor
    - Larynx preservation
    - Cispt 100 mg versus 4 x 25 mg
    - Afatinib post-op trial
    - Salivary gland tumor: RT + cispt
      - Comment from Quynh Le: RTOG 1202 is a similar study; maybe some opportunity for collaboration.
    - HPV+ trial
    - Metastatic trial – collaboration with TCC (Spanish) and AIO (German) groups
    - Oligometastatic: stereotactic versus systemic treatment
    - Early stage: BESTOF trial: transoral surgery versus IMRT in T1 and small T2 oropharyngeal cancers; perhaps in collaboration with EORTC. Maybe of interest to UK, SAKK, others. DAHANCA also expressed interest.
  
- Hellenic Cooperative Oncology Group
  - 5 randomized studies in NP and locally advanced nonsq HNC

- Biobank of FFPE tumor tissue
- Current: Phase II window study of PARP inhibitor: PARP + platinum vs PARP + antiPDL1 (about 60 patients)
- JCOG
  - Largest cooperative group in Japan
  - 0706: phase II of concurrent chemoradiotherapy S1 plus CisPt for advanced disease
  - 1008: randomized phase II/III; now 95 accrued out of 260; potential intergroup trial – now in discussion with Italy, Portugal, and maybe UK
  - Phase I/II
  - Planned phase III trial – therapeutic neck dissection – tongue cancer
- UK NCRI, H&N Clinical Study Group
  - Ten year track record for HN studies, 4 trials published on about 2500 patients.
  - Thirty-one studies open; most are randomized, controlled, comparative studies.
    - COMPARE Trial – in discussion with GORTEC and SAKK – intermediate and high risk HNC – currently looking for collaboration
    - De-escalate study – NCRI + ICORG; one more year to run – similar to RTOG 1016, but only low, not intermediate risk
    - PATHOS - Phase II – oropharyngeal HPV+ treated with surgery and then de-escalate radiation dose for intermediate post-op group and RT/chemo for intermediate high-risk group
    - ARTDECO - Dose escalation chemo rt for laryngeal and hypoharyngeal disease
    - NIMRAD: A Randomised Placebo-controlled Trial of Synchronous NIMorazole Versus RADiotherapy Alone in Patients With Locally Advanced Head and Neck Squamous Cell Carcinoma Not Suitable for Synchronous Chemotherapy or Cetuximab
    - Randomized hyperbaric oxygen preventative study for osteo radionecrosis
  - Just finished 5000 patient HNC study observational cohort study

#### NRG

- Immunotherapy trial
- Post op – intermediate risk RT +/- cetuximab
- Saliva gland tumor– RT with weekly boost
- NPC study with collaboration with Fudan University Medical Center, Hong Kong, Singapore, Taiwan – EBV DNA studies

- Post-op Afatinib – looking for collaboration
- Development work on a re-irradiation study for recurrent metastatic disease

#### NCIC CTG

- Active for about eight years
  - HN6 – randomized – 320 pts
  - Working on EORTC 1219 in Canada

#### Institute Gustave Roussy, H&N group

- Group founded 25 years ago by Pignon et al.
- Continuous update of meta-analysis of HN trials (meta-analysis of chemotherapy in head and neck cancer, MACH-NC)
- Nasopharyngeal carcinoma: induction chemotherapy
- EGFR meta-analysis – trying to pool studies; including those from pharma – to start next year
- Interested to interact with groups to gain sources for datamining, but also to see if they have scientific questions that could be analyzed in the data set.

#### ECOG

- Recently finished: Recurrent metastatic – doublet of choice plus bevacizumab
- Next: randomized phase II 41BB antibody or PD1 Antibody
- Recurrent metastatic in p53 subset: RT vs ChemoRT
- ECOG 3311

#### EORTC

- EORTC 1219 – as above
- Window study with afatinib with translation components
- In discussion: adjuvant PD1 blockade
- Androgen receptor positive salivary study: androgen blockade versus chemotherapy
- BESTOF Trial

#### 9. Next meeting:

- Next meeting – alongside the 2016 Multidisciplinary Head and Neck Symposium in Scottsdale, Arizona. Feb 18, 19:00h.

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#### Action Items:

- Minutes review – Groups will review minutes, make edits/corrections and send back to secretariat by October 15. Secretariat will compile a final version and redistribute to the mailing list.

- Statutes – When final minutes are available, which includes comments on statutes, an updated version of statutes will be circulated by the Secretariat. This update will include a draft organogram. After a two week review period for comments, the secretariat will produce a revised draft, which will be the base document for the next meeting.
- Identification of board members: The membership is asked to provide contact details for their respective cooperative group chairs. The secretariat will send a request to each group chair asking that they send back a letter on official stationery appointing a person as voting representative for that group on the HNCIG board of directors.
- Submission of cooperative group credentials: The membership is asked to submit a background document for their group, which provides evidence of activity of the group to satisfy the membership requirement identified in the statutes.
- HNCIG logo: Membership will submit logo ideas and designs to the secretariat for discussion at the next meeting.
- Web portal and database: GORTEC will review possibility of hosting a HNCIG website.
- Election of executive committee officers: If statutes can be finalized and accepted, and groups have identified their voting members prior to the next face-to-face meeting, the secretariat will solicit those voting members for nominations for these officer positions. Voting can be performed online.