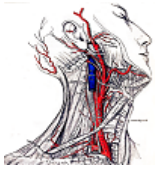

Head and Neck Cancer International Group (HNCIG)

7 October
12:00 – 14:00

Copenhagen Admiral Hotel
Toldbodgade 24-28, 1253 København K

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Minutes (FINAL)

Present: Jens Overgaard (DAHANCA, Denmark), Jorgen Johansen (DAHANCA, Denmark), Claus Andrup Kristensen (DAHANCA, Denmark), Jean-Pierre Pignon (Gustav Roussy, Meta-Analysis, France), Marco Merlano (GONO, Italy), Jan Vermorken (Advisor), Maura L. Gillison (NRG, USA), Martin Forster (NCRN, UK), Ye Guo (Fudan University Cancer Center, China), Darren Poon (Hong Kong Nasopharyngeal Cancer Study Group), Victor Lee (Hong Kong Nasopharyngeal Cancer Study Group), Jean Bourhis (GORTEC, France), Hisham Mehanna (HNCIG Secretary; NCRI, UK), Quynh Le (HNCIG Chair; NRG, USA).

Present by phone: John Waldron (Canadian Clinical Trials Group), Amanda Psyrri (Hellenic H&N Group), Mu-Hung Tsai (Taiwan Cooperative Oncology Group), Sarbani Ghosh (Tata Memorial Centre), Kiattisa Sommat (National Cancer Center Singapore).

1. Introductions and notification of AOB

2. Minutes from the previous meeting (June 2016, Chicago) were approved by acclamation.

3. Prioritized Committees

HNCIG leadership have identified two committees that need to be filled immediately: a membership committee so additional groups can become part of the intergroup, and a committee for harmonization and standardization of H&N cancer clinical trials, a top priority for the intergroup.

a. Membership Committee

At the previous meeting, it was agreed that the membership committee would consist of two representatives from each global region: Americas, Europe, and Asia/Pacific/Oceania. A call was made for nominations, and the following nominations were received:

Americas: Stu Wong (NRG), Barbara Burtness (ECOG), John Waldron (CCTG)
Europe: Jan Vermorken (Advisor) and Amanda Psyrri (Hellenic H&N Group)
Asia/Pacific/Oceania: Kiattisa Sommet (Singapore NCC), Prathamesh Pai (TMC, India), and Sandro Porceddu (TROG)

After review of these nominations, there was discussion. Dr. Overgaard raised some concern over whether the committee formation process was unnecessarily bureaucratic, and recommended that HNCIG minimize the number of committees to be created.

In the interest of geographic diversity, it was agreed that for the Americas, one US representative would be selected, along with Dr. Waldron from Canada. Since NRG already has some representation by virtue of Quynh's involvement in all activities, Dr. Burtness was selected as the US representative.

Similarly, in Asia/Pacific/Oceania, where three nominees had come forward, the decision was made to select Dr. Porceddu from Australia and Dr. Pai from India.

The board approved Drs. Wong, Burtness, Vermorken, Psyrri, Pai, and Porceddu to serve three year terms on the membership committee. After that term, geographic regions not represented in the current round would have preference.

All nominees and nominating institutions were thanked for their participation in this process.

This committee will begin its work by teleconference prior to the next face-to-face meeting.

b. Harmonization Committees

The board agreed to set up a committee to work on international harmonization of 1) protocol and endpoints; 2) radiotherapy; 3) surgery; and 4) immunotherapy. The emphasis was on laying down the ground work so the intergroup can move forward on clinical trials using a common set of tools. Of these areas, the committee will focus first on definitions and endpoints; definitions because protocols need share common language. The committee will identify the most clinically relevant endpoints, and in some cases (e.g., immune) consider establishment of new endpoints. In the longer term, HNCIG is in a position to validate more efficient endpoints within clinical trials, e.g., identifying shorter time-to-event endpoints that predict OS. Patient reported outcomes and evaluation of late toxicity and comorbidities will also be within the purview of this committee.

The next step for formation of this committee is solicitation of membership from groups, and determination of a char and co-chair to lead the committee. Ideally, this group will begin work prior to the next face-to-face meeting of HNCIG. Follow-up on this item will be via email.

DATECAN (DATECAN project - Définition, évaluation et Analyse des criTères de survie dans les Essais randomisés en CANcérologie): Jean-Pierre Pignon presented DATECAN harmonization effort, which recently started to address H&N. The project is primarily European, but has some representation from the Asia and the US. The consensus assessment is based on survey of experts, and in the interest of inclusiveness, it is desirable to expand the number of survey takers. Consequently, the submission date will be delayed and the questionnaire and a paper describing the effort will be distributed to the intergroup. The presentation, paper (Bellera et al. Eur J Cancer

2013;49(4):769-81), and H&N-specific questionnaire are appended to these minutes. Quynh Le will contact DATECAN coordination to settle the cooperation between HNCIG and DATECAN.

4. Intergroup Funding

a. Need for funding and current status

The need for some funding to support the HNCIG was foreseen at the time of its creation, but so far expenses have been relatively minimal and the US NCI has been able to cover the costs associated with teleconferences and meetings. While the NCI is willing to continue this support until the group is firmly established, as the intergroup increases its activities, it will likely incur corresponding expenses. The statutes provide for the collection of dues from members, but at this point, no amount has been set, and the intergroup has not decided to collect dues. At present, there is no mechanism to bring funds, dues or otherwise, into the intergroup.

b. GCIG model

At the last intergroup meeting, it was suggested to ask GCIG what solutions they found for intergroup funding. The following information was extracted from Monica Bacon's response to our query:

- GCIG came together around ovarian cancer trials in 1993 and was formally established in 1997.
- GCIG incorporated in Canada in 2011 as a non-profit (but does not have "charity" status, so it is not a foundation).
- Annual group member dues: $1500 USD
- Annual Industry Partner dues: 10000 Euro.
- GCIG has occasionally received/solicited unrestricted grants in support of specific initiatives or symposia.
- GCIG expenses include:
    - Staff: a part time operations manager, part time assistant operations manager, and hourly contracted book keeper.
    - An annual audit required under Industry Canada.
    - Liability insurance covering D&O (directors and officers of the board), and events.
    - Support for traveling one representative per group to annual harmonization meeting
- The relationship between GCIG and industry is defined in SOPs and statutes (appended to these minutes).

c. Role of Industry

- There was discussion about the how HNCIG would relate to industry: on one hand, concern that accepting funding from industry would lead to industry influence over the group and loss of autonomy in deciding what sorts of intergroup trials to pursue. On the other hand,

industry was viewed as a substantial source of funding, and the argument was made that safeguards could be put in place to carefully define the relationship, preserve academic freedom to pursue the most impactful trials, and to limit contributions to unrestricted grants. No decision was reached on this issue.

d. Next Steps

- Prior to the next face-to-face meeting, HNCIG leadership will approach societies and foundations related to HNC to see if any of them would be willing to maintain an account on behalf of the intergroup. We anticipate that the HNCIG would generate minimal financial activity, particularly in the first few years of our existence, and that this would not be unduly burdensome for an established organization. Progress will be reported at next meeting.
- Support from the European COST Application – Hisham Mehanna reported that his application to the European COST Application had been revised and resubmitted. The five-year, 450000 Euro grant would support activities of the intergroup. This item will be updated at the next meeting.

5. Selected HNC Trials

a. EORTC 1219 : AF CRT +/- Nimorazole in HNSCC
   - EORTC + CCTG + TROG
   - Accrual is behind expectation but new centers are expected to open soon
   - High dose cis-platin had to be eliminated after IDMC review due to unexpectedly high renal toxicity; only the weekly regimen continues.
   - There are no competing study within EORTC, but some potentially competing studieshave been proposed by industry.

b. De-ESCALaTE :
   - Determination of Cetuximab Versus Cisplatin Early and Late Toxicity Events in HPV+ OPSCC
   - Just finished recruitment
   - Requires 2 year follow-up for analysis

c. BESTOF Trial
   - EORTC + GORTEC Intergroup

d. Elderly Proposal
   - On behalf of GONO, Marco Merlano presented a proposal for tailored intensity treatment of H&N Cancers in the elderly (contact: Lisa Licitra).
   - GORTEC are pursuing development of a similar protocol.
   - Danish data covering 30000 patients.
   - The proposal is attached to these minutes.

6. PROBAND-HN (RTOG Foundation 3512)

- RTOG has proposed to conduct PROBAND, A Prospective Multicenter Cohort Study of Patients with Newly Diagnosed Head and Neck Cancer.
- The study would build on LORHAN (Longitudinal Oncology Registry of Head and Neck Carcinoma) registry – initially supported by ImClone. This was a ten-year prospective, longitudinal observational study spanning 100 sites in the USA.
- This next generation registry would be run by the RTOG foundation, with support from unrestricted grants.
- The study will be administrated through a CRO, MedNet Solutions.
- A presentation on PROBAND is appended to these minutes.

7. Meta-analysis of anti-EGFR in locally advanced SCC

   On behalf of the MACH-NC, Jean-Pierre Pignon presented a proposed individual patient data meta-analysis of locally advanced HNSCC, which aims to pool data from 26 randomized trials, 5892 patients, and 7 EGFR-targeted agents (both antibody and TKI). Dr. Pignon solicited the HNCIG endorsement for this project and its members' help to facilitate the identification of eligible trials (a list of trials was circulated during the meeting) and the participation, by providing individual patient data, from cooperative groups and industry partners. The protocol should be drafted by the end of the year, and the intention is to start data collection early in 2017, with analysis by the end of that year for presentation in 2018. Dr. Pignon's presentation is appended to the minutes. The group agreed to support the project.

8. Other New Business

   The HNCIG thanks Dr. Claus Andrup Kristensen of DAHANCA for kindly hosting an informal gathering of the intergroup at his house.

9. Next Meeting

   As previously agreed, the next face-to-face meeting of the HNCIG will occur alongside the March 2017 ICHNO meeting to be held in Barcelona.

10. Adjourn