

HEAD AND NECK CANCER INTERNATIONAL GROUP (HNIG) MEETING

12th February 2015

Room Risso 6 - Acropolis Convention Center (1 Esplanade Kennedy, Nice, France)

DRAFT REPORT

Participants list in appendix 1

1- Welcome and Introductions (Jack Welch, NCI-CGH)

- Brief introduction of all members
- Coordination of international research is part of NCI-CGH's mission
- NCI-CGH's role is to help with the development of the group (communication & coordination)

2- HNIG Mission and Goals

Jack Welch (JW) briefly reminded the mission and the goals of the group.

Mission: to promote and conduct high quality head and neck cancer clinical trials worldwide to improve outcomes in patients diagnosed with these diseases. This is achieved through international collaboration, a strong sense of common purpose, shared expertise, and mutual respect among members

The primary goals of the HNIG are to:

- Promote international cooperation
- Promote clinical research
- Perform studies in rare tumors
- Harmonize the technical aspects of radiation delivery
- Develop a credentialing process for novel radiation or surgical approaches
- Promote translational research
- Stimulate evidence-based medicine
- Support educational activities

3- Gynecologic Cancer Intergroup (GCIG): Lessons Learned - See appendix 2

Brief presentation by Jan Vermorken (JV) on what has been done in order to get GCIG of the ground

- Started from the basis. Conceived in 1993, finalized in 1997, nonprofit status achieved in 2011.
- Collaboration with other cooperative groups, not individual centers - Compliance with specific rules (GCP, adequate indemnity insurance, shown that they were able to complete phase III trials, statistical support)
- 27 member groups, close collaboration with NCI & collaboration with the pharmaceutical industry (that can attend open meetings)
- 20 countries are represented

- Structure & governance:
 - o Chair rotates every two years ("geographical turn")
 - o Executive Board: one representative per member group
 - o Operational manager
 - o 6 representatives from each member group
 - o meetings 2x /year
 - o several committees/working groups
- Importance of the harmonization group to be able to perform international trials
- Academic trials are getting a major attention (specifically rare tumors)
- Promotion of surgical trials
- Consensus meetings every 5 years - Aim: to come on agreement on unmet needs, uniformity and consensus related to trials design, harmonization on quality assurance, what are the best end points in the studies the group is going to conduct. Publication of consensus meetings reports leads to evidence based medicine in relation to trials performance.

Questions/comments

- Contractual & regulatory issues related to the running of international trials
- Funding of academic trials - No funding coming from the intergroup - Initiative from one group that has arranged some funding within the cooperative group & the others can either receive funding from the original funder of the trial or they have to come up with their own funding
- Support of the intergroup could be an asset when applying for support from a pharmaceutical company
- Concept proposals: 2 mechanisms
 1. Favored mechanism: The new proposal is presented to the intergroup at an early stage, discussed within the working groups before coming to a final proposal that will have the label of the intergroup.
 2. Other mechanism: submitting to the group a study that is already running and ask others whether they want to join the study
- Different models of data management
- Biobank at the level of the intergroup is still "virtual"

4- HNIG membership - Introduction made by Brian O'Sullivan (BOS) - See appendix 3

- Brief introduction about the role of US NCI Head and Neck Cancer Scientific Steering Committee - liaison between CTEP & the cooperative groups. In the context of the Head and Neck intergroup: facilitator
- Presentation of the current roster for the H&N Intergroup and how it was created –
 - o Criteria for selection: cooperative groups & large centers that have a track record that demonstrate their ability to conduct phase III clinical trials
 - o Procedure: Invitation of the chairs to make sure that the group is engaged & nomination of representatives
- New members?
 - o Globally open - need to be inclusive

- broad geographical representation
- inclusion of LMICs
- cooperative groups & large centers that have demonstrated the ability to conduct phase III trials H&N trials & to collaborate internationally

- concerns where raised about minimum "qualifications" (quality of phase III clinical trials can vary considerably) - This is an issue that will eventually be dealt with by the leading group who has proposed the trial and who will ultimately decide which center will participate

- process to apply? May be too premature - at the beginning, members need to want to work together and see whether it works out. The willingness to work together is more important than the number of members.

- Some comments about the added value of an intergroup:

- support for academic trials,
- set up of guidelines & need for consensus meeting
- testing new drugs
- leveraging the pharma industry to be able to do new studies
- address the funding issue - "synchronized" calls at the European and international level - how to transfer funding from one European country to another? Role of national charities

Group resolution: *In addition to group already identified, application will be accepted from other clinical trial organizations that have previously demonstrated the ability to conduct phase III H&N trials and collaborate internationally. Incoming applications will be processed by the Executive Committee and presented to the group at the "large" meeting.*

Name of the intergroup

- More "catchy" name?
- Need to include the notion of multidisciplinarity

5- HNIG Governance - Committees & representatives

Executive committee

- About five people, assuring at least one in NA, EU, Asia.
- Should include a representative from EORTC
- GCIG advisor(s) should be invited to help with the establishment of the group
- Will write its own job description - "functional group" that keeps the group moving
- monthly meetings/conference calls

Working groups

- Trials working group
- Harmonization/standardization working group
- The need for a funding committee was also raised. This might be re-discussed at a later stage

6- HNIG website – Public page & private website (Elisabeth Dupont, NCI-CGH)

Brief presentation of the public page and of the private website - Links to the cooperative groups will be added on the public page and invitations to access the private site will be sent to the members. No patients' data on the sites.

7- Proposal for an European network to facilitate and engender co-operation and collaboration in clinical trials in head and neck cancer - Hisham Mehanna, NCRI (UK) - See appendix 4

Hisham Mehanna presented a proposal for EU-funded network to facilitate CT collaboration in H&N cancer; core structure could be used by everyone, although institutional funding would be to EU member and neighbor states.

Aims of the EU cost action mechanism:

- to identify a scientific question around which to build a network
- to build capacity by training early stage researchers/clinicians
- needs to include a patient research advisory group

The group agreed to support the proposal in principle. The application will be circulated for input and comments.

Deadline for submission: mid-March.

Amount of support: 500,000 € over 3 years

It was agreed that, if the application is successful, the funding would be used as seed money to support the harmonization work of the intergroup.

8. HNIG Baseline Questionnaire & HNIG trials

- a- Presentation of the results of the survey (10 minutes - Jack Welch, NCI-CGH) - See appendix 5
Full results will be available on the private website
- b- Definition of HNIG trials
Approval of the following definition: HNIG trials are those Head and Neck cancer trials involving any two or more HNIG member Groups.
- c- On-going trials to bring to the group

NCI will extract from submitted and online data a list of collaborations that already exist between participating groups. With consent of all partners, such trials can be immediately badged as HNIG

It was felt that the first trial that could be labelled as a HNIG trial would be the following one:

| | | | | |
|----------|-------------|---------------------|--------------|---|
| HNIG0001 | NCT01880359 | 1219 - ROG- HNCG | Phase III | AF CRT +/- Nimorazole in HPV/p16 NEG HNSCC |
|----------|-------------|---------------------|--------------|---|

d- New trials to be proposed to the group (see appendix 6-7-8)

Post Post- Operative Concurrent EGFR Inhibition with Afatinib and Radiation Versus Post-Operative Radiation alone in High Risk Cutaneous Squamous Cell Carcinomas of the Head and Neck (presented by Dr Quynh Le)

CompARE: Phase III randomised controlled trial Comparing Alternative Regimens for escalating treatment of intermediate and high-risk oropharyngeal cancer (presented by Dr Hisham Mehanna)

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 (presented by Dr Makoto Tahara and Dr Lisa Licitra)

9. Date of the next meeting

Next in person meeting: ASCO Chicago 2015 (to avoid overlap with GCIG meeting time)

Action items

- Distribute slides from the meeting (presentations & concept proposals)
- Circulate the EuroHN proposal
- Conduct nomination/voting for executive committee
- Forward GCIG structural core documents to HNIG executive committee
- Hold executive committee meeting within the month; agenda: formation of working groups (clinical trials & harmonization), finding a good name that includes "multidisciplinary".
- NCI will extract from submitted and online data a list of collaborations that already exist between participating groups.
- NCI will solicit info on planned trials and collect on central website; we will need a mechanism for partners to update their own material — this will help lighten the central load and keep documents up to date.
- Room reservations for ASCO
- Upload documents to the private website
- Invite members to the HNIG private website
- Public web page - link names of the cooperative groups to their website