



DATECAN Project: Guidelines for endpoint definitions in cancer trials

Anne Aupérin

**For the HNCIG meeting
March 2017 - Barcelona**



Objective of DATECAN

To develop standardized definitions of time to event endpoints in oncology using a formal international consensus process

Bellera et al. Protocol of the Definition for the Assessment of Time-to-event Endpoints in CANcer trials (DATECAN) project: formal consensus method for the development of guidelines for standardised time-to-event endpoints' definitions in cancer clinical trials. **Eur J Cancer 2013;49(4):769-81**

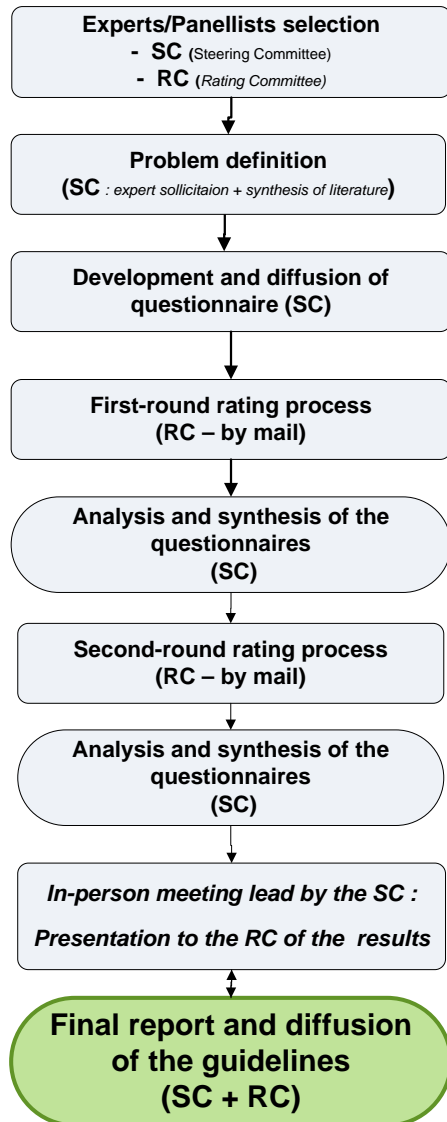


Target cancer sites

- **Done and published**
 - Pancreas cancer (Eur J Cancer 2014)
 - Breast cancer (Ann Oncol 2015)
 - GIST (Ann Oncol 2015)
 - Renal cell cancer (Ann Oncol 2015)

- **In progress**
 - Head & Neck cancer
 - Colo-rectal cancer
 - Stomach/oesophagus
 - Bladder cancer
 - Lung cancer

Consensus method



**Formal Consensus Method
(Delphi method)**
For each cancer site

Inclusion criteria

- **For Steering committee (SC)**
 - Experience in the specialty (>15 years)
 - Principal investigator in ≥3 clinical trials or participation in ≥ 3 research projects
 - ≥ 3 publications in the specialty
- **For Rating committee (RC)**
 - Principal investigator in ≥ 1 clinical trial or participation in ≥ 1 research project
 - ≥ 1 publication in the specialty



Steering Committee for Head and Neck carcinoma part

Name	Specialty	Country
Lisa Licitra	Medical Oncologist	Italy
Kian Ang*	Radiation Oncologist	USA
Bertrand Baujat	Surgeon	France
Gregory Pond	Biostatistician	Canada
Christophe Le Tourneau	Medical Oncologist	France
Catherine Fortpied	Biostatistician	Belgium
Anne Auperin	Biostatistician	France

*Pr Ang unfortunately passed away. We are so much grateful for his contribution to this project.



Problem definition:

Reporting of Time-to-Event End Points and Tracking of Failures in Randomized Trials of Radiotherapy With or Without Any Concomitant Anticancer Agent for Locally Advanced Head and Neck Cancer. C Le Tourneau, S Michiels, HK Gan, LL Siu. J Clin Oncol 2009; 27: 5965-71.

40 trials involving a total of 125 time-to-event end points.

17 different types of end points were reported. Except for survival, the definitions used for all other end points were heterogeneous.

Among 72 end points tracking locoregional failures, 29% did not define the term. The specification of details related to elective neck dissection or salvage surgery to define locoregional failures was deficient.

These results support the **need to standardize the selection, definition, and reporting of time-to-event end points** in clinical trials of locally advanced SCCHN.



Progress status of the Head and Neck carcinoma part:

Questionnaire done by the Steering Committee

List of endpoints and of potential events in five different clinical settings:

- ✓ Initial curative surgery
- ✓ Initial curative radiotherapy +/-chemotherapy
- ✓ Recurrence and/or metastatic disease not suitable for local therapy
- ✓ Organ preservation setting
- ✓ Prevention

Rating committee – first round:

49 experts have filled in the questionnaire of the first round.

Rating Committee for Head and Neck carcinoma part: 49 experts

Continent	N
Europe	36
Asia	7
America	6
Country	N
Belgium	7
France	10
Germany	2
Greece	1
India	1
Italy	8
Japan	6
Netherlands	1
Portugal	2
Spain	3
Switzerland	2
USA	6

Specialty	N
Surgeon	15
Medical oncologist	15
Radiation oncologist	16
Statistician	3

Academic Group	N
EORTC (Europe)	11
Intergroupe ORL – GETTEC – GORTEC - H&N Unicancer (France, Belgium)	11
JCOG (Japan)	5
NRG (RTOG-NSABP-COG) (USA)	4
TTCC - SEOM (Spain)	3
ECOG (USA)	1
FHNO-HNCOG (India)	1
AIRO (Italy)	1
Not specified	12



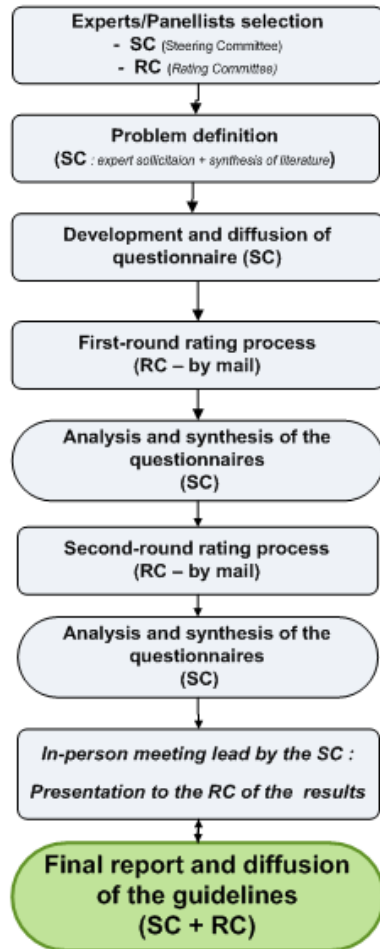
Rating committee for Head and Neck carcinoma part

Some academic groups are not represented in the Rating Committee (DAHANCA, TROG...)

You can still participate by filling in the questionnaire of the first-round rating process.

Deadline to fill in the questionnaire: **End of the ICHNO meeting - 19 March 2017**

DATECAN - Head and Neck



Next step: analysis of the first-round rating
Q2 2017

Contacts for any question

Anne Aupérin: anne.auperin@gustaveroussy.fr

Catherine Fortpied: catherine.fortpied@eortc.be

Christophe Le Tourneau: christophe.letourneau@curie.fr