Year 3, N°9

November 2017

HEAD AND NECK INTERGROUP GORTEC-AIO-TTCC

Enrolment achievement

TPExtreme

Dear Investigators,

The aim of the international phase III randomized trial TPExtreme is to determine the best first-line treatment in recurrent/metastatic head and neck cancer patients in terms of survival : **EXTREME or TPEx.**

We are close to having an answer to this question ! Your contribution was essential during these 3 years. Many thanks to all teams.

Please keep the dynamics to finalize data collection before database lock.

Pr Joël GUIGAY

Contents

Message from the Investigator Coordinator	P.1
Regulatory Update	P.2
Recruitment update	P.2
Important Reminder	P.3
To adequately finish the study	P.3
Study contact Information	P.4

The 540 attended patients had been enrolled in 3 years.

The effort has been considerable and we are grateful for that.

Now comes the time for **data retrieval** and control. This period is also crucial in order to be able to publish the results as close as possible to the date of the end of the research (Last Patient Last Visit).

Thanks therefore to all of you for concentrating your efforts on the data recording in the eCRF and for accepting regular monitoring visits.

This will allow us to get “clean” data faster.

The enrolment of the 540^{h} patient is reached

GORTEC
Groupe Oncologie Radiothérapie Tête Et Cou
Radiotherapy oncology group for head & neck

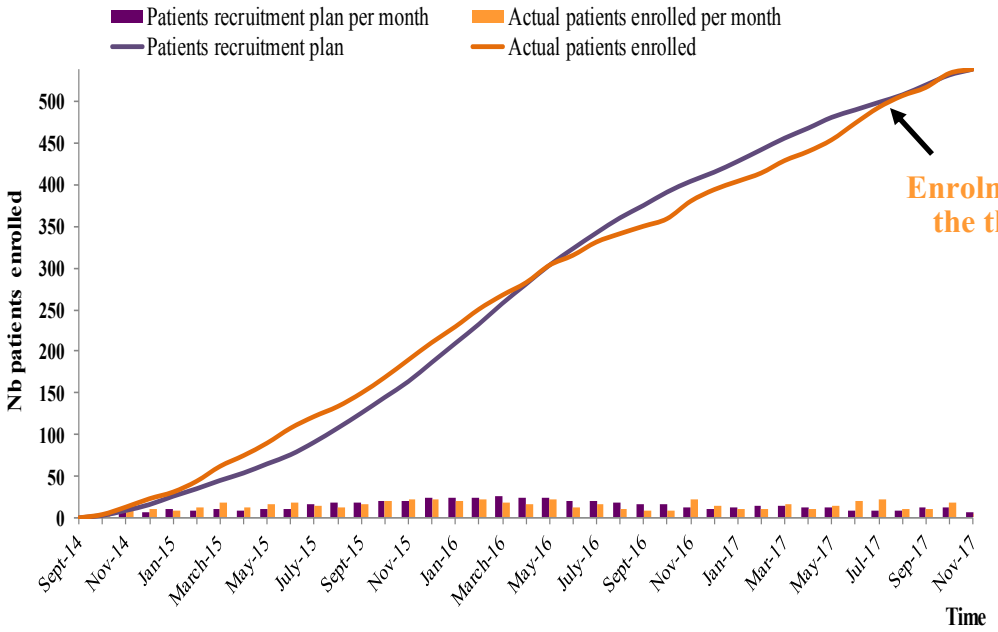
Regulatory Update

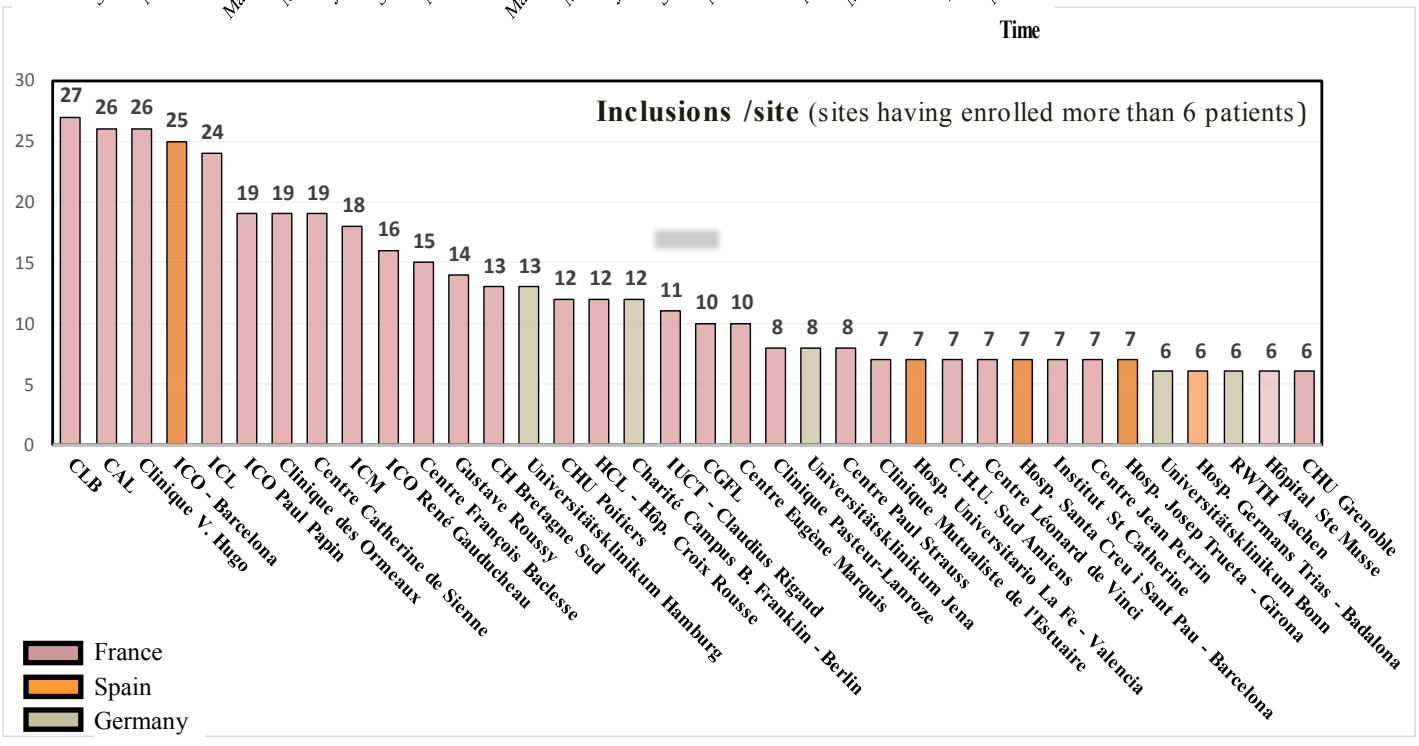
Sites Country	Declared	Initiated	Active sites	Non-active sites: to be closed	Closed or withdrawn
France	61	57	45	5	9
Spain	15	14	11	1	3
Germany	19	14	12	2	5
Total	95	85	68	8	17

Points:
* Close out of inactive sites
* Monitoring ± closure of pharmacy

} will be scheduled within the next months

Recruitment Update





Important Reminder

TREATMENT

* **TPEx arm:** Primary prophylactic administration of **GCSF is mandatory** systematically **after each docetaxel administration** until normalization of ANC (>1.5 x 10^9 /L), usually during 5 days.

Reminder:
No primary prophylactic administration of GCSF is recommended in EXTREME arm.

If chemotherapy is delayed or stopped, patient will continue to receive cetuximab.
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* Dose of cetuximab during maintenance:
  EXTREME arm: **250 mg/m² weekly**
  TPEx arm: **500 mg/m² every 2 weeks**

EXAMS AND PROCEDURES

* **Mandatory Imaging** at Baseline, W6, W12, W18 and W26: **Do not postpone if chemotherapy is delayed**

* **Quality of Life Questionnaires**:
  - EORTC QLQ-C30: Baseline, W12, W18, W26
  - EuroQol-5D (EQ-5D): Baseline, W12, W18, W26 and then every 8 weeks

Make every effort to keep patients on study and **avoid lost to follow-up patients**

* **Follow-up visits** (every 8 weeks), data to collect:
  ⇒ Patient status (alive/deceased/lost to follow-up)
  ⇒ Weight, Performance status
  ⇒ Disease state
  ⇒ New anti-cancer treatment (systemic treatment: type, immune agents ?; surgery; radiotherapy; other loco regional treatment; palliative care)

In case of non progression during the treatment phase, an imaging has to be done every 8 weeks and RECSIT 1.1 data recorded.

eCRF pages to complete: **Follow-Up** (± RECIST), **QLQC30** (W26 only), **EuroQol-5D, Health Econ Study Events** (Second cancer, Death, Signature End)

To adequately finish the study...

URGENT

* According to study procedure, download all complete imaging files (Baseline, W6, W12) on the web platform or alternatively copy them on CD-roms for transmission to your CRA.
  If no monitoring visit is planned, french sites could also send them directly to:

GORTEC
ARC coordonnateur TPExtreme—M. Delhommeau
CHRU Tours—Hôpital Bretonneau
B47
2 Bd Tonnellé, 37044 Tours cedex 9 - FRANCE

* According to study procedure, send by DHL 5 tumor slides for all oropharynx patients to :

Mr Teddy Turinay
Gustave Roussy
Département BIOPATH
Secrétariat Recherche -1
114 rue Edouard-Vaillant
94805 Villejuif Cedex—FRANCE

TPExtreme
Contact Information

SPONSOR GORTEC	Président: Pr J. Bourhis Centre Hospitalier Universitaire Vaudois (CHUV) Phone: +41 21 314 46 66—@: jean.bourhis@chuv.ch
	Hôpital Bretonneau—CORAD 2, bd Tonnelé—37044 Tours (FRANCE)
Global Investigator coordinator	Pr Joël GUIGAY Centre Antoine Lacassagne, Nice Phone: +33 4 92 03 15 01 @: joel.guigay@nice.unicancer.fr
Spain Investigator coordinator (TTCC)	Pr Ricard MESIA Spanish H&N Cancer cooperative Group Institut Català d'Oncologia, Barcelona Phone: +34 93 260 77 44 @: rmesia@iconcologia.net
Germany Investigator coordinator (AIO)	Pr Ulrich KEILHOLZ German Association of Medical Oncology Charité Comprehensive Cancer Center, Berlin Phone: +49 30 450 564 621 @: ulrich.keilholz@charite.de
Global Study Manager	Nadejda VINTONENKO GORTEC, Tours Phone: +33 2 47 31 01 87 @: nadejda.vintonenko@gortec.fr
GORTEC Project Manager (FRANCE)	Cécile MICHEL Phone: +33 4 92 03 15 95 @: cecile.michel@gortec.fr
ASCOPHARM Project Manager (SPAIN)	Jessica BARTHOMEUF Phone: +33 1 56 33 35 52 @: j.barthomeuf@novasco.fr
AIO Project Manager (GERMANY)	Tobias MEYER AIO-Studien-gGmbH Phone: +49 30 81 45 344 39 @: tobias.meyer@aio-studien-ggmbh.de
GORTEC CRA (Monitoring France)	Mélissa DELHOMMEAU (Coordinating CRA) Phone: +33 9 67 27 89 51 @: Melissa.delhommeau@gortec.fr
	Fanny LOUAT, Laura SINIGAGLIA, Martial BINDZI, Natacha COLIN-BATAILHOU Phone: +33 9 67 27 89 51 @: fanny.louat@gortec.fr; laura.sinigaglia@gortec.fr; martial.bindzi@gortec.fr; natacha.colin-batailhou@gortec.fr
	Alexandre CORNELY Phone: +33 1 42 11 49 50 @: alexandre.cornely@gustaveroussy.fr Adeline PECHERY Phone: +33 3 81 98 89 01 @: adeline.pechery@hnfc.fr
ASCOPHARM CRA (Monitoring Spain)	Miguel DE SOUSA DIAS Phone: +33 1 56 33 35 45 @: m.desousadias@novasco.fr
AIO CRA (Monitoring Germany)	Stephan HOFFMANN Phone: +49 696 777 864 8 @: stephan.hofmann@aio-studien-ggmbh.de
Pharmacovigilance (SAE contact)	Dr Salim LAGHOUATI Gustave Roussy, Villejuif Phone: +33 1 42 11 61 00—**Fax: +33 1 42 11 61 50** @: phv@gustaveroussy.fr
Central lab (HPV analysis)	Teddy TURINAY (bioanapath lab coordinator) Gustave Roussy, Villejuif—Morphological Pathology Unit Phone: +33 1 42 11 54 88 @: teddy.turinay@gustaveroussy.fr
Data Manager (Randomization issues)	Cécile CHEVASSUS Gustave Roussy, Villejuif Phone: +33 1 42 11 41 20 @: cecile.chevassus@gustaveroussy.fr
Statistics	Dr Anne AUPERIN Gustave Roussy, Villejuif @: anne.auperin@gustaveroussy.fr