



## Clinical trial results:

### A PHASE II, OPEN-LABEL, MULTICENTER TRIAL OF CABAZITAXEL IN PATIENTS WITH RECURRENT OR METASTATIC HEAD AND NECK CANCER AFTER FAILURE OF CISPLATIN, CETUXIMAB AND TAXANES.

#### Summary

EudraCT number	2011-004712-32
Trial protocol	FR
Global end of trial date	14 May 2014

#### Results information

Result version number	v1 (current)
This version publication date	31 March 2021
First version publication date	31 March 2021

#### Trial information

##### Trial identification

Sponsor protocol code	UC-0130/1106
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01620242
WHO universal trial number (UTN)	-

Notes:

#### Sponsors

Sponsor organisation name	UNICANCER
Sponsor organisation address	101 RUE DE TOLBIAC, PARIS, France, 75013
Public contact	Nourredine AIT RAHMOUNE, UNICANCER, 33 0171936704, n.ait-rahmoune@unicancer.fr
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Notes:

#### Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

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**Results analysis stage**

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Analysis stage	Final
Date of interim/final analysis	09 December 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 March 2014
Global end of trial reached?	Yes
Global end of trial date	14 May 2014
Was the trial ended prematurely?	No

Notes:

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**General information about the trial**

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Main objective of the trial:

To assess the efficacy of cabazitaxel in terms of non-progression at 6 weeks for the treatment of recurrent or metastatic head and neck cancer after failure of cisplatin, cetuximab and taxanes. Non-progression will be assessed after centralized review of CT-scans.

Protection of trial subjects:

In order to ensure the protection of the rights, safety and well-being of trial subjects, this clinical trial was performed in compliance with the principles laid down in the declaration of Helsinki, good Clinical Practice and European regulation.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 April 2012
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	1 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

Country: Number of subjects enrolled	France: 31
Worldwide total number of subjects	31
EEA total number of subjects	31

Notes:

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**Subjects enrolled per age group**

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In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	24

From 65 to 84 years	7
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

Recruitment only in France, first inclusion on 06 April 2012 and last inclusion occurred on 19 April 2013

### Pre-assignment

Screening details:

PATIENTS WITH RECURRENT OR METASTATIC HEAD AND NECK CANCER AFTER FAILURE OF CISPLATIN, CETUXIMAB AND TAXANES

### Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

### Arms

<b>Arm title</b>	cabazitaxel 25 mg/m2 every 3 weeks
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Arm description:

Patients will be treated with intravenous cabazitaxel 25 mg/m2 every 3 weeks (D1=D22) for 6 cycles. In absence of progression disease or unacceptable toxicity, the treatment could be continued until a maximum of 10 cycles.

Arm type	Experimental
Investigational medicinal product name	cabazitaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Patients will be treated with intravenous cabazitaxel 25 mg/m2 every 3 weeks (D1=D22) for 6 cycles. In absence of progression disease or unacceptable toxicity, the treatment could be continued until a maximum of 10 cycles.

<b>Number of subjects in period 1</b>	cabazitaxel 25 mg/m2 every 3 weeks
Started	31
Completed	31

## Baseline characteristics

### Reporting groups

Reporting group title	Overall trial
Reporting group description:	
All patients included	

Reporting group values	Overall trial	Total	
Number of subjects	31	31	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	24	24	
From 65-84 years	7	7	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Female	7	7	
Male	24	24	

## End points

### End points reporting groups

Reporting group title	cabazitaxel 25 mg/m2 every 3 weeks
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Reporting group description:

Patients will be treated with intravenous cabazitaxel 25 mg/m2 every 3 weeks (D1=D22) for 6 cycles. In absence of progression disease or unacceptable toxicity, the treatment could be continued until a maximum of 10 cycles.

### Primary: Principal endpoint Non progression at 6weeks

End point title	Principal endpoint Non progression at 6weeks <sup>[1]</sup>
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End point description:

Non-progression at 6 weeks will be evaluated as per RECIST criteria (v1.1)

End point type	Primary
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End point timeframe:

6 weeks after treatment initiation

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Primary endpoint: The percentage of assessable patients with non progression disease at 6 weeks will be calculated using binomial estimates and reported with its 95% confidence interval (CI).

<b>End point values</b>	cabazitaxel 25 mg/m2 every 3 weeks			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: percent				
arithmetic mean (confidence interval 95%)	27.6 (12.7 to 47.2)			

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Since inclusion until 30 days after last treatment administration (no delay for related SAE)

Adverse event reporting additional description:

The extraction of non serious AEs is not compatible with the filling of the form. For all non serious AEs, the number "1" has been reported in the "Subjects affected number" section and the "Occurrences all number" section.

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	12
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### Reporting groups

Reporting group title	all patients
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Reporting group description: -

Serious adverse events	all patients		
Total subjects affected by serious adverse events			
subjects affected / exposed	18 / 31 (58.06%)		
number of deaths (all causes)	2		
number of deaths resulting from adverse events	1		
Neoplasms benign, malignant and unspecified (incl cysts and polyps) TUMOR PAIN			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders JUGULAR VEIN THROMBOSIS			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders ANEMIA			
subjects affected / exposed	2 / 31 (6.45%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
FEBRILE APLASIA			

subjects affected / exposed	4 / 31 (12.90%)		
occurrences causally related to treatment / all	4 / 4		
deaths causally related to treatment / all	0 / 0		
<b>FEBRILE NEUTROPENIA</b>			
subjects affected / exposed	3 / 31 (9.68%)		
occurrences causally related to treatment / all	3 / 3		
deaths causally related to treatment / all	0 / 0		
<b>General disorders and administration site conditions</b>			
<b>CHRONIC PAIN</b>			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>DISEASE PROGRESSION</b>			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>FACE EDEMA</b>			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
<b>GENERAL PHYSICAL HEALTH DETERIORATION</b>			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>INJURY ASSOCIATED WITH DEVICE</b>			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Gastrointestinal disorders</b>			
<b>DIARRHEA</b>			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		



DYSPHAGIA			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
HEMATEMESIS			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
INTESTINAL OBSTRUCTION			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
ASPIRATION PNEUMONIA			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
DYSPNEA			
subjects affected / exposed	3 / 31 (9.68%)		
occurrences causally related to treatment / all	1 / 4		
deaths causally related to treatment / all	0 / 0		
PNEUMOPATHY			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
STAPHYLOCOCCUS AUREUS PNEUMONIA			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
RENAL INSUFFICIENCY			

subjects affected / exposed	1 / 31 (3.23%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Infections and infestations</b>			
<b>CATHETER INFECTION</b>			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>INFECTION</b>			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>LUNG INFECTION</b>			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
<b>SEPTIC SHOCK</b>			
subjects affected / exposed	2 / 31 (6.45%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	1 / 1		
<b>SEPTICEMIA</b>			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

<b>Non-serious adverse events</b>	all patients		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	31 / 31 (100.00%)		
<b>General disorders and administration site conditions</b>			
<b>DOULEURS TUMORALES</b>			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		

FATIGUE/ASTHENIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
FIEVRE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
OEDEME PERIPHERIQUE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
INFLAMMATION DES MUQUEUSES			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
FRISONS			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
MALAISE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
CHOC SEPTIC			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
TOUX			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DOULEUR OROPHARYNGEE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
PNEUMOPATHIE DE DEGLUTITION			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DYSPNEE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DESATURATION RESPIRATOIRE			

subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
<b>HYPERSECRETION BRONCHIQUES</b>			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
<b>Cardiac disorders</b>			
<b>ARYTHMIE</b>			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
<b>BRADYCARDIE</b>			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
<b>Nervous system disorders</b>			
<b>CEPHALEES</b>			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
<b>ANXIETE/DEPRESSION</b>			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
<b>TROUBLES NEUROMOTEURS</b>			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
<b>TROUBLES NEUROSENSORIELS</b>			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
<b>DYSGUEUSIE</b>			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
<b>VERTIGE</b>			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
<b>LETHARGIE</b>			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
<b>SCIATIQUE</b>			

subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
NEUROPATHIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
PARESTHESIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DYSESTHESIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
TREMBLEMENTS			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
NEUTROPENIE FEBRILE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
ANEMIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DIMINUTION DES LEUCOCYTES			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DIMINUTION DES PLAQUETTES			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DIMINUTION DES NEUTROPHILES			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
LYMPHOPENIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DIMINUTION LYMPHOCYTES			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		

HYPOALBUMINEMIE subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1		
Ear and labyrinth disorders ACOUPHENE subjects affected / exposed occurrences (all)  BOURDONNEMENTS OREILLE DROITE subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1  1 / 31 (3.23%) 1		
Eye disorders CONJONCTIVITE subjects affected / exposed occurrences (all)  LARMOIEMENT AUGMENTE subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1  1 / 31 (3.23%) 1		
Gastrointestinal disorders DIARRHEE subjects affected / exposed occurrences (all)  NAUSEES subjects affected / exposed occurrences (all)  VOMISSEMENTS subjects affected / exposed occurrences (all)  SECHERESSE DE LA BOUCHE subjects affected / exposed occurrences (all)  REFLUX GASTRO-OESOPHAGIEN subjects affected / exposed occurrences (all)  HEMORROIDES subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1  1 / 31 (3.23%) 1  1 / 31 (3.23%) 1  1 / 31 (3.23%) 1  1 / 31 (3.23%) 1  1 / 31 (3.23%) 1		

HEMORRAGIE RECTALE subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1		
DOULEURS ABDOMINALES subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1		
DYSPHAGIE subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1		
CONSTIPATION subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1		
Skin and subcutaneous tissue disorders			
ERYTHEME subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1		
PRURIT subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1		
DEMANGEAISON subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1		
FOLICULITE DU VISAGE subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1		
ONYCHOPATHIE subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1		
NECROSE DE L'ORIFICE DE LA SONDE DE GASTROSTOMIE subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1		
Renal and urinary disorders			
DYSURIE subjects affected / exposed occurrences (all)	1 / 31 (3.23%) 1		
COLIQUE RENALE			

subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
HEMATURIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
POLAKIURIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
HYDRONEPHROSE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
RETENTION URINAIRE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
OBSTRUCTION URETRALE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
INCONTINENCE URINAIRE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
INSUFFISANCE RENALE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
INSUFFISANCE RENALE AIGUE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
ARTHRALGIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DOULEURS DORSALES			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DOULEURS DES EXTREMITES			



subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
SPASMES MUSCULAIRES			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DOULEUR THORACIQUE MUSCULOSQUELETTIQUE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DOULEUR AU NIVEAU DU FLANC			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
MYALGIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DOULEURS OSSEUSES			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DOULEURS JAMBES OSSEUSES			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
TRISMUS			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DOULEURS EPAULES			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
Infections and infestations			
INFECTION DES VOIES RESPIRATOIRES			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
SEPTICEMIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
MUCITE			

subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
ANOREXIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
DESHYDRATATION			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
HYPERGLYCEMIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
HYPOKALIEMIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
HYPOALBUMINEMIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
HYPERKALIEMIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		
HYPERCALCEMIE			
subjects affected / exposed	1 / 31 (3.23%)		
occurrences (all)	1		

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 February 2012	Precision concerning the pregnancy test to be done before inclusion in the clinical trial
22 May 2012	Modification of the inclusion criteria in order to precise the cancer type included. Patient can be included after Platinum Failure (in stead of cisplatin Failure)
16 October 2012	Modification of the protocol according to the new smpc of the product

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported