Clinical trial results:
Essai randomisé de phase II/III évaluant une stratégie thérapeutique post-opératoire individualisée chez les patients opérés d'un carcinome bronchique non à petites cellules (CBNPC) non épidermoïde de stade II – IIIA non N2.

Summary

EudraCT number	2008-004939-38
Trial protocol	FR
Global end of trial date	31 December 2015

Results information

Result version number	v1 (current)
This version publication date	31 December 2022
First version publication date	31 December 2022

Trial information

Trial identification

Sponsor protocol code	IFCT-0801 TASTE

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00775385
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	IFCT
Sponsor organisation address	10 rue de la Grange Batelière , Paris, France, 750009
Public contact	Contact, IFCT, +33 1 56 81 10 45, contact@ifct.fr
Scientific contact	Contact, IFCT, +33 1 56 81 10 45, contact@ifct.fr
Sponsor organisation name	IFCT
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Scientific contact	Contact, IFCT, +33 1 56 81 10 45, contact@ifct.fr

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:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	31 December 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	31 December 2015
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Faisabilité : Pourcentage de patients randomisés ayant, dans un délai de 8 semaines (soit J56) suivant la chirurgie, débuté le traitement après rendu du résultat de l'analyse des biomarqueurs (mutation EGFR et expression d'excision repair cross complementing-1 ou ERCC1).

Protection of trial subjects:

Algorithms for management of adverse events were provided in the protocol.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 April 2009
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 152
Worldwide total number of subjects	152
EEA total number of subjects	152

Notes:

Subjects enrolled per age group

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)	101
From 65 to 84 years	51
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

From May 2009 to July 2012, 29 centers across France recruited a total of 150 patients with completely resected non-squamous stage II or IIIA non-N2 tumors

Pre-assignment

Screening details:

Chemotherapy-naive patients with histologically confirmed and surgically resected stage II or IIIA non-N2 non-squamous NSCLC were eligible, with study inclusion occurring between D2 and D42 postsurgery to be able to deliver biomarker analysis before day 56, then perform random assignment, and then finally start therapy (or follow-up) before D61.

Period 1

Period 1 title	Overall study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Arm A

Arm description:

Standard chemotherapy with cisplatin and pemetrexed.

Arm type	Active comparator
Investigational medicinal product name	Cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Four cycles of cisplatin 75 mg/m² every 21 days

Investigational medicinal product name	Pemetrexed
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Four cycle of pemetrexed 500 mg/m² every 21 days

Arm title	Arm B

Arm description:

For patient presenting activating EGFR mutations were treated with oral erlotinib at 150 mg per day for 1 year.
In the absence of EGFR mutations, ERCC1 expression levels were taken into account :
- Patients with negative ERCC1 status were administered cisplatin plus pemetrexed.
- Patients with positive ERCC1 status underwent exclusively follow-up.

Arm type	Experimental
Investigational medicinal product name	Erlotinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details: Erlotinib at 150 mg per day for 1 year.	
Investigational medicinal product name	Cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: Four cycles of cisplatin 75 mg/m² every 21 days	
Investigational medicinal product name	Pemetrexed
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: Four cycle of pemetrexed 500 mg/m² every 21 days	

Number of subjects in period 1[1]	Arm A	Arm B
Started	74	76
Completed	71	74
Not completed	3	2
Did not received treatment	3	2

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: 2 withdrawals of consent.

Baseline characteristics

Reporting groups	
Reporting group title	Arm A
Reporting group description:	
Standard chemotherapy with cisplatin and pemetrexed.	
Reporting group title	Arm B
Reporting group description:	
For patient presenting activating EGFR mutations were treated with oral erlotinib at 150 mg per day for 1 year. In the absence of EGFR mutations, ERCC1 expression levels were taken into account : - Patients with negative ERCC1 status were administered cisplatin plus pemetrexed. - Patients with positive ERCC1 status underwent exclusively follow-up.	

Reporting group values	Arm A	Arm B	Total
Number of subjects	74	76	150
Age categorical Units: Subjects			
Adults (18-64 years)			0
From 65-84 years			0
Age continuous Units: years			
median	60	59	
full range (min-max)	36 to 75	34 to 73	-
Gender categorical Units: Subjects			
Female	29	30	59
Male	45	46	91
Pathologic stage Units: Subjects			
IIA	34	35	69
IIB	25	23	48
IIIA	14	18	32
IV	1	0	1
Histologic subtype Units: Subjects			
Adenocarcinoma	60	65	125
Other non-squamous	14	11	25
History of smoking Units: Subjects			
Yes	67	70	137
No	7	6	13
ECOG PS Units: Subjects			
PS 0	47	42	89
PS 1	27	34	61
BMI Units: Subjects			
<=20	10	14	24
]20-26[	43	47	90

[26-30[	14	10	24
>30	7	5	12
Weight loss in the 3 months before inclusion Units: Subjects			
≤ 10%	66	69	135
> 10%	8	7	15
Number of pack-year Units: Pack-year			
median	39	38	
full range (min-max)	2 to 100	0 to 165	-

End points

End points reporting groups	
Reporting group title	Arm A
Reporting group description:	
Standard chemotherapy with cisplatin and pemetrexed.	
Reporting group title	Arm B
Reporting group description:	
For patient presenting activating EGFR mutations were treated with oral erlotinib at 150 mg per day for 1 year. In the absence of EGFR mutations, ERCC1 expression levels were taken into account : - Patients with negative ERCC1 status were administered cisplatin plus pemetrexed. - Patients with positive ERCC1 status underwent exclusively follow-up.	

Primary: Patients who started their treatment within 2 months of surgery	
End point title	Patients who started their treatment within 2 months of surgery
End point description:	
Patients who started their treatment within 2 months of surgery, with available biomarker information.	
End point type	Primary
End point timeframe:	
Day 61	

End point values	Arm A	Arm B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	74	76		
Units: % of success				
number (confidence interval 95%)	77 (69.0 to 85.1)	83 (75.8 to 90.0)		

Statistical analyses

Statistical analysis title	Overall success rate
Comparison groups	Arm A v Arm B
Number of subjects included in analysis	150
Analysis specification	Pre-specified
Analysis type	other[1]
P-value	= 0.05
Method	bionomial test
Parameter estimate	Difference Between Proportions
Confidence interval	
level	95 %
sides	2-sided

Notes:

[1] - Fleming single-stage

Secondary: Cisplatin - Pemetrexed exposure

End point title	Cisplatin - Pemetrexed exposure

End point description:

End point type	Secondary

End point timeframe:

Up to 1 year

End point values	Arm A	Arm B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	74	53[2]		
Units: Number of participants				
Cycle 1	71	51		
Cycle 2	69	47		
Cycle 3	68	45		
Cycle 4	61	43		

Notes:

[2] - 53 patients with negative ERCC1 status

Statistical analyses

No statistical analyses for this end point

Secondary: Erlotinib exposure

End point title	Erlotinib exposure[3]

End point description:

End point type	Secondary

End point timeframe:

Up to 1 year

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only applicable for Arm B patients with EGFR mutations who received Erlotinib.

End point values	Arm B			
Subject group type	Reporting group			
Number of subjects analysed	7[4]			
Units: days				
median (full range (min-max))	344 (10 to 367)			

Notes:
[4] - 7 patients with EGFR mutations

Statistical analyses

No statistical analyses for this end point

Secondary: Theoretical dose of cisplatin received

End point title	Theoretical dose of cisplatin received

End point description:

End point type	Secondary

End point timeframe:
Up to 4 cycles

End point values	Arm A	Arm B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	74	53[5]		
Units: Pourcentage of theoretical dose				
median (full range (min-max))				
Cycle 1	99.5 (86 to 111.4)	99.7 (81.6 to 104.4)		
Cycle 2	99.5 (75.1 to 108)	99.5 (83.5 to 104.4)		
Cycle 3	99.3 (47 to 111.6)	99.16 (67.2 to 104.8)		
Cycle 4	99.0 (84.9 to 106.2)	99.2 (48.5 to 103.5)		

Notes:
[5] - 53 patients with negative ERCC1 status

Statistical analyses

No statistical analyses for this end point

Secondary: Theoretical dose of pemetrexed received

End point title	Theoretical dose of pemetrexed received

End point description:

End point type	Secondary

End point timeframe:
Up to 4 cycles

End point values	Arm A	Arm B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	74	53[6]		
Units: Pourcentage of theoretical dose				
median (full range (min-max))				
Cycle 1	99.6 (86 to 106.3)	99.9 (81.6 to 103.1)		
Cycle 2	99.6 (75.9 to 104.2)	99.9 (83.5 to 103)		
Cycle 3	99.5 (76.2 to 107.6)	99.6 (66.9 to 107.9)		
Cycle 4	99.5 (84.9 to 104.6)	99.2 (67.2 to 102.5)		

Notes:

[6] - 53 patients with negative ERCC1 status

Statistical analyses

No statistical analyses for this end point

Post-hoc: EGFR Mutation and ERCC1 Expression Status

End point title	EGFR Mutation and ERCC1 Expression Status

End point description:

Results pertaining to EGFR mutation status and ERCC1 expression levels in the two treatment arms.

End point type	Post-hoc

End point timeframe:

61 days

End point values	Arm A	Arm B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	74	76		
Units: Number of participants				
EGFR mutated, ERCC1 nonexpressed	0	5		
EGFR mutated, ERCC1 positive	2	2		
EGFR mutated, ERCC1 undetermined	1	0		
EGFR nonmutated, ERCC1 nonexpressed	39	41		
EGFR nonmutated, ERCC1 positive	16	17		
EGFR nonmutated, ERCC1 undetermined	10	8		
EGFR undetermined, ERCC1 nonexpressed	2	2		
EGFR undetermined, ERCC1 positive	1	0		
EGFR undetermined, ERCC1 undetermined	3	1		

Statistical analyses

No statistical analyses for this end point

Post-hoc: EGFR Mutation

End point title	EGFR Mutation

End point description:

End point type	Post-hoc

End point timeframe:
61 days

End point values	Arm A	Arm B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	74	76		
Units: Number of participants				
Mutated	3	7		
Nonmutated	65	66		
Undetermined	6	3		

Statistical analyses

No statistical analyses for this end point

Post-hoc: ERCC1 Expression Status

End point title	ERCC1 Expression Status

End point description:

End point type	Post-hoc

End point timeframe:
61 days

End point values	Arm A	Arm B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	74	76		
Units: Number of participants				
Nonexpressed	41	49		
Positive	19	19		
Undetermined	14	8		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were collected for a patient from the date of signature of inform consent form, during treatment period and until 30 days after the last dose of study treatment. Deaths were collected until data analysis.

Adverse event reporting additional description:

The maximal grade of adverse events was collected by cycle of treatment.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.0

Reporting groups

Reporting group title	Safety population

Reporting group description: -

Serious adverse events	Safety population		
Total subjects affected by serious adverse events			
subjects affected / exposed	25 / 145 (17.24%)		
number of deaths (all causes)	30		
number of deaths resulting from adverse events			
Vascular disorders			
Pulmonary embolism			
subjects affected / exposed	2 / 145 (1.38%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Thrombosis			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Chest pain			

subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reduced general condition			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Bronchial fistula			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pleural effusion			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumopathy			
subjects affected / exposed	2 / 145 (1.38%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pneumothorax			
subjects affected / exposed	2 / 145 (1.38%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Psychosis			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Investigations			
Creatinine increased			
subjects affected / exposed	2 / 145 (1.38%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		

Hypokalemia			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Pericarditis			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Intracranial hemorrhage			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Hemoglobin decreased			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Neutrophils count increased			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	3 / 145 (2.07%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Anorexia			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Diarrhea			

subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Gastritis			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal obstruction			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorder			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	2 / 145 (1.38%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Injection site reaction			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute renal failure			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

Renal failure			
subjects affected / exposed	3 / 145 (2.07%)		
occurrences causally related to treatment / all	3 / 4		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abscess			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bronchitis			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Febrile neutropenia			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Localized infection			
subjects affected / exposed	1 / 145 (0.69%)		
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 %

Non-serious adverse events	Safety population		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	141 / 145 (97.24%)		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	99 / 145 (68.28%)		
occurrences (all)	261		
Weight loss			
subjects affected / exposed	9 / 145 (6.21%)		
occurrences (all)	13		
Chest pain			

subjects affected / exposed occurrences (all)	46 / 145 (31.72%) 102		
Respiratory, thoracic and mediastinal disorders Epistaxis subjects affected / exposed occurrences (all) Cough subjects affected / exposed occurrences (all) Dyspnoea subjects affected / exposed occurrences (all)	 7 / 145 (4.83%) 11 30 / 145 (20.69%) 70 62 / 145 (42.76%) 154		
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all)	 10 / 145 (6.90%) 14		
Investigations Creatine increased subjects affected / exposed occurrences (all)	 13 / 145 (8.97%) 23		
Nervous system disorders Neuropathy subjects affected / exposed occurrences (all) Paresthesia subjects affected / exposed occurrences (all) Headache subjects affected / exposed occurrences (all)	 9 / 145 (6.21%) 9 14 / 145 (9.66%) 25 15 / 145 (10.34%) 27		
Blood and lymphatic system disorders Haemoglobin decreased subjects affected / exposed occurrences (all) Neutrophil count decreased	 88 / 145 (60.69%) 269 		

subjects affected / exposed	87 / 145 (60.00%)		
occurrences (all)	226		
Platelet count decreased			
subjects affected / exposed	36 / 145 (24.83%)		
occurrences (all)	83		
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	14 / 145 (9.66%)		
occurrences (all)	27		
Eye disorders			
Eyes tearing			
subjects affected / exposed	9 / 145 (6.21%)		
occurrences (all)	19		
Gastrointestinal disorders			
Anorexia			
subjects affected / exposed	38 / 145 (26.21%)		
occurrences (all)	70		
Constipation			
subjects affected / exposed	29 / 145 (20.00%)		
occurrences (all)	37		
Diarrhoea			
subjects affected / exposed	26 / 145 (17.93%)		
occurrences (all)	50		
Dysgeusia			
subjects affected / exposed	10 / 145 (6.90%)		
occurrences (all)	19		
Nausea			
subjects affected / exposed	100 / 145 (68.97%)		
occurrences (all)	256		
Oral mucosal irritation			
subjects affected / exposed	24 / 145 (16.55%)		
occurrences (all)	29		
Vomiting			
subjects affected / exposed	42 / 145 (28.97%)		
occurrences (all)	66		
Abdominal pain			

subjects affected / exposed occurrences (all) Gastralgia subjects affected / exposed occurrences (all)	10 / 145 (6.90%) 11 9 / 145 (6.21%) 14		
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all) Erythema subjects affected / exposed occurrences (all) Rash subjects affected / exposed occurrences (all) Scar pain subjects affected / exposed occurrences (all)	 11 / 145 (7.59%) 29 7 / 145 (4.83%) 8 12 / 145 (8.28%) 35 11 / 145 (7.59%) 27		
Renal and urinary disorders Renal failure subjects affected / exposed occurrences (all)	 17 / 145 (11.72%) 39		
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all) Joint pain subjects affected / exposed occurrences (all)	 14 / 145 (9.66%) 24 10 / 145 (6.90%) 11		
Infections and infestations Bronchitis subjects affected / exposed occurrences (all) Conjunctivitis subjects affected / exposed occurrences (all)	 16 / 145 (11.03%) 18 15 / 145 (10.34%) 28		

Rhinitis subjects affected / exposed occurrences (all)	9 / 145 (6.21%) 16		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 May 2009	A first modification of the protocol was done in order to: - Add new sites - Remove a scanner done prior inclusion of the patient - Clarify the follow-up of the patients - Complete the adverse events list of erlotinib
26 April 2011	A 2nd modification was done after the analysis of the first 108 patients. The steering committee of the study decided to extend the study to 56 additional patients because the frequency of EGFR mutations and ERCC1 over-expressions was not the expected frequencies. Fifty-six additional patients were necessary to verify the phase III hypothesis for the number of patients.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The Phase III part was cancelled due to the unreliability of the ERCC1 IHC read-outs.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/24638013