ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 07/09/2014

A Study of Avastin (Bevacizumab) in Combination With Docetaxel and Cisplatin in Patients With Metastatic or Locally Advanced Non-small Cell Lung Cancer

This study has been completed.

Sponsor:	Hoffmann-La Roche
Collaborators:	
Information provided by (Responsible Party):	Hoffmann-La Roche
ClinicalTrials.gov Identifier:	NCT00661778

Purpose

This study assessed the efficacy and safety of Avastin in combination with docetaxel and cisplatin as first-line treatment of patients with metastatic or locally advanced non-small cell lung cancer. Patients received Avastin 15 mg/kg intravenously (IV), docetaxel 75 mg/m^2, and cisplatin 75 mg/m^2 on Day 1 of each 3-week cycle for a maximum of 6 cycles.

Condition	Intervention	Phase
Non-small Cell Lung Cancer	Drug: Bevacizumab Drug: Cisplatin Drug: Docetaxel	Phase 2

Study Type: Interventional
Study Design: Treatment, Single Group Assignment, Open Label, Non-Randomized, Safety/Efficacy Study
Official Title: An Open Label Study to Assess the Effect of First-line Treatment With Avastin in Combination With Docetaxel and Cisplatin on Progression-free Survival in Patients With Metastatic or Locally Advanced Non-small Cell Lung Cancer

Further study details as provided by Hoffmann-La Roche:

Primary Outcome Measure:

- Progression-free Survival [Time Frame: Baseline to the end of the study (up to 4 years)] [Designated as safety issue: No]

Progression-free survival was defined as the time from enrollment in the study to the first documented disease progression using Response Evaluation Criteria In Solid Tumors (RECIST) or death from any cause, whichever occurred first.

Secondary Outcome Measures:

- Percentage of Participants With an Objective Response [Time Frame: Baseline to the end of the study (up to 4 years)] [Designated as safety issue: No]
  An objective response was defined as a complete or partial response determined on 2 consecutive occasions ≥ 4 weeks apart using Response Evaluation Criteria in Solid Tumors (RECIST). Complete response was defined as the disappearance of all target and non-target lesions. Any pathological lymph nodes (whether target or non-target) must be < 10 mm on the short axis. Partial response was defined as at least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum.
- Duration of the Objective Response [Time Frame: Baseline to the end of the study (up to 4 years)] [Designated as safety issue: No]
  Duration of the objective response is defined as the time from a complete or partial response to disease progression or death due to disease.
- Overall Survival [Time Frame: Baseline to the end of the study (up to 4 years)] [Designated as safety issue: No]
  Overall survival is defined as the time from the first dose of study medication until death.
- 1-year Survival [Time Frame: Baseline to 1 year] [Designated as safety issue: No]
  The probability of surviving 1 year was estimated using the Kaplan-Meier method.

Enrollment: 50
Study Start Date: July 2007
Primary Completion Date: July 2011
Study Completion Date: July 2011

Arms	Assigned Interventions
Experimental: Bevacizumab + cisplatin + docetaxel Participants received bevacizumab 15 mg/kg intravenously (IV) followed by docetaxel 75 mg/kg IV in combination with cisplatin 75 mg/m^2 IV on Day 1 of each 3-week cycle for a maximum of 6 cycles. After completing the 6 cycles of combined chemotherapy, participants received bevacizumab 15 mg/kg IV until disease progression, unacceptable toxicity, or withdrawal of consent.	Drug: Bevacizumab Bevacizumab was supplied as a sterile liquid in glass vials. Other Names: Avastin Drug: Cisplatin Bevacizumab was supplied as a sterile liquid in glass vials. Drug: Docetaxel Bevacizumab was supplied as a sterile liquid in glass vials. Other Names: Taxotere

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Adult patients, ≥ 18 years of age.
- Stage IIIb or IV non-small cell lung cancer.
- Chemotherapy-naive.

Exclusion Criteria:

- Previous treatment for non-small cell lung cancer.
- Previous malignant tumor within last 5 years, except for basal cell skin cancer or preinvasive cervical cancer.
- Major surgical procedure, open biopsy, or significant traumatic injury within 28 days prior to start of study.
- Recent or current chronic treatment with aspirin (> 325 mg/day).

Contacts and Locations

Locations

Spain

Cádiz, Cadiz, Spain, 11009
Castellon, Castellon, Spain, 12002
San Sebastian, Guipuzcoa, Spain, 20080
Palma de Mallorca, Islas Baleares, Spain, 07198
Alcala de Henares, Madrid, Spain, 28805
Madrid, Madrid, Spain, 28935
Madrid, Madrid, Spain, 28036
Malaga, Malaga, Spain, 29010
Palencia, Palencia, Spain, 34005
Sagunto, Valencia, Spain, 46520
Valencia, Valencia, Spain, 46017
Valladolid, Valladolid, Spain, 47010
Valladolid, Valladolid, Spain, 47005
Zamora, Zamora, Spain, 49021

Investigators

Study Director:	Clinical Trials	Hoffmann-La Roche

More Information

Responsible Party:	Hoffmann-La Roche
Study ID Numbers:	ML20081 2006-005619-88 [EudraCT Number]
Health Authority:	Spain: Ministry of Health

Study Results

Participant Flow

Pre-Assignment Details	The data listed in Participant Flow are for discontinuation from treatment, not discontinuation from the study. Data for discontinuation from the study are not available.

Reporting Groups

	Description
Bevacizumab + Cisplatin + Docetaxel	Participants received bevacizumab 15 mg/kg intravenously (IV) followed by docetaxel 75 mg/kg IV in combination with cisplatin 75 mg/m^2 IV on Day 1 of each 3-week cycle for a maximum of 6 cycles. After completing the 6 cycles of combined chemotherapy, participants received bevacizumab 15 mg/kg IV until disease progression, unacceptable toxicity, or withdrawal of consent.

Overall Study

	Bevacizumab + Cisplatin + Docetaxel
Started	50
Completed	0
Not Completed	50
Disease Progression	23
Adverse Event	18
Reason not Specified	6
Protocol Violation	2
Withdrawal of Consent	1

Baseline Characteristics

Analysis Population Description

Intent-to-treat population: All enrolled participants who received at least 1 treatment.

Reporting Groups

	Description
Bevacizumab + Cisplatin + Docetaxel	Participants received bevacizumab 15 mg/kg intravenously (IV) followed by docetaxel 75 mg/kg IV in combination with cisplatin 75 mg/m^2 IV on Day 1 of each 3-week cycle for a maximum of 6 cycles. After completing the 6 cycles of combined chemotherapy, participants received bevacizumab 15 mg/kg IV until disease progression, unacceptable toxicity, or withdrawal of consent.

Baseline Measures

	Bevacizumab + Cisplatin + Docetaxel
Number of Participants	50
Age, Continuous [units: Years] Mean (Standard Deviation)	58.31 (9.54)
Gender, Male/Female [units: Participants]	
Female	12
Male	38

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Progression-free Survival
Measure Description	Progression-free survival was defined as the time from enrollment in the study to the first documented disease progression using Response Evaluation Criteria In Solid Tumors (RECIST) or death from any cause, whichever occurred first.
Time Frame	Baseline to the end of the study (up to 4 years)
Safety Issue?	No

Analysis Population Description

Per protocol population: All participants who received at least 1 dose of study medication and had no major protocol deviations.

Reporting Groups

	Description
Bevacizumab + Cisplatin + Docetaxel	Participants received bevacizumab 15 mg/kg intravenously (IV) followed by docetaxel 75 mg/kg IV in combination with cisplatin 75 mg/m^2 IV on Day 1 of each 3-week cycle for a maximum of 6 cycles. After completing the 6 cycles of combined chemotherapy, participants received bevacizumab 15 mg/kg IV until disease progression, unacceptable toxicity, or withdrawal of consent.

Measured Values

	Bevacizumab + Cisplatin + Docetaxel
Number of Participants Analyzed	49
Progression-free Survival [units: Months] Median (95% Confidence Interval)	8.95 (6.92 to 9.97)

2. Secondary Outcome Measure:

Measure Title	Percentage of Participants With an Objective Response
Measure Description	An objective response was defined as a complete or partial response determined on 2 consecutive occasions ≥ 4 weeks apart using Response Evaluation Criteria in Solid Tumors (RECIST). Complete response was defined as the disappearance of all target and non-target lesions. Any pathological lymph nodes (whether target or non-target) must be < 10 mm on the short axis. Partial response was defined as at least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum.
Time Frame	Baseline to the end of the study (up to 4 years)
Safety Issue?	No

Analysis Population Description

Evaluable population: All participants who received at least 2 treatment cycles, have had all baseline lesions assessed on at least 1 occasion after receiving the 2nd treatment cycle, and have not had any major protocol violations.

Reporting Groups

	Description
Bevacizumab + Cisplatin + Docetaxel	Participants received bevacizumab 15 mg/kg intravenously (IV) followed by docetaxel 75 mg/kg IV in combination with cisplatin 75 mg/m^2 IV on Day 1 of each 3-week cycle for a maximum of 6 cycles. After completing the 6 cycles of combined chemotherapy, participants received bevacizumab 15 mg/kg IV until disease progression, unacceptable toxicity, or withdrawal of consent.

Measured Values

	Bevacizumab + Cisplatin + Docetaxel
Number of Participants Analyzed	46
Percentage of Participants With an Objective Response [units: Percentage of participants]	67.39

3. Secondary Outcome Measure:

Measure Title	Duration of the Objective Response
Measure Description	Duration of the objective response is defined as the time from a complete or partial response to disease progression or death due to disease.
Time Frame	Baseline to the end of the study (up to 4 years)
Safety Issue?	No

Outcome Measure Data Not Reported

4. Secondary Outcome Measure:

Measure Title	Overall Survival
Measure Description	Overall survival is defined as the time from the first dose of study medication until death.
Time Frame	Baseline to the end of the study (up to 4 years)
Safety Issue?	No

Analysis Population Description

Per protocol population: All participants who received at least 1 dose of study medication and had no major protocol deviations.

Reporting Groups

	Description
Bevacizumab + Cisplatin + Docetaxel	Participants received bevacizumab 15 mg/kg intravenously (IV) followed by docetaxel 75 mg/kg IV in combination with cisplatin 75 mg/m^2 IV on Day 1 of each 3-week cycle for a maximum of 6 cycles. After completing the 6 cycles of combined chemotherapy, participants received bevacizumab 15 mg/kg IV until disease progression, unacceptable toxicity, or withdrawal of consent.

Measured Values

	Bevacizumab + Cisplatin + Docetaxel
Number of Participants Analyzed	46
Overall Survival [units: Months] Median (95% Confidence Interval)	12.74 (9.48 to 17.79)

5. Secondary Outcome Measure:

Measure Title	1-year Survival
Measure Description	The probability of surviving 1 year was estimated using the Kaplan-Meier method.
Time Frame	Baseline to 1 year
Safety Issue?	No

Analysis Population Description

Per protocol population: All participants who received at least 1 dose of study medication and had no major protocol deviations.

Reporting Groups

	Description
Bevacizumab + Cisplatin + Docetaxel	Participants received bevacizumab 15 mg/kg intravenously (IV) followed by docetaxel 75 mg/kg IV in combination with cisplatin 75 mg/m^2 IV on Day 1 of each 3-week cycle for a maximum of 6 cycles. After completing the 6 cycles of combined chemotherapy, participants received bevacizumab 15 mg/kg IV until disease progression, unacceptable toxicity, or withdrawal of consent.

Measured Values

	Bevacizumab + Cisplatin + Docetaxel
Number of Participants Analyzed	46
1-year Survival [units: Percentage of participants] Number (95% Confidence Interval)	53.46 (39.19 to 67.45)

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	Safety population: All enrolled participants who received at least 1 treatment and who satisfied all inclusion criteria and none of the exclusion criteria. One participant satisfied an exclusion criterion and was not included in the safety population.

Reporting Groups

	Description
Bevacizumab + Cisplatin + Docetaxel	Participants received bevacizumab 15 mg/kg intravenously (IV) followed by docetaxel 75 mg/kg IV in combination with cisplatin 75 mg/m^2 IV on Day 1 of each 3-week cycle for a maximum of 6 cycles. After completing the 6 cycles of combined chemotherapy, participants received bevacizumab 15 mg/kg IV until disease progression, unacceptable toxicity, or withdrawal of consent.

Serious Adverse Events

	Bevacizumab + Cisplatin + Docetaxel
	Affected/At Risk (%)
Total	26/49 (53.06%)
Blood and lymphatic system disorders	
Febrile neutropenia [A] †	5/49 (10.2%)
Cardiac disorders	
Myocardial infarction [A] †	1/49 (2.04%)
Palpitations [A] †	1/49 (2.04%)
Gastrointestinal disorders	
Diarrhoea [A] †	2/49 (4.08%)
Vomiting [A] †	1/49 (2.04%)
General disorders	
Asthenia [A] †	1/49 (2.04%)
Death [A] †	1/49 (2.04%)
Mucosal inflammation [A] †	2/49 (4.08%)
Pyrexia [A] †	3/49 (6.12%)
Reaction at the injection site [A] †	1/49 (2.04%)
Infections and infestations	
Anal abscess [A] †	1/49 (2.04%)
Infection [A] †	1/49 (2.04%)

	Bevacizumab + Cisplatin + Docetaxel
	Affected/At Risk (%)
Oral candidiasis [A] †	1/49 (2.04%)
Pneumonia [A] †	1/49 (2.04%)
Respiratory tract infection [A] †	2/49 (4.08%)
Injury, poisoning and procedural complications	
Fracture [A] †	1/49 (2.04%)
Wound evisceration [A] †	1/49 (2.04%)
Investigations	
Decreased leukocyte count [A] †	1/49 (2.04%)
Neutrophil count increased [A] †	6/49 (12.24%)
Positron emission tomography [A] †	1/49 (2.04%)
Respiratory, thoracic and mediastinal disorders	
Dyspnea [A] †	3/49 (6.12%)
Haemoptysis [A] †	2/49 (4.08%)
Pneumothorax [A] †	1/49 (2.04%)
Pulmonary embolism [A] †	1/49 (2.04%)
Surgical and medical procedures	
Appendectomy [A] †	1/49 (2.04%)
Vascular disorders	
Deep vein thrombosis [A] †	1/49 (2.04%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (8.1)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	Bevacizumab + Cisplatin + Docetaxel
	Affected/At Risk (%)
Total	48/49 (97.96%)
Blood and lymphatic system disorders	
Bone marrow depression [A] †	1/49 (2.04%)
Febrile neutropenia [A] †	5/49 (10.2%)
Lymphopenia [A] †	2/49 (4.08%)
Cardiac disorders	
Myocardial infarction [A] †	1/49 (2.04%)
Palpitations [A] †	1/49 (2.04%)
Tachycardia [A] †	1/49 (2.04%)
Ear and labyrinth disorders	
Tinnitus [A] †	1/49 (2.04%)
Endocrine disorders	
Hypothyroidism [A] †	1/49 (2.04%)
Eye disorders	
Conjunctivitis [A] †	1/49 (2.04%)
Increased lacrimation [A] †	1/49 (2.04%)
Gastrointestinal disorders	
Abdominal distension [A] †	1/49 (2.04%)
Abdominal pain [A] †	4/49 (8.16%)
Aphthous stomatitis [A] †	1/49 (2.04%)
Constipation [A] †	11/49 (22.45%)
Diarrhoea [A] †	27/49 (55.1%)

	Bevacizumab + Cisplatin + Docetaxel
	Affected/At Risk (%)
Dry mouth [A] †	8/49 (16.33%)
Dysphagia [A] †	1/49 (2.04%)
Flatulence [A] †	1/49 (2.04%)
Gingival bleeding [A] †	1/49 (2.04%)
Hematemesis [A] †	1/49 (2.04%)
Hemorrhoids [A] †	1/49 (2.04%)
Nausea [A] †	19/49 (38.78%)
Odynophagia [A] †	2/49 (4.08%)
Oesophagitis [A] †	2/49 (4.08%)
Proctalgia [A] †	1/49 (2.04%)
Rectal bleeding [A] †	2/49 (4.08%)
Retching [A] †	1/49 (2.04%)
Vomiting [A] †	18/49 (36.73%)
General disorders	
Asthenia [A] †	3/49 (6.12%)
Chest pain [A] †	2/49 (4.08%)
Death [A] †	1/49 (2.04%)
Edema [A] †	2/49 (4.08%)
Extravasation [A] †	1/49 (2.04%)
Fatigue [A] †	36/49 (73.47%)
Mucosal inflammation [A] †	21/49 (42.86%)
Pain [A] †	6/49 (12.24%)

	Bevacizumab + Cisplatin + Docetaxel
	Affected/At Risk (%)
Peripheral edema [A] †	2/49 (4.08%)
Pyrexia [A] †	15/49 (30.61%)
Reaction at the injection site [A] †	2/49 (4.08%)
Infections and infestations	
Anal abscess [A] †	1/49 (2.04%)
Furuncle [A] †	1/49 (2.04%)
Infection [A] †	3/49 (6.12%)
Oral candidiasis [A] †	1/49 (2.04%)
Oral infection [A] †	1/49 (2.04%)
Parotiditis [A] †	1/49 (2.04%)
Pneumonia [A] †	2/49 (4.08%)
Respiratory tract infection [A] †	5/49 (10.2%)
Respiratory tract infection [A] †	2/49 (4.08%)
Tooth infection [A] †	1/49 (2.04%)
Upper respiratory tract infection [A] †	1/49 (2.04%)
Injury, poisoning and procedural complications	
Fracture [A] †	1/49 (2.04%)
Wound evisceration [A] †	1/49 (2.04%)
Investigations	
Abnormal coagulation test [A] †	1/49 (2.04%)
Abnormal transaminases [A] †	3/49 (6.12%)
Alanine aminotransferase [A] †	1/49 (2.04%)

	Bevacizumab + Cisplatin + Docetaxel
	Affected/At Risk (%)
Blood urea [A] †	1/49 (2.04%)
Decreased blood creatinine [A] †	1/49 (2.04%)
Decreased calcium in blood [A] †	1/49 (2.04%)
Decreased hemoglobin [A] †	21/49 (42.86%)
Decreased leukocyte count [A] †	9/49 (18.37%)
Decreased lymphocyte count [A] †	3/49 (6.12%)
Decreased monocyte count [A] †	1/49 (2.04%)
Decreased neutrophil count [A] †	2/49 (4.08%)
Decreased platelet count [A] †	11/49 (22.45%)
Decreased total protein [A] †	3/49 (6.12%)
Elevated alanine aminotransferase [A] †	4/49 (8.16%)
Elevated aspartate aminotransferase [A] †	1/49 (2.04%)
Elevated blood bilirubin [A] †	2/49 (4.08%)
Elevated blood creatinine [A] †	10/49 (20.41%)
Elevated blood lactate dehydrogenase [A] †	2/49 (4.08%)
Elevated blood urea [A] †	3/49 (6.12%)
Elevated ferritin in serum [A] †	1/49 (2.04%)
Elevated gamma glutamyl transferase [A] †	2/49 (4.08%)
Elevated leukocyte count [A] †	2/49 (4.08%)
Elevated triglycerides in blood [A] †	1/49 (2.04%)
Gamma glutamyltransferase [A] †	7/49 (14.29%)
High neutrophil count [A] †	14/49 (28.57%)

	Bevacizumab + Cisplatin + Docetaxel
	Affected/At Risk (%)
Hipofonesis [A] †	1/49 (2.04%)
Increased blood alkaline phosphatase [A] †	2/49 (4.08%)
Increased international normalised ratio [A] †	1/49 (2.04%)
Lymphocyte count [A] †	1/49 (2.04%)
Positron emission tomography [A] †	1/49 (2.04%)
Prolonged activated partial thromboplastin time [A] †	1/49 (2.04%)
Urinary urobilin [A] †	2/49 (4.08%)
White blood count [A] †	1/49 (2.04%)
Metabolism and nutrition disorders	
Anorexia [A] †	17/49 (34.69%)
Dehydration [A] †	1/49 (2.04%)
Hypercalcemia [A] †	2/49 (4.08%)
Hypercholesterolemia [A] †	5/49 (10.2%)
Hyperglycemia [A] †	11/49 (22.45%)
Hyperpotassemia [A] †	5/49 (10.2%)
Hypertriglyceridemia [A] †	2/49 (4.08%)
Hyperuricemia [A] †	1/49 (2.04%)
Hypoalbuminemia [A] †	4/49 (8.16%)
Hypocalcemia [A] †	1/49 (2.04%)
Hyponatremia [A] †	7/49 (14.29%)
Musculoskeletal and connective tissue disorders	
Arthralgia [A] †	5/49 (10.2%)

	Bevacizumab + Cisplatin + Docetaxel
	Affected/At Risk (%)
Back pain [A] †	3/49 (6.12%)
Bone pain [A] †	2/49 (4.08%)
Fistula [A] †	1/49 (2.04%)
Hypokalemia [A] †	5/49 (10.2%)
Musculoskeletal pain [A] †	2/49 (4.08%)
Myalgia [A] †	4/49 (8.16%)
Pain in one extremity [A] †	1/49 (2.04%)
Pain in sacrum [A] †	1/49 (2.04%)
Pain in the chest wall [A] †	1/49 (2.04%)
Shoulder pain [A] †	1/49 (2.04%)
Nervous system disorders	
Decreased consciousness [A] †	1/49 (2.04%)
Dizziness [A] †	1/49 (2.04%)
Dysgeusia [A] †	2/49 (4.08%)
Headache [A] †	1/49 (2.04%)
Neuropathy [A] †	13/49 (26.53%)
Paresthesia [A] †	1/49 (2.04%)
Syncope [A] †	1/49 (2.04%)
Psychiatric disorders	
Anxiety [A] †	4/49 (8.16%)
Depression [A] †	3/49 (6.12%)
Disorientation [A] †	1/49 (2.04%)

	Bevacizumab + Cisplatin + Docetaxel
	Affected/At Risk (%)
Renal and urinary disorders	
Hematuria [A] †	1/49 (2.04%)
Proteinuria [A] †	7/49 (14.29%)
Reproductive system and breast disorders	
Amenorrhea [A] †	1/49 (2.04%)
Respiratory, thoracic and mediastinal disorders	
Cough [A] †	4/49 (8.16%)
Dysphonia [A] †	3/49 (6.12%)
Dyspnea [A] †	10/49 (20.41%)
Epistaxis [A] †	19/49 (38.78%)
Haemoptysis [A] †	3/49 (6.12%)
Hiccupping [A] †	1/49 (2.04%)
Hypoxia [A] †	1/49 (2.04%)
Orthopnea [A] †	1/49 (2.04%)
Perforation of the nasal septum [A] †	1/49 (2.04%)
Pleuritic pain [A] †	1/49 (2.04%)
Pneumothorax [A] †	1/49 (2.04%)
Pulmonary embolism [A] †	1/49 (2.04%)
Skin and subcutaneous tissue disorders	
Alopecia [A] †	22/49 (44.9%)
Cutaneous toxicity [A] †	1/49 (2.04%)
Dermatitis acneiform [A] †	1/49 (2.04%)
Erythema [A] †	1/49 (2.04%)

	Bevacizumab + Cisplatin + Docetaxel
	Affected/At Risk (%)
Erythrodermic psoriasis [A] †	1/49 (2.04%)
Generalised erythema [A] †	1/49 (2.04%)
Hirsutism [A] †	1/49 (2.04%)
Hyperpigmentation of the skin [A] †	1/49 (2.04%)
Onycholysis [A] †	3/49 (6.12%)
Pigmentation disorder [A] †	1/49 (2.04%)
Pruritus [A] †	1/49 (2.04%)
Rash [A] †	2/49 (4.08%)
Ungueal toxicity [A] †	2/49 (4.08%)
Surgical and medical procedures	
Appendectomy [A] †	1/49 (2.04%)
Vascular disorders	
Deep vein thrombosis [A] †	2/49 (4.08%)
Flushing [A] †	1/49 (2.04%)
Haemorrhage [A] †	1/49 (2.04%)
Hypertension [A] †	8/49 (16.33%)
Hypotension [A] †	1/49 (2.04%)
Phlebitis [A] †	4/49 (8.16%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (8.1)

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The Study being conducted under this Agreement is part of the Overall Study. Investigator is free to publish in reputable journals or to present at professional conferences the results of the Study, but only after the first publication or presentation that involves the Overall Study. The Sponsor may request that Confidential Information be deleted and/or the publication be postponed in order to protect the Sponsor's intellectual property rights.

Results Point of Contact:

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