Macitentan Use in an Idiopathic Pulmonary Fibrosis Clinical Study (MUSIC)

This study has been completed.

Sponsor:
Actelion

Information provided by (Responsible Party):
Actelion

ClinicalTrials.gov Identifier:
NCT00903331

First received: May 14, 2009
Last updated: January 2, 2014
Last verified: January 2014
History of Changes

Results First Received: October 29, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Idiopathic Pulmonary Fibrosis
Interventions:	Drug: ACT-064992 (macitentan) Drug: Placebo

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
The study was conducted at 48 centers in Australia, Canada, France, Germany, Israel, Italy, Slovenia, South Africa, Spain, Sweden, Turkey, and the USA.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
The study included a screening period of up to 28 days followed by a double-blind treatment phase that was further divided into two periods. 300 patients were screened and 178 randomized in a 2:1 ratio to study treatment with ACT-064922 or placebo

Reporting Groups

	Description
Placebo	Matching placebo, once daily Placebo : matching placebo, once daily
ACT-064922	ACT-064922 tablet, 10 mg, once daily ACT-064992 (macitentan) : tablet, 10 mg, once daily

Participant Flow: Overall Study

	Placebo	ACT-064922
STARTED	**59**	**119**
COMPLETED	**54**	**101**

NOT COMPLETED	**5**	**18**
Death	**4**	**8**
Withdrawal of consent	**1**	**8**
Lung transplant	**0**	**2**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Placebo	Matching placebo, once daily Placebo : matching placebo, once daily
ACT-064922	ACT-064922 tablet, 10 mg, once daily ACT-064992 (macitentan) : tablet, 10 mg, once daily
Total	Total of all reporting groups

Baseline Measures

	Placebo	**ACT-064922**	**Total**
Overall Participants Analyzed [Units: Participants]	**59**	**119**	**178**
Age [Units: Years] Mean (Standard Deviation)	**64.5 (6.32)**	**65.1 (7.85)**	**64.9 (7.37)**
Gender [Units: Participants]			
Female	**22**	**35**	**57**
Male	**37**	**84**	**121**
Region of Enrollment [Units: Participants]			
Australia	**9**	**18**	**27**
Canada	**5**	**10**	**15**
France	**10**	**16**	**26**
Germany	**5**	**8**	**13**
Israel	**2**	**5**	**7**
Italy	**1**	**7**	**8**
Slovenia	**1**	**1**	**2**
South Africa	**1**	**1**	**2**
Spain	**4**	**7**	**11**
Sweden	**0**	**1**	**1**
Turkey	**3**	**8**	**11**
United States	**18**	**37**	**55**

Outcome Measures

Show All Outcome Measures

1. Primary: Forced Vital Capacity (FVC) at Baseline and End of Period 1 [Time Frame: 12 months]

Hide Outcome Measure 1

Measure Type	Primary
Measure Title	Forced Vital Capacity (FVC) at Baseline and End of Period 1
Measure Description	FVC was measured at baseline and at the end of Period 1. The same equipment and tester were used during the course of the study. The equipment was calibrated and the calibration documented prior to each patient's measurement. The person responsible for conducting the pulmonary function tests was required to comply with the study guidelines and the American Thoracic Society/European Respiratory Society joint criteria on lung function testing.
Time Frame	12 months
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All randomized patients

Reporting Groups

	Description
Placebo	Matching placebo, once daily Placebo : matching placebo, once daily
ACT-064922	ACT-064922 tablet, 10 mg, once daily ACT-064992 (macitentan) : tablet, 10 mg, once daily

Measured Values

	Placebo	**ACT-064922**
Participants Analyzed [Units: Participants]	**59**	**119**
Forced Vital Capacity (FVC) at Baseline and End of Period 1 [Units: Litres] Median (95% Confidence Interval)		
Baseline	**2.74** **(2.49 to 3.04)**	**2.83** **(2.65 to 3.06)**
End of Period 1	**2.40** **(2.10 to 2.70)**	**2.57** **(2.28 to 2.79)**

Statistical Analysis 1 for Forced Vital Capacity (FVC) at Baseline and End of Period 1

Groups [1]	All groups
Method [2]	Wilcoxon Rank Sum
P Value [3]	0.9631
Median Difference (Net) [4]	0.00
95% Confidence Interval	-0.09 to 0.08

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The null hypothesis was that there was no difference between ACT-064922 and placebo for the change in FVC from baseline to the end of Period 1. The aim was to detect a placebo-corrected change in FVC of ≥ 0.1 L (Standard Deviation = 0.2 L) at a two-sided 0.05 type 1 error level and 80% power.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

[4]	Other relevant estimation information:
	No text entered.

2. Secondary: Number of Patients at Risk of Event of Disease Worsening or Death up to the End of Study [Time Frame: Up to end of study (Up to 24 months)]

Hide Outcome Measure 2

Measure Type	Secondary
Measure Title	Number of Patients at Risk of Event of Disease Worsening or Death up to the End of Study
Measure Description	Disease worsening was indicated by pulmonary function test/idiopathic pulmonary fibrosis worsening (PFT/IPF) or acute respiratory decompensation of IPF. PFT/IPF worsening was indicated by the occurrence of both of the following: confirmed by two tests at least 4 weeks apart, as defined by the occurrence of both of the following: decrease from baseline ≥ 10% in forced vital capacity and decrease from baseline ≥ 15% in corrected diffusing capacity of the lung for carbon monoxide. Acute respiratory decompensation of IPF was defined as an unexplained rapid deterioration (over a period of less than 4 weeks) of the patient's condition with increasing shortness of breath requiring oxygen supplementation ≥ 5 L/min to maintain a resting oxygen saturation ≥ 90% or arterial oxygen pressure ≥ 55 mmHg (sea level) or 50 mmHg (high altitude).
Time Frame	Up to end of study (Up to 24 months)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All randomized patients

Reporting Groups

	Description
Placebo	Matching placebo, once daily Placebo : matching placebo, once daily
ACT-064922	ACT-064922 tablet, 10 mg, once daily ACT-064992 (macitentan) : tablet, 10 mg, once daily

Measured Values

	Placebo	ACT-064922
Participants Analyzed [Units: Participants]	**59**	**119**
Number of Patients at Risk of Event of Disease Worsening or Death up to the End of Study [Units: Participants]		
Patients at Risk of Event at Month 4	**59**	**112**
Patients at Risk of Event at Month 8	**57**	**103**
Patients at Risk of Event at Month 12	**44**	**81**
Patients at Risk of Event at Month 16	**22**	**43**
Patients at Risk of Event at Month 20	**8**	**14**
Patients at Risk of Event at Month 24	**2**	**1**

Statistical Analysis 1 for Number of Patients at Risk of Event of Disease Worsening or Death up to the End of Study

Groups [1]	All groups
Method [2]	Log Rank
P Value [3]	0.7056
Hazard Ratio (HR) [4]	1.118

95% Confidence Interval	0.626 to 1.996

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Up to 28 days after treatment discontinuation, approximately 2 years
Additional Description	No text entered.

Reporting Groups

	Description
Placebo	Matching placebo, once daily Placebo : matching placebo, once daily
ACT-064922	ACT-064922 tablet, 10 mg, once daily ACT-064992 (macitentan) : tablet, 10 mg, once daily

Serious Adverse Events

	Placebo	ACT-064922
Total, serious adverse events		
# participants affected / at risk	**20/59 (33.90%)**	**37/119 (31.09%)**
Blood and lymphatic system disorders		
THROMBOCYTOPENIA † 1		
# participants affected / at risk	**0/59 (0.00%)**	**2/119 (1.68%)**
Cardiac disorders		
ANGINA PECTORIS † 1		
# participants affected / at risk	**1/59 (1.69%)**	**1/119 (0.84%)**
ACUTE MYOCARDIAL INFARCTION † 1		
# participants affected / at risk	**0/59 (0.00%)**	**1/119 (0.84%)**
ARTERIOSPASM CORONARY † 1		
# participants affected / at risk	**0/59 (0.00%)**	**1/119 (0.84%)**
ATRIAL FLUTTER † 1		
# participants affected / at risk	**0/59 (0.00%)**	**1/119 (0.84%)**
CORONARY ARTERY DISEASE † 1		
# participants affected / at risk	**0/59 (0.00%)**	**1/119 (0.84%)**
DIASTOLIC DYSFUNCTION † 1		
# participants affected / at risk	**0/59 (0.00%)**	**1/119 (0.84%)**
ANGINA UNSTABLE † 1		
# participants affected / at risk	**1/59 (1.69%)**	**0/119 (0.00%)**
CARDIAC ARREST † 1		
# participants affected / at risk	**1/59 (1.69%)**	**0/119 (0.00%)**

SINUS BRADYCARDIA † 1		
# participants affected / at risk	1/59 (1.69%)	0/119 (0.00%)
Gastrointestinal disorders		
GASTRIC MUCOSAL HYPERTROPHY † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
HIATUS HERNIA † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
SMALL INTESTINAL OBSTRUCTION † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
UMBILICAL HERNIA † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
VOMITING † 1		
# participants affected / at risk	1/59 (1.69%)	0/119 (0.00%)
General disorders		
CHEST PAIN † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
DEVICE MALFUNCTION † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
HERNIA OBSTRUCTIVE † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
PYREXIA † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
Hepatobiliary disorders		
CHOLELITHIASIS † 1		
# participants affected / at risk	1/59 (1.69%)	1/119 (0.84%)
Immune system disorders		
ALLERGY TO ARTHROPOD BITE † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
Infections and infestations		
PNEUMONIA † 1		
# participants affected / at risk	2/59 (3.39%)	6/119 (5.04%)
LOWER RESPIRATORY TRACT INFECTION † 1		
# participants affected / at risk	2/59 (3.39%)	1/119 (0.84%)
COMMUNITY ACQUIRED INFECTION † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
LOWER RESPIRATORY TRACT INFECTION BACTERIAL † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
Injury, poisoning and procedural complications		
CYSTITIS RADIATION † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
INCISIONAL HERNIA † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
LACERATION † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
POST PROCEDURAL HAEMORRHAGE † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
JOINT DISLOCATION † 1		
# participants affected / at risk	1/59 (1.69%)	0/119 (0.00%)
SNAKE BITE † 1		
# participants affected / at risk	1/59 (1.69%)	0/119 (0.00%)
TRAUMATIC BRAIN INJURY † 1		
# participants affected / at risk	1/59 (1.69%)	0/119 (0.00%)
Metabolism and nutrition disorders		

FLUID RETENTION † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
Musculoskeletal and connective tissue disorders		
PAIN IN EXTREMITY † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
BACK PAIN † 1		
# participants affected / at risk	1/59 (1.69%)	0/119 (0.00%)
OSTEONECROSIS † 1		
# participants affected / at risk	1/59 (1.69%)	0/119 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
HEAD AND NECK CANCER † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
MALIGNANT MEDIASTINAL NEOPLASM † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
MYELODYSPLASTIC SYNDROME † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
RECTAL CANCER † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
SQUAMOUS CELL CARCINOMA † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
LUNG NEOPLASM † 1		
# participants affected / at risk	1/59 (1.69%)	0/119 (0.00%)
LUNG SQUAMOUS CELL CARCINOMA STAGE UNSPECIFIED † 1		
# participants affected / at risk	1/59 (1.69%)	0/119 (0.00%)
Nervous system disorders		
CEREBROVASCULAR ACCIDENT † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
TRANSIENT ISCHAEMIC ATTACK † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
DIZZINESS † 1		
# participants affected / at risk	1/59 (1.69%)	0/119 (0.00%)
PARAESTHESIA † 1		
# participants affected / at risk	1/59 (1.69%)	0/119 (0.00%)
Renal and urinary disorders		
RENAL FAILURE ACUTE † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
Respiratory, thoracic and mediastinal disorders		
IDIOPATHIC PULMONARY FIBROSIS † 1		
# participants affected / at risk	6/59 (10.17%)	10/119 (8.40%)
RESPIRATORY FAILURE † 1		
# participants affected / at risk	2/59 (3.39%)	4/119 (3.36%)
HYPOXIA † 1		
# participants affected / at risk	2/59 (3.39%)	3/119 (2.52%)
ACUTE RESPIRATORY FAILURE † 1		
# participants affected / at risk	1/59 (1.69%)	2/119 (1.68%)
PULMONARY EMBOLISM † 1		
# participants affected / at risk	2/59 (3.39%)	1/119 (0.84%)
ACUTE RESPIRATORY DISTRESS SYNDROME † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
PNEUMONIA ASPIRATION † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
HAEMOPTYSIS † 1		
# participants affected / at risk	1/59 (1.69%)	0/119 (0.00%)

PLEURAL EFFUSION † 1		
# participants affected / at risk	1/59 (1.69%)	0/119 (0.00%)
PULMONARY ARTERIAL HYPERTENSION † 1		
# participants affected / at risk	1/59 (1.69%)	0/119 (0.00%)
PULMONARY HYPERTENSION † 1		
# participants affected / at risk	1/59 (1.69%)	0/119 (0.00%)
Skin and subcutaneous tissue disorders		
SKIN HAEMORRHAGE † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
Surgical and medical procedures		
INTESTINAL OPERATION † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
MALIGNANT TUMOUR EXCISION † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
SKIN LESION EXCISION † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
HIP ARTHROPLASTY † 1		
# participants affected / at risk	2/59 (3.39%)	0/119 (0.00%)
Vascular disorders		
AORTIC ANEURYSM † 1		
# participants affected / at risk	1/59 (1.69%)	1/119 (0.84%)
HYPOTENSION † 1		
# participants affected / at risk	0/59 (0.00%)	1/119 (0.84%)
HYPERTENSION † 1		
# participants affected / at risk	1/59 (1.69%)	0/119 (0.00%)
WEGENER'S GRANULOMATOSIS † 1		
# participants affected / at risk	1/59 (1.69%)	0/119 (0.00%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 14.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	Up to 28 days after treatment discontinuation, approximately 2 years
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5

Reporting Groups

	Description
Placebo	Matching placebo, once daily Placebo : matching placebo, once daily
ACT-064922	ACT-064922 tablet, 10 mg, once daily ACT-064992 (macitentan) : tablet, 10 mg, once daily

Other Adverse Events

	Placebo	ACT-064922
Total, other (not including serious) adverse events		
# participants affected / at risk	57/59 (96.61%)	114/119 (95.80%)
Blood and lymphatic system disorders		

ANAEMIA † 1		
# participants affected / at risk	0/59 (0.00%)	13/119 (10.92%)
Cardiac disorders		
ANGINA PECTORIS † 1		
# participants affected / at risk	3/59 (5.08%)	3/119 (2.52%)
MITRAL VALVE INCOMPETENCE † 1		
# participants affected / at risk	3/59 (5.08%)	2/119 (1.68%)
Ear and labyrinth disorders		
VERTIGO † 1		
# participants affected / at risk	3/59 (5.08%)	1/119 (0.84%)
Gastrointestinal disorders		
NAUSEA † 1		
# participants affected / at risk	2/59 (3.39%)	9/119 (7.56%)
DIARRHOEA † 1		
# participants affected / at risk	5/59 (8.47%)	8/119 (6.72%)
CONSTIPATION † 1		
# participants affected / at risk	3/59 (5.08%)	5/119 (4.20%)
GASTROOESOPHAGEAL REFLUX DISEASE † 1		
# participants affected / at risk	4/59 (6.78%)	1/119 (0.84%)
General disorders		
OEDEMA PERIPHERAL † 1		
# participants affected / at risk	4/59 (6.78%)	14/119 (11.76%)
CHEST PAIN † 1		
# participants affected / at risk	3/59 (5.08%)	7/119 (5.88%)
FATIGUE † 1		
# participants affected / at risk	2/59 (3.39%)	6/119 (5.04%)
PYREXIA † 1		
# participants affected / at risk	5/59 (8.47%)	3/119 (2.52%)
ASTHENIA † 1		
# participants affected / at risk	4/59 (6.78%)	1/119 (0.84%)
Infections and infestations		
UPPER RESPIRATORY TRACT INFECTION † 1		
# participants affected / at risk	12/59 (20.34%)	20/119 (16.81%)
BRONCHITIS † 1		
# participants affected / at risk	9/59 (15.25%)	16/119 (13.45%)
LOWER RESPIRATORY TRACT INFECTION † 1		
# participants affected / at risk	5/59 (8.47%)	7/119 (5.88%)
Investigations		
PULMONARY FUNCTION TEST DECREASED † 1		
# participants affected / at risk	5/59 (8.47%)	9/119 (7.56%)
ALANINE AMINOTRANSFERASE INCREASED † 1		
# participants affected / at risk	4/59 (6.78%)	9/119 (7.56%)
ASPARTATE AMINOTRANSFERASE INCREASED † 1		
# participants affected / at risk	4/59 (6.78%)	8/119 (6.72%)
WEIGHT DECREASED † 1		
# participants affected / at risk	2/59 (3.39%)	6/119 (5.04%)
Metabolism and nutrition disorders		
DIABETES MELLITUS † 1		
# participants affected / at risk	3/59 (5.08%)	2/119 (1.68%)
Musculoskeletal and connective tissue disorders		
ARTHRALGIA † 1		
# participants affected / at risk	2/59 (3.39%)	6/119 (5.04%)
BACK PAIN † 1		

# participants affected / at risk	6/59 (10.17%)	3/119 (2.52%)
NECK PAIN † 1		
# participants affected / at risk	4/59 (6.78%)	2/119 (1.68%)
Nervous system disorders		
DIZZINESS † 1		
# participants affected / at risk	5/59 (8.47%)	11/119 (9.24%)
HEADACHE † 1		
# participants affected / at risk	8/59 (13.56%)	7/119 (5.88%)
Psychiatric disorders		
INSOMNIA † 1		
# participants affected / at risk	3/59 (5.08%)	8/119 (6.72%)
Respiratory, thoracic and mediastinal disorders		
DYSPNOEA † 1		
# participants affected / at risk	9/59 (15.25%)	24/119 (20.17%)
COUGH † 1		
# participants affected / at risk	21/59 (35.59%)	22/119 (18.49%)
IDIOPATHIC PULMONARY FIBROSIS † 1		
# participants affected / at risk	10/59 (16.95%)	17/119 (14.29%)
Skin and subcutaneous tissue disorders		
RASH † 1		
# participants affected / at risk	3/59 (5.08%)	4/119 (3.36%)
Vascular disorders		
HYPERTENSION † 1		
# participants affected / at risk	5/59 (8.47%)	4/119 (3.36%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 14.0

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

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

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

The agreement is:

☑ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Results Point of Contact:

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Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

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Responsible Party:	Actelion
ClinicalTrials.gov Identifier:	NCT00903331 History of Changes
Other Study ID Numbers:	**AC-055B201**
Study First Received:	May 14, 2009
Results First Received:	October 29, 2013
Last Updated:	January 2, 2014
Health Authority:	Canada: Ethics Review Committee Canada: Health Canada United States: Food and Drug Administration France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) France: Committee of Protection of Individuals SUD-EST IV (Lyon) Slovenia: Agency for Medicinal Products - Ministry of Health Slovenia: Ethics Committee Australia: Department of Health and Ageing Therapeutic Goods Administration Australia: Human Research Ethics Committee Australia: District Research Governance Germany: Ethics Commission Germany: Federal Institute for Drugs and Medical Devices South Africa: Human Research Ethics Committee South Africa: Medicines Control Council Turkey: Ethics Committee Turkey: Ministry of Health Israel: Ethics Commission Israel: Israeli Health Ministry Pharmaceutical Administration Italy: Ethics Committee Spain: Comité Ético de Investigación Clínica Spain: Spanish Agency of Medicines Sweden: Medical Products Agency Sweden: Regional Ethical Review Board