

# PHASE 3 MULTI-CENTER, DOUBLE-BLIND, RANDOMIZED, PLACEBOCONTROLLED, PARALLEL GROUP EVALUATION OF THE EFFICACY, SAFETY, AND TOLERABILITY OF BOCOCIZUMAB (PF-04950615) , IN REDUCING THE OCCURRENCE OF MAJOR CARDIOVASCULAR EVENTS IN HIGH RISK SUBJECTS - SPIRE 2

Published: 08-11-2013

Last updated: 23-04-2024

The primary objective of this clinical trial is to demonstrate the superior efficacy of bococizumab compared with placebo in reducing the risk of major CV events, a composite endpoint which includes adjudicated and confirmed CV death, non fatal MI (...)

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Lipid metabolism disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON44656

### Source

ToetsingOnline

### Brief title

9002/0239 (B1481038)

### Condition

- Lipid metabolism disorders

**Synonym**

cardiovascular disease; dyslipidemia

**Research involving**

Human

**Sponsors and support**

**Primary sponsor:** Pfizer

**Source(s) of monetary or material Support:** Pfizer

**Intervention**

**Keyword:** cardiovascular disease, Double-blind randomized controlled trial, PF-04950615, Phase 3

**Outcome measures****Primary outcome**

The primary endpoint is defined as the time from randomization to the first adjudicated and confirmed occurrence of a major CV event, a composite endpoint that includes CV death, non fatal MI, non fatal stroke, and hospitalization for unstable angina needing urgent revascularization.

**Secondary outcome**

Key Secondary Endpoints

The times from randomization to the first adjudicated and confirmed occurrence of the following endpoints (as defined in Appendix 4 of the protocol):

- \* A composite endpoint of CV death, non fatal MI, and non fatal stroke;
- \* A composite endpoint of all-cause death, non fatal MI, non fatal stroke, and hospitalization for unstable angina needing urgent revascularization;
- \* A composite endpoint of all cause death, non fatal MI and non fatal stroke;
- \* Hospitalization for unstable angina needing urgent revascularization.

## Other Secondary Clinical Endpoints

The times from randomization to the first adjudicated and confirmed occurrence of the following endpoints:

- \* A composite endpoint of CV death, non fatal MI, and non fatal stroke, and hospitalization for unstable angina;
- \* CV death;
- \* Any MI (fatal and non-fatal);
- \* Fatal MI;
- \* Non fatal MI;
- \* Any stroke (fatal and non-fatal);
- \* Any stroke (fatal and non-fatal), of any etiology;
- \* Fatal stroke;
- \* Non-fatal stroke;
- \* Hospitalization for unstable angina;
- \* Hospitalization for congestive heart failure (CHF);
- \* Any coronary revascularization procedure;
- \* CABG;
- \* PCI;
- \* Any arterial revascularizations;
- \* All-cause

## Other Secondary Circulating Biomarker Endpoints

The LDL-C biomarker endpoints are the percent change and nominal change, from

baseline at Week 14 and percent change to the last available post randomization

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value, in LDL-C (direct measurement).

Other lipid endpoints include the percent change from baseline at Week 14 in levels of:

- \* Non HDL C;
- \* Total cholesterol;
- \* VLDL C;
- \* RLP-C;
- \* Apo B;
- \* Lp(a);
- \* Triglycerides;
- \* HDL-C;
- \* Apo A I.
- \* Inflammatory biomarker endpoint

## Safety Endpoints

Safety endpoints include investigator reported adverse events, (including Type 1 and 3 hypersensitivity reactions and injection site reactions), serious adverse events, vital signs, examination observations (physical and neurological examinations and cognitive testing), 12 lead ECG recordings, and safety laboratory tests, including hematology, blood chemistry studies (including liver function tests and creatine kinase tests), urinalysis studies, and ADA assessments.

See Section 7.2 of the protocol for details.

## Study description

### Background summary

Bococizumab (previously numbered PF 04950615, RN-316, and J16) is a humanized monoclonal antibody against the proprotein convertase subtilisin kexin type 9 (PCSK9) enzyme responsible for the regulation of the low density lipoprotein receptor (LDLR), being developed for the following indications: (1) the treatment of primary hyperlipidemia or mixed dyslipidemia and (2) cardiovascular (CV) risk reduction, in subjects at high and very high risk of major cardiovascular events.

Cardiovascular disease (CVD) due to atherosclerosis continues to be the leading single cause of death in industrialized countries. High serum lipid levels, and especially high low density lipoprotein cholesterol (LDL C) levels, have been demonstrated to strongly and directly correlate with cardiovascular disease risks by numerous epidemiological studies. Moreover, large prospective clinical outcome trials have demonstrated that lowering LDL C decreases cardiovascular morbidity and mortality.<sup>45</sup> Despite the availability of highly effective lipid lowering therapies such as statins and ezetimibe, a significant percentage of patients remain at high risk for CVD.

PCSK9 is the ninth member of the subtilisin family of kexin like proconvertases to be identified<sup>14</sup> and is closely related to proteinase K. PCSK9 is linked to serum LDL C levels by binding to and down regulating LDLR levels on hepatocytes. This reduction in LDLR results in reduced cellular uptake of LDL C and, consequently, higher LDL C levels in serum.<sup>17</sup> In contrast, a decrease in active PCSK9 leads to an increase in hepatocyte LDLR, causing an increase in LDL uptake from circulation and consequently a subsequent reduction in serum LDL C levels.<sup>15,16</sup> Loss of function mutations lead to higher levels of the LDLR, and consequently lower plasma LDL-C levels, and protection from coronary heart disease.<sup>18,19,20,21,22</sup> This loss of PCSK9 appears to have no discernible adverse consequences in the affected subjects.<sup>21,22</sup>

Bococizumab targets the evolutionarily conserved LDLR binding domain of PCSK9 with high affinity. Bococizumab administered either as a single or multiple doses, either alone or in combination with current lipid lowering agents, was generally well tolerated in completed studies. No subjects in completed studies met the categorical criteria of drug-induced liver injury according to the Hy\*<sup>s</sup> law definition. Seven percent of subjects (37/517) exposed to bococizumab across all completed studies developed anti-drug antibodies (ADAs). The presence of ADAs was not associated with clinical signs or

symptoms of hypersensitivity.

## Study objective

The primary objective of this clinical trial is to demonstrate the superior efficacy of bococizumab compared with placebo in reducing the risk of major CV events, a composite endpoint which includes adjudicated and confirmed CV death, non fatal MI (myocardial infarction), non fatal stroke, and hospitalization for unstable angina with urgent revascularization (as defined in Appendix 4), in subjects at high or very high risk of major CV events who are on background lipid lowering treatment and have an LDL C \*100 mg/dL (2.59 mmol/L) or non HDL C (non-high density lipoprotein cholesterol) \*130 mg/dL (3.36 mmol/L)

### Clinical Secondary Objectives

The key secondary objectives of this clinical trial are to demonstrate in subjects with high or very high risk of major CV events, who are on background lipid lowering treatment and have an LDL C \*100 mg/dL (2.59 mmol/L) or non HDL C \*130 mg/dL (3.36 mmol/L), the superior efficacy of bococizumab compared with placebo in reducing the risk of adjudicated and confirmed key secondary endpoints (as defined in Appendix 4) of:

- \* A composite endpoint of CV death, non fatal MI, and non fatal stroke;
- \* A composite endpoint of all-cause death, non fatal MI, non fatal stroke, and hospitalization for unstable angina needing urgent revascularization;
- \* A composite endpoint of all-cause death, non-fatal MI and non-fatal stroke;
- \* Hospitalization for unstable angina needing urgent revascularization.

Please refer to protocol section 2.1.2 for additional secondary objectives

## Study design

This is an event driven, Phase 3 multi center, double blind, randomized parallel group evaluation of the efficacy, safety, and tolerability of bococizumab compared with placebo, in reducing the occurrence of major CV events in subjects at risk, who are on background lipid lowering treatment and have an LDL C \*100 mg/dL (2.59 mmol/L) or non HDL C \*130 mg/dL (3.36 mmol/L). After obtaining informed consent, there will be a pre-screening visit. At this visit subjects will have consented to have had lipid levels assessed and provide medical records for review, only, so as to determine which of the two CV outcomes studies the subject is most likely to qualify for, Study B1481022 or Study B1481038. This will be followed by a screening visit, and a run in period of approximately 6 weeks, during which subjects will be fully assessed with respect to the trial enrollment criteria and compliance with the self-administration of subcutaneous injections. The run-in period will be followed by the treatment period, the duration of which will be determined by the number of subjects with primary endpoint events, and concluded by a safety follow-up period.

Approximately 45,000 subjects may be screened and approximately 9,000 will be randomized. The study will be conducted in North America, Latin America, Europe, Africa, Asia, and Australia in approximately thirty countries. After randomization to PF 04950615, subjects will receive 150 mg every two weeks (Q2wks), or placebo, in a 1:1 ratio.

The trial is intended to complete when approximately 508 subjects have accrued adjudicated and confirmed primary endpoint events, or 12 months following the randomization date of the last subject, whichever occurs later. Potential endpoint events will be adjudicated by an independent adjudication committee. Subject safety will be monitored by an independent data monitoring committee (DMC). An independent statistical data analysis center will provide analyses to the DMC according to the DMC's charter.

## **Intervention**

Subjects will be randomized to PF-04950615 150 mg or placebo Q2wks in a 1:1 ratio. Subjects will self-inject, or if unable to self-inject, have investigational product administered by a caregiver (eg, a family member or health care assistant).

## **Study burden and risks**

The potential benefit of participation in this study for all subjects in this study is close monitoring of their medical condition and safety. Those randomized to the active treatment arm may have a benefit of a lower risk of major CV events. Those randomized to the placebo arm are not expected to obtain any additional benefit, beyond close monitoring of their medical condition and safety. A potential risk of participation, for all subjects, is the occurrence of injection site reactions. For those receiving active treatment, there may be an additional risk of achieving a very low LDL C. It is not known if there are any risks associated with very low LDL C.

## **Contacts**

### **Public**

Pfizer

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### **Scientific**

Pfizer

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New York 10017  
US

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Subjects must meet all of the following inclusion criteria to be eligible for enrollment into the study:

#### 1. Informed Consent

There must be evidence of personally signed and dated, informed consent documents for both the pre-screening and screening visits indicating that the subject has been informed of all pertinent aspects of the study. The pre-screening visit informed consent form will be limited to study activities up until the screening visit. The screening visit informed consent form will cover all aspects of the study. Subjects should be reconsented if there are modifications to the original informed consent document, at the next available opportunity.

#### ;2. Compliance

Subjects must be willing and able to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures.;

3. Age  
Subjects who have not had a prior CVD event must be age \* 50 years, if a man, and must be age \* 60 years, if a woman, with the following exceptions: Subjects who have not had a prior CVD event, but who have a condition of elevated LDL-C, (heterozygous familial hypercholesterolemia [heFH] or a history of LDL-C\*190 mg/dL [4.9 mmol/L]) should be \* 35 years of age if a man, and \* 45 years of age, if a woman.;

4. Acceptance of administration of IP  
Subjects must be willing and able to self-administer or be administered sub-cutaneous injections of investigational product.;

5. Requirements for background lipid lowering treatment  
There should be no plans at the time of pre-screening and randomization to modify the dose of statin for the duration of the trial. Unless the background lipid lowering treatment exceptions described below are met, subjects must be treated with one of the following highly effective statins at the specified daily doses for \* 4 weeks prior to the screening visit:

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- \* atorvastatin, at least 40 milligrams (mg) once a day;
- \* rosuvastatin, at least 20 mg, once a day;
- \* simvastatin, at least 40 mg, once a day or, if a subject has been on that dose for > 1 year, 80 mg, once a day.

Combination medications that contain atorvastatin, rosuvastatin, or simvastatin components described at the aforementioned, or lower, doses will be permitted. ;Background lipid lowering treatment exceptions

The following background lipid lowering treatment exceptions are permitted:

- \* Lower doses of statins due to partial statin intolerance

Subjects may be on a lower dose of one of the highly effective statins described above if there is documented intolerance to any one of them (atorvastatin, rosuvastatin, or simvastatin) at the aforementioned doses.

Intolerance to any dose of any statin must be documented as historical adverse events attributed to the statin in question, in the source documentation and case report form (CRF).

- \* Regulatory limitations

Subjects may be on a lower dose of one of the highly effective statins described above if the highest locally approved dose for one of the stated statins is lower than those doses shown above (e.g., in Japan, atorvastatin 20 mg, once a day, is the highest locally approved dose) or due to label restrictions.;

\* Alternative statins  
Subjects may be treated with other statins (pravastatin, fluvastatin, pitavastatin, or lovastatin), different from the highly effective statins listed above, if there is documented intolerance to any two different highly effective statins (atorvastatin, rosuvastatin, simvastatin) at the lowest available daily dose for at least one of those highly effective statins. Intolerance to any statin must be documented as historical adverse events attributed to the statin in question, in the source documentation and CRF.;

\* No background statin therapy  
Subjects may be enrolled who are only on non-statin lipid lowering therapy (drug and/or preventive cardiology lifestyle change guidance), if complete statin intolerance has been documented. Subjects with complete statin intolerance must be unable to tolerate at least two statins: one statin at the lowest available daily dose AND another statin at any dose. Intolerance to any statin must be documented as historical adverse events attributed to the statin in question, in the source documentation and CRF. The sole exception, for which a subject may participate in the study with documentation of intolerance to only one statin, is a documented history of rhabdomyolysis attributed to that statin or a history of documented statin allergy, precluding challenge with an alternative statin.

See Protocol Section 4.1 for inclusion criteria 6-8

## Exclusion criteria

### 1. Personnel involved in the conduct of the study.

Subjects who are investigational site staff members directly involved in the conduct of the trial and their family members, site staff members otherwise supervised by the Investigator, or subjects who are Pfizer employees directly involved in the conduct of the trial.;

2. Exclusionary prior CV events or planned revascularization procedures

A planned coronary (PCI or CABG) or other arterial revascularization;  
Myocardial infarction, stroke, or any non-coronary arterial revascularization \* 30 days prior to screening; Coronary revascularization \* 90 days prior to screening; Subjects with SAEs that would have potentially met the criteria for a CVD event (as defined in Appendix 4), between Visit 0 and Visit 5, should be excluded. Such subjects may be rescreened at a later date.;3.

Participation in prior clinical research studies

Participation in other studies involving small molecule investigational drug(s) (Phases 1-4) within 1 month, or five half-lives, of Visit 1, whichever is longer; any participation in a cholesteryl ester transfer protein (CETP) inhibitor trial within 1 year of Visit 1; or any biological agents within 6 months or 5 half-lives, of Visit 1, whichever is longer (the investigator should refer to documents provided by the subject on the other study to determine the IP half-life). If the blind of the prior study has been broken and the investigator provides documentation that the subject received placebo, the potential subject can be included, regardless of when participation occurred.;4. Other exclusionary conditions.

Other severe, acute, or chronic medical or psychiatric condition or laboratory abnormality that may increase the risk associated with study participation or investigational product administration or may interfere with the interpretation of study results and, in the judgment of the investigator, would make the subject inappropriate for entry into this study.;5.

Childbearing potential and/or breast feeding

Childbearing potential and/or breast feeding Pregnant female subjects; breastfeeding female subjects; and male subjects with partners currently pregnant who are sexually active; male subjects able to father children and female subjects of childbearing potential, who are at risk of pregnancy with their partners and are unwilling or unable to use a highly effective method of contraception as outlined in this protocol for the duration of the study and for 63 days after last dose of investigational product (refer to Section 4.4.2).;6. Latex sensitivity

Latex sensitive individuals (due to potential for exposure to natural dry rubber in the pre-filled syringe cap of IP, during administration).;7. Apheresis

Undergoing lipid apheresis, within 6 weeks of pre-screening, or planned start of lipid apheresis.;8. Severe congestive heart failure

Congestive heart failure of New York Heart Association (NYHA) Class IV, or if there is prior documentation of left ventricular ejection fraction (LVEF) of < 25%, measured by imaging. For subjects who have had serial assessments of LVEF, only the most recent study is used for the purposes of this exclusion requirement.;9. Dialysis

Potential subjects with end stage renal disease on dialysis.;10. Chronic renal insufficiency

Potential subjects with an eGFR of < 30 ml/min/1.73m<sup>2</sup> by MDRD formula at Visit 1.;11.

Hypertension

Poorly controlled hypertension at any screening visit or at randomization, defined as the average of two systolic blood pressure (BP) measurements > 180 mmHg or the average of two diastolic BP measurements > 110 mmHg even with treatment. Subjects who have hypertension and are controlled on stable doses of anti-hypertensive medications may be included. An additional BP measurement may be performed within the hour or at the completion of the office visit, to determine if a subject may be included in the study, given the potential for "white coat hypertension." The final set of measurements will be the measurements of record.;12. Cerebral hemorrhage risk

A prior history of hemorrhagic stroke or lacunar infarct resulting in a stroke (a lacunar infarct which was seen with cerebral imaging is not exclusionary in the absence of a clinical stroke).

A prior ischemic stroke which resulted in hemorrhagic transformation is not exclusionary. ;13.

Tissue donation

Plans to donate tissues (eg, blood, sperm, or other tissues, including participating in in vitro fertilization) during the study.;14. Substance abuse

Current history of alcoholism or drug addiction according to diagnostic and statistical manual of mental disorders (DSM) IV criteria within 12 months prior to screening. Use of any

recreational drugs within 12 months prior to screening.;15. Human immunodeficiency virus

Medical history of positive testing for human immunodeficiency virus (HIV).;See Protocol

Section 4.2 for exclusion criteria 16-23.

## Study design

### Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	12-06-2014
Enrollment:	900
Type:	Actual

### Medical products/devices used

Product type:	Medicine
Brand name:	Bococizumab (PF-04950616)

## Ethics review

Approved WMO

Date:	08-11-2013
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	25-02-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	17-03-2014
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	18-03-2014
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	06-06-2014
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	19-06-2014
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	01-09-2014
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	15-09-2014
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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(Assen)

Approved WMO

Date: 22-12-2014

Application type: Amendment

Review commission: BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date: 06-01-2015

Application type: Amendment

Review commission: BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date: 15-01-2015

Application type: Amendment

Review commission: BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date: 13-02-2015

Application type: Amendment

Review commission: BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date: 13-03-2015

Application type: Amendment

Review commission: BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date: 03-04-2015

Application type: Amendment

Review commission: BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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Application type: Amendment

Review commission: BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date: 29-04-2015

Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	12-05-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	18-05-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	19-05-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	30-06-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	07-07-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	17-07-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	29-07-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO	
Date:	19-08-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	21-10-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	11-12-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	17-12-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	01-02-2016
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	04-02-2016
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	22-04-2016
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	
Date:	17-05-2016
Application type:	Amendment

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	30-06-2016
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	08-03-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
EudraCT	EUCTR2013-002795-41-NL
CCMO	NL46223.056.13