Statistical Analysis Plan

Version 1.0

TITLE: ^{99m}Tc-rhAnnexin V-128 Planar and SPECT Imaging of Apoptosis in Asymptomatic or Previously Symptomatic with Transient Ischemic Attack (TIA) Patients with Carotid Atherosclerotic Plaque

PROTOCOL #: AAA-Annexin-04 v.5.0 dated 02 February 2018

NCT #: NCT02667457

PHASE: Proof of Concept and Phase II study

DATE: Final version 1.0 dated 24 May 2019

DESIGN: Single centre, single dose, controlled vs healthy volunteers study

INVESTIGATIONAL PRODUCT: Kit for the Preparation of Tc-99m Recombinant Human Annexin V-128 for Injection

APPROVAL/REVISION HISTORY

Autorship/Approval

Author:	[redacted]	Date
Approved by:	Advanced Accelerator Application S.A. (Sponsor), [redacted]	Date

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2 List of abbreviations

AAA	Advanced Accelerator Applications
AE	Adverse Event
ALAT	Alanine Aminotransferase
ALP	Alkanine Phosphatase
ALT	Alanine Transaminase
ASAT	Aspartate Aminotransferase
AST	Aspartate Transaminase
ATC	Anatomical Therapeutic Chemical classification system
BMI	Body Mass Index
BP	Blood Pressure
BUN	Blood Urea Nitrogen
C.I.	Confidence Interval
CRF	Case Report Form
CRO	Clinical Research Organization
CT	Computed Tomography
DMC	Data Monitoring Committee
eCRF	electronic Case Report Form
[redacted]	[redacted]
FAS	Full Analysis Set
GGT	Gamma-Glutamyl Transpeptidase
Hb	Hemoglobin
HR	Heart Rate
ICH	International Conference on Harmonization
ID	Identification
IP	Intraperitoneal
IQR	Interquartile Range
kVp	Peak Kilovoltage
LDH	Lactate Dehydrogenase

LLT	Lowest Level Term
MBq	Mega Becquerel
MCID	Minimal Clinically Important Difference
MCV	Mean Corpuscular Volume
MHLTC	Ministry of Health and Long Term Care
MedDRA	Medical Dictionary for Regulatory Activities
OHSN-REB	Ottawa Hospital Science Network Research Ethics Board
PoC	Proof of Concept
PP	Per Protocol
PT	Preferred Term
RBC	Red Blood Cell
ROC	Receiver Operator Characteristic curve
[redacted]	[redacted]
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
S.D.	Standard Deviation
SPECT	Single Photon Emission Computed Tomography
SOC	System Organ Class
TEAEs	Treatment emergent Adverse events
VOIs	Volumes Of Interest
WBC	White Blood Cell

3 Protocol title and number

^{99m}Tc-rhAnnexin V-128 Planar and SPECT Imaging of Apoptosis in Asymptomatic or Previously Symptomatic with Transient Ischemic Attack (TIA) Patients with Carotid Atherosclerotic Plaque (Protocol Number AAA-Annexin-04 v.5.0 dated 02 February 2018).

4 INFORMATION TAKEN FROM THE PROTOCOL

4.1 Study objectives

4.1.1 Primary objective

The primary objective of this investigation is to determine the feasibility of imaging apoptotic activity in carotid atherosclerotic plaques of asymptomatic or previous symptomatic with TIA only patients with significant carotid artery disease by using ^{99m}Tc-rhAnnexin V-128 imaging and to report the prevalence of abnormal ^{99m}Tc-rhAnnexin V-128 scans.

4.1.1.1 Primary hypothesis

^{99m}Tc-rhAnnexin V-128 imaging can be used to detect apoptosis in carotid plaque in asymptomatic or previously symptomatic with TIA only patients with at least 50% carotid stenosis as defined by ultrasound. In this population, the anticipated prevalence of carotid apoptosis will be 0.3 to 0.5.

4.1.2 Secondary objective

The secondary objectives are:

- To establish the uptake of ^{99m}Tc-rhAnnexin V-128 in a control group of participants with normal carotid ultrasounds.
- To assess the ^{99m}Tc-rhAnnexin V-128 uptake versus plaque echogenicity and echolucency.
- To measure aortic uptake of ^{99m}Tc-rhAnnexin V-128 and assess the correlation with its carotid uptake.

4.1.2.1 Secondary hypotheses

- ^{99m}Tc-rhAnnexin V-128 uptake will be increased in plaque with greater echogenicity.
- ^{99m}Tc-rhAnnexin V-128 uptake will be decreased in plaque with greater echolucency.
- ^{99m}Tc-rhAnnexin V-128 imaging can be used to detect apoptosis in the aorta in asymptomatic patients with at least one 50% carotid stenosis as defined by ultrasounds.
- Aortic uptake of ^{99m}Tc-rhAnnexin V-128 will be correlated with carotid uptake of ^{99m}Tc-rhAnnexin V-128.

4.2 Study design

This is a single-centre, single dose, Proof of Concept (PoC), Phase II study. Participants will receive a single intravenous bolus of 350 MBq ± 10 % of ^{99m}Tc-rhAnnexin V-128 followed by SPECT/CT imaging of the carotids and aortas. Carotid plaque echogenicity and echolucency will be assessed by carotid ultrasounds carried out within 8 weeks of ^{99m}Tc-rhAnnexin V-128 SPECT/CT imaging. SPECT/CT ^{99m}Tc-rhAnnexin V-128 carotid imaging will be obtained in 35 asymptomatic participants with at least one ≥ 50% carotid stenosis and in 10 participants with normal carotid ultrasounds.

4.2.1 Study population

Approval for the study was obtained from the Ottawa Hospital Science Network Research Ethics Board (OHSN-REB) and Health Canada. All participants will provide written informed consent prior to the initiation of any study procedures. Thirty-five participants with carotid stenosis and ten age and sex matched control participants will be enrolled.

4.2.1.1 Inclusion criteria

For all participants:

1. Males and females age 18 years or greater;
2. Able and willing to comply with the study procedures;
3. Negative pregnancy test for women of childbearing potential at screening and on the day of administration of ^{99m}Tc-rhAnnexin V-128.

For participants with carotid artery disease:

4. Evidence of 50% or more carotid stenosis in one or more carotid arteries on carotid ultrasound within 10 years;

For control participants:

4. No significant carotid artery disease on carotid ultrasound.

4.2.1.2 Exclusion criteria

1. Previous carotid stenting or endarterectomy, or stroke;
2. Diagnosis of vasculitis, dissection, or non-atherosclerotic carotid disease (Ehlers-Danlos, Marfans);
3. Pregnancy or lactation;

4. History of any disease or relevant physical or psychiatric condition or abnormal physical finding which may interfere with the study objectives at the investigator judgment;
5. Know hypersensitivity to the investigational product or any of its components;
6. Claustrophobia or inability to lie still in a supine position;
7. Participation in another clinical trial within 4 weeks before study inclusion, except for patients who have participated or who are currently participating in a study without any study drug administration;
8. Unwillingness to provide consent.

4.2.2 Study exposure

Subjects will be exposed to only one injection of ^{99m}Tc-rhAnnexin V-128 for SPECT/CT imaging of the carotids and aortas.

4.3 Methods and procedures

4.3.1 Source of study population

The carotid artery study population will be adult male and female patients who are referred to the outpatient cardiology clinics and/or the non-invasive Diagnostic Imaging Department at the University of Ottawa Heart Institute. The control population will be healthy volunteers who do not have carotid atherosclerosis as assessed by ultrasounds and whose lab values are within the normal range.

4.3.2 Participants study identification

Each participant will be identified with a participant ID number. A unique participant identification number (Participant ID) will be assigned at the start of the screening period to each participant who signs the informed consent form. This number will identify the participant throughout the study. Participant IDs will include the 2-digit protocol number (04), the 2-letter code (CA) and a 3- digit participant number (ex: 04-CA-001 for first participant in).

4.3.3 Study procedure

Voluntary written informed consent will be obtained prior to the initiation of any study-related procedures. Study conduct procedures will include a screening visit, the imaging studies, a phone visit within 24 hour post ^{99m}Tc-rhAnnexin V-128 administration visit and a visit at 30 days.

4.3.3.1 Baseline assessments

- Each participant's date of birth (mm/yyyy), gender, ethnicity, weight, height, medical history, and relevant baseline characteristics will be recorded.
- Results from any standard of care testing related to the participant's condition will be collected.
- Women of childbearing potential must have negative pregnancy test at screening and before the investigational product administration.
- Limited physical exam (height, weight, BMI) and vital signs (systolic and diastolic blood pressure, heart rate), will be recorded.

4.3.3.2 Laboratory assessments

Blood samples for hematology, biochemistry and urinalysis will be obtained at baseline for screening, 30 ± 3 days post IP administration and following any adverse events.

In case of clinically significant abnormalities in baseline laboratory values, the participant will be declared as a screening failure.

Hematology	**Coagulation**	**Blood Chemistry**	**Urinalysis**
• WBC with differential • RBC • Platelets • Hb • MCV • Hematocrit	• PT • PTT • INR	• BUN • Uric Acid • Albumin • Direct bilirubin • LDH • Calcium • Chloride • Phosphorus • Total cholesterol • Total protein • Serum creatinine • Total bilirubin • ALP • AST/ASAT • ALT/ALAT • Gamma-GT • Sodium • Potassium • Glucose • β-HCG at screening	• Dipstick test[1] • Pregnancy test *(before injection of study product, if applicable)*

[1] In case one of the assessments of the dipstick test is positive, a microscopic analysis of the urine must be performed.

Laboratory Assessments will be performed by the [redacted] The Ottawa Hospital according to Ministry of Health and Long Term Care (MHLTC) standards.

To rule out development of anti-annexin V-128 antibodies, venous blood samples will also be drawn for each participant at screening and 30 ± 3 days post ^{99m}Tc-rhAnnexin V-128 injection. Assays for anti-rhAnnexin V-128 IgG and IgM antibodies will be performed in serum samples by ELISA. For this purpose, 10 mL of blood will be collected for each assay.

4.3.3.3 ^{99m}Tc-rhAnnexin V-128 Planar and SPECT Imaging of the Carotid Arteries and Aorta and Image Analysis

Planar and SPECT imaging of the carotids and aorta will be performed 60 and 120 minutes after injection of tracer.

Administration of the ^{99m}Tc-rhAnnexin V-128 (350 MBq ± 10%) will be as a single bolus via an intravenous catheter in an antecubital vein followed by a saline flush. Negative pregnancy test for women of childbearing potential will be confirmed on the day of administration.

All images will be acquired with a dual head SPECT/CT gamma camera with low-energy high-resolution collimators. The energy acceptance window for the ^{99m}Tc photopeak will be 140 keV (± 10%). A low dose CT scan (helical, 120 kVp, 1 mA with 1.9 pitch) will be acquired of the neck, thorax and abdomen for attenuation correction.

Reconstruction will be done using iterative reconstruction incorporating CT-based attenuation correction and dual-energy-window scatter correction. SPECT images of the carotid arteries and thoracic and abdominal aorta will be acquired at 1 and 2 hours post-injection. Acquired images will be stored for off-line analysis using a Hermes Gold workstation (Hermes Medical Solutions). Volumes-of-interest (VOIs) will be placed over the carotids and the thoracic and abdominal aortic sections to determine image counts from the attenuation and scatter corrected images. A ^{99m}Tc source of known activity will be imaged and used to determine the imaging system calibration factor for converting reconstructed image counts into an activity concentration (MBq/cc or % injected dose/gram).

A normal database of carotid and aortic uptake will be determined from 10 control participants and used to identify abnormal uptake in carotid artery disease participants.

Inter and intra-observer variability will be determined by repeated analysis of the images of 20 participants. Two observers will carry out the assessment of inter-observer variability. Images will be anonymized prior to analysis and observers will be blinded to all clinical data.

4.3.3.4 ^{99m}Tc-rhAnnexin V-128 Radiation Risk Assessment

Participants will receive radiation from 1) ^{99m}Tc-rhAnnexin V-128 (350 MBq) for a dose of 2.2 mSv (7.7 ± 0.8 uSv/MBq) and 2) the CT scan for attenuation correction for a dose of 1.8 mSv. Total dose for ^{99m}Tc-rhAnnexin V-128 and CT components will be 4.0 mSv.

4.3.3.5 Ultrasound Examination

Clinical evidence of 50% or more carotid stenosis in one or more carotid arteries on carotid ultrasound within 10 years prior to enrolment is required for inclusion in the trial.

Evidence of 50% or more carotid stenosis has to be confirmed in a more recent US imaging within 8 weeks prior to ^{99m}Tc-rhAnnexin V-128 administration. If not confirmed, the participant will be declared as a screening failure.

B-mode and color Doppler ultrasound studies will be acquired of both carotid arteries and performed with an ultrasound scanner equipped with a 5- to 7-MHz transducer. Plaque morphology, as echogenicity, defined as reflectance of the emitted ultrasound signal, will be assessed as previously described and graded from 1 to 4 as echolucent, predominantly echolucent, predominantly echogenic, or echogenic. The vessel lumen will be used as the reference structure for defining echolucency, and the bright echo zone produced by the media-adventitia interface in the far wall will be used as the reference structure for defining echogenicity. Interobserver reproducibility of plaque morphology in stenotic arteries has been previously assessed (κ=0.56, 95% C.I. 0.38 to 0.74).

The degree of stenosis will be calculated by the following equation: (1−PSVr/PSVs)×100%, where PSVr denotes peak systolic velocity at the point of reference (here, the distal carotid artery) and PSVs the peak systolic velocity in the stenosis.

4.3.3.6 Withdrawal/discontinuation

The withdrawal of a study participant is mandatory in the following cases:

- Pregnancy
- Protocol violation determined as critical
- Lost to follow-up
- Serious inter-current illness or other safety reasons for what the Investigator considers it is in the best interest of the participant to withdraw from the study
- Screening failure

A “screening failure” is a participant who has signed the informed consent, but who does not meet all selection criteria following the screening evaluations. For participants not considered eligible after the screening period, the reason for not being eligible must be documented. No additional assessments are needed. Participant information collected at the screening visit will be entered in the eCRF and will be used in the study analysis.

The participants may withdraw from the study if they decide to do so, at any time and irrespective of the reason, or this may be the Investigator’s decision. The primary reason for a participant’s withdrawal from the study should be determined if possible. The date and reason for discontinuation will be documented in the eCRF.

4.3.4 Schedule of assessments

Participants who have signed the informed consent and are eligible to participate in the study will undergo the following assessments:

- A screening visit will be conducted within 8 weeks prior to the ^{99m}Tc-rhAnnexin V-128 imaging. Eligible and consenting participants will undergo a limited physical examination (height, weight, BMI), vital signs (systolic and diastolic blood pressure, heart rate), blood analysis and urinalysis. The following blood analysis will be conducted: CBC with automated differential, general chemistry panel (SMA-20) including PT/PTT, INR (international normalized ratio for PT values) and assessment of anti-annexin V-128 antibodies.
- Carotid ultrasound will be carried out within 8 weeks prior to the ^{99m}Tc-rhAnnexin V-128 SPECT/CT imaging. SPECT Imaging visit: dedicated SPECT/CT imaging of the carotids and aorta will be done 60 minutes after injection of tracer, and 120 minutes after injection. Vital signs assessment/participant monitoring will be done throughout the visit.
- Within 24 hours after the administration of ^{99m}Tc-rhAnnexin V-128, participants will be called for the assessment of possible adverse events.
- 30 ± 3 days post ^{99m}Tc-rhAnnexin V-128 injection, all participants will return to clinic for a final blood sampling to rule out the development of anti-annexin V-128 antibodies. The following blood analysis will also be conducted: CBC with automated differential, general chemistry panel (SMA-20) including PT/PTT, and INR.
- Once the first 15 patients and 5 normals have been administered with ^{99m}Tc-rhAnnexin V-128 and have performed the imaging visits, the Data Monitoring Committee will review the images. The visual assessment of the scans in these first 20 participants will support the continuation or the termination of the Phase II study.

The following table summarizes all the procedures and evaluations to be conducted during the study:

Study Procedures	Screening (Within 8 weeks prior to Day 0)	SPECT/CT Visit (Day 0)	24 hours post IP injection[1]	30 ± 3 days post IP injection (Day 30)
Written informed consent	X			
Inclusion/exclusion criteria	X	X		
Medical history	X			
Concomitant medications	X	X	X	X
Physical examination (height, weight, BMI)	X	X		
Vital signs (BP, HR)	X	X		
Lab analysis (hematology, PT/PTT/INR, biochemistry, urine)	X			X
Immunogenicity by ELISA[2]	X			X
Pregnancy test	X	X		
Carotid ultrasound[3]	X			
rh-Annexin V-128 administration		X		
Planar & SPECT/CT imaging		X		
Adverse events assessment		X	X	X

[1]Within 24 hours after injection of ^{99m}Tc-rhAnnexin V-128, each participant will be called to review any signs or symptoms of AEs.

[2]Anti-rhAnnexin V-128 IgG and IgM antibodies will be quantified in serum samples by ELISA. For this purpose 10 mL blood samples will be collected at screening and Day 30 (±3 days) post administration of investigation product. Serum will be prepared, divided into six aliquots and frozen (-80°C). Three out of six serum samples per time-point will then be shipped to the [redacted] central laboratory.

[3]Within 8 weeks prior to ^{99m}Tc-rhAnnexin V-128 SPECT imaging.

4.3.5 Planned sample size

The primary hypothesis is that ^{99m}Tc-rhAnnexin V-128 carotid imaging can detect apoptosis. We anticipate that the prevalence of positive ^{99m}Tc-rhAnnexin V-128 carotid scans will be about 0.3 to 0.5 of the patients. A sample size of 30 patients produces a 95% confidence interval with a precision of about 0.17 to 0.20 when the estimated proportion is 0.3 to 0.5. Sample size was also estimated for the comparison of ^{99m}Tc-rhAnnexin V-128 uptake in asymptomatic or symptomatic with TIA patients with carotid disease versus normals using a 5% significance level and power of 95%. The measured neck uptake in 12 normals was 0.8 ± 0.27% ID/gm in the Phase I study. Assuming a similar SD of 0.27% ID/gm in the patients and a minimal clinically important difference (MCID) of

50% or a change of 0.4 in uptake, the required sample size is 9 normals and 25 patients. Allowing for attrition, we plan to recruit 10 normals and 35 patients.

5 SUBJECT POPULATIONS (ANALYSIS SETS)

5.1 Efficacy

5.1.1 Full analysis set (FAS)

In accordance with the Intention To Treat (ITT) principle, the FAS population includes all subjects who received the study drug and completed the ^{99m}Tc-rhAnnexin V-128 imaging procedure.

5.1.2 Per Protocol population (PP)

All subjects in the FAS population for whom no major protocol violations/deviations occurred. The criteria defining the major protocol deviations will be established before the data base locking.

5.2 Safety set

The safety population is made up of all subjects who received the administration of ^{99m}Tc-rhAnnexin V-128.

5.3 Primary population

The primary and secondary efficacy analysis will be based on the FAS population.

The primary efficacy analysis on the Primary endpoint of Phase II will be also performed on the PP population as supportive analysis.

The assessment of safety and tolerability will be based on the Safety population.

6 STATISTICAL METHODS

6.1 Statistical analysis strategy

The statistical analyses will be performed in accordance with the principles of ICH E9 guideline and the guideline on clinical evaluation of diagnostic agents and they will be based on data from the study site, unless otherwise stated.

The statistical analysis will be performed by [redacted] – Italy.

6.1.1 General statistical considerations

For continuous variables, descriptive summary statistics will include the number of non-missing values, number of missing values, mean, standard deviation, 95% 2-sided confidence interval, median, lower and upper quartile, minimum and maximum. Box plot graphs will also be presented when appropriate.

For categorical variables, descriptive summary statistics will include counts and percentages per category.

For analysis purposes, baseline for a given assessment will be defined as the last non-missing value prior to the administration of ^{99m}Tc-rhAnnexin V-128, unless stated otherwise.

6.1.2 Efficacy endpoint(s)

6.1.2.1 Primary endpoint of PoC

The feasibility of imaging apoptotic activity in carotid atherosclerotic plaques using ^{99m}Tc-rhAnnexin V-128 will be assessed by the data monitoring committee (visual image review and consensus) using the first 15 patient and 5 control scans.

The frequency and severity of abnormal carotid scans will be determined in the patient and control groups by review of the number, localization, length and uptake intensity grade of each plaque to define a positive or negative scan at each time point.

DMC outputs were defined in the DMC charter.

6.1.2.2 Primary endpoint of Phase II

The primary endpoint of Phase II is the prevalence of abnormal ^{99m}Tc-rhAnnexin V-128 Planar and SPECT/CT scans in patient and control groups.

The prevalence of apoptotic activity is defined as the proportion of patients with “abnormal” SPECT imaging scans (also described as positive scans). Activity concentrations (MBq/cc or % injected dose/gram) determined from reconstructed image counts as described in section 4.3.3.3 will be compared with the normal database of carotid and aortic uptake from the 10 control participants and used to identify abnormal uptake in carotid artery disease participants that will define an abnormal SPECT/CT result.

The prevalence of abnormal ^{99m}Tc-rhAnnexin V-128 scans will be reported with the related 95% C.I. for both carotid participating group and the control group at each time point and overall.

The overall result of ^{99m}Tc-rhAnnexin V-128 imaging will be unique: patients with at least one SPECT/CT positive result (after 60 min or after 120 min from ^{99m}Tc-rhAnnexin V-128 injection) will be considered as abnormal, patients with both SPECT/CT images negative will be considered as normal.

The results of ^{99m}Tc-rhAnnexin V-128 will also be reported in contingency tables as normal and abnormal for each group (patient and control) at each time point (60 min and 120 min after injection) in order to assess where any difference between the time points occurred.

Results of Carotid Ultrasound and SPECT procedures will be included in the data listing. The listings will also flag which patients had a history of TIA.

The primary efficacy analysis will be performed on the FAS population.

6.1.2.3 Secondary endpoints

The secondary endpoints of Phase II and the related statistical analysis are:

- Descriptive statistics of ^{99m}Tc-rhAnnexin V-128 uptake in patients vs control participants will be presented by areas of interest (left carotid, right carotid, thoracic aorta, abdominal aorta and aortic arch) and by time points to assess the background uptake profile and the pathologic profile. Comparison of uptake in patients vs controls at each timepoint will be explored by the most appropriate test i.e. two sample t-test .
- The relationship between carotid uptake (separately for left and right) and ultrasound grade of plaque echolucency/echogenicity (1 – echolucent, 2 – predominantly echolucent, 3 – predominantly echogenic, 4 – echogenic) will be assessed for all patients using box plots and

summaries of uptakes by the levels of echolucency/echogenicity for each time point. Only carotids with stenosis (defined as ≥ 50% as per protocol) will be included in this analysis (i.e. a patient with only 1 carotid with stenosis ≥ 50% will contribute data for that carotid uptake value and the associated plaque echolucency/echogenicity value for the same carotid, patients with stenosis in both carotids will contribute data on uptake and echolucency/echogenicity for each of their carotids).

- Association between carotid and aortic uptake will be assessed for patients and controls, by time point, using scatter plots. All carotids with ≥ 50% stenosis (as described above) will be included in this plot, and different colours/symbols will be used for left and right carotid results. If further investigation is considered appropriate, the correlation coefficients (Pearson's or Spearman's) within left carotids and right carotids separately will be calculated.

6.1.3 Safety endpoint(s)

Safety and tolerability will be primarily evaluated by the incidence of adverse events, clinical laboratory values (hematology, blood chemistry and urinalysis), development of anti-Annexin V-128 antibodies, vital signs (blood pressure and heart rate) and physical examination findings.

All safety data will be included in the data listings and summary tables will be based on the safety population. The statistical analysis of safety data will be mainly descriptive in nature.

6.1.3.1 Adverse events

All original AE/SAE terms will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) Version 19.0.

Adverse events (AEs) will be listed on an individual basis, including relationship and severity, LLT (Lowest Level Term) and verbatim term. Treatment emergent Adverse events (TEAEs) and Adverse Drug Reactions (ADRs) will be summarized by System Organ Class (SOC) and Preferred Term (PT), grouping patients versus control subjects, and also including a total column for all subjects who received Annexin. Participants with more than one adverse event within a particular SOC and PT will be counted only once for that SOC and PT reporting the highest level in severity. The incidence of TEAEs and ADRs will also be summarized by subject type and severity.

Listings and summaries of serious adverse events (SAEs), adverse events leading to withdrawal and listings of deaths will also be presented.

Treatment Emergent Adverse Events and Adverse Drug Reactions will be defined as below:

- Treatment Emergent Adverse Events: Events that emerge after the ^{99m}Tc-rhAnnexin V-128 injection and up to 30 days after the injection that were absent before it or worsen relative to the pre-treatment state.
- Adverse Drug Reactions: Treatment emergent adverse events possibly or probably related to study treatment.

6.1.3.2 Clinical laboratory values

Hematology, blood chemistry, urinalysis and immunogenicity values are recorded at baseline for screening, 30 ± 3 days post IP administration and following any adverse events. Descriptive statistics including shift tables will be generated for all laboratory tests performed i.e. the actual values and the changes from pre-injection.

Data listing will be ordered by subject and measuring time. Listings of abnormal results (both clinically and non-clinically relevant) will also be reported.

6.1.3.3 Vital signs and physical examination

Vital signs and physical examination data are recorded once at screening visit and twice at imaging visit (SPECT/CT Visit, Day 0), before the injection of ^{99m}Tc-rhAnnexin V-128 and at the end of SPECT/CT (after the ^{99m}Tc-rhAnnexin V-128 injection). Descriptive statistics will be tabulated by measuring time for raw data and changes from baseline. Data listings will be ordered by subject and measuring time.

6.1.4 Missing data and outliers

6.1.4.1 Missing data

As stated in the protocol, missing data will not be replaced.

6.1.4.2 Missing or incomplete dates

Incomplete dates due to missing day will be recorded as full dates replacing the missing day with the first day of month (01). Incomplete dates due to missing day and month will be recorded as full dates replacing the missing day and month with the first day of month and first month of the year (01/January). The trial database will record the information about incomplete dates due to missing day or due to missing day and month.

Only the incomplete dates related to medical history (date of diagnosis and end date), concomitant medications (start and end date) and AEs (start and end date) will be replaced according to the above rule.

Calculation, sorting or assignation based on dates, in case of incomplete dates, will be performed using the related full dates defined by the above rule.

In all listings, missing dates will be missing and incomplete dates will be reported as full dates. In all listings will also be reported the information about incomplete dates according to the following coding: missing value = full date, Day = missing day, Day&Month = missing day and month.

6.1.4.3 Outliers

For categorical or score data, like adverse events, physical exam's findings and disease assessment parameters, outliers are not expected.

Demographic, vital signs, and clinical laboratory (hematology, blood chemistry and urinalysis) parameters will be checked for outliers according to data plausibility, normal ranges and the range between mean ± 2 S.D.

For each identified outlier, [redacted] will inform the Sponsor in order to assess any errors. If data cannot be verified or if relevant, the descriptive statistics of the related parameters will be reported with and without the outliers. If appropriate, outliers can also be specifically identified in the boxplots.

6.1.5 Subject disposition

A listing of dates of assessments (relative day) and their study exposure will be presented by subject.

A summary table and a flow chart will be presented for each subject population presenting the number of subjects at each assessment procedure and identifying the number of subjects who withdrew over time.

6.1.6 Withdrawals

Discontinued subjects will be listed and a summary table of the number and percentage of subjects who withdrew from the study and the reasons for withdrawal will be presented for all screened subjects.

6.1.7 Demographic and baseline characteristics

All demographic and baseline characteristics will be listed by subject. Summary statistics will be provided for demographic and baseline characteristics for FAS and Safety population (if different from FAS).

6.1.8 Medical and surgical history

Medical and surgical history will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) Version 19.0.

Medical and surgical history will be listed on an individual basis, including Preferred Term (PT) and verbatim term; the listings will be sorted by subject.

A frequency table of the number and percentage of subjects will be provided for all medical and surgical history by primary SOC and PT for Safety population.

6.1.9 Subject compliance

After reconstitution and radiolabeling, ^{99m}Tc-rhAnnexin V-128 is administered as a single intravenous bolus of 350 MBq ± 10% at the imaging visit (Day 0). The administered dose recorded in the eCRF will not be the difference between the pre-injection dose and the post-injection residual dose but will be the decay corrected dose which takes into account the natural product half-life.

A listing will be presented for imaging product administration (dose, quality, date) by subject. Deviations from observed and scheduled times will be presented. Summary tables will be presented for all the continuous variables.

A listing will be presented for concomitant medications.

All the protocol deviations will be also listed by subject.

6.1.10 Prior and concomitant medications

Concomitant medications will be coded using ATC Drug Dictionary Version 2016.

Listings will be presented for ATC name (third level) and verbatim text. The listings will be sorted by subject, chronological start date, ATC name, verbatim text and active substance.

A frequency table of the number and percentage of subjects will be provided for concomitant medications by pharmacological subgroup and chemical substance for Safety population. Two different tables will report Prior Medications (the medications taken and stopped within 30 days prior the ^{99m}Tc-rhAnnexin V-128 injection) and Prior and Concomitant Medications (the medications

started within 30 days prior the ^{99m}Tc-rhAnnexin V-128 injection and continued after the ^{99m}Tc-rhAnnexin V-128 injection and the medications started after the ^{99m}Tc-rhAnnexin V-128 injection).

6.1.11 Derived data

The derived data are variables which are calculated from the raw data in the CRF and not included in the database (e.g.: Age, BMI). The formula used for derived data and the strategy for missing data are provided in Section 12.1.

6.1.12 Visit windows

The screening visit can occur anytime within 8 weeks before the injection day (Day 0).

The first follow-up visit (phone call) should occur within 24 hours after the injection. The second follow-up visit should occur 30 days after the injection with a window of 3 days, i.e. the visit has to be performed between the 27th and the 33rd day from the ^{99m}Tc-rhAnnexin V-128 administration.

6.1.13 Rules and data formats

Data will be presented using an appropriate number of decimal places (i.e. the number of decimal places used does not imply undue precision). Raw data will be presented to the number of decimal places collected, and derived data will be presented to an appropriate number of decimal places. The appropriate number of decimal places will be determined by general practice, mathematical rationale or scientific rationale (e.g. age should be presented in whole numbers).

For summary statistics, the following will be presented: number of non-missing values (n), number of missing values, arithmetic mean, standard deviation, median, the IQR (first quartile, third quartile), the range (minimum, maximum) and, only if appropriate, 95% 2-sided confidence interval.

Mean, standard deviation, first quartile, median, third quartile and confidence interval values will be rounded to one more decimal place than the raw data whereas minimum and maximum will be reported with the same precision as the raw data.

Percentages will be reported to one decimal place. Percentages will be calculated using a denominator of all subjects in a specified population. The denominator will be specified in a footnote to the tables for clarification if necessary.

p-values will be reported to four decimal places (e.g., p=0.0037), after rounding; p-values which are less than 0.0001 will be presented as “<0.0001”.

All text fields must be left justified and numeric or numeric with some text specification (e.g., not done, unknown, <4.5, …) must be decimal justified. Dates will be presented in the format [dd/mm/yyyy] and times in the format [hh:mm] using 24-hour clock scale.

6.1.14 Pooling of centres

Not applicable.

6.1.15 Interim analysis

No formal interim analysis will be done; however the DMC will analyse Planar and SPECT/CT images of the first 15 patients and of the first 5 controls in order to determine the feasibility of imaging apoptotic activity in carotid atherosclerotic plaques of asymptomatic or symptomatic with TIA patients with significant carotid disease, by using ^{99m}Tc-rhAnnexin V-128 imaging, and to report the prevalence of abnormal ^{99m}Tc-rhAnnexin V-128 scans.

6.1.16 Role of independent data monitoring committee (DMC) / interim data review committee

The Data Monitoring Committee (DMC) consists of investigators and Sponsor representatives, as well as external persons such as independent experts, if deemed necessary by the Sponsor. The main function of the committee will be to review and evaluate the images of the first 15 patients and of the first 5 healthy participants in terms of image quality, carotid target uptake and clinical relevance of the study product. The DMC will also review the safety data. The frequency of abnormal carotid scans will be determined in the participant and control groups. The study will be terminated if there is a low frequency of positive scans in the carotid participant group or high frequency of positive scans in the control group.

The DMC will promptly give recommendations to continue or terminate the study. The DMC report will be prepared by the Sponsor and sent to the REB and regulatory authorities as required. Preliminary results can be used by the Sponsor for publication purpose, before the end of the main trial.

6.1.17 Covariates and analysis of subgroups

The analysis on the efficacy endpoints will be performed on the two groups of enrolled subjects (patients and control group). Patient group will also be divided into two groups (normal and abnormal) depending on imaging results (negative or positive).

If deemed relevant some additional analysis might be conducted to explore the impact of clinically relevant covariates such as the level of carotid stenosis (as determined by ultrasound), history of TIA and any other relevant factors on the results.

6.1.18 Sensitivity analysis

Not Applicable.

6.1.19 Multiplicity

As stated in the protocol, no adjustments will be made for multiplicity.

6.1.20 Significance testing and estimation

All statistical tests will be two-sided at the 5% level of significance.

7 COMPUTER SYSTEMS, SOFTWARE AND VALIDATION OF PROGRAMS

7.1 Hardware

The statistical analysis will be performed using Dell personal computer with Windows 7 professional (64 bit) as operating system.

7.2 Software

All tables, listings and figures will be produced and statistical analysis performed using SAS version 9.4. All output will be in Word format.

7.3 Validation programs

An Independent Statistician is responsible for reviewing each project program and output associated with the deliverable product. Program logs are reviewed for logical, syntax and fatal errors. The review in SAS includes, but is not limited to, all ERRORS, WARNINGS, NOTES, and variables check. Program logs are also reviewed for accurate and consistent variable and observation counts following each procedure and data step.

The Independent Statistician is also responsible for checking and reviewing the work produced using whatever method he/she feels is appropriate (e.g. SAS commands review, hand calculation, etc.) to reassure of the quality of the output.

Outputs are reviewed for typographical errors, misspellings and nonsensical values or results and to check the consistency with the reporting and analysis plan. Outputs are cross-checked against each other for accuracy and consistency. For statistical tables, listings, and figures, this procedure includes comparison of subject group numbers, counts of subjects at each observation point, and consistency of results for variables between outputs.

Findings of the quality control reviews are communicated to the party responsible for making necessary changes. The programs will be retested after modifications.

After final review, and when no further changes are required to produce the deliverables, the Independent Statistician needs to complete and sign the SAS Outputs, to indicate that he has successfully performed all of his responsibilities.

8 CHANGES FROM PROTOCOL

No changes from the protocol were made.

9 REFERENCES

Not applicable.

10 DATA PRESENTATION

Data listings are presented for all screened subjects.

Footnotes should be used to clarify ambiguities (e.g.: the denominator used to calculate a percentage or notes for the programmer). If the number of footnotes is high, they could be presented only in the last page, with on each page the following footnote “See last page for listing notes”. The order of the footnotes for key symbols (*, ~) will be in the order that they appear in the listing.

10.1 Listings index

16.2 SUBJECT DATA LISTINGS

16.2.1 Discontinued subjects

Listing 16.2.1.1: Subject Disposition – All Subjects

Listing 16.2.1.2: Subject Disposition – Study Withdrawals

Listing 16.2.1.3: Inclusion Criteria

Listing 16.2.1.4: Exclusion Criteria

Listing 16.2.1.5: Screening Failures

16.2.2 Protocol deviations

Listing 16.2.2: Protocol Deviations and Reasons for Exclusion from the Study Populations

16.2.3 Subjects excluded from the efficacy analysis

Not applicable

16.2.4 Demographic data

Listing 16.2.4.1: Demographics

Listing 16.2.4.2: Carotid Ultrasound

Listing 16.2.4.3: Medical History and Associated Pathologies

Listing 16.2.4.4: Prior and Concomitant Medications

16.2.5 Compliance and/or drug concentration data

Listing 16.2.5.1: Study Drug Administration and Extent of Subject Exposure

16.2.6 Individual efficacy response data

Listing 16.2.6.1: Carotid and Aorta Imaging Assessment

Listing 16.2.6.2: Carotid and Aorta Imaging Assessment – Uptake – Data Recorded on DMC Assessement Form

16.2.7 Adverse event listings (each subject)

Listing 16.2.7.1: All Adverse Events

Listing 16.2.7.2: Serious Adverse Events

Listing 16.2.7.3: Adverse Events Leading to Withdrawal

Listing 16.2.7.4: Adverse Events with Outcome Death

16.2.8 Listing of individual laboratory measurements by subject

Listing 16.2.8.1: Hematology

Listing 16.2.8.2: Blood Chemistry

Listing 16.2.8.3: Urinalysis

Listing 16.2.8.4: Immunogenicity

16.2.9 Listing of other safety data

Listing 16.2.9.1: Pregnancy Test

Listing 16.2.9.2: Physical Examination

Listing 16.2.9.3: Vital Signs

10.2 Listing templates

Listing templates are provided in Appendix 11.1. The listings will be presented in landscape, in a fixed font (Arial) with a minimum size as 8.

10.3 Tables index

14. TABLES, FIGURES AND GRAPHS

14.1 DEMOGRAPHIC DATA

Table 14.1.1: Subject Disposition

Table 14.1.2: Analysis Populations

Table 14.1.3: Protocol Deviations

Table 14.1.4.1: Demographics – FAS Population

Table 14.1.5.1: Carotid Ultrasound – FAS Population

Table 14.3.1.2: Number (%) of Subjects Reporting Treatment Emergent Adverse Events by Primary System Organ Class and Preferred Term – Safety Population

Table 14.3.1.3: Number (%) of Subjects Reporting Treatment Emergent Adverse Events by Severity – Safety Population

Table 14.3.1.4: Number (%) of Subjects Reporting Adverse Drug Reactions by Severity – Safety Population

Table 14.3.1.5: Number (%) of Subjects Reporting Treatment Emergent Serious Adverse Events by Primary System Organ Class and Preferred Term – Safety Population

Table 14.3.1.6: Number (%) of Subjects Reporting Treatment Emergent Serious Adverse Events by Severity – Safety Population

Table 14.3.1.7: Number (%) of Subjects Reporting Serious Adverse Drug Reactions by Severity – Safety Population

14.3.2 Listings of Deaths, Other Serious and Significant Adverse Events

Table 14.3.2.1: Listing of Adverse Events with Outcome Death – Safety Population

Table 14.3.2.2: Listing of Serious Adverse Events – Safety Population

14.3.3 Narratives of Deaths, Other Serious and Certain Other Significant Adverse Events

Only raw narratives will be presented in this section if any.

14.3.4 Abnormal Laboratory Value Listing (each patient)

Only patients with clinically significant abnormal laboratory value(s) will be presented in this section if any.

Table 14.3.4: Abnormal Laboratory Value Listing (Each Patient) – Safety Population

14.3.5 Laboratory Measurements

Table 14.3.5.1: Hematology – Safety Population

Table 14.3.5.2: Blood Chemistry – Safety Population

Table 14.3.5.3: Urinalysis – Safety Population

14.3.6 Other Safety Data

Table 14.3.6.1: Vital Signs – Safety Population

10.4 Table templates

Table templates are provided for each unique table in Appendix 11.2. The tables will be presented in landscape, in a fixed font (arial) with a minimum size as 8.

All tables, in table number order, must be presented in a single Word file.

10.5 Figures index

14. TABLES, FIGURES AND GRAPHS

14.2 EFFICACY DATA

Figure 14.2.1.1: Left Carotid Target to Background Ratio (TBR) Imaging Assessment - Patients – Carotid with Stenosis ≥ 50% – FAS Population - 60 mins after IP injection

Figure 14.2.1.2: Left Carotid Target to Background Ratio (TBR) Imaging Assessment - Patients – Carotid with Stenosis ≥ 50% – FAS Population - 120 mins after IP injection

Figure 14.2.1.3: Right Carotid Target to Background Ratio (TBR) Imaging Assessment - Patients – Carotid with Stenosis ≥ 50% – FAS Population 60 mins after IP injection

Figure 14.2.1.4: Right Carotid Target to Background Ratio (TBR) Imaging Assessment - Patients – Carotid with Stenosis ≥ 50% – FAS Population - 120 mins after IP injection

Figure 14.2.1.5: Scatterplot between Left and Right Carotid and Thoracic Aorta Target to Background Ratio (TBR) – Patients – FAS Population - 60 mins after IP injection

Figure 14.2.1.6: Scatterplot between Left and Right Carotid and Thoracic Aorta Target to Background Ratio (TBR) – Patients – FAS Population - 120 mins after IP injection

Figure 14.2.1.7: Scatterplot between Left and Right Carotid and Abdominal Aorta Target to Background Ratio (TBR) – Patients – FAS Population - 60 mins after IP injection

Figure 14.2.1.8: Scatterplot between Left and Right Carotid and Abdominal Aorta Target to Background Ratio (TBR) – Patients – FAS Population - 120 mins after IP injection

Figure 14.2.1.9: Scatterplot between Left and Right Carotid and Aortic Arch Target to Background Ratio (TBR) – Patients – FAS Population - 60 mins after IP injection

Figure 14.2.1.10: Scatterplot between Left and Right Carotid and Aortic Arch Target to Background Ratio (TBR) – Patients – FAS Population - 120 mins after IP injection

10.6 Figure templates

Figure templates are provided for each unique figure in Appendix 11.3. The figures will be presented in landscape, in a fixed font (arial) with a minimum size as 8.

All figures, in figure number order, must be presented in a single Word file.

10.7 Statistical appendix

A statistical appendix for inclusion in the study report will be provided. All the methods used in checking the assumptions of the analyses and conclusions should be included and explained. Transformation of the data or other methods used for the statistical analysis other than the ones detailed in the SAP will be described and the change will be justified. All the SAS output will be included without reworking the data (raw output).

This output should contain the study number, the date, the number of pages printed by SAS and the table number to which it refers. Any other relevant information (e.g. statistical references…) will be added in the statistical appendix.

11 APPENDICES

11.1 Standard listings

All listings must contain examples of possible data and be presented in fixed font (arial) with a minimum size as 8.

Listing 16.2.1.1: Subject Disposition – All Subjects

Subject ID	Screening date	Informed consent date	Subject group*	Visit 1 date	Phone call 2 date	Visit 3 date	Premature study discontinuation date	FAS	PP	Safety
PAT_PATNUMBER	PAT_FIRSTVISITDATE	PAT_INFCONS_DATE	PAT_INFCONS_TYPE	PATV_VISITDATE	PATV_VISITDATE	PATV_VISITDATE	SD_DATE	[Derived data]	[Derived data]	[Derived data]
04-CA-001	11/03/2011	11/03/2011	Patient	11/04/2011	12/04/2011	11/05/2011		Yes	Yes	Yes
04-CA-002	09/04/2011	09/04/2011	Control	09/04/2011	10/04/2011	10/05/2011		Yes	Yes	Yes
04-CA-003	10/07/2011	10/07/2011	Control	15/07/2011	16/07/2011	NA	10/08/2011	Yes	No	Yes

Data Source Table: W_PATIENT, W_PATIENTVIS, W_SD.

Note: NA = Not Available for patient early withdrawal

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.1.2: Subject Disposition – Study Withdrawals

Subject ID	Screening date	Informed consent date	Informed consent type*	Premature study discontinuation date	Reason for withdrawal	Explanation	Notes	FAS	PP	Safety
PAT_PATNUMBER	PAT_FIRSTVISITDATE	PAT_INFCONS_DATE	PAT_INFCONS_TYPE	SD_DATE	SD_OUTCOME	SD_OUTCOME_SP	SD_NOTES	[Derived data]	[Derived data]	[Derived data]
04-CA-001	11/03/2011	11/03/2011	Patient	10/05/2012	XXXXXX	XXXXXX	XXXXXX	Yes	No	Yes
04-CA-002	09/04/2011	09/04/2011	Control	10/05/2012	XXXXXX	XXXXXX	XXXXXX	Yes	No	Yes
04-CA-003	10/07/2011	10/07/2011	Control	10/05/2012	XXXXXX	XXXXXX	XXXXXX	Yes	No	Yes

Data Source Table: W_PATIENT, W_SD.

Note: NA = Not Available for patient early withdrawal

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.1.3: Inclusion Criteria

					Inclusion criteria				
Subject ID	Subject group*	Sex	Age	Screening date	First	Second	Third	Fourth	Fifth
PAT_PATNUMBER	PAT_INFCONS_TYPE	PAT_GENDER	PAT_AGEYEAR	PAT_FIRSTVISITDATE	IC_1	IC_2	IC_3	IC_4	IC_5
04-CA-001	Patient	Male	54	11/03/2011	Yes	Yes	Not applicable	Yes	Yes
04-CA-002	Control	Female	68	09/04/2011	Yes	Yes	Yes	Not applicable	Not applicable
04-CA-003	Control	Female	59	10/07/2011	No	Yes	Yes	Yes	No

Data Source Table: W_PATIENT, W_PATIENTVIS, W_IEC.

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.1.4: Exclusion Criteria

					Exclusion criteria							
Subject ID	Subject group*	Sex	Age	Screening date	First	Second	Third	Fourth	Fifth	Sixth	Seventh	Eighth
PAT_PATNUMBER	PAT_INFCONS_TYPE	PAT_GENDER	PAT_AGEYEAR	PAT_FIRSTVISITDATE	EC_1	EC_2	EC_3	EC_4	EC_5	EC_6	EC_7	EC_8
04-CA-001	Patient	Male	54	11/03/2011	No	No	Not applicable	No	No	No	No	No
04-CA-002	Control	Female	68	09/04/2011	No	Yes	No	No	No	No	No	No
04-CA-003	Control	Female	59	10/07/2011	Yes	No	No	No	No	No	No	No

Data Source Table: W_PATIENT, W_PATIENTVIS, W_IEC.

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.1.5: Screening Failures

Subject ID	Subject group*	Screening failure	Reason for screen failure
PAT_PATNUMBER	PAT_INFCONS_TYPE	[Derived data]	[Derived data]
04-CA-001	Patient	Yes	XXXXX
04-CA-002	Control	No	XXXXX
04-CA-003	Control	No	XXXXX

Data Source Table: W_PATIENT, W_PATIENTVIS, W_IEC, W_SD.

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.2: Protocol Deviations and Reasons for Exclusion from the Study Populations

Subject ID	Subject group*	Screening date	FAS	PP	Safety	Deviation description	Reason for exclusion
PAT_PATNUMBER	PAT_INFCONS_TYPE	PAT_FIRSTVISITDATE	[Derived data]	[Derived data]	[Derived data]	[Derived data]	[Derived data]
04-CA-001	Patient	11/03/2011	Yes	Yes	No	XXXXXX	XXXXXX
04-CA-002	Control	09/04/2011	No	Yes	Yes	XXXXXX	XXXXXX
04-CA-003	Control	10/07/2011	Yes	No	Yes	XXXXXX	XXXXXX

Data Source Table: W_PATIENT, W_PATIENTVIS, W_SD.

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.4.1: Demographics

Subject ID	Subject group*	Screening date	Sex	Date of birth (month/year)	Age	Ethnicity	Specify other ethnicity	FAS	PP	Safety
PAT_PATNUMBER	PAT_INFCONS_TYPE	PAT_FIRSTVISITDATE	PAT_GENDER	PAT_BIRTH_MONTH PAT_BIRTH_YEAR	PAT_AGEYEAR	PAT_ETHNIC	PAT_ETHNIC_SP	[Derived data]	[Derived data]	[Derived data]
04-CA-001	Patient	11/03/2011	Male	03/1959	54	Other	XXXXXXXX	Yes	Yes	No
04-CA-002	Control	09/04/2011	Female	09/1945	68	Caucasian		No	Yes	Yes
04-CA-003	Control	10/07/2011	Female	02/1954	59	Asian		Yes	No	Yes

Data Source Table: W_PATIENT.

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.4.2: Carotid Ultrasound

				Right Side		Left Side	
Subject ID	Subject group*	Has patient history of TIA?	Carotid ultrasound date	Carotid stenosis	Echolucency/Echogenicity Grade#	Carotid stenosis	Echolucency/ Echogenicity Grade#
PAT_PATNUMBER	PAT_INFCONS_TYPE	[Derived data]	CU_DATE	CU_STEN_R	CU_ECHO_R	CU_STEN_L	CU_ECHO_L
04-CA-001	Patient	No	11/03/2011	80%	1	35%	2
04-CA-002	Control	No	09/04/2011	35%	3	58%	4
04-CA-003	Control	Yes	10/07/2011	20%	5	80%	6

Data Source Table: W_PATIENT, W_CU, W_MH.

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Echolucency/Echogenicity grade: 1 = echolucent; 2 = predominantly echolucent; 3 = predominantly echogenic; 4 = echogenic

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.4.3: Medical History and Associated Pathologies

Subject ID	Subject group*	Medical condition	Preferred term	Date of diagnosis	Partial date	Ongoing?	Currently treated?	Resolution date	Partial date
PAT_PATNUMBER	PAT_INFCONS_TYPE	MH_MEDCOND	MEDDRA_PT	MH_DIAGN_DATE	MH_PARTIAL_START_DATE	MH_ONGOING_YN	MH_TREATED_YN	MH_END_DATE	MH_PARTIAL_END_DATE
04-CA-001	Patient	XXXXXX	XXXXXX	15/08/1990	Day	No		14/04/1994	
04-CA-002	Control	XXXXXX	XXXXXX	31/12/2007		No		15/06/2008	Day&Month
04-CA-003	Control	XXXXXX	XXXXXX	05/05/2005		Yes	Yes		

Data Source Table: W_PATIENT, W_MH.

Dictionary Name: MedDRA Version: 19.0

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.4.4/1: Prior and Concomitant Medications

Subject ID	Subject group*	Medication trade name	ATC description (third level)	Enrollment date	Start date	Partial date	Ongoing?	End date	Partial date
PAT_PATNUMBER	PAT_INFCONS_TYPE	CM_NAME	ATC_LV3_DESCR	PAT_FIRSTVISITDATE	CM_START_DATE	CM_PARTIAL_START_DATE	CM_ONGOING_YN	CM_END_DATE	CM_PARTIAL_END_DATE
04-CA-001	Patient	XXXXXXXX	XXXXXX	11/03/2011	15/08/1990	Day	No	14/04/1994	
04-CA-002	Control	XXXXXXXX	XXXXXX	09/04/2011	31/12/2007		No	15/06/2008	Day&Month
04-CA-003	Control	XXXXXXXX	XXXXXX	10/07/2011	05/05/2005		Yes		

Data Source Table: W_PATIENT, W_CM.

Dictionary Name: ATC Drug Dictionary Version: 2016

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.4.4/2: Prior and Concomitant Medications

Subject ID	Subject group*	Medication trade name	ATC description (third level)	Total daily dose	Unit	Specify other unit	Frequency of administration	Specify other frequency	Route of administration	Specify other route
PAT_PATNUMBER	PAT_INFCONS_TYPE	CM_NAME	ATC_LV3_DESCR	CM_DOSE	CM_DOSEU	CM_DOSEU_SP	CM_FREQ	CM_FREQ_SP	CM_ROUTE	CM_ROUTE_SP
04-CA-001	Patient	XXXXXXXX	XXXXXX	3	G		BID		Otherl	XXXXXX
04-CA-002	Control	XXXXXXXX	XXXXXX	3	Other	XXXXXX	TID		Intramuscolar	
04-CA-003	Control	XXXXXXXX	XXXXXX	12	Mg		Other	XXXXXX	Subcutaneous	

Data Source Table: W_PATIENT, W_CM.

Dictionary Name: ATC Drug Dictionary Version: 2016

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.5.1/1: Study Drug Administration and Extent of Subject Exposure

Subject ID	Subject group*	Has the injection been performed?	Reason for not performing the injection	Injection date	Injection time	Batch of kit	Batch of ^{99m}Tc generator
PAT_PATNUMBER	PAT_INFCONS_TYPE	ANN_YN	ANN_YN_SP	ANN_DATE	ANN_TIME	ANN_KIT	ANN_GEN
04-CA-001	Patient	Yes		11/03/2011	10:50	09101-110631	09101-110631
04-CA-002	Control	Yes		03/03/2011	10:00	09101-110981	09101-110981
04-CA-003	Control	No	XXXXXXX				

Data Source Table: W_PATIENT, W_ANN.

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.5.1/2: Study Drug Administration and Extent of Subject Exposure

Subject ID	Subject group*	Has the injection been performed?	Radiochemical purity	Pre-injection total activity-dose in the syringe (MBq)	Post-injection residual activity-dose in the syringe (MBq)	Actual dose injected (MBq)	Volume of administered solution (mL)
PAT_PATNUMBER	PAT_INFCONS_TYPE	ANN_YN	ANN_TEST1	ANN_TEST2_PRE	ANN_TEST2_POST	ANN_TEST2_EFF	ANN_TEST2_VOL
04-CA-001	Patient	Yes	98.7%	123	123	123	123
04-CA-002	Control	Yes	99.1%	456	456	456	456
04-CA-003	Control	No					

Data Source Table: W_PATIENT, W_ANN.

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.6.1: Carotid and Aorta Imaging Assessment

Subject ID	Subject group*	Has patient history of TIA?	Imaging procedure	Time from IP injection (min)	Has the imaging been completed?	Reason for non completion	Date	Time	Have images been received and reviewed?	Result
PAT_PATNUMBER	PAT_INFCONS_TYPE	[Derived data]	[Derived data]	[Derived data]	SP_YN SPCT_YN	SP_YN_SP SPCT_YN_SP	SP_DATE SPCT_DATE	SP_TIME SPCT_TIME	SP_REV_YN SPCT_REV_YN	SP_RESULT SPCT_RESULT
04-CA-001	Patient	No	SPECT	60	Yes		11/03/2011	10:50	Yes	Positive
04-CA-001	Patient	No	SPECT/CT	120	Yes		11/03/2011	11:45	Yes	Negative
04-CA-002	Control	No	SPECT	60	Yes		03/03/2011	10:00	Yes	Negative
04-CA-002	Control	No	SPECT/CT	120	No	XXXXXXX				

Data Source Table: W_PATIENT, W_MH, W_SPECT_SPECTCT.

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.6.2: Carotid and Aorta Imaging Assessment – Uptake

					Target to Background Ratio				
Subject ID	Subject group*	Has patient history of TIA?	Imaging procedure	Time from IP injection (min)	Left carotid	Right carotid	Thoracic aorta	Abdominal aorta	Aortic arch
PAT_PATNUMBER	PAT_INFCONS_TYPE	[Derived data]	[Derived data]	[Derived data]					
04-CA-001	Patient	No	SPECT	60	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
04-CA-001	Patient	No	SPECT/CT	120	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
04-CA-002	Control	No	SPECT	60	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
04-CA-002	Control	No	SPECT/CT	120	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx

Data Source: Data provided by Sponsor.

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Listing 16.2.7.1/1: All Adverse Events

Subject ID	Subject group*	Event ID	Event description	Primary system organ class	Preferred term	Lowest level term	Study day of onset (days)§	Ongoing?	Duration (days)	TEAE^
PAT_PATNUMBER	PAT_INFCONS_TYPE	ID_WEB	AE_NAME	MEDDRA_SOC	MEDDRA_PT	MEDDRA_LLT	[Derived data]	AE_ONGOING_YN	[Derived data]	[Derived data]
04-CA-001	Patient	XXX	XXXXXX	XXXXXX	XXXXXXXX	XXXXXXXX	YY	No	YY	Yes
04-CA-002	Control	XXX	XXXXXX	XXXXXX	XXXXXXXX	XXXXXXXX	YY	No	YY	Yes
04-CA-003	Control	XXX	XXXXXX	XXXXXX	XXXXXXXX	XXXXXXXX	YY	Yes	YY	Yes

Data Source Table: W_PATIENT, W_AE.

Dictionary Name: MedDRA Version: XX.X

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

§ Study day of onset is defined as days from Annexin injection

^ TEAE: Treatment Emergent Adverse Event as defined in paragraph 6.1.3.1

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.7.1/2: All Adverse Events

Subject ID	Subject group*	Event ID	Event description	AE caused premature withdrawal?	SAE	SAE seriousness	Maximal severity	Causal relationship with medication or procedure	Possible cause	Specify other possible cause	TEAE^
PAT_PATNUMBER	PAT_INFCONS_TYPE	ID_WEB	AE_NAME	AE_WITHD_YN	AE_SAE_YN	[Derived data]	AE_MAXSEV	AE_REL	AE_CAUSE	AE_CAUSE_SP	[Derived data]
04-CA-001	Patient	XXX	XXXXXXXX	Yes	Yes	XXXXXX / XXXXX	Grade 2 (Moderate)	Possible	Other	XXXXXXXXXX	Yes
04-CA-002	Control	XXX	XXXXXXXX	No	No	XXXXXX / XXXXX	Grade 1 (Mild)	Unlikely	Pre-existing/ underlying disease	XXXXXXXXXX	Yes
04-CA-003	Control	XXX	XXXXXXXX	No	No	XXXXXX / XXXXX	Grade 3 (Severe)	Unrelated	Other treatment	XXXXXXXXXX	Yes

Data Source Table: W_PATIENT, W_AE.

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

^ TEAE: Treatment Emergent Adverse Event as defined in paragraph 6.1.3.1

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.7.1/3: All Adverse Events

Subject ID	Subject group*	Event ID	Event description	Action taken	Other action taken	Other action taken, specify	Outcome	TEAE^
PAT_PATNUMBER	PAT_INFCONS_TYPE	ID_WEB	AE_NAME	AE_ACT	[Derived data]	AE_ACT_OTH_SP	AE_OUTCOME	[Derived data]
04-CA-001	Patient	XXX	XXXXXXXX	No action	XXX/XXXXX/XXX		Resolved	Yes
04-CA-002	Control	XXX	XXXXXXXX	Dose modification in next treatment	XXX/XXXXX	XXXXXX	Worsened	Yes
04-CA-003	Control	XXX	XXXXXXXX	Unknown	XXX		Persisting	Yes

Data Source Table: W_PATIENT, W_AE.

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

^ TEAE: Treatment Emergent Adverse Event as defined in paragraph 6.1.3.1

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.7.2/1: Serious Adverse Events

Subject ID	Subject group*	Event ID	Event description	Primary system organ class	Preferred term	Lowest level term	Study day of onset (days)§	Ongoing?	Duration (days)	TEAE^
PAT_PATNUMBER	PAT_INFCONS_TYPE	ID_WEB	AE_NAME	MEDDRA_SOC	MEDDRA_PT	MEDDRA_LLT	[Derived data]	AE_ONGOING_YN	[Derived data]	[Derived data]
04-CA-001	Patient	XXX	XXXXXX	XXXXXX	XXXXXXXX	XXXXXXXX	YY	No	YY	Yes
04-CA-002	Control	XXX	XXXXXX	XXXXXX	XXXXXXXX	XXXXXXXX	YY	No	YY	Yes
04-CA-003	Control	XXX	XXXXXX	XXXXXX	XXXXXXXX	XXXXXXXX	YY	Yes	YY	Yes

Data Source Table: W_PATIENT, W_AE.

Dictionary Name: MedDRA Version: XX.X

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

§ Study day of onset is defined as days from Annexin injection

^ TEAE: Treatment Emergent Adverse Event as defined in paragraph 6.1.3.1

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.7.2/2: Serious Adverse Events

Subject ID	Subject group*	Event ID	Event description	AE caused premature withdrawal?	SAE	SAE seriousness	Maximal severity	Causal relationship with medication or procedure	Possible cause	Specify other possible cause	TEAE^
PAT_PATNUMBER	PAT_INFCONS_TYPE	ID_WEB	AE_NAME	AE_WITHD_YN	AE_SAE_YN	[Derived data]	AE_MAXSEV	AE_REL	AE_CAUSE	AE_CAUSE_SP	[Derived data]
04-CA-001	Patient	XXX	XXXXXXXX	Yes	Yes	XXXXXX / XXXXX	Grade 2 (Moderate)	Possible	Other	XXXXXXXXXX	Yes
04-CA-002	Control	XXX	XXXXXXXX	No	No	XXXXXX / XXXXX	Grade 1 (Mild)	Unlikely	Pre-existing/ underlying disease	XXXXXXXXXX	Yes
04-CA-003	Control	XXX	XXXXXXXX	No	No	XXXXXX / XXXXX	Grade 3 (Severe)	Unrelated	Other treatment	XXXXXXXXXX	Yes

Data Source Table: W_PATIENT, W_AE.

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

^ TEAE: Treatment Emergent Adverse Event as defined in paragraph 6.1.3.1

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.7.2/3: Serious Adverse Events

Subject ID	Subject group*	Event ID	Event description	Action taken	Other action taken	Other action taken, specify	Outcome	TEAE^
PAT_PATNUMBER	PAT_INFCONS_TYPE	ID_WEB	AE_NAME	AE_ACT	[Derived data]	AE_ACT_OTH_SP	AE_OUTCOME	[Derived data]
04-CA-001	Patient	XXX	XXXXXXXX	No action	XXX/XXXXX/XXX		Resolved	Yes
04-CA-002	Control	XXX	XXXXXXXX	Dose modification in next treatment	XXX/XXXXX	XXXXXX	Worsened	Yes
04-CA-003	Control	XXX	XXXXXXXX	Unknown	XXX		Persisting	Yes

Data Source Table: W_PATIENT, W_AE.

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

^ TEAE: Treatment Emergent Adverse Event as defined in paragraph 6.1.3.1

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.7.3/1: Adverse Events Leading to Withdrawal

Subject ID	Subject group*	Event ID	Event description	Primary system organ class	Preferred term	Lowest level term	Study day of onset (days)§	Ongoing?	Duration (days)	TEAE^
PAT_PATNUMBER	PAT_INFCONS_TYPE	ID_WEB	AE_NAME	MEDDRA_SOC	MEDDRA_PT	MEDDRA_LLT	[Derived data]	AE_ONGOING_YN	[Derived data]	[Derived data]
04-CA-001	Patient	XXX	XXXXXX	XXXXXX	XXXXXXXX	XXXXXXXX	YY	No	YY	Yes
04-CA-002	Control	XXX	XXXXXX	XXXXXX	XXXXXXXX	XXXXXXXX	YY	No	YY	Yes
04-CA-003	Control	XXX	XXXXXX	XXXXXX	XXXXXXXX	XXXXXXXX	YY	Yes	YY	Yes

Data Source Table: W_PATIENT, W_AE.

Dictionary Name: MedDRA Version: XX.X

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

§ Study day of onset is defined as days from Annexin injection

^ TEAE: Treatment Emergent Adverse Event as defined in paragraph 6.1.3.1

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.7.3/2: Adverse Events Leading to Withdrawal

Subject ID	Subject group*	Event ID	Event description	AE caused premature withdrawal?	SAE	SAE seriousness	Maximal severity	Causal relationship with medication or procedure	Possible cause	Specify other possible cause	TEAE^
PAT_PATNUMBER	PAT_INFCONS_TYPE	ID_WEB	AE_NAME	AE_WITHD_YN	AE_SAE_YN	[Derived data]	AE_MAXSEV	AE_REL	AE_CAUSE	AE_CAUSE_SP	[Derived data]
04-CA-001	Patient	XXX	XXXXXXXX	Yes	Yes	XXXXXX / XXXXX	Grade 2 (Moderate)	Possible	Other	XXXXXXXXXX	Yes
04-CA-002	Control	XXX	XXXXXXXX	No	No	XXXXXX / XXXXX	Grade 1 (Mild)	Unlikely	Pre-existing/ underlying disease	XXXXXXXXXX	Yes
04-CA-003	Control	XXX	XXXXXXXX	No	No	XXXXXX / XXXXX	Grade 3 (Severe)	Unrelated	Other treatment	XXXXXXXXXX	Yes

Data Source Table: W_PATIENT, W_AE.

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

^ TEAE: Treatment Emergent Adverse Event as defined in paragraph 6.1.3.1

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.7.3/3: Adverse Events Leading to Withdrawal

Subject ID	Subject group*	Event ID	Event description	Action taken	Other action taken	Other action taken, specify	Outcome	TEAE^
PAT_PATNUMBER	PAT_INFCONS_TYPE	ID_WEB	AE_NAME	AE_ACT	[Derived data]	AE_ACT_OTH_SP	AE_OUTCOME	[Derived data]
04-CA-001	Patient	XXX	XXXXXXXX	No action	XXX/XXXXX/XXX		Resolved	Yes
04-CA-002	Control	XXX	XXXXXXXX	Dose modification in next treatment	XXX/XXXXX	XXXXXX	Worsened	Yes
04-CA-003	Control	XXX	XXXXXXXX	Unknown	XXX		Persisting	Yes

Data Source Table: W_PATIENT, W_AE.

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

^ TEAE: Treatment Emergent Adverse Event as defined in paragraph 6.1.3.1

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.7.4/1: Adverse Events with Outcome Death

Subject ID	Subject group*	Event ID	Event description	Primary system organ class	Preferred term	Lowest level term	Study day of onset (days)§	Ongoing?	Duration (days)	TEAE^
PAT_PATNUMBER	PAT_INFCONS_TYPE	ID_WEB	AE_NAME	MEDDRA_SOC	MEDDRA_PT	MEDDRA_LLT	[Derived data]	AE_ONGOING_YN	[Derived data]	[Derived data]
04-CA-001	Patient	XXX	XXXXXX	XXXXXX	XXXXXXXX	XXXXXXXX	YY	No	YY	Yes
04-CA-002	Control	XXX	XXXXXX	XXXXXX	XXXXXXXX	XXXXXXXX	YY	No	YY	Yes
04-CA-003	Control	XXX	XXXXXX	XXXXXX	XXXXXXXX	XXXXXXXX	YY	Yes	YY	Yes

Data Source Table: W_PATIENT, W_AE.

Dictionary Name: MedDRA Version: XX.X

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

§ Study day of onset is defined as days from Annexin injection

^ TEAE: Treatment Emergent Adverse Event as defined in paragraph 6.1.3.1

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.7.4/2: Adverse Events with Outcome Death

Subject ID	Subject group*	Event ID	Event description	AE caused premature withdrawal?	SAE	SAE seriousness	Maximal severity	Causal relationship with medication or procedure	Possible cause	Specify other possible cause	TEAE^
PAT_PATNUMBER	PAT_INFCONS_TYPE	ID_WEB	AE_NAME	AE_WITHD_YN	AE_SAE_YN	[Derived data]	AE_MAXSEV	AE_REL	AE_CAUSE	AE_CAUSE_SP	[Derived data]
04-CA-001	Patient	XXX	XXXXXXXX	Yes	Yes	XXXXXX / XXXXX	Grade 2 (Moderate)	Possible	Other	XXXXXXXXXX	Yes
04-CA-002	Control	XXX	XXXXXXXX	No	No	XXXXXX / XXXXX	Grade 1 (Mild)	Unlikely	Pre-existing/ underlying disease	XXXXXXXXXX	Yes
04-CA-003	Control	XXX	XXXXXXXX	No	No	XXXXXX / XXXXX	Grade 3 (Severe)	Unrelated	Other treatment	XXXXXXXXXX	Yes

Data Source Table: W_PATIENT, W_AE.

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

^ TEAE: Treatment Emergent Adverse Event as defined in paragraph 6.1.3.1

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.7.4/3: Adverse Events with Outcome Death

Subject ID	Subject group*	Event ID	Event description	Action taken	Other action taken	Other action taken, specify	Outcome	TEAE^
PAT_PATNUMBER	PAT_INFCONS_TYPE	ID_WEB	AE_NAME	AE_ACT	[Derived data]	AE_ACT_OTH_SP	AE_OUTCOME	[Derived data]
04-CA-001	Patient	XXX	XXXXXXXX	No action	XXX/XXXXX/XXX		Resolved	Yes
04-CA-002	Control	XXX	XXXXXXXX	Dose modification in next treatment	XXX/XXXXX	XXXXXX	Worsened	Yes
04-CA-003	Control	XXX	XXXXXXXX	Unknown	XXX		Persisting	Yes

Data Source Table: W_PATIENT, W_AE.

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

^ TEAE: Treatment Emergent Adverse Event as defined in paragraph 6.1.3.1

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.8.1/1: Hematology

Subject ID	Subject group*	Visit	Have hematology tests been done?	Sample collection date	Sample collection time	Parameter	Result	Unit	Abnormality
PAT_PATNUMBER	PAT_INFCONS_TYPE	VISIT_NAME	HE_YN	HE_DATE	HE_TIME		HE_RBC		HE_RBC_ABN
04-CA-001	Patient	Screening	Yes	11/03/2011	10:52	Red Blood Cells	99.99	10^6/uL	Abnormal Non-Clinical Relevant
						Hematocrit	99.99	%	Abnormal Non-Clinical Relevant
						Etc.	99.99		Abnormal Non-Clinical Relevant
04-CA-001	Patient	Visit 3	Yes	09/04/2011	15:00		99.99		Abnormal Clinical Relevant
04-CA-002	Control	Screening	Yes	10/07/2011	09:38		Not done		
04-CA-003	Control	Visit 3	No: XXXX						

Listing 16.2.8.2/1: Blood Chemistry

Repeat table 16.2.8.1 for Blood Chemistry parameters

Listing 16.2.8.3/1: Urinalysis

Repeat table 16.2.8.1 for Urinalysis parameters

Listing 16.2.8.4: Immunogenicity

Subject ID	Subject group*	Visit	Has venous sample been done?	Reason for non performance	Sample collection date	Sample collection time
PAT_PATNUMBER	PAT_INFCONS_TYPE	VISIT_NAME	IM_YN	IM_YN_SP	IM_DATE	IM_TIME
04-CA-001	Patient	Screening	Yes		11/03/2011	10:52
04-CA-001	Patient	Visit 3	Yes		09/04/2011	15:00
04-CA-002	Control	Screening	Yes		10/07/2011	09:38
04-CA-003	Control	Visit 3	No	XXXXXXXXX		

Data Source Table: W_PATIENT, W_PATIENTVIS, W_IM. Other data source: database provided by Sponsor: XXXXXXXX.

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.9.1: Pregnancy Test

Subject ID	Subject group*	Sex	Age	Visit	Has the pregnancy test been performed?	Reason for non performance	Specify reason	Pregnancy test date	Pregnancy test time	Pregnancy test result
PAT_PATNUMBER	PAT_INFCONS_TYPE	PAT_GENDER	PAT_AGEYEAR	VISIT_NAME	PT_YN	PT_NOTDONE	PT_NOTDONE_SP	PT_DATE	PT_TIME	PT_RESULT
04-CA-001	Patient	Male	54	Screening	Not applicable					
04-CA-001	Patient	Male	54	Visit 1	Not applicable					
04-CA-002	Control	Female	38	Screening	Yes			09/04/2011	12:00	Negative
04-CA-002	Control	Female	38	Visit 1	Yes			12/04/2011	10:00	Negative
04-CA-003	Control	Female	59	Screening	No	Menopause				

Data Source Table: W_PATIENT, W_PATIENTVIS, W_PT.

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.9.2: Physical Examination

									Specify		
Subject ID	Subject group*	Visit	Evaluation period	Has physical examination been done?	Reason for non performance	Physical examination date	Physical examination time	Any clinically relevant finding?	First finding	Second finding	Third finding
PAT_PATNUMBER	PAT_INFCONS_TYPE	VISIT_NAME	[Derived data]	PE_YN PE_POST_YN	PE_YN_SP PE_POST_YN_SP	PE_DATE PE_POST_DATE	PE_TIME PE_POST_TIME	PE_RELFIND_YN PE_POST_RELFIND_YN	PE_RELFIND1 PE_POST_RELFIND1	PE_RELFIND2 PE_POST_RELFIND2	PE_RELFIND3 PE_POST_RELFIND3
04-CA-001	Patient	Screening		Yes		09/04/2011	12:00	No			
04-CA-001	Patient	Visit 1	Before injection	Yes		12/04/2011	10:00	No			
04-CA-001	Patient	Visit 1	After injection	Yes		12/04/2011	12:45	Yes	XXXXX	XXXXXX	XXXXXX
04-CA-002	Control	Screening		No	XXXXXXXX						

Data Source Table: W_PATIENT, W_PATIENTVIS, W_PE_VS, W_PE_VS_POST.

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.9.3/1: Vital Signs

Subject ID	Subject group*	Visit	Evaluation period	Have vital signs been evaluated?	Reason for non evaluation	Vital signs evaluation date	Vital signs evaluation time	Systolic BP (mmHg)	Diastolic BP (mmHg)	Heart rate (beats/min)
PAT_PATNUMBER	PAT_INFCONS_TYPE	VISIT_NAME	[Derived data]	VS_YN VS_POST_YN	VS_YS_SP VS_POST_YN_SP	VS_DATE VS_POST_DATE	VS_TIME VS_POST_TIME	VS_SBP VS_POST_SBP	VS_DBP VS_POST_DBP	VS_HR VS_POST_HR
04-CA-001	Patient	Screening		Yes		09/04/2011	12:00	165	99	77
04-CA-001	Patient	Visit 1	Before injection	Yes		12/04/2011	10:00	129	93	60
04-CA-001	Patient	Visit 1	After injection	Yes		12/04/2011	12:45	147	68	76
04-CA-002	Control	Screening		No	XXXXXXXX					

Data Source Table: W_PATIENT, W_PATIENTVIS, W_PE_VS, W_PE_VS_POST.

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

File directory: *path of directory status from study level downwards* /XXXXXX.sas

Listing 16.2.9.3/2: Vital Signs

Subject ID	Subject group*	Visit	Has physical examination been done?	Reason for non performance	Physical examination date	Physical examination time	Height (cm)	Weight (Kg)	BMI (Kg/m^2)
PAT_PATNUMBER	PAT_INFCONS_TYPE	VISIT_NAME	PE_YN	PE_YN_SP	PE_DATE	PE_TIME	HEIGHT	WEIGHT	BMI
04-CA-001	Patient	Screening	Yes		09/04/2011	12:00	180	68.5	23.8
04-CA-002	Control	Visit 1	Yes		12/04/2011	10:00	NA	72.3	22.1
04-CA-003	Control	Screening	Yes		06/05/2013	9:45	178	85.9	27.3

Data Source Table: W_PATIENT, W_PATIENTVIS, W_PE_VS.

Note: NA = Not Available

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

File directory: *path of directory status from study level downwards* /XXXXXX.sas

11.2 Standard Tables

[redacted]

Table 14.1.1: Subject Disposition

POPULATION	STATISTIC	PATIENT* (N=xx)	CONTROL* (N=xx)	ALL SUBJECTS (N=xx)
Screened subjects	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Screen failures	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Reason 1	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
…	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Reason m	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Enrolled subjects	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Dosed subjects	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Completed study subjects	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Discontinued study subjects	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Reason 1	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
…	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Reason m	n (%)	99 (99.9)	99 (99.9)	99 (99.9)

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

Note: All percentages are based upon the number of screened subjects.

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.1.2: Analysis Populations

ANALYSIS SET	STATISTIC	PATIENT* (N=xx)	CONTROL* (N=xx)	ALL SUBJECTS (N=xx)
Full Analysis Set (FAS)	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Per Protocol population (PP)	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Safety population	n (%)	99 (99.9)	99 (99.9)	99 (99.9)

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

Note: All percentages are based upon the number of screened subjects.

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

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Table 14.1.3: Protocol Deviations

PROTOCOL DEVIATION	STATISTIC	PATIENT* (N=xx)	CONTROL* (N=xx)	ALL SUBJECTS (N=xx)
Subjects with any minor protocol deviations	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Minor deviation 1	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
…	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Minor deviation m	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Subjects with any major protocol deviations	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Major deviation 1	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
…	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Major deviation m	n (%)	99 (99.9)	99 (99.9)	99 (99.9)

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

Note: All percentages are based upon the number of screened subjects.

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.1.4.1: Demographics – FAS Population

PARAMETER		STATISTIC	PATIENT* (N=xx)	CONTROL* (N=xx)	ALL SUBJECTS (N=xx)
Age (years)		n	99	99	99
		Missing	99	99	99
		Mean	99.9	99.9	99.9
		S.D.	99.9	99.9	99.9
		Median	99.9	99.9	99.9
		Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
		Min, Max	99, 99	99, 99	99, 99
Sex	Male	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
	Female	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
	Missing	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Ethnicity	Asian	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
	Black	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
	Caucasian	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
	Hispanic	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
	Other	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
	Missing	n (%)	99 (99.9)	99 (99.9)	99 (99.9)

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

Note: All percentages are based upon the number of enrolled subjects by group.

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.1.5.1/1: Carotid Ultrasound – FAS Population

RIGHT SIDE		STATISTIC	PATIENT* (N=xx)	CONTROL* (N=xx)
Carotid stenosis (%)		n	99	99
		Missing	99	99
		Mean	99.9	99.9
		S.D.	99.9	99.9
		Median	99.9	99.9
		Q1, Q3	99.9, 99.9	99.9, 99.9
		Min, Max	99, 99	99, 99
Echolucency/echogenicity grade	Echolucent	n (%)	99 (99.9)	99 (99.9)
	Predominantly echolucent	n (%)	99 (99.9)	99 (99.9)
	Predominantly echogenic	n (%)	99 (99.9)	99 (99.9)
	Echogenic	n (%)	99 (99.9)	99 (99.9)
	Missing	n (%)	99 (99.9)	99 (99.9)

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

Note: All percentages are based upon the number of enrolled subjects by group.

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.1.5.1/2: Carotid Ultrasound – FAS Population

LEFT SIDE		STATISTIC	PATIENT* (N=xx)	CONTROL* (N=xx)
Carotid stenosis (%)		n	99	99
		Missing	99	99
		Mean	99.9	99.9
		S.D.	99.9	99.9
		Median	99.9	99.9
		Q1, Q3	99.9, 99.9	99.9, 99.9
		Min, Max	99, 99	99, 99
Echolucency/echogenicity grade	Echolucent	n (%)	99 (99.9)	99 (99.9)
	Predominantly echolucent	n (%)	99 (99.9)	99 (99.9)
	Predominantly echogenic	n (%)	99 (99.9)	99 (99.9)
	Echogenic	n (%)	99 (99.9)	99 (99.9)
	Missing	n (%)	99 (99.9)	99 (99.9)

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

Note: All percentages are based upon the number of enrolled subjects by group.

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.1.6.1: Medical History and Associated Pathologies – Safety Population

PRIMARY SYSTEM ORGAN CLASS PREFERRED TERM	STATISTIC	PATIENT* (N=xx)	CONTROL* (N=xx)
Any medical and surgical history	n (%)	99 (99.9)	99 (99.9)
System organ class 1	n (%)	99 (99.9)	99 (99.9)
Preferred term 1	n (%)	99 (99.9)	99 (99.9)
…	n (%)	99 (99.9)	99 (99.9)
Preferred term m	n (%)	99 (99.9)	99 (99.9)
System organ class …	n (%)	99 (99.9)	99 (99.9)
Preferred term 1	n (%)	99 (99.9)	99 (99.9)
…	n (%)	99 (99.9)	99 (99.9)
Preferred term m	n (%)	99 (99.9)	99 (99.9)
System organ class m	n (%)	99 (99.9)	99 (99.9)
Preferred term 1	n (%)	99 (99.9)	99 (99.9)
…	n (%)	99 (99.9)	99 (99.9)
Preferred term m	n (%)	99 (99.9)	99 (99.9)

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

Dictionary Name: MedDRA Version: XX.X

Notes: All percentages are based upon the number of enrolled subjects by group.

Subjects with more than one event within a particular SOC and PT will be counted only once for that SOC and PT.

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.1.7.1: Prior Medications or Non-Drug Therapies – Safety Population

PHARMACOLOGICAL SUBGROUP CHEMICAL SUBSTANCE	STATISTIC	PATIENT* (N=xx)	CONTROL* (N=xx)
Any medication or therapy	n (%)	99 (99.9)	99 (99.9)
Pharmacological subgroup 1	n (%)	99 (99.9)	99 (99.9)
Chemical substance 1	n (%)	99 (99.9)	99 (99.9)
…	n (%)	99 (99.9)	99 (99.9)
Chemical substance m	n (%)	99 (99.9)	99 (99.9)
Pharmacological subgroup …	n (%)	99 (99.9)	99 (99.9)
Chemical substance 1	n (%)	99 (99.9)	99 (99.9)
…	n (%)	99 (99.9)	99 (99.9)
Chemical substance m	n (%)	99 (99.9)	99 (99.9)
Pharmacological subgroup m	n (%)	99 (99.9)	99 (99.9)
Chemical substance 1	n (%)	99 (99.9)	99 (99.9)
…	n (%)	99 (99.9)	99 (99.9)
Chemical substance m	n (%)	99 (99.9)	99 (99.9)

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

Dictionary Name: ATC Drug Dictionary Version: 2016

Notes: All percentages are based upon the number of enrolled subjects by group.

Subjects with more than one medication within a particular pharmacological subgroup and chemical substance will be counted only once for that pharmacological subgroup and chemical substance.

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.1.7.2: Prior and Concomitant Medications or Non-Drug Therapies – Safety Population

PHARMACOLOGICAL SUBGROUP CHEMICAL SUBSTANCE	STATISTIC	PATIENT* (N=xx)	CONTROL* (N=xx)
Any medication or therapy	n (%)	99 (99.9)	99 (99.9)
Pharmacological subgroup 1	n (%)	99 (99.9)	99 (99.9)
Chemical substance 1	n (%)	99 (99.9)	99 (99.9)
…	n (%)	99 (99.9)	99 (99.9)
Chemical substance m	n (%)	99 (99.9)	99 (99.9)
Pharmacological subgroup …	n (%)	99 (99.9)	99 (99.9)
Chemical substance 1	n (%)	99 (99.9)	99 (99.9)
…	n (%)	99 (99.9)	99 (99.9)
Chemical substance m	n (%)	99 (99.9)	99 (99.9)
Pharmacological subgroup m	n (%)	99 (99.9)	99 (99.9)
Chemical substance 1	n (%)	99 (99.9)	99 (99.9)
…	n (%)	99 (99.9)	99 (99.9)
Chemical substance m	n (%)	99 (99.9)	99 (99.9)

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

Dictionary Name: ATC Drug Dictionary Version: 2016

Notes: All percentages are based upon the number of enrolled subjects by group.

Subjects with more than one medication within a particular pharmacological subgroup and chemical substance will be counted only once for that pharmacological subgroup and chemical substance.

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.1.8.1/1: Study Drug Administration – Safety Population

QUALITY CONTROL ON THE FINAL PRODUCT	STATISTIC	PATIENT* (N=xx)	CONTROL* (N=xx)
Radiochemical purity (%)	n	99	99
	Missing	99	99
	Mean	99.9	99.9
	S.D.	99.9	99.9
	Median	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

Note: Acceptance criteria is radiochemical purity ≥ 90%.

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.1.8.1/2: Study Drug Administration – Safety Population

QUALITY CONTROL ON THE FINAL PRODUCT	STATISTIC	PATIENT* (N=xx)	CONTROL* (N=xx)
Pre-injection total activity-dose in the syringe (MBq)	n	99	99
	Missing	99	99
	Mean	99.9	99.9
	S.D.	99.9	99.9
	Median	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99
Post-injection residual activity-dose in the syringe (MBq)	n	99	99
	Missing	99	99
	Mean	99.9	99.9
	S.D.	99.9	99.9
	Median	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.1.8.1/3: Study Drug Administration – Safety Population

QUALITY CONTROL ON THE FINAL PRODUCT	STATISTIC	PATIENT* (N=xx)	CONTROL* (N=xx)
Actual dose injected (MBq)	n	99	99
	Missing	99	99
	Mean	99.9	99.9
	S.D.	99.9	99.9
	Median	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99
Volume of administered solution (mL)	n	99	99
	Missing	99	99
	Mean	99.9	99.9
	S.D.	99.9	99.9
	Median	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.2.1.1: Carotid and Aorta Imaging Assessment – Prevalence of Positive Scans – FAS Population

TIME POINT		STATISTIC	PATIENT* (N=xx)	CONTROL* (N=xx)
60 mins after IP injection	Positive	n (%)	99 (99.9)	99 (99.9)
		95% C.I.	99.9 - 99.9	99.9 - 99.9
	Negative	n (%)	99 (99.9)	99 (99.9)
	Missing	n (%)	99 (99.9)	99 (99.9)
120 mins after IP injection	Positive	n (%)	99 (99.9)	99 (99.9)
		95% C.I.	99.9 - 99.9	99.9 - 99.9
	Negative	n (%)	99 (99.9)	99 (99.9)
	Missing	n (%)	99 (99.9)	99 (99.9)
Overall[#]	Positive	n (%)	99 (99.9)	99 (99.9)
		95% C.I.	99.9 - 99.9	99.9 - 99.9
	Negative	n (%)	99 (99.9)	99 (99.9)
	Missing	n (%)	99 (99.9)	99 (99.9)

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

Notes: All percentages are based upon the number of enrolled subjects by group.

Confidence intervals are estimated using the exact (Clopper-Pearson) formula for binomial proportions.

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

[#] Subjects with either a positive scan at 60 or 120 minutes post injection will be considered overall positive

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.2.1.2: Carotid and Aorta Imaging Assessment – Prevalence of Positive Scans – PP Population

IMAGING PROCEDURE		STATISTIC	PATIENT* (N=xx)	CONTROL* (N=xx)
SPECT (60 mins after IP injection)	Positive	n (%)	99 (99.9)	99 (99.9)
		95% C.I.	99.9 - 99.9	99.9 - 99.9
	Negative	n (%)	99 (99.9)	99 (99.9)
	Missing	n (%)	99 (99.9)	99 (99.9)
SPECT/CT (120 mins after IP injection)	Positive	n (%)	99 (99.9)	99 (99.9)
		95% C.I.	99.9 - 99.9	99.9 - 99.9
	Negative	n (%)	99 (99.9)	99 (99.9)
	Missing	n (%)	99 (99.9)	99 (99.9)
Overall[#]	Positive	n (%)	99 (99.9)	99 (99.9)
		95% C.I.	99.9 - 99.9	99.9 - 99.9
	Negative	n (%)	99 (99.9)	99 (99.9)
	Missing	n (%)	99 (99.9)	99 (99.9)

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

Notes: All percentages are based upon the number of enrolled subjects by group.

Confidence intervals are estimated using the exact (Clopper-Pearson) formula for binomial proportions.

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

[#] Subjects with either a positive scan at 60 or 120 minutes post injection will be considered overall positive

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.2.1.3: Patient Carotid and Aorta Imaging Assessment – Comparison between time points – FAS Population

60 MINS AFTER IP INJECTION	120 MINS AFTER IP INJECTION	STATISTIC	PATIENT* (N=xx)
Positive	Positive	n (%)	99 (99.9)
Positive	Negative	n (%)	99 (99.9)
Positive	Total	n (%)	99 (99.9)
Negative	Positive	n (%)	99 (99.9)
Negative	Negative	n (%)	99 (99.9)
Negative	Total	n (%)	99 (99.9)
Total	Positive	n (%)	99 (99.9)
Total	Negative	n (%)	99 (99.9)
Total	Total	n (%)	99 (99.9)
		p-value	0.9999

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

Notes: All percentages are based upon the number of subjects who performed both imaging procedures.

p-value is based on McNemar's test.

* Patient = Subject with asymptomatic plaque

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.2.1.4: Left Carotid Uptake Imaging Assessment – Target to Background Ratio (TBR) – FAS Population

TIME POINT	STATISTIC	PATIENT* (N=xx)	CONTROL* (N=xx)
60 mins after IP injection	n	99	99
	Missing	99	99
	Mean	99.9	99.9
	S.D.	99.9	99.9
	Median	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99
	p-value^		0.9999
120 mins after IP injection	n	99	99
	Missing	99	99
	Mean	99.9	99.9
	S.D.	99.9	99.9
	Median	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99
	p-value^		0.9999

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer ^p-value is based on T- test.

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.2.1.5: Right Carotid Uptake Imaging Assessment – Target to Background Ratio (TBR) – FAS Population

TIME POINT	STATISTIC	PATIENT* (N=xx)	CONTROL* (N=xx)
60 mins after IP injection	n	99	99
	Missing	99	99
	Mean	99.9	99.9
	S.D.	99.9	99.9
	Median	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99
	p-value^		0.9999
120 mins after IP injection	n	99	99
	Missing	99	99
	Mean	99.9	99.9
	S.D.	99.9	99.9
	Median	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99
	p-value^		0.9999

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer ^p-value is based on T- test.

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.2.1.6: Thoracic Aorta Uptake Imaging Assessment – Target to Background Ratio (TBR) – FAS Population

TIME POINT	STATISTIC	PATIENT* (N=xx)	CONTROL* (N=xx)
60 mins after IP injection	n	99	99
	Missing	99	99
	Mean	99.9	99.9
	S.D.	99.9	99.9
	Median	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99
	p-value^		0.9999
120 mins after IP injection	n	99	99
	Missing	99	99
	Mean	99.9	99.9
	S.D.	99.9	99.9
	Median	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99
	p-value^		0.9999

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* * Patient = Subject with asymptomatic plaque; Control = Healthy volunteer ^p-value is based on T- test.

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.2.1.7: Abdominal Aorta Uptake Imaging Assessment – Target to Background Ratio (TBR) – FAS Population

TIME POINT	STATISTIC	PATIENT* (N=xx)	CONTROL* (N=xx)
60 mins after IP injection	n	99	99
	Missing	99	99
	Mean	99.9	99.9
	S.D.	99.9	99.9
	Median	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99
	p-value^		0.9999
120 mins after IP injection	n	99	99
	Missing	99	99
	Mean	99.9	99.9
	S.D.	99.9	99.9
	Median	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99
	p-value^		0.9999

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer ^p-value is based on T- test.

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.2.1.8: Aortic Arch Uptake Imaging Assessment – Target to Background Ratio (TBR) – FAS Population

TIME POINT	STATISTIC	PATIENT* (N=xx)	CONTROL* (N=xx)
60 mins after IP injection	n	99	99
	Missing	99	99
	Mean	99.9	99.9
	S.D.	99.9	99.9
	Median	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99
	p-value^		0.9999
120 mins after IP injection	n	99	99
	Missing	99	99
	Mean	99.9	99.9
	S.D.	99.9	99.9
	Median	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99
	p-value^		0.9999

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer ^p-value is based on T-test.

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.2.1.9: Left Carotid Uptake Imaging Assessment by ultrasound grade of plaque echolucency/echogenicity – Target to Background Ratio (TBR) – Patients - FAS Population

TIME POINT	STATISTIC	ECHOLUCENT	PREDOMINANTLY ECHOLUCENT	PREDOMINANTLY ECHOGENIC	ECHOGENIC
60 mins after IP injection	n	99	99	99	99
	Missing	99	99	99	99
	Mean	99.9	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9	99.9
	Median	99.9	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99	99, 99
120 mins after IP injection	n	99	99	99	99
	Missing	99	99	99	99
	Mean	99.9	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9	99.9
	Median	99.9	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

Patient = Subject with asymptomatic plaque

Only left carotid with stenosis >50% are taken into account.

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.2.1.10: Right Carotid Uptake Imaging Assessment by ultrasound grade of plaque echolucency/echogenicity – Target to Background Ratio (TBR) – Patients - FAS Population

TIME POINT	STATISTIC	ECHOLUCENT	PREDOMINANTLY ECHOLUCENT	PREDOMINANTLY ECHOGENIC	ECHOGENIC
60 mins after IP injection	n	99	99	99	99
	Missing	99	99	99	99
	Mean	99.9	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9	99.9
	Median	99.9	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99	99, 99
120 mins after IP injection	n	99	99	99	99
	Missing	99	99	99	99
	Mean	99.9	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9	99.9
	Median	99.9	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

Patient = Subject with asymptomatic plaque

Only right carotid with stenosis >50% are taken into account.

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.1.1: Overall Summary of Adverse Events – Safety Population

ADVERSE EVENT CATEGORY	STATISTIC	PATIENT* (N=xx)	CONTROL* (N=xx)	ALL SUBJECTS (N=xx)
Treatment emergent Aes	n (%) [n. events]	99 (99.9) [99]	99 (99.9) [99]	99 (99.9) [99]
Treatment emergent adverse drug reactions	n (%) [n. events]	99 (99.9) [99]	99 (99.9) [99]	99 (99.9) [99]
Treatment emergent SAEs	n (%) [n. events]	99 (99.9) [99]	99 (99.9) [99]	99 (99.9) [99]
Treatment emergent serious adverse drug reactions	n (%) [n. events]	99 (99.9) [99]	99 (99.9) [99]	99 (99.9) [99]
Treatment emergent AEs leading to withdrawal	n (%) [n. events]	99 (99.9) [99]	99 (99.9) [99]	99 (99.9) [99]
Treatment emergent AEs leading to death	n (%) [n. events]	99 (99.9) [99]	99 (99.9) [99]	99 (99.9) [99]

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

Note: Format is number of subjects (percent of subjects) [number of events].

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.1.2: Number (%) of Subjects Reporting Treatment Emergent Adverse Events by Primary System Organ Class and Preferred Term – Safety Population

PRIMARY SYSTEM ORGAN CLASS PREFERRED TERM	STATISTIC	PATIENT* (N=xx)	CONTROL* (N=xx)	ALL SUBJECTS (N=xx)
Any adverse events	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
System organ class 1	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term 1	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
…	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term m	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
System organ class …	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term 1	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
…	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term m	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
System organ class m	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term 1	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
…	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term m	n (%)	99 (99.9)	99 (99.9)	99 (99.9)

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}* Dictionary Name: MedDRA Version: 19.0

Notes: All percentages are based upon the number of enrolled subjects by group.

Subjects with more than one event within a particular SOC and PT will be counted only once for that SOC and PT.

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.1.3: Number (%) of Subjects Reporting Treatment Emergent Adverse Events by Severity – Safety Population

PRIMARY SYSTEM ORGAN CLASS PREFERRED TERM	Grade 1 (Mild)		Grade 2 (Moderate)		Grade 3 (Severe)		Grade 4 (Threatening/ disabling)		Grade 5 (Death)		Missing		Total	
	Patient*	Control*	Patient*	Control*	Patient*	Control*	Patient*	Control*	Patient*	Control*	Patient*	Control*	Patient*	Control*
Any adverse events	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
System organ class 1	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term 1	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
…	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term m	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
System organ class …	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term 1	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
…	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term m	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
System organ class m	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term 1	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
…	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term m	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}* Dictionary Name: MedDRA Version: 19.0

Notes: All percentages are based upon the number of enrolled subjects by group.

Subjects with more than one event within a particular SOC and PT will be counted only once for that SOC and PT and the maximum CTC grade will be reported.

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

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Table 14.3.1.4: Number (%) of Subjects Reporting Treatment Emergent Adverse Drug Reactions by Severity – Safety Population

PRIMARY SYSTEM ORGAN CLASS PREFERRED TERM	Grade 1 (Mild)		Grade 2 (Moderate)		Grade 3 (Severe)		Grade 4 (Threatening/ disabling)		Grade 5 (Death)		Missing		Total	
	Patient*	Control*	Patient*	Control*	Patient*	Control*	Patient*	Control*	Patient*	Control*	Patient*	Control*	Patient*	Control*
Any adverse drug reactions	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
System organ class 1	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term 1	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
…	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term m	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
System organ class …	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term 1	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
…	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term m	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
System organ class m	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term 1	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
…	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term m	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}* Dictionary Name: MedDRA Version: 19.0

Notes: All percentages are based upon the number of enrolled subjects by group.

Subjects with more than one event within a particular SOC and PT will be counted only once for that SOC and PT and the maximum CTC grade will be reported.

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

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Table 14.3.1.5: Number (%) of Subjects Reporting Treatment Emergent Serious Adverse Events by Primary System Organ Class and Preferred Term – Safety Population

PRIMARY SYSTEM ORGAN CLASS PREFERRED TERM	STATISTIC	PATIENT* (N=xx)	CONTROL* (N=xx)	ALL SUBJECTS (N=xx)
Any serious adverse events	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
System organ class 1	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term 1	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
…	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term m	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
System organ class …	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term 1	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
…	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term m	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
System organ class m	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term 1	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
…	n (%)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term m	n (%)	99 (99.9)	99 (99.9)	99 (99.9)

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}* Dictionary Name: MedDRA Version: 19.0

Notes: All percentages are based upon the number of enrolled subjects by group.

Subjects with more than one event within a particular SOC and PT will be counted only once for that SOC and PT.

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

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Table 14.3.1.6: Number (%) of Subjects Reporting Treatment Emergent Serious Adverse Events by Severity – Safety Population

PRIMARY SYSTEM ORGAN CLASS PREFERRED TERM	Grade 1 (Mild)		Grade 2 (Moderate)		Grade 3 (Severe)		Grade 4 (Threatening/ disabling)		Grade 5 (Death)		Missing		Total	
	Patient*	Control*	Patient*	Control*	Patient*	Control*	Patient*	Control*	Patient*	Control*	Patient*	Control*	Patient*	Control*
Any serious adverse events	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
System organ class 1	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term 1	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
…	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term m	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
System organ class …	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term 1	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
…	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term m	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
System organ class m	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term 1	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
…	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term m	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}* Dictionary Name: MedDRA Version: 19.0

Notes: All percentages are based upon the number of enrolled subjects by group.

Subjects with more than one event within a particular SOC and PT will be counted only once for that SOC and PT and the maximum CTC grade will be reported.

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

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Table 14.3.1.7: Number (%) of Subjects Reporting Treatment Emergent Serious Adverse Drug Reactions by Severity – Safety Population

PRIMARY SYSTEM ORGAN CLASS PREFERRED TERM	Grade 1 (Mild)		Grade 2 (Moderate)		Grade 3 (Severe)		Grade 4 (Threatening/ disabling)		Grade 5 (Death)		Missing		Total	
	Patient*	Control*	Patient*	Control*	Patient*	Control*	Patient*	Control*	Patient*	Control*	Patient*	Control*	Patient*	Control*
Any serious adverse drug reactions	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
System organ class 1	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term 1	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
…	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term m	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
System organ class …	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term 1	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
…	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term m	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
System organ class m	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term 1	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
…	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)
Preferred term m	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)	99 (99.9)

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}* Dictionary Name: MedDRA Version: 19.0

Notes: All percentages are based upon the number of enrolled subjects by group.

Subjects with more than one event within a particular SOC and PT will be counted only once for that SOC and PT and the maximum CTC grade will be reported.

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

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Table 14.3.2.1: Listing of Adverse Events with Outcome Death – Safety Population

Subject ID	Subject group*	Primary cause of death	Study drug injection date	Study drug injection time	Date of death	Time between study drug injection and death (days)	Relationship with study treatment
04-CA-001	Patient	Heart Attack	10/05/2012	11:30	17/05/2012	7	Probable
04-CA-002	Control	Aneurysm	05/10/2012	12:38	08/10/2012	3	Possible
04-CA-003	Control	Tuberculosis	15/07/2012	09:45	16/10/2012	1	Unlikely
…	…	…	…	…	…	…	…

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

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Table 14.3.2.2: Listing of Serious Adverse Events – Safety Population

Subject ID	Subject group*	Event description	Primary system organ class	Preferred term	SAE date	Study day of onset (days)#	Duration (days)	SAE criteria	Relationship with study treatment	Outcome
04-CA-001	Patient	Vertigo	Ear and labyrinth disorders	Vertigo	14/05/2012	1	<1	2, 3	Unlikely	Resolved
04-CA-002	Control	Fainting	Nervous system disorders	Syncope	10/09/2012	15	<1	2	Unlikely	Resolved with sequelae
04-CA-003	Control	Internal bleeding	Vascular disorders	Internal haemorrhage	16/11/2011	4	3	5	Probable	Improved
…	…	…	…	…	…	…	…	…	…	…

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}* Dictionary name: MedDRA Version 19.0

Note: SAE criteria: 1=Death, 2=Life-threatening, 3=Involved or prolonged hospitalization, 4=Congenital anomaly, 5=Persistent or significant disability or incapacity, 6=Significant from a medical standpoint.

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Study day of onset is the day since Annexin administration which is defined as day 1.

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.4: Abnormal Laboratory Value Listing (Each Patient) – Safety Population

Subject ID	Subject group*	Sex	Age	Dose of IP injected	Study day of onset (days)#	Laboratory test type	Laboratory test name	Laboratory test value	Abnormal non-clinically relevant	Abnormal clinical relevant
04-CA-001	Patient	Male	54	150	6	Hematology	Red blood cells	1000	Yes	No
04-CA-002	Control	Female	68	152	12	Hematology	White blood cells	1000	No	Yes
04-CA-003	Control	Female	59	150	26	Blood chemistry	Gamma-GT	-54	Yes	No
…	…	…	…	…	…	…	…	…	…	…

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Study day of onset is the day since Annexin administration which is defined as day 1.

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Table 14.3.5.1/1: Hematology – Red blood cells (10^{12}/L) – Safety Population

RED BLOOD CELLS (10^12/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

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Table 14.3.5.1/2: Hematology – Hematocrit (L/L) – Safety Population

HEMATOCRIT (L/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.5.1/3: Hematology – Hemoglobin (g/L) – Safety Population

HEMOGLOBIN (g/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.5.1/4: Hematology – White blood cells (10^9/L) – Safety Population

WHITE BLOOD CELLS (10^9/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.5.1/5: Hematology – Basophils (10^9/L) – Safety Population

BASOPHILS (10^9/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

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Table 14.3.5.1/6: Hematology – Eosinophils (10^9/L) – Safety Population

EOSINOPHILS (10^9/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.5.1/7: Hematology – Lymphocytes (10^9/L) – Safety Population

LYMPHOCYTES (10^9/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

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Table 14.3.5.1/8: Hematology – Monocytes (10^9/L) – Safety Population

MONOCYTES (10^9/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

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Table 14.3.5.1/9: Hematology – Neutrophils (10^9/L) – Safety Population

NEUTROPHILS (10^9/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

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Table 14.3.5.1/10: Hematology – Platelet Count (10^9/L) – Safety Population

PLATELET COUNT (10^9/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.5.1/11: Hematology – PT (Second) – Safety Population

PT (Second)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

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Table 14.3.5.1/12: Hematology – PTT (Second) – Safety Population

PTT (Second)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

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Table 14.3.5.1/13: Hematology – INR – Safety Population

INR	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

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Table 14.3.5.2/1: Blood Chemistry – ALP (U/L) – Safety Population

ALP (U/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

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Table 14.3.5.2/2: Blood Chemistry – ALT (U/L) – Safety Population

ALT (U/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

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Table 14.3.5.2/3: Blood Chemistry – AST (U/L) – Safety Population

AST (U/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

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Table 14.3.5.2/4: Blood Chemistry – Total Bilirubin (µmol/L) – Safety Population

TOTAL BILIRUBIN (µmol/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.5.2/5: Blood Chemistry – Direct Bilirubin (µmol/L) – Safety Population

DIRECT BILIRUBIN (µmol/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.5.2/6: Blood Chemistry – Gamma-GT (U/L) – Safety Population

GAMMA-GT (U/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

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Table 14.3.5.2/7: Blood Chemistry – Blood Urea Nitrogen (mmol/L) – Safety Population

BLOOD UREA NITROGEN (mmol/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.5.2/8: Blood Chemistry – Albumin (g/L) – Safety Population

ALBUMIN (g/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.5.2/9: Blood Chemistry – Serum Creatinine (µmol/L) – Safety Population

SERUM CREATININE (µmol/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.5.2/10: Blood Chemistry – Uric Acid (µmol/L) – Safety Population

URIC ACID (µmol/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.5.2/11: Blood Chemistry – Sodium (mmol/L) – Safety Population

SODIUM (mmol/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.5.2/12: Blood Chemistry – Potassium (mmol/L) – Safety Population

POTASSIUM (mmol/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.5.2/13: Blood Chemistry – Phosphorus (mmol/L) – Safety Population

PHOSPHORUS (mmol/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.5.2/14: Blood Chemistry – Chloride (mmol/L) – Safety Population

CHLORIDE (mmol/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.5.2/15: Blood Chemistry – Corrected Calcium (mmol/L) – Safety Population

CORRECTED CALCIUM (mmol/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.5.2/16: Blood Chemistry – Glucose (mmol/L) – Safety Population

GLUCOSE (mmol/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.5.2/17: Blood Chemistry – Total Protein (g/L) – Safety Population

TOTAL PROTEIN (g/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.5.2/18: Blood Chemistry – LDH (U/L) – Safety Population

LDH (U/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

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Table 14.3.5.2/19: Blood Chemistry – Total Cholesterol (mmol/L) – Safety Population

TOTAL CHOLESTEROL (mmol/L)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.5.3/1: Urinalysis – Blood – Safety Population

BLOOD			STATISTIC	SCREENING VISIT	VISIT 3
Patient*	Test result	Negative	n (%)	99 (99.9)	99 (99.9)
		Positive	n (%)	99 (99.9)	99 (99.9)
		Not Done	n (%)	99 (99.9)	99 (99.9)
		Missing	n (%)	99 (99.9)	99 (99.9)
	Change from baseline	Missing	n	-	99
		Negative/Negative	n (%)	-	99 (99.9)
		Negative/Positive	n (%)	-	99 (99.9)
		Positive/Negative	n (%)	-	99 (99.9)
		Positive/Positive	n (%)	-	99 (99.9)
Control*	Test result	Negative	n (%)	99 (99.9)	99 (99.9)
		Positive	n (%)	99 (99.9)	99 (99.9)
		Not Done	n (%)	99 (99.9)	99 (99.9)
		Missing	n (%)	99 (99.9)	99 (99.9)
	Change from baseline	Missing	n	-	99
		Negative/Negative	n (%)	-	99 (99.9)
		Negative/Positive	n (%)	-	99 (99.9)
		Positive/Negative	n (%)	-	99 (99.9)
		Positive/Positive	n (%)	-	99 (99.9)

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.5.3/2: Urinalysis – pH – Safety Population

pH	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

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Table 14.3.5.3/3: Urinalysis – Specific Gravity – Safety Population

SPECIFIC GRAVITY	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

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Table 14.3.5.3/4: Urinalysis – Protein – Safety Population

PROTEIN			STATISTIC	SCREENING VISIT	VISIT 3
Patient*	Test result	Negative	n (%)	99 (99.9)	99 (99.9)
		Positive	n (%)	99 (99.9)	99 (99.9)
		Not Done	n (%)	99 (99.9)	99 (99.9)
		Missing	n (%)	99 (99.9)	99 (99.9)
	Change from baseline	Missing	n	-	99
		Negative/Negative	n (%)	-	99 (99.9)
		Negative/Positive	n (%)	-	99 (99.9)
		Positive/Negative	n (%)	-	99 (99.9)
		Positive/Positive	n (%)	-	99 (99.9)
Control*	Test result	Negative	n (%)	99 (99.9)	99 (99.9)
		Positive	n (%)	99 (99.9)	99 (99.9)
		Not Done	n (%)	99 (99.9)	99 (99.9)
		Missing	n (%)	99 (99.9)	99 (99.9)
	Change from baseline	Missing	n	-	99
		Negative/Negative	n (%)	-	99 (99.9)
		Negative/Positive	n (%)	-	99 (99.9)
		Positive/Negative	n (%)	-	99 (99.9)
		Positive/Positive	n (%)	-	99 (99.9)

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

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Table 14.3.5.3/5: Urinalysis – Glucose – Safety Population

GLUCOSE			STATISTIC	SCREENING VISIT	VISIT 3
Patient*	Test result	Negative	n (%)	99 (99.9)	99 (99.9)
		Positive	n (%)	99 (99.9)	99 (99.9)
		Not Done	n (%)	99 (99.9)	99 (99.9)
		Missing	n (%)	99 (99.9)	99 (99.9)
	Change from baseline	Missing	n	-	99
		Negative/Negative	n (%)	-	99 (99.9)
		Negative/Positive	n (%)	-	99 (99.9)
		Positive/Negative	n (%)	-	99 (99.9)
		Positive/Positive	n (%)	-	99 (99.9)
Control*	Test result	Negative	n (%)	99 (99.9)	99 (99.9)
		Positive	n (%)	99 (99.9)	99 (99.9)
		Not Done	n (%)	99 (99.9)	99 (99.9)
		Missing	n (%)	99 (99.9)	99 (99.9)
	Change from baseline	Missing	n	-	99
		Negative/Negative	n (%)	-	99 (99.9)
		Negative/Positive	n (%)	-	99 (99.9)
		Positive/Negative	n (%)	-	99 (99.9)
		Positive/Positive	n (%)	-	99 (99.9)

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

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Table 14.3.5.3/6: Urinalysis – Ketones – Safety Population

KETONES			STATISTIC	SCREENING VISIT	VISIT 3
Patient*	Test result	Negative	n (%)	99 (99.9)	99 (99.9)
		Positive	n (%)	99 (99.9)	99 (99.9)
		Not Done	n (%)	99 (99.9)	99 (99.9)
		Missing	n (%)	99 (99.9)	99 (99.9)
	Change from baseline	Missing	n	-	99
		Negative/Negative	n (%)	-	99 (99.9)
		Negative/Positive	n (%)	-	99 (99.9)
		Positive/Negative	n (%)	-	99 (99.9)
		Positive/Positive	n (%)	-	99 (99.9)
Control*	Test result	Negative	n (%)	99 (99.9)	99 (99.9)
		Positive	n (%)	99 (99.9)	99 (99.9)
		Not Done	n (%)	99 (99.9)	99 (99.9)
		Missing	n (%)	99 (99.9)	99 (99.9)
	Change from baseline	Missing	n	-	99
		Negative/Negative	n (%)	-	99 (99.9)
		Negative/Positive	n (%)	-	99 (99.9)
		Positive/Negative	n (%)	-	99 (99.9)
		Positive/Positive	n (%)	-	99 (99.9)

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.5.3/7: Urinalysis – RBC (per high power field) – Safety Population

RBC (PER HIGH POWER FIELD)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.5.3/8: Urinalysis – WBC (per high power field) – Safety Population

WBC (PER HIGH POWER FIELD)	STATISTIC	SCREENING VISIT	VISIT 3	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.5.3/9: Urinalysis – Casts – Safety Population

CASTS			STATISTIC	SCREENING VISIT	VISIT 3
Patient*	Test result	Negative	n (%)	99 (99.9)	99 (99.9)
		Positive	n (%)	99 (99.9)	99 (99.9)
		Not Done	n (%)	99 (99.9)	99 (99.9)
		Missing	n (%)	99 (99.9)	99 (99.9)
	Change from baseline	Missing	n	-	99
		Negative/Negative	n (%)	-	99 (99.9)
		Negative/Positive	n (%)	-	99 (99.9)
		Positive/Negative	n (%)	-	99 (99.9)
		Positive/Positive	n (%)	-	99 (99.9)
Control*	Test result	Negative	n (%)	99 (99.9)	99 (99.9)
		Positive	n (%)	99 (99.9)	99 (99.9)
		Not Done	n (%)	99 (99.9)	99 (99.9)
		Missing	n (%)	99 (99.9)	99 (99.9)
	Change from baseline	Missing	n	-	99
		Negative/Negative	n (%)	-	99 (99.9)
		Negative/Positive	n (%)	-	99 (99.9)
		Positive/Negative	n (%)	-	99 (99.9)
		Positive/Positive	n (%)	-	99 (99.9)

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.6.1/1: Vital Signs – Systolic Blood Pressure (mmHg) – Safety Population

SYSTOLIC BLOOD PRESSURE (mmHg)	STATISTIC	BASELINE	VISIT 1 (POST INJECTION)	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Baseline is the latest available assessment between screening and pre-injection visits.

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.6.1/2: Vital Signs – Diastolic Blood Pressure (mmHg) – Safety Population

DIASTOLIC BLOOD PRESSURE (mmHg)	STATISTIC	BASELINE	VISIT 1 (POST INJECTION)	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Baseline is the latest available assessment between screening and pre-injection visits.

Program: <path of directory, study level downwards>/ xxxx.sas

Table 14.3.6.1/3: Vital Signs – Heart Rate (beats/min) – Safety Population

HEART RATE (beats/min)	STATISTIC	BASELINE	VISIT 1 (POST INJECTION)	CHANGE
Patient*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99
Control*	n	99	99	99
	Missing	99	99	99
	Mean	99.9	99.9	99.9
	S.D.	99.9	99.9	99.9
	Median	99.9	99.9	99.9
	Q1, Q3	99.9, 99.9	99.9, 99.9	99.9, 99.9
	Min, Max	99, 99	99, 99	99, 99

Source: Data listings *{Specify data listing number(s)}* Analysis dataset: *{Specify datasets}*

* Patient = Subject with asymptomatic plaque; Control = Healthy volunteer

Baseline is the latest available assessment between screening and pre-injection visits.

Program: <path of directory, study level downwards>/ xxxx.sas

11.3 Standard Figures

The different lines on the figures should look different (e.g. dotted lines) rather than using different colours so that the lines can be distinguished when using a non-colour printer.

Figure 14.2.1.1: Left Carotid Target to Background Ratio (TBR) Imaging Assessment - Patients – Carotid with Stenosis ≥ 50% – FAS Population - 60 mins after IP injection

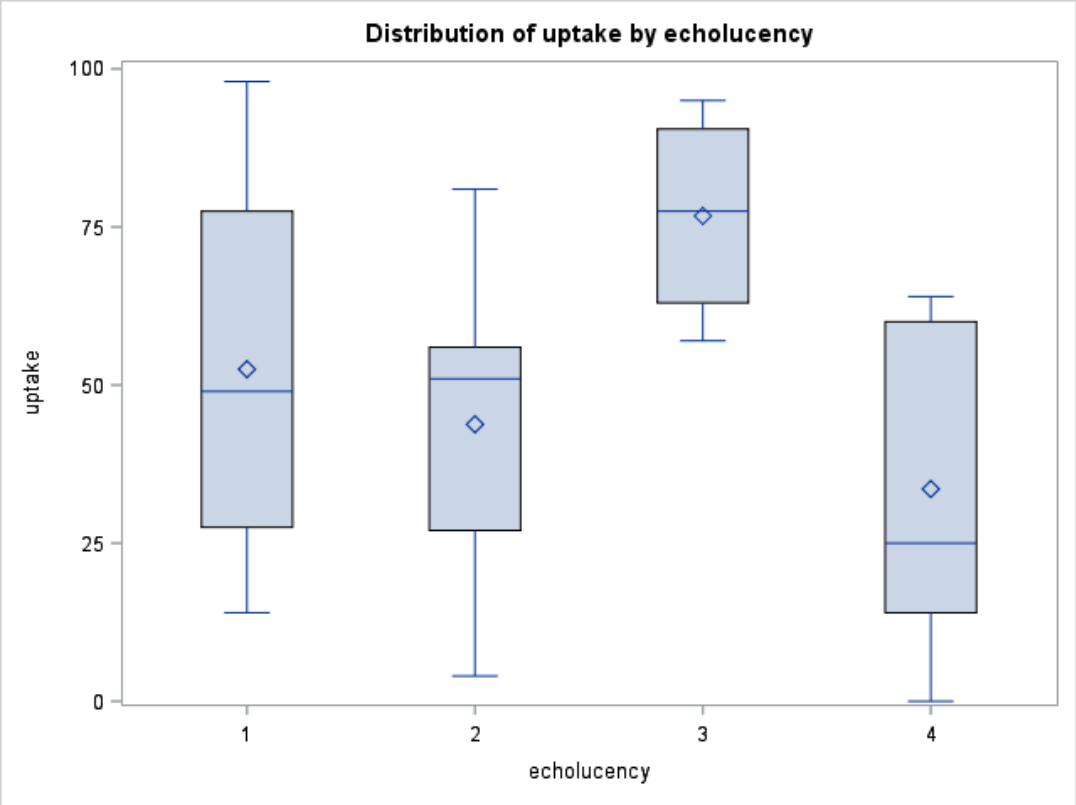


Figure 14.2.1.2: Left Carotid Target to Background Ratio (TBR) Imaging Assessment - Patients – Carotid with Stenosis ≥ 50% – FAS Population - 120 mins after IP injection

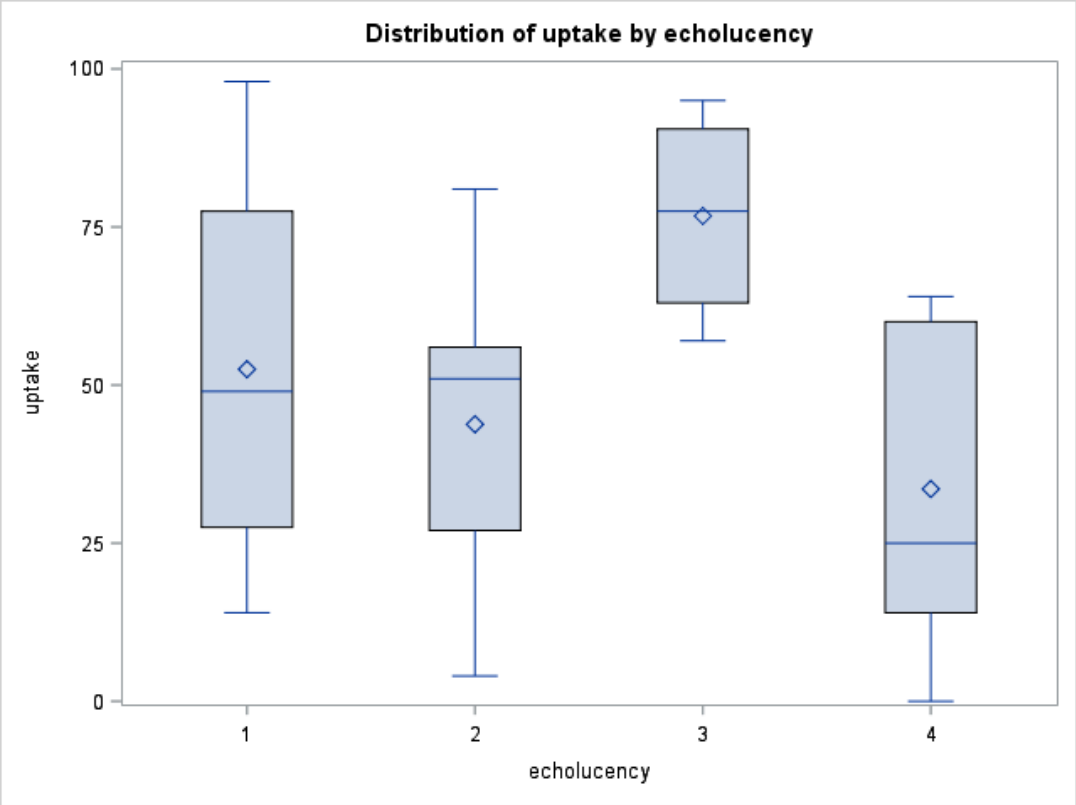


Figure 14.2.1.3: Right Carotid Target to Background Ratio (TBR) Imaging Assessment - Patients – Carotid with Stenosis ≥ 50% – FAS Population - 60 mins after IP injection

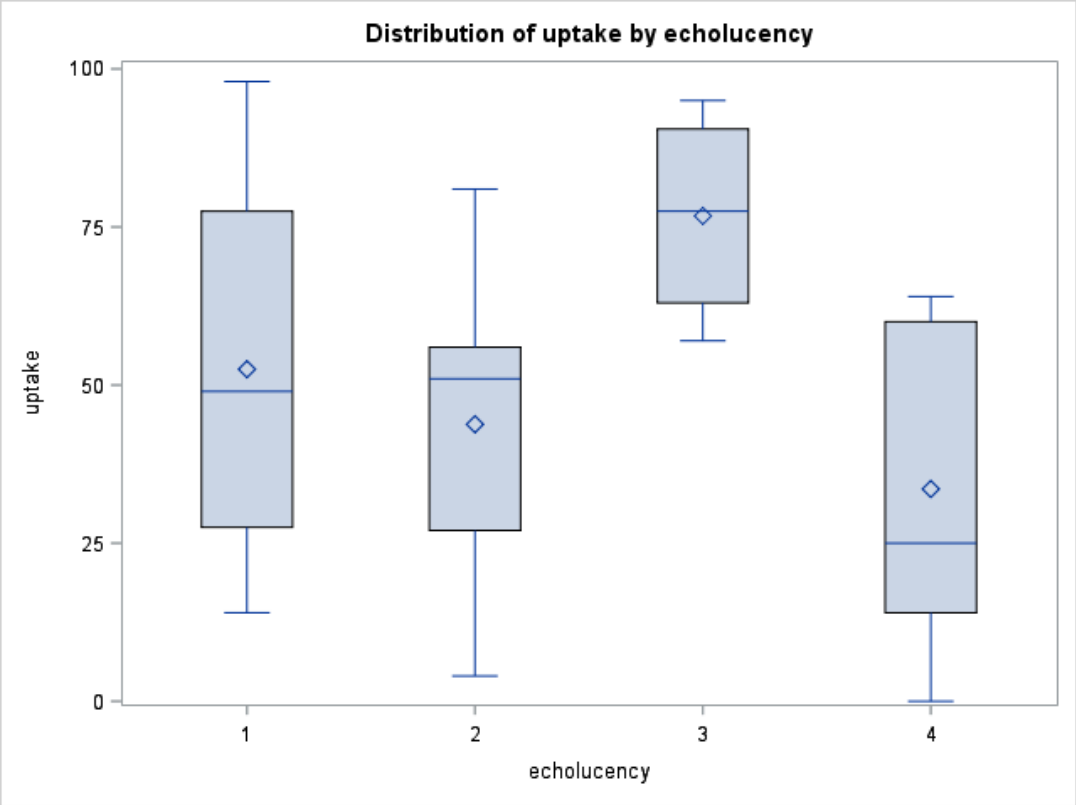


Figure 14.2.1.4: Right Carotid Target to Background Ratio (TBR) Imaging Assessment - Patients – Carotid with Stenosis ≥ 50% – FAS Population - 120 mins after IP injection

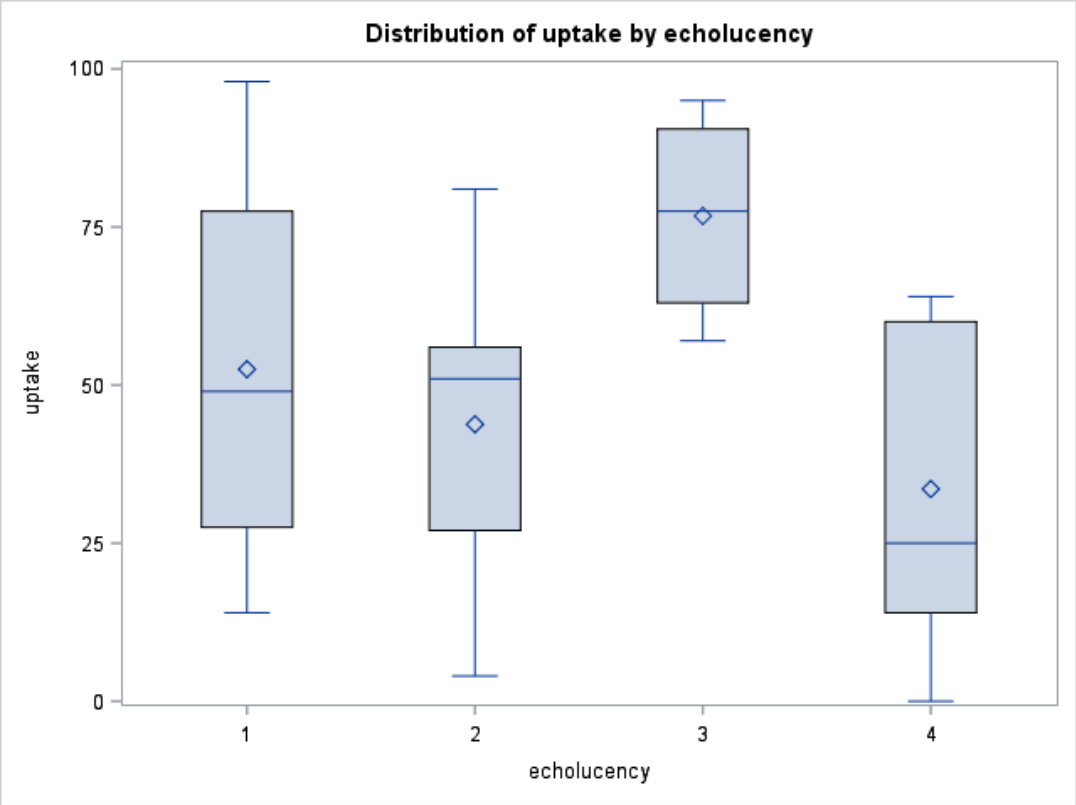


Figure 14.2.1.5: Scatterplot between Left and Right Carotid and Thoracic Aorta Target to Background Ratio (TBR) – Patients – FAS Population - 60 mins after IP injection

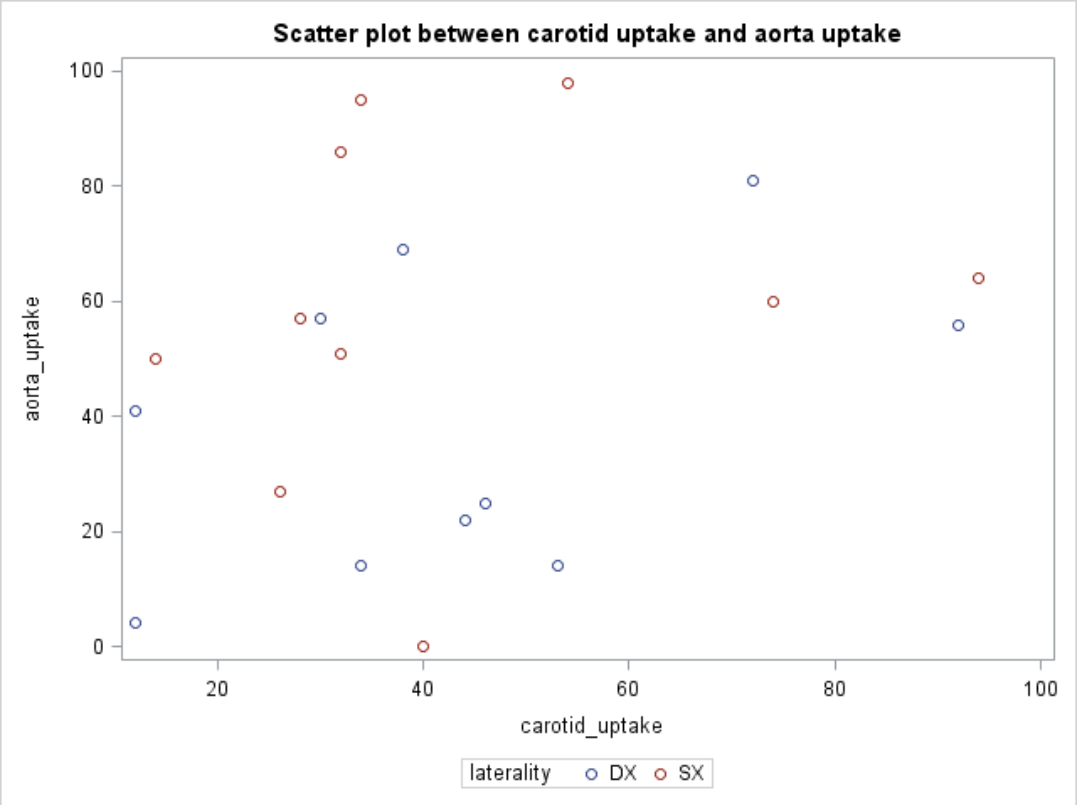


Figure 14.2.1.6: Scatterplot between Left and Right Carotid and Thoracic Aorta Target to Background Ratio (TBR) – Patients – FAS Population - 120 mins after IP injection

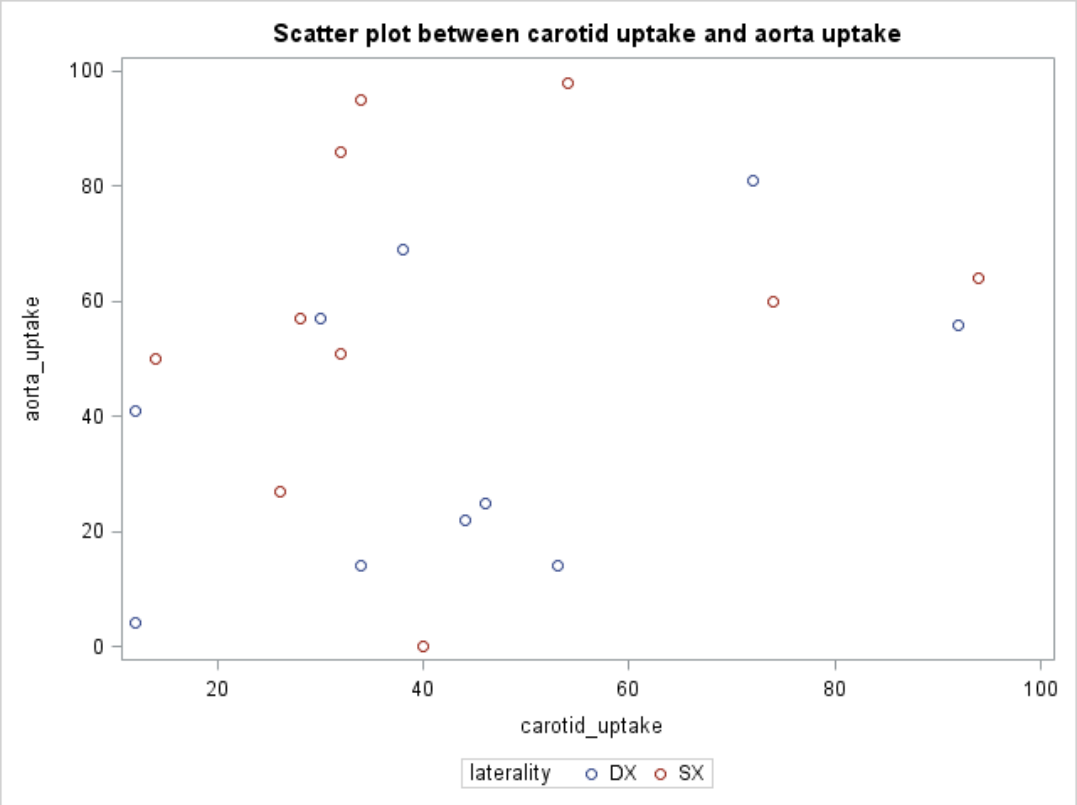


Figure 14.2.1.7: Scatterplot between Left and Right Carotid and Abdominal Aorta Target to Background Ratio (TBR) – Patients – FAS Population - 60 mins after IP injection

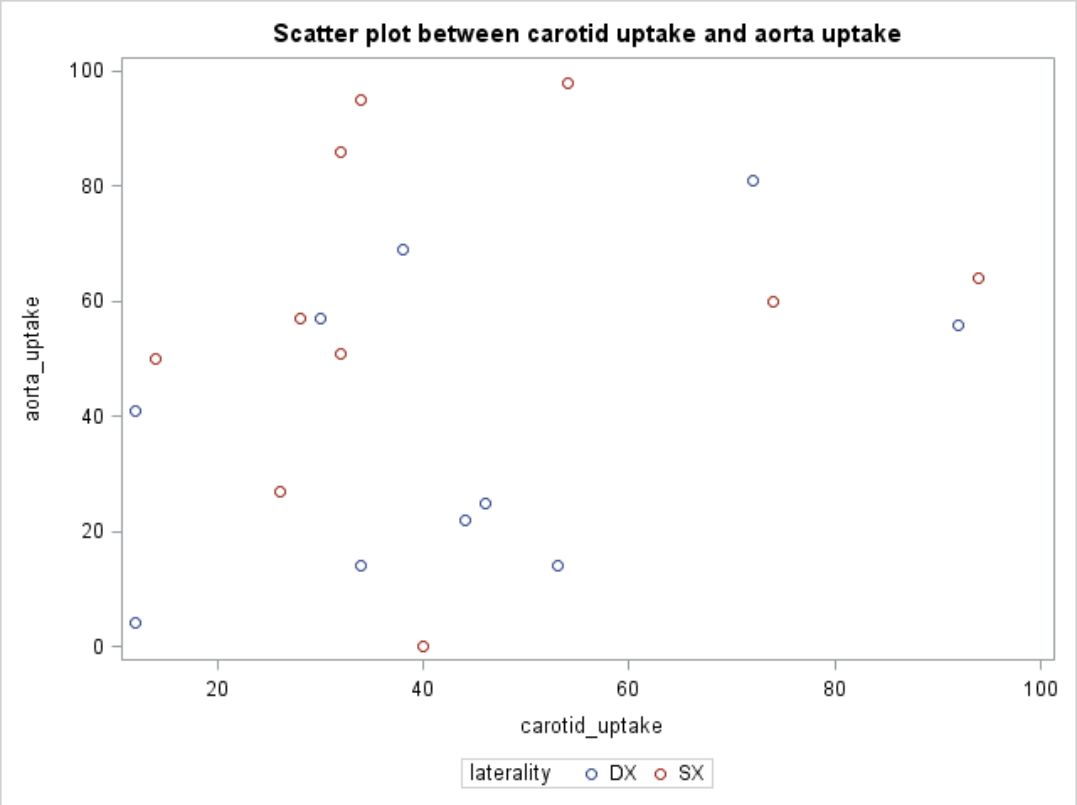


Figure 14.2.1.8: Scatterplot between Left and Right Carotid and Abdominal Aorta Target to Background Ratio (TBR) – Patients – FAS Population - 120 mins after IP injection

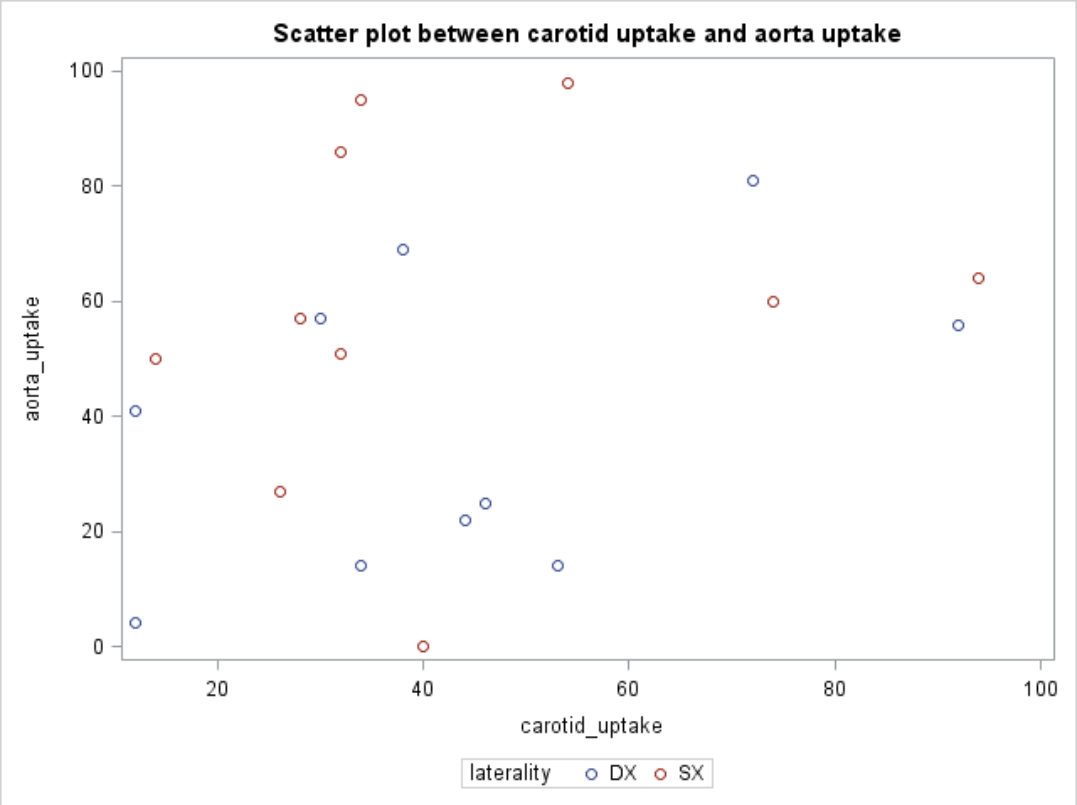


Figure 14.2.1.9: Scatterplot between Left and Right Carotid and Aortic Arch Target to Background Ratio (TBR) – Patients – FAS Population - 60 mins after IP injection

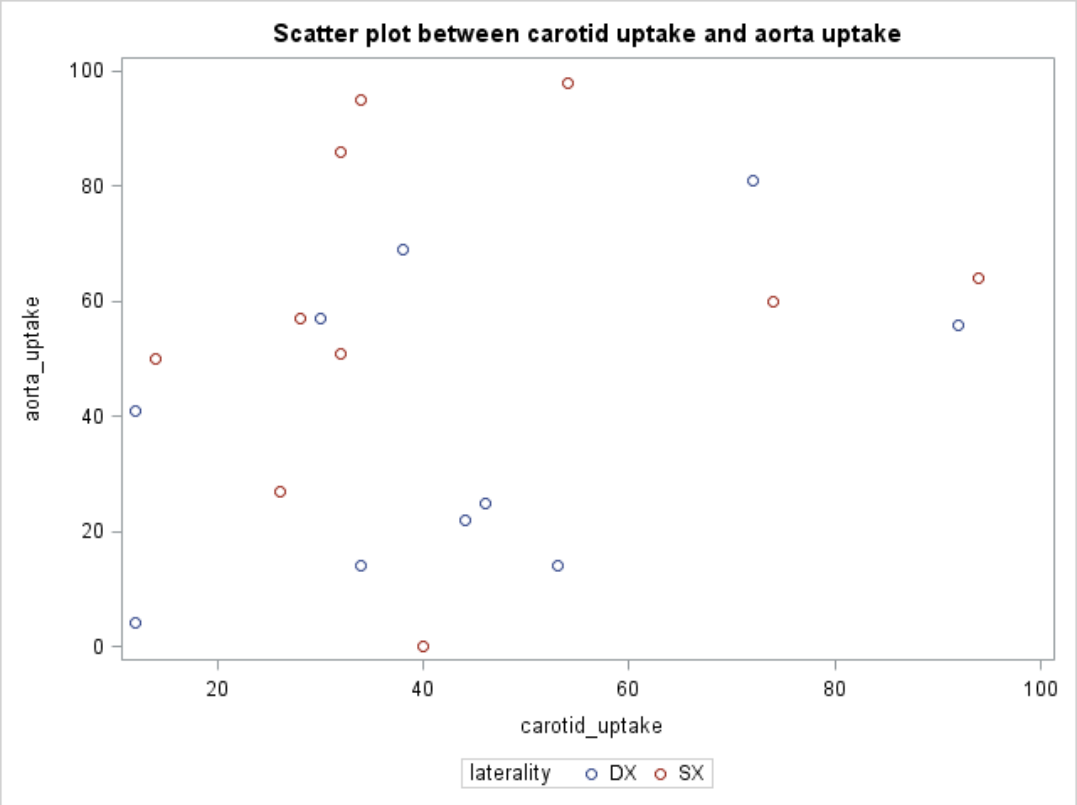
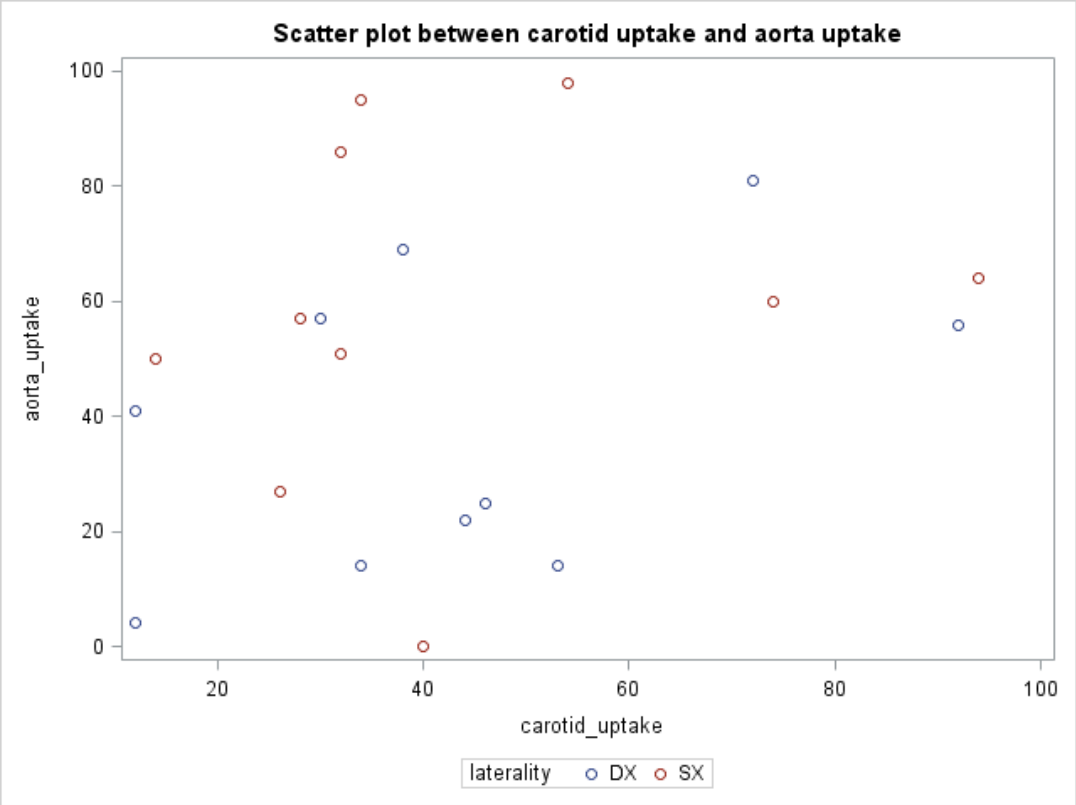


Figure 14.2.1.10: Scatterplot between Left and Right Carotid and Aortic Arch Target to Background Ratio (TBR) – Patients – FAS Population - 120 mins after IP injection



12 APPENDICES TO THE SAP TEMPLATE

12.1 Derived data

The following derived data will be calculated and included in the listings or in the tables:

(1) **Age**

Subject age (years) will be derived as (informed conset date - birth date)/365.25 and truncated to the largest integer that is less than or equal to the calculated result. Since birth date is truncated (i.e. only month and year will be filled in the eCRF), it will be approximated using “01” as value for the day.

(2) **BMI**

BMI (kg/m^2) will be automatically derived as [weight] (kg)/([height](cm)/100)^2 and rounded to the nearest decimal.

(3) **Time from injection**

Time from injection (min) will be derived as the difference between SPECT/CT scan time [SP_TIME/SPCT_TIME] and injection time [ANN_TIME].

(4) **Adverse event duration**

If the start and end dates of the adverse event are identical then “<1” day will be presented with the duration in hh:mm recorded in the eCRF if it is available. If times are available, the duration will be calculated as (end date/time - start date/time) and presented in days hh:mm. If at least one time is missing and if the duration is greater than 24 hours then it will be calculated as (end date - start date)+1 and presented in days. If the recorded end date is CONT. (for continuing), the end date will be listed as “ongoing” and the duration will be approximated as “≥(last attended visit date - start date)+1” day(s). If the start date or the end date are partial the duration will be presented as a superior inequality “≥ xx” day(s) (i.e. “≥2” where start date = 31JAN2004 and end date = FEB2004 or start date = JAN2004 and end date = 01FEB2004).

(5) **Study day of onset**

If the start date of the adverse event is identical to the date of injection, then “1” day will be presented with the time to onset in hh:mm recorded in the eCRF if it is available. If the date of onset is greater than the date of injection then it will be calculated as (start date - injection date+1) and presented in days. If the date of onset precedes the date of injection the study day will be calculated as (start date - injection date). If the start date is partial, the time since injection will be presented as a superior

inequality (i.e. for an AE started in FEB2004 after the injection performed on 31JAN2004, the delay of onset will be “≥2” days).

12.2 SAS programs

This section provides the SAS programs related to the statistical tests specified in the statistical methods section 6. All computer output from SAS statistical programs used as a basis for extracted results should be retained for review by Responsible of statistical analysis.

1 Data manipulation

Proc Format

Proc Print

Proc Sort

Proc SQL

Proc Transpose

2 Descriptive statistics

Proc Corr

Proc Freq

Proc Means

Proc Tabulate

3 Test statistics

Proc Ttest

4 Graphs

Proc Boxplot

Proc Sgplot