Title: Exploratory study of the effect of omega-3-acid ethyl esters on vascular endothelial function in patients with hyperlipidemia by flow mediated dilation

NCT Number: NCT02824432
Statistical analysis plan Approve Date: 14-Nov-2017

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This may include, but is not limited to, redaction of the following:

- Named persons or organizations associated with the study.
- Patient identifiers within the text, tables, or figures or in by-patient data listings.
- Proprietary information, such as scales or coding systems, which are considered confidential information under prior agreements with license holder.
- Other information as needed to protect confidentiality of Takeda or partners, personal information, or to otherwise protect the integrity of the clinical study.

If needed, certain appendices that contain a large volume of personally identifiable information or company confidential information may be removed in their entirety if it is considered that they do not add substantially to the interpretation of the data (eg, appendix of investigator’s curriculum vitae).

Note: This document was translated into English as the language on original version was Japanese.
Exploratory study of the effect of omega-3-acid ethyl esters on vascular endothelial function in patients with hyperlipidemia by flow mediated dilation

(Protocol number: TAK-085-4001)

Statistical Analysis Plan

(Ver.4.0: 14 Nov 2017)

Sponsor: Takeda Pharmaceutical Company Limited

Authorizer:
Takeda Pharmaceutical Company Limited

Biostatistics Manager:
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1. DEFINITIONS of TERMS
   • Summary Statistics: Number of subjects, mean, SDs, maximum values, minimum values, and quartiles
   • Treatment Group: Omega-3-acid ethyl esters 2g, Omega-3-acid ethyl esters 4g

2. TIME WINDOW
   For each inspection, observation and evaluation item, evaluable data is handled according to the following table. When there are multiple data that can be evaluated at the same visit, the one with the closest inspection date, observation, and evaluation date to the reference date is adopted, and if the difference from the reference date is the same, the later data is adopted.

   < FMD (Fasting, 4h postprandial) >

<table>
<thead>
<tr>
<th>Visit</th>
<th>Reference implementation date</th>
<th>Time Allowance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start of Treatment Period</td>
<td>Days after the Administration: -1</td>
<td>-15 to -1</td>
</tr>
<tr>
<td>Treatment period 4 week</td>
<td>Days after the Administration: 28</td>
<td>1 to 41</td>
</tr>
<tr>
<td>Treatment period 8 week</td>
<td>Days after the Administration: 56</td>
<td>42 to 70</td>
</tr>
</tbody>
</table>

   < Other than FMD >

<table>
<thead>
<tr>
<th>Visit</th>
<th>Reference implementation date</th>
<th>Time Allowance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start of Treatment Period</td>
<td>Days after the Administration: -1</td>
<td>-29 to -1</td>
</tr>
<tr>
<td>Treatment period 4 week</td>
<td>Days after the Administration: 28</td>
<td>1 to 41</td>
</tr>
<tr>
<td>Treatment period 8 week</td>
<td>Days after the Administration: 56</td>
<td>42 to 70</td>
</tr>
</tbody>
</table>

   • The reference implementation date and the number of days after administration in the treatment period are indicated as “Day -1” for the day before study drug administration and “Day 1” for the administration day. As the administration is started from the day after the visit, 4 weeks of the treatment period and 8 weeks of the treatment period are 28 days and 56 days after the study drug administration.

3. ANALYSIS SET
   • Full Analysis Set
     The subjects who were randomized and given at least one dose of the study drug.
4. CONSIDERATIONS for ANALYSIS
   • Confidence coefficient
     95% (two-sided estimation)
   • Display digit
     [Mean, Confidence coefficient, Quartiles]
     Round statistics off to the 1 digits lower than significant digits of the data.
     [Standard Deviation]
     Round statistics off to the 2 digits lower than significant digits of the data.
     [Minimum and Maximum Values]
     Display the data at the significant digits.
     [Proportion, Percentage]
     Round statistics off to 1 decimal places.

5. OTHER DATA HANDLING
   [Data Handling for Study Drug]
   • Duration of Treatment
     Duration of Treatment = Date of the Last Dose - Date of the First Dose + 1

   [Data Handling for Adverse Event]
   • Adverse Events
     An adverse event is defined as any untoward medical occurrence in a patient or a subject receiving a pharmaceutical product (including the study drug). It does not necessarily have an apparent causal relationship with this pharmaceutical product (including study drug).
   • Time to Occurrence of Adverse Event
     Time to Occurrence of Adverse Event = Onset Date of Adverse Event - Date of the First Dose + 1
   • Non-serious Adverse Events
     Adverse events, excluding serious adverse events (protocol 10.1.4), shall be non-serious adverse events in the case of an incidence of over 5% in at least one treatment group.

   [Data Handling for Duration of Dyslipidemia (year)]
   • Duration of Dyslipidemia (year)
Duration of Dyslipidemia (year) = (Date of Informed Consent (year/month) – Onset Date of Dyslipidemia (year/month)) / 12 (rounded off to two decimal places)
If only the month of the onset of dyslipidemia is unknown, the month of the onset of dyslipidemia is regarded as “January”.

6. SUBJECTS, DEMOGRAPHIC and OTHER BASELINE CHARACTERISTICS
6.1. Subject Disposition

6.1.1. Study Information
Analysis Set: All subjects who were obtained informed consent
Analysis Variables: The earliest date of informed consent
The latest date of the last date of administration
Version of MedDRA
Version of SAS
Analysis Methods: For the above analysis variables, the following analysis is performed.
(1) Show above items.

6.1.2. Eligibility of Subjects
Analysis Set: All subjects who were obtained informed consent
Analysis Variables: Randomization into the treatment period of the study
[Yes, No (and the reason)]
Analysis Methods: For the above analysis variables, the following analysis is performed.
(1) Frequency Count

6.1.3. Subject Disposition
6.1.3.1. Study completion status
Analysis Set: Randomized subjects
Analysis Variables: Study completion status
[Complete, Incomplete (and the reason)]
Analysis Methods: For the above analysis variables, the following analysis is performed for each treatment group and all subjects in the analysis set.
(1) Frequency Count
6.1.4. Protocol Deviations and Analysis Datasets

6.1.4.1. Protocol Deviations

Analysis Set: Randomized subjects
Analysis Variables: Protocol Deviations
[Major GCP Violations, Deviations of Protocol Entry Criteria, Deviations of Discontinuation Criteria, Deviations Related to Treatment Procedure or Dose, Deviations Concerning Excluded Medication or Therapy, Deviations to Avoid Emergency Risk, Other Deviations]

Analysis Methods: For the above analysis variables, the following analysis is performed for each treatment group and all subjects in the analysis set.
(1) Frequency Count
Summarize the number of subjects who have deviated from the protocol, classify the deviations into above category, and show the breakdown of deviations. Subjects applicable for multiple categories will be counted once in each category.

6.1.4.2. Datasets Analyzed

Analysis Set: Randomized subjects
Analysis Variables: Subjects excluded from analysis datasets
[Reason of exclusion]
Full Analysis Set [Adopted]
Safety Analysis Set [Adopted]

Analysis Methods: For the above analysis variables, the following analysis is performed for each treatment group (both (1) and (2)) and all subjects (for (2)) in the analysis set. For analysis (1), Subjects applicable for multiple categories will be counted once in each category.
(1) Frequency count in each analysis set about handling for subjects
(2) Frequency count in each analysis set of adopted subjects.

6.2. Demographics and Other Baseline Characteristics

6.2.1. Distribution of Demographics

Analysis Set: Safety Analysis Set
Analysis Variables:

Age (years old) [Min<= - <65, 65<= - <75, 75<= - <=Max]
Sex [Male, Female]
Height (Observation period) (cm)
[Min<= - <150, 150<= - <160, 
160<= - <170, 170<= - <=Max]
Weight (Observation period) (kg)
[Min<= - <50.0, 50.0<= - <60.0, 
60.0<= - <70.0, 70.0<= - <80.0, 
80.0<= - <=Max]
BMI (Observation period) (kg/m²)
[Min<= - <18.5, 18.5<= - <25.0, 
25.0<= - <=Max]
Duration of Dyslipidemia (year)
[Min<5, 5<=Max, Unknown]
Last Menstrual Period
[<2 years, 2 years <=, Not Applicable]
Frequency of Consumption of Fish
[Almost every day, About Every Two Days, About 
Once or Twice Per Week, Rarely]
Smoking Classification
[Never Smoked, Current Smoker, Ex-Smoker]
Drink Alcohol Almost Every Day?
[Yes, No]
TG level (fasting) (Start of Treatment Period) (mg/dL)
[Min<= - <200, 200<= - <500, 500<= - <=Max]
TG level (4h postprandial) (Start of Treatment Period) (mg/dL)
[Min<= - <200, 200<= - <500, 500<= - <=Max]
Plasma Fatty acid Fraction EPA/AA ratio (Start of Treatment Period)
[Min<0.3, 0.3<=Max]

Analysis Methods: For the above analysis variables, the following analysis is 
performed for each treatment group and all subjects in the 
analysis set.
(1) Frequency count for discrete variables and summary 
statistics for continuous variables
6.2.2. Medical History and Concurrent Disease
Analysis Set: Safety Analysis Set
Analysis Variables: Medical history, Concurrent disease
Analysis Methods: For the above analysis variables, the following analysis is performed for each treatment group. Analysis variables will be coded using the MedDRA dictionary and be summarized into SOC and PT. SOCs will be sorted in alphabetical order, then PTs will be sorted in frequency order.
   (1) Frequency of medical history by SOC/PT
   (2) Frequency of concurrent disease by SOC/PT
The method of accounting for the frequency is as follows.
[Number of Subjects]
Within each summary, subjects with one or more events within a level of SOC term is counted only once in that level. Similarly, subjects with one or more events within a level of PT term is counted only once in that level.

6.2.3. Prior and Concomitant Medication
Analysis Set: Safety Analysis Set
Analysis Variables: Prior medication
Concomitant medication
Analysis Methods: For the above analysis variables, the following analysis is performed for each treatment group. Analysis variables will be coded using the WHO (World Health Organization) Drug. Coded medications will be sorted in frequency order. Medications used more than once within a subject will be counted only once for the subject.
   (1) Frequency of prior medication
   (2) Frequency of concomitant medication which was completed administration before study drug administration
   (3) Frequency of concomitant medication which was started administration before study drug administration and was continued administered after start of study drug administration
   (4) Frequency of concomitant medication which was started administration after start of study drug administration
6.3. Treatment Compliance

6.3.1. Study Medication Compliance

Analysis Set: Safety Analysis Set
Analysis Variables: Study medication compliance

\[ \text{[Min} \leq - < 50.0\%, \quad 50.0\% \leq - \leq \text{Max]} \]

Visit: Treatment Period 4 week and 8 week
Analysis Methods: For the above analysis variables, the following analysis is performed for each treatment group and all subjects in the analysis set by visit.

(1) Frequency Count

6.3.2. Food and Drink Consumption before the Visit

Analysis Set: Safety Analysis Set
Analysis Variables: Did you consume alcohol from 9:00 pm two days before the hospital visit to the time of the fasting test, or consume food from 9:00 pm on the day before to the time of the fasting test? [Yes, No]
Did you experience excess and extreme change of dietary content (Eating/Drinking) on the day before the fasting test. [Yes, No]

Visit: Treatment Period 4 week and 8 week
Analysis Methods: For the above analysis variables, the following analysis is performed for each treatment group and all subjects in the analysis set by visit.

(1) Frequency Count

6.3.3. Study Medication Exposure

Analysis Set: All Subjects Administered
Analysis Variables: Duration of exposure (days)

\[ [1 \leq - < 29, 29 \leq - < 57, 57 \leq - \leq \text{Max}] \]
Analysis Methods: For the above analysis variables, the following analysis is performed for each treatment group and all subjects in the analysis set by visit.

(1) Frequency Count
analysis set.

(1) Frequency count for discrete variables and summary statistics for continuous variables

7. EFFICACY EVALUATIONS

7.1. Primary Endpoint and the Analytical Methods

Analysis Set: Full Analysis Set
Analysis Variables: %FMD (fasting)
Visit: Start of Treatment Period, Treatment Period 4 week and 8 week
Stratification Factor: Fasting TG at Observation Period
\[150\leq - <200, 200\leq - <500\]
Analysis Methods: For the above analysis variables, the following analysis is performed.

(1) Summary statistics by treatment group and a two-sided 95% confidence interval for the mean will be calculated at each visit during the treatment period, and a diagram illustrating the change in the mean ± SD will be prepared.

(2) The change for each treatment group (Treatment Period 4 week/8 week – Start of Treatment Period) will be calculated at each visit during the treatment period and the same analysis as in (1) will be performed.

(3) Summary statistics using stratification factor and two-sided 95% confidence interval (CI) of mean value by visit will be calculated by treatment group.

(4) Using stratification factor, the change for each treatment group (Treatment Period 4 week/8 week – Start of Treatment Period) will be calculated at each visit during the treatment period and the same analysis as in (3) will be performed.

(5) Analyses same as (1) - (4) are performed, excluding subjects with missing of %FMD (fasting) data at any visit as sensibility analysis.

7.2. Secondary Endpoints and the Analytical Methods

Analysis Set: Full Analysis Set
Analysis Variables: %FMD (4h postprandial)
TG level (fasting)
TG level (4h postprandial)
Plasma fatty acid fraction
Visit: Start of Treatment Period, Treatment Period 4 week and 8 week
* Treatment period 4 is excluded about %FMD (4h postprandial)
Stratification Factor: Fasting TG at Observation Period
[150<= - <200, 200<= - <500]
Analysis Methods: For the above analysis variables, the same analyses describes in
7.1 (1) - (4) are performed by visit.

7.3. Analysis of other endpoints
7.3.1. Efficacy Endpoints
Analysis Set: Full Analysis Set
Analysis Variables: Total cholesterol (fasting and 4h postprandial)
LDL-C(fasting and 4h postprandial)
HDL-C(fasting and 4h postprandial)
Remnant-like particle (RLP) cholesterol
(fasting and 4h postprandial)
Apoprotein B-48 (fasting and 4h postprandial)
C-reactive protein (CRP) (fasting)
8-epi-PGF2α quantitative (urinary) (fasting)
Visit: Start of Treatment Period, Treatment Period 4 week and 8 week
Analysis Methods: For the above analysis variables, the same analyses describes in
7.1 (1) and (2) are performed by visit.

8. SAFETY EVALUATION
8.1. Frequency of Adverse Event Occurrence
8.1.1. Brief Summary of Adverse Events
Analysis Set: Safety Analysis Set
Analysis Variables: Adverse Event
Category Classification:
Causal Relationship with the Study Drug [Related, Unrelated]
Severity [Mild, Moderate, Severe]
Time of Onset [1<= - <29, 29<= - <57,]
Analysis Methods: For the above analysis variables, the following analysis is performed for each treatment group.

1. Tabulation of frequencies of all adverse events
2. Tabulation of frequency of adverse events with a causal relationship to the study drug
3. Tabulation of frequency of all adverse events by severity
4. Tabulation of frequency of adverse events with a causal relationship to the study drug by severity
5. Tabulation of frequency of adverse events leading to study drug discontinuation
6. Tabulation of frequency of serious adverse events
7. Tabulation of frequency of non-serious adverse events
8. Tabulation of frequency of serious adverse events with a causal relationship to the study drug
9. Tabulation of frequency of serious adverse events leading to study drug discontinuation
10. Tabulation of frequency of adverse events leading to death
11. Tabulation of frequency of all adverse events by time of onset

Incidence rates will be calculated as following on each analysis.

[Frequency of Subjects]

- Frequency by Severity
  Subjects with one or more adverse events within a level of MedDRA term is counted only once in that level using the most severe incident. The denominator when calculating the incidence of adverse events is the number of subjects of safety analysis set.

- Frequency by Time of Onset
  Subjects with one or more adverse events within a level of MedDRA term is counted only once in that category of time of onset. The denominator when calculating the incidence of adverse events is the number of subjects “whose study drug administration has been continued at that time point and later” or “who experienced an onset of adverse events at that time point or later” in safety analysis set and numerator is the number of subjects “experienced an onset of adverse events at that time point”.

- Analyses Other Than the Above
Subjects with one or more adverse events within a level of MedDRA term is counted only once for that MedDRA term. The denominator when calculating the incidence of adverse events is the number of subjects of safety analysis set.

8.1.2. Display of Adverse Event

Analysis Set: Safety Analysis Set

Analysis Variables: Adverse Event

Category Classification:

<table>
<thead>
<tr>
<th>Causal Relationship with the Study Drug [Related, Unrelated]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severity                                          [Mild, Moderate, Severe]</td>
</tr>
<tr>
<td>Time of Onset                    [1&lt;= - &lt;29, 29&lt;= - &lt;57, 57&lt;= - &lt;=Max]</td>
</tr>
</tbody>
</table>

Analysis Methods: For the above analysis items, the following analysis is performed for each treatment group. Analysis variables will be coded using the MedDRA dictionary and be summarized into SOC and PT. SOCs will be sorted in alphabetical order, then PTs will be sorted in frequency order.

(1) Tabulation of frequencies of all adverse events (by SOC/PT)

(2) Tabulation of frequency of adverse events with a causal relationship to the study drug (by SOC/PT)

(3) Tabulation of frequency of all adverse events by severity (by SOC/PT)

(4) Tabulation of frequency of adverse events with a causal relationship to the study drug by severity (by SOC/PT)

(5) Tabulation of frequency of adverse events leading to study drug discontinuation (by SOC/PT)

(6) Tabulation of frequency of serious adverse events (by SOC/PT)

(7) Tabulation of frequency of Non-serious adverse events (by SOC/PT)

(8) Tabulation of frequency of serious adverse events with a causal relationship to the study drug (by SOC/PT)
(9) Tabulation of frequency of serious adverse events leading to study drug discontinuation (by SOC/PT)

(10) Tabulation of frequency of adverse events leading to death (by SOC/PT)

(11) Tabulation of frequency of all adverse events by time of onset (by SOC/PT)

Incidence rates will be calculated as following on each analysis.

[Frequency of Subjects]

- Frequency (by SOC/PT)
  Within each summary, subjects with one or more adverse events within a level of SOC term is counted only once in that level. Similarly, subjects with one or more adverse events within a level of PT term is counted only once in that level. The denominator when calculating the incidence of adverse events is the number of subjects of safety analysis set.

- Frequency by Severity (by SOC/PT)
  Subjects with one or more adverse events within a level of SOC/PT term is counted only once in that level using the most severe incident. The denominator when calculating the incidence of adverse events is the number of subjects of safety analysis set.

- Frequency by Time of Onset (by SOC/PT)
  Subjects with one or more adverse events within a level of SOC/PT term is counted only once in that category of time of onset. The denominator when calculating the incidence of adverse events is the number of subjects “whose study drug administration has been continued at that time point and later” or “who experienced an onset of adverse events at that time point or later” in safety analysis set and numerator is the number of subjects “experienced an onset of adverse events at that time point”.

8.2. Other Endpoints and the Analytical Methods

8.2.1. Vital Sign

Analysis Set: Safety Analysis Set

Analysis Variables: Body Weight, Blood Pressure in the Sitting Position (Systolic, Diastolic), Pulse in the Sitting Position

Visit: Start of Treatment Period, Treatment Period 4 week and 8 week

Analysis Methods: The following analysis is performed for Safety Analysis Set.
(1) Summary statistics of measurements by treatment group at each visit during the treatment period will be calculated and a diagram of the change of individual data will be created.

(2) The change for each treatment group (Treatment Period 4 week/8 week – Start of Treatment Period) will be calculated at each visit during the treatment period and the same analysis as in (1) will be performed.

(3) Regarding evaluation results based on standard values, shift tables of start of treatment period and each visit of treatment period 4 week and 8 week will be prepared.

8.2.2. Laboratory Test
Analysis Set: Safety Analysis Set
Analysis Variables: Fasting Plasma Glucose (FPG)
Visit: Start of Treatment Period, Treatment Period 4 week and 8 week
Analysis Methods: The following analysis is performed for Safety Analysis Set.

(1) Summary statistics of measurements by treatment group at each visit during the treatment period will be calculated and a diagram of the change of individual data will be created.

(2) The change for each treatment group (Treatment Period 4 week/8 week – Start of Treatment Period) will be calculated at each visit during the treatment period and the same analysis as in (1) will be performed.

(3) Regarding evaluation results based on standard values, shift tables of start of treatment period and each visit of treatment period 4 week and 8 week will be prepared.

9. LISTING
Following lists will be create for randomized subjects.

• Demographics
• Discontinuation
• Protocol Deviation
• Subjects Excluded from Analyses
10. CONSIDERATIONS on STATISTICAL ANALYSIS

10.1. Adjustments for Covariates
In the analysis for primary endpoint for Full Analysis Set, stratified analysis of %FMD (fasting) is performed with Fasting TG value (150 <= - <200, 200 <= - <500) at the start of treatment as a layer. Details are described in 7.1 (3) and (4).

10.2. Handling of Dropouts or Missing Data
For laboratory test, values below quantitation limit are treated as zero.

10.3. Criteria for Interim Analysis and Early Discontinuation
Interim analysis will not be performed.

10.4. Multicenter Studies
Analyses for consideration of medical institution will not be performed.

10.5. Multiple Comparisons/Multiplicity
It does not adjust multiplicity.

10.6. Examination of Subgroups
Subgroup analysis will not be performed.
### 11. REVISION HISTORY

<table>
<thead>
<tr>
<th>Ver.</th>
<th>Date</th>
<th>Author</th>
<th>Revised Content</th>
<th>Reason for Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>23 May 2016</td>
<td>PPD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.0</td>
<td>4 Aug 2016</td>
<td>PPD</td>
<td>[2.TIME WINDOW] Add &lt;Exploratory biomarker evaluation&gt;</td>
<td>For exploratory evaluation item addition</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Add 7.3.2. Exploratory evaluation item (exploratory biomarker evaluation)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Analysis of exploratory biomarker is performed after March in 2018</td>
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<tr>
<td>3.0</td>
<td>29 Aug 2017</td>
<td>PPD</td>
<td>[Title page] Modify affiliation of approver and biostatistics manager.</td>
<td>For organization change and company integration</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>[2.TIME WINDOW] Delete &lt;Exploratory biomarker evaluation&gt;</td>
<td></td>
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<tr>
<td></td>
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<td></td>
<td>Delete 7.3.2. Exploratory evaluation item (exploratory biomarker evaluation)</td>
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<tr>
<td></td>
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<td></td>
<td>As required by Clinical Trial.gov</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>[6.1.3 Subject Disposition] Change of Analysis Variables</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(“Exit Status of Stud Drug” → “Exit status from the study”)</td>
<td>For mistake correction</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>[7.1. Primary Endpoint and the Analytical Methods] Add analysis of Complete Case</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>[8.1.1. Brief Summary of Adverse Events] Add “Non-serious Adverse Event”</td>
<td>As required by Clinical Trial.gov</td>
</tr>
<tr>
<td></td>
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<td>[8.1.2. Display of Adverse Event]</td>
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<tr>
<td>4.0</td>
<td>14 Nov 2017</td>
<td><strong>PPD</strong></td>
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<tr>
<td><strong>[10.2. Handling of Dropouts or Missing Data]</strong></td>
<td>To clarify the definition of handling below quantitation limit</td>
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<tr>
<td>Add handling of values below quantitation limit in laboratory test</td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>[Title page]</strong></td>
<td>For organization change</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Modify affiliation of biostatistics manager.</td>
<td></td>
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</tr>
<tr>
<td><strong>[5. OTHER DATA HANDLING]</strong></td>
<td>To clarify the specification</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Add &lt; Data Handling for Duration of Dyslipidemia (year) &gt;</td>
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<td></td>
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<tr>
<td><strong>[General]</strong></td>
<td>Due to the data review, stratification factor was found to be &quot;Fasting TG at Observation Period&quot;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correct stratification factor from &quot;Fasting TG at the Start of Treatment&quot; to &quot;Fasting TG at Observation Period&quot;</td>
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</tr>
<tr>
<td><strong>[7.2. Secondary Endpoints and the Analytical Methods]</strong></td>
<td>Analysis for complete case is performed only for primary endpoint.</td>
<td></td>
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</tr>
<tr>
<td>&quot;the same analyses describes in 7.1 are performed by visit” → &quot;the same analyses describes in 7.1 (1) - (4) are performed by visit”</td>
<td></td>
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<tr>
<td><strong>[9. LISTING]</strong></td>
<td>For creation of lists</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Add list to be created</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>