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Protocol Number:	P15-743 (HCV RWE)
Protocol Title:	Real world evidence of the effectiveness of Paritaprevir/r – Ombitasvir ± Dasabuvir ± Ribavirin in patients with chronic hepatitis C in the Russian Federation – an observational, multi-center study
SAP version:	Final 2.0
Effective date:	05 February 2018

Revision History

№	Version	Date	Changes
1	1.0	31.08.2017	New Document
2	2.0	02.02.2018	Protocol version was updated. Due to the fact that in the Russian clinical practice tests for HCV RNA often have limit of detection higher than 50 IU/mL (for example, 60 or 100 IU/mL), performing of additional effectiveness analysis was added to SAP. Section 9 and corresponding tables shells was updated.

TABLE OF CONTENTS

1 Abbreviations and definitions

The abbreviations and the definitions used in this document (except of common) are listed below.

Abbreviation	Abbreviation in Full
ABBVIE REGIMEN	Paritaprevir/R – Ombitasvir ± Dasabuvir
AE	Adverse event
CHC	Chronic hepatitis C
CP	Core population
CRF	Case report form
CSR	Clinical study report
CPSFU	Core population with sufficient follow-up data
DAA	Direct-acting antiviral agent
DMC	Data Monitoring Committee
eCRF	Electronic CRF
EoT	End of treatment
EQ-5D-5L	EuroQol 5 dimension 5 level
IL28B	Interleukin 28B
NCP	Non-core population
PAM-13	Patient Activate Measure 13
PSP	Patient support program
PRO	Patient reported outcome
PT	Preferred term
RBV	Ribavirin
SP	Safety population
SOC	System organ class
SVR	Sustained virological response
SVR12	SVR at 12 weeks after EoT
TAI	Total activity impairment
TP	Target population
TWP	Total work productivity impairment
VAS	Visual analogue scale
WPAI	Work productivity and activity impairment
WPAI	Work productivity and activity impairment
WPAI:SHP	WPAI questionnaire: specific health problem

2 Introduction

This document describes the planned data statistical analysis of an post-marketing, observational, multicenter, real world evidence study of the effectiveness of Paritaprevir/r – Ombitasvir ± Dasabuvir ± Ribavirin in patients with chronic hepatitis C in the Russian Federation (HCV RWE).

This SAP is written according to ICH E9 Guideline [1] and Data MATRIX LLC SOP [2] using the Protocol Final version 4.0 dated 11 July 2017 and CRF Final version 2.0 dated 25 May 2016.

The purpose of this document is to provide a more technical and detailed elaboration of the principal features of the analysis, described in the Protocol, and to include detailed procedures for executing the statistical analysis.

The SAP needs to be finalized and signed prior to database soft lock. Revisions to the approved SAP may be made prior to database soft lock. In case of deviation from the finalized SAP, explanation will be provided in the CSR.

3 Study objectives and variables[1]

3.1 Study Objectives

The research question of this study: what is the effectiveness, patient reported outcome, work productivity and healthcare resource utilization of the interferon-free ABBVIE REGIMEN ± ribavirin (RBV) in patients with CHC in a real life setting across clinical practice patient populations?

3.1.1 Primary objective

The Protocol defines the following primary objective of this study:

- to describe in routine clinical practice the effectiveness of the interferon-free ABBVIE REGIMEN ± RBV in patients with CHC as evidenced by Sustained Virological Response at Week 12 after End of Treatment (SVR12).

3.1.2 Secondary Objectives

The Protocol defines the following secondary objectives of this study:

- to provide real world evidence for predictive factors of virological response;
- to collect information on co-morbidities and concomitant medication in the Russian population;
- to describe the tolerability of the ABBVIE REGIMEN ± RBV;
- to document the effect of the ABBVIE REGIMEN ± RBV on patient-reported outcomes (PROs) and work productivity in the Russian population;
- to determine the impact of the ABBVIE REGIMEN ± RBV on healthcare resource utilization.

[1] This section is based on the sections 8 “Research Question and Objectives”, 9.3 “Variables”, 9.7.3.1 “Primary Effectiveness Endpoints” and 9.7.3.2 “Secondary Effectiveness Endpoints” of clinical study Protocol.

3.2 Variables

3.2.1 Primary variable

The primary variable of this study (and also effectiveness endpoint) is:
- the percentage of patients achieving SVR12 (single last HCV RNA <50 IU/mL 12 weeks [i.e. ≥70 days] after the last actual dose of the ABBVIE REGIMEN).

3.2.2 Secondary variables

- effectiveness endpoints:
  - the percentage of patients with virological response (HCV RNA <50 IU/mL) at EoT;
  - the percentage of patients with relapse (defined as HCV RNA <50 IU/mL at EoT followed by HCV RNA ≥50 IU/mL);
  - the percentage of patients with breakthrough (defined as at least one documented HCV RNA <50 IU/mL followed by HCV RNA ≥50 IU/mL during treatment);
  - the number and percentage of patients meeting each and any of the following SVR12 non-response categories:
    - on-treatment virologic failure: breakthrough (defined as above) or failure to suppress (each measured on-treatment HCV RNA value ≥50 IU/mL);
    - relapse (defined as HCV RNA <50 IU/mL at EoT or at the last on-treatment HCV RNA measurement followed by HCV RNA ≥50 IU/mL post-treatment);
    - premature study drug discontinuation with no on-treatment virologic failure;
    - missing SVR12 data and/or none of the above criteria;
- co-morbidities and concomitant medication;
- serious and non-serious adverse events and pregnancy occurrences;
- questionnaires on PROs: EQ-5D-5L questionnaire and WPAI questionnaires prior to treatment initiation at EoT as well as SVR12 and SVR24 (12 and 24 weeks after EoT respectively);
- Patient Activate Measure 13 (PAM-13), patient support program (PSP) satisfaction and utilization questionnaires.

4 Study design

4.1 General study design and plan[1]

This is a post-marketing, prospective, multicenter, observational study in patients receiving the interferon-free ABBVIE REGIMEN (Paritaprevir/r – Ombitasvir ± Dasabuvir) with or without RBV.

This study is focusing on collecting real-world data. Adult patients chronically infected with HCV, receiving the interferon-free ABBVIE REGIMEN will be offered the opportunity to participate in this study during a routine clinical visit at the participating sites. The prescription of a treatment regimen is at the discretion of the physician in accordance with local clinical practice and label, is made independently from this observational study and precedes the decision to offer a patient the opportunity to participate in this study.

[1] This section is based on the sections 9.1 "Study Design", 9.2.2 "Study duration", and 9.4.1 "Data to be documented" of clinical study Protocol.

After written informed consent has been obtained, patient data including demographic data, HCV disease characteristics, co-morbidities, co-medication, treatment details, and laboratory assessments as recorded in the patient's medical records (source documentation) will be documented in the eCRF. No patient identifiable information will be captured, a unique patient number will be automatically allocated by the web based eCRF system once the investigator or designee creates a new patient file.

Patients will be observed for the duration of the ABBVIE REGIMEN therapy and for up to 24 weeks after treatment completion. Procedures and diagnostic methods, treatment and follow-up visits will be consistent with physicians' routine clinical practice.

The flowchart of study design is indicated in Figure 1. This schedule is based on the anticipated regular follow-up for patients undergoing treatment for CHC.

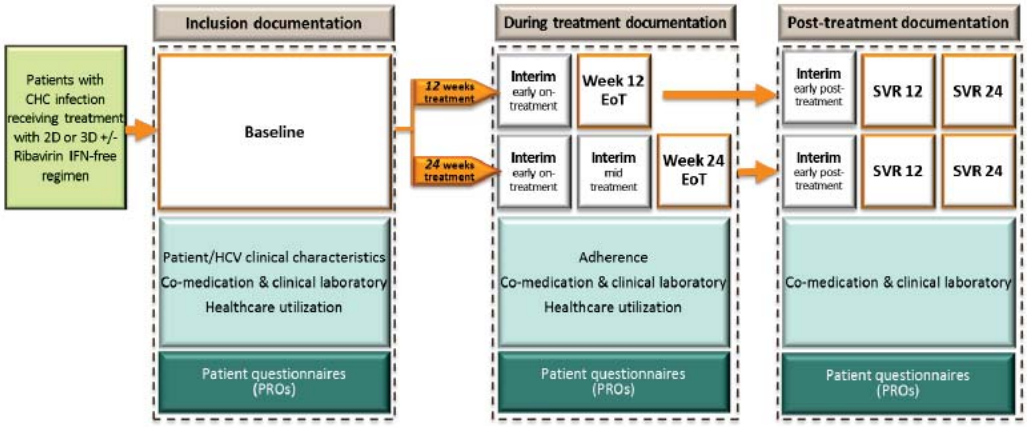

Figure 4.1 – Study flowchart

As indicated in Figure 1, each patient will be receive 12 or 24 weeks of ABBVIE REGIMEN.

The inclusion period will be approximately 8 months and the observational period of the study will be from baseline visit until 24 weeks post-treatment. The observational period for patients receiving 12 weeks of ABBVIE REGIMEN will be maximum 36 weeks (12 weeks treatment and 24 weeks post-treatment observation) and for patients receiving 24 weeks of ABBVIE REGIMEN the observational period will be maximum 48 weeks (24 weeks treatment and 24 weeks post-treatment observation).

Both regimens include four visits and several time windows for interim data collection (two for 12-week and three for 24-week). Data documented will be those closest to these time windows.

4.2 Sample size[1]

The sample size is justified in the clinical study Protocol.

The expected SVR12 rate is 90%. This value is based on results of previous sponsor's studies investigating the interferon-free ABBVIE REGIMEN ± RBV.

[1] This section is based on the section 9.5 "Study Size" of clinical study Protocol.

The sample size calculation was performed in order to obtain assessments of qualitative features with exact two-sided 95% Clopper-Pearson confidence interval, which doesn't exceed ±5% (i.e. total spread is not more than 10%) from the point estimate.

With 158 evaluable patients 95% CI will be 84.2%-94.2%, i.e. not more than 10%. Therefore, 158 patients should be enrolled during the inclusion period of 8 months.

4.3 Randomization and blinding

This study is observational. Randomization and blinding procedures are not applicable.

4.4 Planned analyses

The only final statistical analysis report will be performed for this study.
No analyses for DMC meetings and no interim analysis are planned in the study.

5 General considerations

5.1 Reference start date/time, study day, baseline

Study Day will be calculated from the reference start date, and will be used to show start/ stop day of assessments and events.

Reference start date is defined as the day of the ABBVIE REGIMEN start treatment ("EXSTDTC" variable from "EX" domain of the database where "EXTRT" equal "ABBVIE REGIMEN").

If the date of the event is on or after the reference date then
study day = (date of event – reference date) + 1.

If the date of the event is prior to the reference date then
study day = (date of event – reference date) – 1.

Baseline value is defined as the measurement taken on Baseline visit, unless otherwise specified.

5.2 Windowing conventions

Due to exploratory nature of the study all interim time-points will be separated into visits in the analysis stage. The most detailed possible situation is:

- on-treatment Week 4 from 15 to 42 study days;
- on-treatment Week 8 from 43 to 70 study days;
- on-treatment Week 12 from 71 to 98 study days;
- on-treatment Week 16 from 99 to 126 study days;
- post-treatment Week 4 from 15 to 56 days post EoT.

Table 5.1 describes assignment of time point windows to the following data for purposes of effectiveness, safety and tolerability analyses.

Table 5.1 – Analysis time windows[1]

Time point	Time Window	
	12 weeks treatment	**24 weeks treatment**
Baseline	Last value prior to start of study treatment (i.e. ≤study day 1)	
EoT[2]	Last value between	
	56 and 98 study days	140 and 182 study days
SVR12	Last value between 57 and 112 days post the study day of last dose	
SVR24	Last value between 141 and 196 days post the study day of last dose	

6 Analysis populations[3]

The target population (TP) – all patients, who fulfill the following criteria:

- treatment-naïve or treatment-experienced adult (age at least 18 years) male or female patients with confirmed CHC with genotype 1 (1a and/or 1b) only, receiving combination therapy with the interferon-free ABBVIE REGIMEN ± RBV according to standard of care and in line with the current local label. The prescribed ABBVIE REGIMEN needs to be known;
- if RBV is co-administered with the ABBVIE REGIMEN, it has been prescribed in line with the current local label (with special attention to contraception requirements and contraindication during pregnancy);
- patients with voluntarily signed and dated a patient authorization to use and/or disclosure his/her anonymized health data (or informed consent) prior to inclusion into the study;
- patients must not be participating or intending to participate in a concurrent interventional therapeutic study.

Patients who prematurely discontinue earlier than ≤study day 55 (for 12 weeks treatment) or ≤study day 139 (for 24 weeks treatment) will be used in analyses on the population with actual EoT time point without windowing conventions adjustment for EoT.

The core population (CP) – all patients of the TP, who have started the treatment combination recommended in the current local label for their disease characteristics. Patients, who fulfill at least one of the following conditions, will be excluded from the CP:

- patients with unknown fibrosis status;
- cirrhotic patients with genotype 1a not receiving ribavirin;
- patients with genotype 1 for whom two direct-acting antiviral agents regimen (2DAA) instead of 3DAA is prescribed;
- patients with EoT ≤study day 55 (for 12 weeks treatment) or ≤study day 139 (for 24 weeks treatment).

The safety population (SP) – all patients who received at least one dose of the ABBVIE REGIMEN.

[1] This table is based on the table 4 “Analysis time windows” of clinical study Protocol.
[2] These time windows are intended for the CP allocation filter only. In case of the TP, all patients will be used for the analysis regardless of actual EoT day relevance to EoT time windows.
[3] This section is based on the sections 9.7.1 “Analysis population, time windows and handling of missing data” and 9.2.1 “Target population” of clinical study Protocol.

The non-core population (NCP) – patients not receiving the treatment recommended in the local label (patients with EoT ≤study day 55 for 12 weeks treatment and patients with EoT ≤study day 139 for 24 weeks treatment).

The core population with sufficient follow-up data (CPSFU) – all CP patients, who fulfil one of the following criteria:

- evaluable HCV RNA data ≥70 days after the last actual dose of the ABBVIE REGIMEN (i.e. data within the SVR12 time window);
- a HCV RNA value ≥50 IU/mL at the last measurement post-baseline (i.e. no virological response achieved at the last measurement on-treatment or post-treatment);
- HCV RNA <50 IU/mL at the last measurement post-baseline, but no HCV RNA measurement ≥70 days after the last actual dose of the ABBVIE REGIMEN due to reasons related to safety (e.g. dropped out due to AE) or incomplete efficacy information (e.g. virologic failure such as relapse is reported in the eCRF but date and value of the corresponding HCV RNA test is missing).

In this way, only patients who had virological response at their last on-treatment or post-treatment measurement, but had no HCV RNA measurements ≥70 days post-treatment for reasons not related to safety or effectiveness (e.g. lost-to-follow-up or patient not willing to perform an additional HCV RNA test ≥70 days post-treatment) will be excluded from this analysis.

Figure 6.1 illustrates the patients selection for CPSFU.

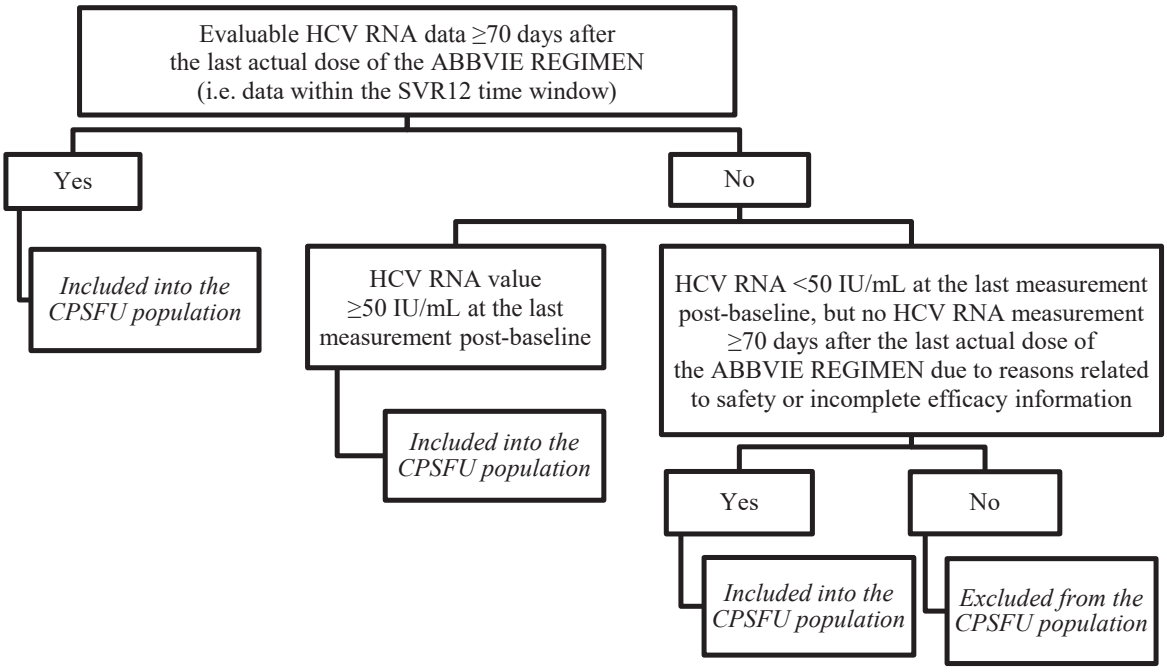

Figure 6.1 – The core population with sufficient follow-up data (CPSFU) allocation

7 Statistical considerations

7.1 Standard descriptive statistics

The data of continuous type will be presented with following statistics: *n* (the number of subjects with non-missing data), mean, median, standard deviation (SD), interquartile range (IQR), minimum and maximum values. In quantitative tests the values less than LLoQ will be replaced to 1/2 of LLoQ, the values more than ULoQ will be replaced to ULoQ.

The data of categorical type (including clinical evaluations) will be presented with *n* (the number of subjects with no missing data), frequencies and percentages. Unless otherwise specified, percentages by categories will be based on the number of subjects with no missing data.

Confidence intervals will be calculated for all effectiveness endpoints and questionnaires results.

The number of decimals for each descriptive statistical value will be determined by the following rules:

- mean, median and IQR: +1 decimal place compared to the analyzed variable values;
- standard deviation: +2 decimal places compared to the analyzed variable values;
- minimum and maximum values: the same as for the analyzed variable values;
- percentages (including CI) will be rounded to one decimal place.

The maximum number of decimal places in the statistical report is four. If some descriptive statistical value has more than four decimal places after above mentioned rules application, this value will be rounded to four decimal places .

7.2 Statistical tests and common calculations

Unless otherwise specified in the description of the analyses, the following arrangements will be applied:

- all tests will be two-sided with the default significant level 5%;
- confidence intervals will be 95% and will be determined using the Clopper-Pearson method.

Type I error values (p-values) will be rounded to four decimal symbols.

For quantitative measurements of clinical laboratory data, changes from baseline will be calculated as (measurement at visit X – measurement at baseline).

7.3 Missing Data

No data will be imputed for any effectiveness or safety analyses.

If information about adverse event start date and time is missing or incomplete, the following rules (table 7.1) will be used for the classification of AEs for AEs of the study period and AEs, which occurred before the start of treatment.

Table 7.1 – AEs missing management.

Day	Month	Year	Processing
is missing	is known	is known	AE will be classified as AE of the study period, if month and year ≥ month and year of the first study drug administration date
is missing	is missing	is known	AE will be classified as AE of the study period, if year ≥ year of the first study drug administration date
is known	is missing	is known	
is missing	is known	is missing	AE will be classified as AE of the study period
is known	is missing	is missing	
is missing	is missing	is missing	

7.4 Multicenter studies

The clinical study Protocol doesn't contain information about the number of centers.

Data from all centers will be merged and analyzed as one population for all study endpoints.

7.5 Multiple comparisons

No adjustments for multiplicity are required.

8 Summary of study data

Each study variable will be analyzed for relevant population.

Unless otherwise specified all raw data will be listed and sorted by unique subject identifier and study period/assessment (i.e. time point), where applicable.

Demographic characteristics, baseline variables, concurrent illnesses and medical conditions, prior and concurrent medications will be reported for *the core population* (*CP*), *the target population* (*TP*) and *the safety population* (*SP*).

The results will be reported overall and for scheduled treatment combination (± Dasabuvir, ± RBV) and duration (12 or 24 weeks) groups.

Additionally and only for *the core population* (*CP*) the results will be presented for the CP analysis groups by the following parameters:

- HCV genotype and subtype[1] (1a or 1b);
- fibrosis status[2] (the Child Pugh Score class: A, B or C);
- treatment experienced or naïve patients[3] (with/without prior treatment for CHC).

[1] Parameter "HCV Genotype and Subtype" from eCRF form "CHC DISEASE CHARACTERISTICS".
[2] Parameter "Class" in section "Child Pugh Score" from eCRF form "Liver fibrosis stage".
[3] Parameter "Prior treatment for CHC?" from eCRF form "MOST RECENT PRIOR THERAPY FOR CHC".

8.1 Subject Disposition

Subject disposition will be represented in tables and listings for *all patients who signed the Consent for use/disclosure of data form (informed consent)* and will include the following results:

- the number of subjects who signed the Consent for use/disclosure of data form;
- the number of subjects in each analyzed population;
- the number of subjects who has HCV RNA assessment performed at least 10 weeks post-treatment (i.e. >= 70 days after EoT);
- the number of subjects without HCV RNA assessment performed at least 10 weeks post-treatment (i.e. >= 70 days after EoT) and the reasons of it;
- the number of patients with the violations of the eligibility criteria and the corresponding violated inclusion/exclusion criteria.

8.2 Protocol Deviations

The presentation of Protocol deviations is not planned in this study.

8.3 Demographic characteristics

Descriptive statistics will be displayed in accordance with section 7.1 for the following demographic characteristics:

- gender;
- race/ethnic origin;
- height;
- weight;
- BMI[1].

All corresponding listings will be presented.

8.4 Baseline variables

Tables with descriptive statistics in accordance with section 7.1 will be presented for the following parameters, which are evaluated on baseline visit:

- duration of HCV infection diagnosis[2] (in years);
- IL28B genotypes;
- HCV genotype and subtype;
- presence of prior treatment of CHC;
- most likely mode of HCV infection;
- liver fibrosis diagnostic method;
- liver biopsy diagnostic results (staging by histopathological scoring system):
  - ISHAK fibrosis score;
  - METAVIR fibrosis score;
  - BATTS/LUDWIG fibrosis score;
  - KNODELL fibrosis score;
  - SCHEUER fibrosis score;

[1] Body mass index will be calculated as weight (kg) / [height (m)^2].
[2] This parameter will be calculated as (year of signed the informed consent – year of HCV infection diagnosys).

- FibroScan results (kPa);
- FibroTest;

– presence of esophageal varices;
– history of liver decompensation;
– Child Pugh score:
  - points;
  - classes;
– liver decompensation characteristics:
  - current signs/symptoms of liver decompensation;
– cirrhosis characteristics:
  - total bilirubin, µmol/l (mg/dl);
  - serum albumin, g/dl;
  - prothrombin time, prolongation (secs);
  - ascites;
  - hepatic encephalopathy;
– outpatient hospitalizations:
  - number of hospitalization periods in the 4 weeks prior to starting the ABBVIE REGIMEN;
  - duration of each hospitalization periods (in days);
  - technical interventions performed in each hospitalization period;
  - symptoms treated in each hospitalization period;
– outpatient consultations:
  - number of consultations in the 4 weeks prior to starting the ABBVIE REGIMEN;
  - technical interventions performed in each hospitalization period;
  - symptoms treated in each hospitalization period;
– alcohol consumption:
  - alcohol use;
  - number of units/drinks per week (for patients who regular use alcohol);

All corresponding listings will be presented.

8.5 Concurrent Illnesses and Medical Conditions

Medical history will be coded using the MedDRA version 20.0 (or further updating) and summarized by system organ class (SOC) and preferred term (PT) according to Data MATRIX LLC SOP [3] and will be presented in listings and tables.

Tables with descriptive statistics in accordance with section 7.1 will be presented for the following parameters, which are evaluated on baseline visit:

– presence of co-infection with other relevant diseases;
– HIV characteristics:
  - CD4 T-cell count (for HIV co-infected patients);
  - HIV-RNA test results (for HIV co-infected patients);
– liver and/or CHC related co-morbidities;
– other co-morbidities.

All corresponding listings will be presented.

8.6 Prior and Concurrent Medications

All medications will be coded using WHODD version Jun 2015 (or actual version on the time of the study completion) according to Data MATRIX LLC SOP [3]. Prior and concurrent medications will be presented in a separate listings and tables.

Prior medication will be determined using "MOST RECENT PRIOR THERAPY FOR CHC" flag in the CMCAT variable of CM domain of the database. Concurrent medications will be determined using "CO-MEDICATION" flag in the CMCAT variable of CM domain of the database.

The "treatment profile No" from "CO-MEDICATION" eCRF form will be presented in the separate listing.

All corresponding listings will be presented. Additionally listings will contain the following information for prior CHC therapy:

- presence of prior treatment for CHC;
- generic drug name;
- initial dose (by genetic drug name groups and units groups);
- start frequency (frequency of drug administration at the start by genetic drug name groups);
- duration (by genetic drug name groups, in weeks);
- outcome of prior treatment.

9 Effectiveness analysis

Effectiveness analysis will be conducted on *the core population* (*CP*), *the target population* (*TP*) and *the core population with sufficient follow-up data* (*CPSFU*).

The results will be reported overall and for scheduled treatment combination (± RBV) and duration (12 or 24 weeks) groups. Additionally and only for *the core population* (*CP*) the results will be presented for the CP analysis groups by the following parameters:

- HCV genotype and subtype[1] (1a or 1b);
- fibrosis status[2] (the Child Pugh Score class: A, B or C);
- treatment experienced or naïve patients[3] (with/without prior treatment for CHC).

Tables with descriptive statistics will be prepared in accordance with section 7.1. Confidence intervals will be presented according the section 7.2. All corresponding listings will be presented. Additional listings for *the non-core population* (*NCP*) will be created.

The following effectiveness endpoints will be analyzed:

- the percentage of patients achieving SVR12 (single last HCV RNA <50 IU/mL 12 weeks after the last actual dose of the ABBVIE REGIMEN);
- the percentage of patients with at least one and each of SVR12 non-response categories:
  - breakthrough (at least one documented HCV RNA <50 IU/mL followed by HCV RNA ≥50 IU/mL during treatment);
  - failure to suppress (each measured on-treatment HCV RNA value ≥50 IU/mL);

[1] Parameter "HCV Genotype and Subtype" from eCRF form "CHC DISEASE CHARACTERISTICS".
[2] Parameter "Class" in section "Child Pugh Score" from eCRF form "Liver fibrosis stage".
[3] Parameter "Prior treatment for CHC?" from eCRF form "MOST RECENT PRIOR THERAPY FOR CHC".

- relapse (HCV RNA <50 IU/mL at EoT or at the last on-treatment HCV RNA measurement followed by HCV RNA ≥50 IU/mL post-treatment);
- premature study drug discontinuation with no on-treatment virologic failure;
- missing SVR12 data;

– the percentage of patients achieving SVR24 (single last HCV RNA <50 IU/mL 24 weeks after the last actual dose of the ABBVIE REGIMEN);
– the percentage of patients with virological response (HCV RNA <50 IU/mL) at EoT.

Due to the fact that in the Russian clinical practice tests for HCV RNA often have limit of detection higher than 50 IU/mL (for example, 60 or 100 IU/mL), additional analysis will be performed. In this case all above mentioned effectiveness endpoints will be analyzed with the following definitions:

– the percentage of patients achieving SVR12 (single last HCV RNA value <50 IU/mL or undetectable/negative 12 weeks after the last actual dose of the ABBVIE REGIMEN);
– the percentage of patients with at least one and each of SVR12 non-response categories:
  - breakthrough (at least one documented HCV RNA value <50 IU/mL or undetectable/negative followed by HCV RNA value ≥50 IU/mL or positive during treatment);
  - failure to suppress (each measured on-treatment HCV RNA value ≥50 IU/mL or positive);
  - relapse (HCV RNA value <50 IU/mL or undetectable/negative at EoT or at the last on-treatment HCV RNA measurement followed by HCV RNA ≥50 IU/mL or positive post-treatment);
  - premature study drug discontinuation with no on-treatment virologic failure;
  - missing SVR12 data and/or none of the above criteria;
– the percentage of patients achieving SVR24 (single last HCV RNA value <50 IU/mL or undetectable/negative 24 weeks after the last actual dose of the ABBVIE REGIMEN);
– the percentage of patients with virological response (HCV RNA value <50 IU/mL or undetectable/negative) at EoT.

Achieving SVR12 and presence of breakthrough, relapse or failure to suppress as well as virological response at EoT will be analyzed using univariate logistic regression for both cases (main and sensitivity analyses). These analyses will be of exploratory nature, data driven, and will be repeatedly performed for various CP analysis groups, since not each covariate might be predictive in each patient group. The following parameters can be included in the univariate models as explanatory variables (fixed effect or covariate):

– key demographic information:
  - age;
  - gender;
  - race;
– mode of CHC infection:
  - Most likely mode of HCV infection;
  - HCV Genotype and Subtype;
– HCV RNA level at baseline;
– most recent stage of liver fibrosis:
  - Severity of cirrhosis by Child-Pugh classification;
  - Result of FibroTest;
  - ISHAK Fibrosis Score;
  - METAVIR Fibrosis Score;

- BATTS/LUDWIG Fibrosis Score;
- KNODELL Fibrosis Score;
- SCHEUER Fibrosis Score;

– liver and/or CHC related co-morbidities;
– treatment experience (Interferon, Ribavirin, DAA);
– outcome of most recent prior CHC treatment
– laboratory hematology[1]:
  - hemoglobin;
  - platelets;
  - prothrombin time, international normalized ratio (INR);
– laboratory clinical chemistry:
  - ALT;
  - AST;
  - gamma-GT;
  - total bilirubin;
  - albumin;
  - creatinine clearance;
  - alpha-1-fetoprotein.

After univariate model analyses all covariates with a p-value <0.25 in the corresponding univariate logistic regression analysis will be included to multiple logistic regression (MLR) model. MLR will be performing only if more than one explanatory variables will have a p-value <0.25 in the univariate model analyses.

Statistical significant correlated variables with correlation coefficient ≥ 40 should be considered and managed. All solutions about choosing explanatory variables will be of exploratory nature, data driven, and will be described with presenting of results of the "*PROC CORR"* SAS procedure.

Backward selection procedures will be applied to generate the final MLR models. A p-value <0.05 will be used for the covariates to stay in the model in a backward elimination step.

The SAS procedure LOGISTIC will be used for the analysis with following statements:
– SELECTION= BACKWARD;
– SLENTRY=0.05.

To avoid the multicollinearity problem all possible explanatory variables will be examined using following SAS script:

```
ods graphics on;
PROC CORR data=<dataset> plots=all;
  VAR <variables>;
RUN;
ods graphics off;
```

All data for Effectiveness Analyses will be listed in separate listings (for each effectiveness analyses endpoint). Additional listings for NCP population will be created.

[1] Note that all Hematology variables and all Clinical Chemistry should be in the same units. If it is impossible to bring units to the same the smallest units groups will be accepted as missing. If it is impossible to identify the smallest units groups the corresponding covariate will be deleted from the analysis.

10 Quality of life analysis

Patient questionnaires analysis will be conducted on *the core population* (*CP*), *the target population* (*TP*) and *the core population with sufficient follow-up data* (*CPSFU*).

The results will be reported overall and for scheduled treatment combination (± RBV) and duration (12 or 24 weeks) groups.

Tables with descriptive statistics for baseline and post-baseline time points will be prepared for each questionnaire results in accordance with section 7.1. Confidence intervals will be presented according the section 7.2. All corresponding listings will be presented. Additional listings for *the non-core population* (*NCP*) will be created.

10.1 EQ-5D-5L

The following EQ-5D-5L parameters will be analyzed:
- the EQ-5D-5L descriptive system dimensions:
  - mobility;
  - self-care;
  - usual activities;
  - pain/discomfort;
  - anxiety/depression;
- the EQ VAS;
- the EQ-5D-5L index value.

Descriptive statistics for each of the 5 dimensions comprising the EQ-5D descriptive system will be reported in two ways:
- using a division into 5 levels of perceived problems:
  - no problems (level 1);
  - slight problems (level 2);
  - moderate problems (level 3);
  - severe problems (level 4);
  - extreme problems (level 5);
- using a division into 2 levels of perceived problems:
  - no problems;
  - problems.

The EQ-5D-5L index value will be calculated by applying US weights. In case of missing items no index value will be calculated.

Summary tables for the EQ VAS and the EQ-5D-5L index value will show descriptive statistics for time point values and changes from baseline value.

Also a graphical representation of the EQ-5D-5L results will be presented.

In addition the models of *analysis of covariance* (ANCOVA) will be applied for EoT and SVR12 time points to investigate the effect of the different ABBVIE REGIMENS (± RBV and duration) on EQ-5D-5L endpoints (EQ VAS and EQ-5D-5L index score).

For each time point (EoT and SVR12) a separate model will be built. The EQ-5D-5L results for each time point will be used as dependent variables. Treatment regimen group will be used as factor. Baseline values will be used as covariates. *Independent-samples t-test* will be

used for post-hoc comparisons. If there are more than two treatment groups, *no adjustment* will be used to counteract the problem of multiple comparisons due to the explanatory study nature.

ANCOVA results will be prepared using SAS PROC MIXED. Studentized residuals figures will be presented for each ANCOVA analyses.

As a supporting analysis the comparisons using Mann-Whitney U-test will be performed.

10.2 WPAI

Assessments of work productivity and activity impairment as assessed by the WPAI Hepatitis C will be evaluated according to the WPAI:SHP v2.0 scoring manual.

The following WPAI parameters will be analyzed:
- the WPAI Hep C v2.0 question answers;
- the WPAI:SHP scores.

The WPAI Hep C v2.0 consists of six questions:
- currently employed (Q1);
- hours missed due to hepatitis C in the last seven days (Q2);
- hours missed due to other reasons in the last seven days (Q3);
- hours actually worked in the last seven days (Q4);
- degree hepatitis C affected productivity while working (Q5);
- degree hepatitis C affected regular activities (Q6).

If any of the items Q1-Q6 will be presented as interval it will be replace by mean value for calculations.

WPAI outcomes are expressed as impairment percentages, with higher numbers indicating greater impairment and less productivity, i.e. worse outcomes.

The following four WPAI:SHP scores will be calculated and analyzed:
- absenteeism as percentage of work time missed due to hepatitis C:

$$100 \times \frac{Q_2}{Q_2+Q_4};$$

- presenteeism as percentage of impairment while working due to hepatitis C):

$$100 \times \frac{Q_5}{10};$$

- TWP (percentage of overall work impairment due to hepatitis C):

$$100 \times \frac{Q_2}{Q_2+Q_4} + \frac{Q_4}{Q_2+Q_4} \times \frac{Q_5}{10};$$

- TAI (percentage of general (non-work) activity impairment due to hepatitis C):

$$100 \times \frac{Q_6}{10}.$$

A score will be set to missing if one or more of the items Q1-Q6 that are needed for the calculation of the score is missing.

10.3 PSP

The information about utilization and the contribution of the patient support program (PSP) to disease control, treatment continuation and patient satisfaction will be reported as descriptive statistics only in accordance with section 7.1.

All percentages will be calculated with number of patients, which have utilized any components from the AbbVie Patient Support Program as a denominator (valid percent).

The following parameters will be analyzed on all applicable visits:
- the number of patients who participated in the PSP[1];
- the number of patients who utilized any components from the AbbVie PSP since the last visit;
- level of general satisfaction of the AbbVie PSP;
- the AbbVie PSP's relevance to patients' needs;
- frequency of and satisfaction from using education and information materials.

10.4 PAM-13

The following PAM-13 parameters will be analyzed:
- items of scale;
- PAM 13 score;
- levels of activation.

The 13 items have four possible response options with scores from 1 to 4 (1 – strongly disagree, 2 – disagree, 3 – agree, 4 – strongly agree) and an additional "not applicable" option.

PAM 13 score is a value on scale from 0 to 100. This score will is converted to one of the four levels of activation:
- disengaged and overwhelmed (1);
- becoming aware, but still struggling (2);
- taking action (3);
- maintaining behaviors and pushing further (4).

The PAM 13 score and the level of activation will be obtained using Excel file "PAM 13 Scoring Spreadsheet 2015.xlsm" which was received from the Sponsor's company.

In case of missing item values, the value for replacement will be determined as the integer part of the available items mean value (i.e. worst-case value imputation).

However, if there are less than ten items answered, no summary score will be calculated (the answers of this patient will be reported only in tables with descriptive statistics for items of scales).

Summary tables for the PAM 13 score will show descriptive statistics for time point values and changes from baseline value. Summary tables for the levels of activation will show descriptive statistics for time point values.

[1] Parameter "Will patient participate / or is patient participating in the AbbVie patient support program (PSP)?" from eCRF form "DEMOGRAPHICS".

In addition the models of analysis of covariance (ANCOVA) will be applied for EoT time point to investigate the effect of the different ABBVIE REGIMENS (± RBV and duration) on the PAM 13 score using the corresponding baseline value as covariates.

The PAM 13 result for EoT time point will be used as dependent variable. Treatment regimen group will be used as factor. Baseline values will be used as covariates. Independent-samples t-test will be used for post-hoc comparisons. If there are more than two treatment groups, the no adjustment will be used to counteract the problem of multiple comparisons due to explanatory study nature. The obtained p-values of significance levels will be presented before and after the application of the correction.

ANCOVA results will be prepared using SAS PROC MIXED. Studentized residuals figures will be presented for each ANCOVA analyses.

As a supporting analysis the comparisons using Mann-Whitney U-test will be performed.

11 Safety analysis

Safety analysis will be conducted on *the safety population* (*SP*). The results will be reported overall and for scheduled treatment combination (± RBV) and duration (12 or 24 weeks) groups.

The following parameters will be analyzed:
- study drug exposure;
- adverse events;
- pregnancies;
- clinical laboratory evaluations.

11.1 Exposure

Tables with descriptive statistics in accordance with section 7.1 will be presented for the following parameters:
- actual duration ABBVIE REGIMEN (in days);
- the number of patients with collected deviating duration reasons;
- adherence ABBVIE REGIMEN (calculated for Paritaprevir/R-Ombitasvir, Dasabuvir and Ribavirin separately):
  - percentage of target dose taken in treatment intervals (weeks 1-4, 5-8 and 9-12) for Paritaprevir/R-Ombitasvir and for Dasabuvir;
  - percentage of patients who missed of study drug administration for at least 7 days in a row (only for Paritaprevir/R-Ombitasvir and Dasabuvir).

All corresponding listings will be presented.

11.2 Adverse Events

Only treatment-emergent adverse events will be analyzed.

Treatment-emergent AE is any reported event that begins or worsens in severity after initiation of study drug through 30 days post-study drug dosing.

All analyzed AEs will be coded using the MedDRA version 20.0 (or further updating) and tabulated in the report with grouping by primary system organ class (SOC) and preferred term (PT).

The frequency of a specific AE occurrence will be presented by the proportion of patients with this AE emergence as well as the total number of episodes this AE for a diagnosis.

The following tables with descriptive statistics in accordance with section 7.1 will be presented:

- all AE / SAE;
- AE / SAE by severity;
- AE / SAE by relationship to the study drug.

Tables of AE/SAE by severity (relationship to the study drug) will be prepared using the following rules. Each SOC / PT category will include only the AEs with the highest severity (relationship to the drug) in each patient, while in the Total category all AEs of this patient will be considered. At the same time, each patient will be counted only once with highest severity (relationship to the study drug) in each SOC and each PT level as well as Total level.

Also all AEs will be presented in listings. Additional listings for unintended medication errors will be provided.

11.3 Pregnancies

Female subjects will be tested for pregnancy at each study visit. The results of these tests and pregnancies episodes will be reported in the listing.

11.4 Clinical Laboratory Evaluations

Clinical laboratory evaluations include the following parameters:

- hematology results;
- blood chemistry results.

The following parameters, which are evaluated at each study visit, will be analyzed in tables and presented in listings:

- hematology:
  - hemoglobin;
  - platelets;
  - prothrombin time (seconds);
  - prothrombin time (INR);
- blood chemistry:
  - ALT;
  - AST;
  - GGT;
  - total bilirubin;
  - alpha-1-fetoprotein;
  - albumin;
  - creatinine;
  - creatinine clearance.

The results of clinical laboratory evaluations statistical analysis will be represented in accordance with section 7.1 as the following outputs:

- tables with descriptive statistics of measurement values and changes from baseline visit;
- frequency tables of out of range and clinically significant evaluates will be presented;
- shift tables based on clinical evaluation of measurements at baseline visit.

11.5 Other Safety Measures

No other safety measures will be analyzed in this study.

12 Pharmacokinetics

No pharmacokinetic and pharmacodynamic parameters will be analyzed in this study.

13 Other analyses

No other analyses will be performed in this study.

14 Interim analyses and data monitoring

No interim analysis is planned for this study.

15 Technical details and reporting conventions

Statistical analysis will be performed using SAS 9.4.

One (final) statistical analysis report will be prepared in the Microsoft Office Word *(.docx*) format after the end of data collection and database lock. The results of statistical analysis will be presented in the form of tables, figures and listings in English.

16 Summary of changes to the Protocol

The analyses methods in this SAP is fully consistent with the clinical study Protocol. The MLR analysis for the PSP results will not be performed due to lack of main predictor variability (the fact of the PSP usage is always “Yes”).

17 References

1) Committee for Proprietary Medicinal Products (CPMP). International Conference on Harmonisation (ICH) Topic E9: Note for Guidance on Statistical Principles for Clinical Trials; September 1998.
2) DataMatrix_SOP_STAT001_Statistical Principles_ver.2.0_June 2016.
3) DataMatrix_SOP_DM010_Dictionary Management and Data Coding_ver.2.0_August 2015.

18 Tables shells

Subject disposition

AbbVie LLC
P15-743 (HCV RWE)
Table 1.1 Subject Disposition
All patients
Page X of X

	ABBVIE REGIMEN + RBV 12 weeks n (%)	ABBVIE REGIMEN – RBV 12 weeks n (%)	...	Overall n (%)
Subjects who signed the Consent for use/disclosure of data form (informed consent)	XX	XX	...	XX
The target population (TP)	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
The core population (CP)	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
The safety population (SP)	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
The non-core population (NCP)	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
The core population with sufficient follow-up data (CPSFU)	XX (XX.X)	XX (XX.X)	...	XX (XX.X)

n: the number of subjects within a specific category.
Percentages were calculated from the number of subjects who signed the Consent for use/disclosure of data form (informed consent) overall and in the treatment groups.

Program code, date, time

Data extracted: DD.MM.YYYY

AbbVie LLC
P15-743 (HCV RWE)
Table 1.2 The reasons of early withdrawal
The target population
Page X of X

	ABBVIE REGIMEN + RBV 12 weeks (N = XX) n (%)	ABBVIE REGIMEN – RBV 12 weeks (N = XX) n (%)	...	Overall (N = XX) n (%)
Subjects with HCV RNA assessment performed at least 10 weeks post-treatment (i.e. >= 70 days after EoT)	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Subjects without HCV RNA assessment performed at least 10 weeks post-treatment (i.e. >= 70 days after EoT)	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Reason if HCV RNA assessment on SVR12 not done:				
Failure to return	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Insufficient virological response	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Withdrawn consent	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Death	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
...	...	...	...	...

N: the number of subjects in the target population.
n: the number of subjects within a specific category. Percentages were calculated as (100 x n/N).

Program code, date, time

Data extracted: DD.MM.YYYY

AbbVie LLC
P15-743 (HCV RWE)
Table 1.3 Violation of eligibility criteria
The target population
Page X of X

	ABBVIE REGIMEN + RBV 12 weeks (N = XX) n (%)	ABBVIE REGIMEN – RBV 12 weeks (N = XX) n (%)	...	Overall (N = XX) n (%)
Patients with violation of inclusion criteria	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Inclusion criterion #1	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Inclusion criterion #2	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
...	...	...	...	...
Patients with violation of exclusion criteria	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Exclusion criterion #1	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Exclusion criterion #2	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
...	...	...	...	...
Subject has fulfilled all the inclusion and does not meet any exclusion criteria and is eligible for the trial	XX (XX.X)	XX (XX.X)	...	XX (XX.X)

N: the number of subjects in the target population.
n: the number of subjects within a specific category. Percentages are calculated as (100 x n/N).

Program code, date, time

Data extracted: DD.MM.YYYY

Demographic and anthropometric characteristics

AbbVie LLC
P15-743 (HCV RWE)
Table 1.4.1 Demographics and anthropometric characteristics
The core population
Page X of X

	ABBVIE REGIMEN + RBV 12 weeks (N = XX)	ABBVIE REGIMEN – RBV 12 weeks (N = XX)	...	Overall (N = XX)
Age (years)				
n	XX	XX	...	XX
Mean	XX.X	XX.X	...	XX.X
SD	XX.XX	XX.XX	...	XX.XX
Median	XX.X	XX.X	...	XX.X
IQR	XX.X	XX.X	...	XX.X
Min	XX	XX	...	XX
Max	XX	XX	...	XX
Age				
n	XX	XX	...	XX
18-64 years	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
≥65 years	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Gender				
n	XX	XX	...	XX
Male	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Female	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Race				
n	XX	XX	...	XX
White/Caucasian	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Black	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Asian/Oriental	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Native American/American Indian	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Other	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Weight (kg)				
n	XX	XX	...	XX
Mean	XX.X	XX.X	...	XX.X
SD	XX.XX	XX.XX	...	XX.XX
Median	XX.X	XX.X	...	XX.X
IQR	XX.X	XX.X	...	XX.X
Min	XX	XX	...	XX
Max	XX	XX	...	XX

	ABBVIE REGIMEN + RBV 12 weeks (N = XX)	ABBVIE REGIMEN – RBV 12 weeks (N = XX)	...	Overall (N = XX)
Height (cm)				
n	XX	XX	...	XX
Mean	XX.X	XX.X	...	XX.X
SD	XX.XX	XX.XX	...	XX.XX
Median	XX.X	XX.X	...	XX.X
IQR	XX.X	XX.X	...	XX.X
Min	XX	XX	...	XX
Max	XX	XX	...	XX
BMI (kg/m^2)				
n	XX	XX	...	XX
Mean	XX.X	XX.X	...	XX.X
SD	XX.XX	XX.XX	...	XX.XX
Median	XX.X	XX.X	...	XX.X
IQR	XX.X	XX.X	...	XX.X
Min	XX	XX	...	XX
Max	XX	XX	...	XX

N: the number of subjects in the core population.
n: the number of valid measurements.
IQR: interquartile range.
Body Mass Index (BMI): weight (kg) / [height (m)^2].
Percentages are calculated from the number of subjects in the core population.
Age is calculated as the number of full years between the date of birth and the date of signing the Consent for use/disclosure of data form (informed consent).

Program code, date, time

Data extracted: DD.MM.YYYY

Similar to table 1.4.1, the following tables will be constructed:

Table 1.4.2 Demographics and anthropometric characteristics (overall – HCV genotype groups[1])
Table 1.4.3 Demographics and anthropometric characteristics (overall – Child Pugh classes groups[2])
Table 1.4.4 Demographics and anthropometric characteristics (overall – prior treatment groups[3])

These tables will be repeated for each treatment group:

Table 1.4.X Demographics and anthropometric characteristics (treatment group X – HCV genotype and subtype groups)
Table 1.4.X Demographics and anthropometric characteristics (treatment group X – Child Pugh classes groups)
Table 1.4.X Demographics and anthropometric characteristics (treatment group X – prior treatment groups)

Also the table 1.4.1 will be repeated for the target population and the safety population[4]:

Table 1.4.X Demographics and anthropometric characteristics
Table 1.4.X Demographics and anthropometric characteristics

[1] Patients will be divided into subgroups by HCV genotype (1a or 1b). Patients with genotypes combination will be divided into separate subgroups.
[2] Patients will be divided into subgroups by Child Pugh classes A, B and C.
[3] Patients will be divided into subgroups by presence of prior treatment: “INF”, “RBV”, “DAA”, “Treatment-experienced all” and “Naïve”. Patients with prior treatment components combination will be divided into separate subgroups.
[4] If the target population and the safety population will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.

CHC disease characteristics

AbbVie LLC
P15-743 (HCV RWE)
Table 1.5.1 CHC disease characteristics
The core population
Page X of X

	ABBVIE REGIMEN + RBV 12 weeks (N = XX)	ABBVIE REGIMEN – RBV 12 weeks (N = XX)	...	Overall (N = XX)
Duration of HCV infection diagnosis (years)				
n	XX	XX	...	XX
Mean	XX.X	XX.X	...	XX.X
SD	XX.XX	XX.XX	...	XX.XX
Median	XX.X	XX.X	...	XX.X
IQR	XX.X	XX.X	...	XX.X
Min	XX	XX	...	XX
Max	XX	XX	...	XX
HCV genotype and subtype				
n	XX	XX	...	XX
1a	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
1b	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
4	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
IL28B genotypes				
rs12979860				
n	XX	XX	...	XX
CC	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
CT	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
TT	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
unknown	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
rs8099917				
n	XX	XX	...	XX
TT	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
TG	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
GG	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
unknown	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Most likely mode of HCV infection				
n	XX	XX	...	XX
intravenous drug use	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
blood transfusions	XX (XX.X)	XX (XX.X)	...	XX (XX.X)

	ABBVIE REGIMEN + RBV 12 weeks (N = XX)	ABBVIE REGIMEN – RBV 12 weeks (N = XX)	...	Overall (N = XX)
hemodialysis	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
...	...	...	...	...
unknown	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Prior treatment for CHC				
n	XX	XX	...	XX
Yes	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
No	XX (XX.X)	XX (XX.X)	...	XX (XX.X)

N: the number of subjects in the core population.
n: the number of valid measurements.
IQR: interquartile range.
Percentages are calculated from the number of subjects in the core population.

Program code, date, time

Data extracted: DD.MM.YYYY

Similar to table 1.5.1, the following tables will be constructed:

Table 1.5.2 CHC disease characteristics (overall – HCV genotype groups[1])
Table 1.5.3 CHC disease characteristics (overall – Child Pugh classes groups[2])
Table 1.5.4 CHC disease characteristics (overall – prior treatment groups[3])

These tables will be repeated for each treatment group:

Table 1.5.X CHC disease characteristics (treatment group X – HCV genotype and subtype groups)
Table 1.5.X CHC disease characteristics (treatment group X – Child Pugh classes groups)
Table 1.5.X CHC disease characteristics (treatment group X – prior treatment groups)

Also the table 1.5.1 will be repeated for the target population and the safety population[4]:

Table 1.5.X CHC disease characteristics
Table 1.5.X CHC disease characteristics

[1] Patients will be divided into subgroups by HCV genotype (1a or 1b). Patients with genotypes combination will be divided into separate subgroups.
[2] Patients will be divided into subgroups by Child Pugh classes A, B and C.
[3] Patients will be divided into subgroups by presence of prior treatment: “INF”, “RBV”, “DAA”, “Treatment-experienced all” and “Naïve”. Patients with prior treatment components combination will be divided into separate subgroups.
[4] If the target population and the safety population will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.

Liver fibrosis stage

AbbVie LLC
P15-743 (HCV RWE)
Table 1.6.1 Liver fibrosis stage
The core population
Page X of X

	ABBVIE REGIMEN + RBV 12 weeks (N = XX)	ABBVIE REGIMEN – RBV 12 weeks (N = XX)	...	Overall (N = XX)
Liver fibrosis diagnostic method				
n	XX	XX	...	XX
Biopsy (invasive)	XX.X	XX.X	...	XX.X
Non-invasive	XX.XX	XX.XX	...	XX.XX
Clinical / best quess	XX.X	XX.X	...	XX.X
ISHAK Fibrosis Score				
n	XX	XX	...	XX
0	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
1	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
...	...	...	...	...
METAVIR Fibrosis Score				
n	XX	XX	...	XX
0	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
...	...	...	...	...
BATTS/LUDWIG Fibrosis Score				
...	...	...	...	...
KNODELL Fibrosis Score				
...	...	...	...	...
SCHEUER Fibrosis Score				
...	...	...	...	...
FibroScan (kPa)				
n	XX	XX	...	XX
<8.8	XX.X	XX.X	...	XX.X
8.8-<9.6	XX.XX	XX.XX	...	XX.XX
...	...	...	...	...
FibroTest				
n	XX	XX	...	XX
<=0.21	XX.X	XX.X	...	XX.X
0.22-0.27	XX.XX	XX.XX	...	XX.XX

	ABBVIE REGIMEN + RBV 12 weeks (N = XX)	ABBVIE REGIMEN – RBV 12 weeks (N = XX)	...	Overall (N = XX)
...	...	...	...	...
Presence of esophageal varices				
n	XX	XX	...	XX
Yes	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
No	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Unknown	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
History of liver decompensation				
n	XX	XX	...	XX
No, never decompensated	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Yes, but currently compensated	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Yes, still decompensated	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Child Pugh Score				
Points				
n	XX	XX	...	XX
Mean	XX.X	XX.X	...	XX.X
SD	XX.XX	XX.XX	...	XX.XX
Median	XX.X	XX.X	...	XX.X
IQR	XX.X	XX.X	...	XX.X
Min	XX	XX	...	XX
Max	XX	XX	...	XX
Class				
n	XX	XX	...	XX
A	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
B	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
C	XX (XX.X)	XX (XX.X)	...	XX (XX.X)

N: the number of subjects in the core population.
n: the number of valid measurements.
IQR: interquartile range.
Percentages are calculated from the number of subjects in the core population.

Program code, date, time Data extracted: DD.MM.YYYY

Similar to table 1.6.1, the following tables will be constructed:

Table 1.6.2 Liver fibrosis stage (overall – HCV genotype groups[1])
Table 1.6.3 Liver fibrosis stage (overall – Child Pugh classes groups[2])
Table 1.6.4 Liver fibrosis stage (overall – prior treatment groups[3])

These tables will be repeated for each treatment group:

Table 1.6.X Liver fibrosis stage (treatment group X – HCV genotype and subtype groups)
Table 1.6.X Liver fibrosis stage (treatment group X – Child Pugh classes groups)
Table 1.6.X Liver fibrosis stage (treatment group X – prior treatment groups)

Also the table 1.6.1 will be repeated for the target population and the safety population[4]:

Table 1.6.X Liver fibrosis stage
Table 1.6.X Liver fibrosis stage

[1] Patients will be divided into subgroups by HCV genotype (1a or 1b). Patients with genotypes combination will be divided into separate subgroups.
[2] Patients will be divided into subgroups by Child Pugh classes A, B and C.
[3] Patients will be divided into subgroups by presence of prior treatment: “INF”, “RBV”, “DAA”, “Treatment-experienced all” and “Naïve”. Patients with prior treatment components combination will be divided into separate subgroups.
[4] If the target population and the safety population will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.

Liver decompensation

AbbVie LLC
P15-743 (HCV RWE)
Table 1.7.1 Liver decompensation
The core population
Page X of X

	ABBVIE REGIMEN + RBV 12 weeks (N = XX)	ABBVIE REGIMEN – RBV 12 weeks (N = XX)	...	Overall (N = XX)
History of liver decompensation				
n	XX	XX	...	XX
No, never decompensated	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Yes, but currently compensated	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Yes, still decompensated	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Current signs/symptoms of liver decompensation				
n	XX	XX	...	XX
Coagulopathy	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Hyperbilirubinemia	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
...	...	...	...	...
Bleeding from esophageal varices	XX (XX.X)	XX (XX.X)	...	XX (XX.X)

N: the number of subjects in the core population.
n: the number of valid measurements.
IQR: interquartile range.
Percentages are calculated from the number of subjects in the core population.

Program code, date, time

Data extracted: DD.MM.YYYY

Similar to table 1.7.1, the following tables will be constructed:

Table 1.7.2 Liver decompensation (overall – HCV genotype groups[1])
Table 1.7.3 Liver decompensation (overall – Child Pugh classes groups[2])
Table 1.7.4 Liver decompensation (overall – prior treatment groups[3])

These tables will be repeated for each treatment group:

Table 1.7.X Liver decompensation (treatment group X – HCV genotype and subtype groups)
Table 1.7.X Liver decompensation (treatment group X – Child Pugh classes groups)
Table 1.7.X Liver decompensation (treatment group X – prior treatment groups)

Also the table 1.7.1 will be repeated for the target population and the safety population[4]:

Table 1.7.X Liver decompensation
Table 1.7.X Liver decompensation

[1] Patients will be divided into subgroups by HCV genotype (1a or 1b). Patients with genotypes combination will be divided into separate subgroups.
[2] Patients will be divided into subgroups by Child Pugh classes A, B and C.
[3] Patients will be divided into subgroups by presence of prior treatment: “INF”, “RBV”, “DAA”, “Treatment-experienced all” and “Naïve”. Patients with prior treatment components combination will be divided into separate subgroups.
[4] If the target population and the safety population will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.

Cirrhosis characteristics

AbbVie LLC
P15-743 (HCV RWE)
Table 1.8.1 Cirrhosis characteristics
The core population
Page X of X

	ABBVIE REGIMEN + RBV 12 weeks (N = XX)	ABBVIE REGIMEN – RBV 12 weeks (N = XX)	...	Overall (N = XX)
Total bilirubin, µmol/l (mg/dl)				
n	XX	XX	...	XX
<34 (<2)	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
34-50 (2-3)	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
>50 (>3)	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Serum albumin, g/dl				
n	XX	XX	...	XX
>3.5	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
2.8-3.5	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
<2.8	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Prothrombin time, prolongation (secs)				
n	XX	XX	...	XX
<4.0	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
4.0-6.0	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
>6.0	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Ascites				
n	XX	XX	...	XX
None	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Mild	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Moderate to Severe	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Hepatic encephalopathy				
n	XX	XX	...	XX
None	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Grade I-II (or suppressed with medication)	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Grade III-IV (or refractory)	XX (XX.X)	XX (XX.X)	...	XX (XX.X)

N: the number of subjects in the core population.
n: the number of valid measurements.
IQR: interquartile range.
Percentages are calculated from the number of subjects in the core population.

Similar to table 1.8.1, the following tables will be constructed:

Table 1.8.2 Cirrhosis characteristics (overall – HCV genotype groups[1])
Table 1.8.3 Cirrhosis characteristics (overall – Child Pugh classes groups[2])
Table 1.8.4 Cirrhosis characteristics (overall – prior treatment groups[3])

These tables will be repeated for each treatment group:

Table 1.8.X Cirrhosis characteristics (treatment group X – HCV genotype and subtype groups)
Table 1.8.X Cirrhosis characteristics (treatment group X – Child Pugh classes groups)
Table 1.8.X Cirrhosis characteristics (treatment group X – prior treatment groups)

Also the table 1.8.1 will be repeated for the target population and the safety population[4]:

Table 1.8.X Cirrhosis characteristics
Table 1.8.X Cirrhosis characteristics

[1] Patients will be divided into subgroups by HCV genotype (1a or 1b). Patients with genotypes combination will be divided into separate subgroups.
[2] Patients will be divided into subgroups by Child Pugh classes A, B and C.
[3] Patients will be divided into subgroups by presence of prior treatment: “INF”, “RBV”, “DAA”, “Treatment-experienced all” and “Naïve”. Patients with prior treatment components combination will be divided into separate subgroups.
[4] If the target population and the safety population will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.

Outpatient consultations

AbbVie LLC
P15-743 (HCV RWE)
Table 1.9.1 Outpatient consultations
The core population
Page X of X

	ABBVIE REGIMEN + RBV 12 weeks (N = XX)	ABBVIE REGIMEN – RBV 12 weeks (N = XX)	...	Overall (N = XX)
The number of outpatient consultations in 4 weeks prior to starting the ABBVIE REGIMEN				
n	XX	XX	...	XX
0	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
1	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
...	...	...	...	...
Technical interventions performed				
Lab test panels ordered				
consultation 1	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
consultation 2	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
...				
Blood transfusion				
consultation 1	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
consultation 2	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
...				
Administration of Erythropoetic Growth Factor				
...	...	...	...	...
Administration of G-CSF				
...	...	...	...	...
Invasive diagnostic intervention				
...	...	...	...	...
Symptoms treated				
Abdominal distension				
consultation 1	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
consultation 2	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
...	...	...	...	...
Abdominal pain				

	ABBVIE REGIMEN + RBV 12 weeks (N = XX)	ABBVIE REGIMEN − RBV 12 weeks (N = XX)	...	Overall (N = XX)
consultation 1	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
consultation 2	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
...	...	...	...	...
Alopecia				
...	...	...	...	...
Anemia				
...	...	...	...	...
Anxiety				
...	...	...	...	...
...	...	...	...	...

N: the number of subjects in the core population.
n: the number of valid measurements.
IQR: interquartile range.
Percentages are calculated from the number of subjects in the core population.

Program code, date, time

Data extracted: DD.MM.YYYY

Similar to table 1.9.1, the following tables will be constructed:

Table 1.9.2 Outpatient consultations (overall – HCV genotype groups[1])
Table 1.9.3 Outpatient consultations (overall – Child Pugh classes groups[2])
Table 1.9.4 Outpatient consultations (overall – prior treatment groups[3])

These tables will be repeated for each treatment group:

Table 1.9.X Outpatient consultations (treatment group X – HCV genotype and subtype groups)
Table 1.9.X Outpatient consultations (treatment group X – Child Pugh classes groups)
Table 1.9.X Outpatient consultations (treatment group X – prior treatment groups)

Also the table 1.9.1 will be repeated for the target population and the safety population[4]:

Table 1.9.X Outpatient consultations
Table 1.9.X Outpatient consultations

[1] Patients will be divided into subgroups by HCV genotype (1a or 1b). Patients with genotypes combination will be divided into separate subgroups.
[2] Patients will be divided into subgroups by Child Pugh classes A, B and C.
[3] Patients will be divided into subgroups by presence of prior treatment: “INF”, “RBV”, “DAA”, “Treatment-experienced all” and “Naïve”. Patients with prior treatment components combination will be divided into separate subgroups.
[4] If the target population and the safety population will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.

Hospitalization periods

AbbVie LLC
P15-743 (HCV RWE)
Table 1.10.1 Hospitalization periods
The core population
Page X of X

	ABBVIE REGIMEN + RBV 12 weeks (N = XX)	ABBVIE REGIMEN – RBV 12 weeks (N = XX)	...	Overall (N = XX)
The number of hospitalization periods in 4 weeks prior to starting the ABBVIE REGIMEN				
n	XX	XX	...	XX
0	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
1	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
...	...	...	...	...
Duration (days)				
Hospitalization period 1				
n	XX	XX	...	XX
Mean	XX.X	XX.X	...	XX.X
SD	XX.XX	XX.XX	...	XX.XX
Median	XX.X	XX.X	...	XX.X
IQR	XX.X	XX.X	...	XX.X
Min	XX	XX	...	XX
Max	XX	XX	...	XX
Hospitalization period 2				
...	...	...	...	...
Hospitalization period 3				
...	...	...	...	...
Hospitalization period 4				
...	...	...	...	...
Technical interventions performed				
Lab test panels ordered				
consultation 1	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
consultation 2	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
...	...	...	...	...
Blood transfusion				
consultation 1	XX (XX.X)	XX (XX.X)	...	XX (XX.X)

	ABBVIE REGIMEN + RBV 12 weeks (N = XX)	ABBVIE REGIMEN − RBV 12 weeks (N = XX)	...	Overall (N = XX)
consultation 2	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
...	...	...	...	...
Administration of Erythropoetic Growth Factor				
...	...	...	...	...
Administration of G-CSF				
...	...	...	...	...
Invasive diagnostic intervention				
...	...	...	...	...
Liver transplantation				
...	...	...	...	...
Symptoms treated				
Abdominal distension				
consultation 1	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
consultation 2	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
...	...	...	...	...
Abdominal pain				
consultation 1	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
consultation 2	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
...	...	...	...	...
Alopecia				
...	...	...	...	...
Anemia				
...	...	...	...	...
Anxiety				
...	...	...	...	...
...	...	...	...	...

N: the number of subjects in the core population.
n: the number of valid measurements.
IQR: interquartile range.
Percentages are calculated from the number of subjects in the core population.

Similar to table 1.10.1, the following tables will be constructed:

Table 1.10.2 Hospitalization periods (overall – HCV genotype groups[1])
Table 1.10.3 Hospitalization periods (overall – Child Pugh classes groups[2])
Table 1.10.4 Hospitalization periods (overall – prior treatment groups[3])

These tables will be repeated for each treatment group:

Table 1.10.X Hospitalization periods (treatment group X – HCV genotype and subtype groups)
Table 1.10.X Hospitalization periods (treatment group X – Child Pugh classes groups)
Table 1.10.X Hospitalization periods (treatment group X – prior treatment groups)

Also the table 1.10.1 will be repeated for the target population and the safety population[4]:

Table 1.10.X Hospitalization periods
Table 1.10.X Hospitalization periods

[1] Patients will be divided into subgroups by HCV genotype (1a or 1b). Patients with genotypes combination will be divided into separate subgroups.
[2] Patients will be divided into subgroups by Child Pugh classes A, B and C.
[3] Patients will be divided into subgroups by presence of prior treatment: “INF”, “RBV”, “DAA”, “Treatment-experienced all” and “Naïve”. Patients with prior treatment components combination will be divided into separate subgroups.
[4] If the target population and the safety population will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.

Alcohol consumption

AbbVie LLC
P15-743 (HCV RWE)
Table 1.11.1 Alcohol consumption
The core population
Page X of X

	ABBVIE REGIMEN + RBV 12 weeks (N = XX)	ABBVIE REGIMEN – RBV 12 weeks (N = XX)	...	Overall (N = XX)
Alcohol use				
n	XX	XX	...	XX
None	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Yes, occasional	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Yes, regular	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Ex-drinker	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Number of units/drinks per week				
n	XX	XX	...	XX
Mean	XX.X	XX.X	...	XX.X
SD	XX.XX	XX.XX	...	XX.XX
Median	XX.X	XX.X	...	XX.X
IQR	XX.X	XX.X	...	XX.X
Min	XX	XX	...	XX
Max	XX	XX	...	XX

N: the number of subjects in the prior treatment groups of the core population.
n: the number of valid measurements.
IQR: interquartile range.
Percentages are calculated from the number of subjects in the core population.

Program code, date, time

Data extracted: DD.MM.YYYY

Similar to table 1.11.1, the following tables will be constructed:

Table 1.11.2 Alcohol consumption (overall – HCV genotype groups[1])
Table 1.11.3 Alcohol consumption (overall – Child Pugh classes groups[2])
Table 1.11.4 Alcohol consumption (overall – prior treatment groups[3])

These tables will be repeated for each treatment group:

Table 1.11.X Alcohol consumption (treatment group X – HCV genotype and subtype groups)
Table 1.11.X Alcohol consumption (treatment group X – Child Pugh classes groups)
Table 1.11.X Alcohol consumption (treatment group X – prior treatment groups)

Also the table 1.11.1 will be repeated for the target population and the safety population[4]:

Table 1.11.X Alcohol consumption
Table 1.11.X Alcohol consumption

[1] Patients will be divided into subgroups by HCV genotype (1a or 1b). Patients with genotypes combination will be divided into separate subgroups.
[2] Patients will be divided into subgroups by Child Pugh classes A, B and C.
[3] Patients will be divided into subgroups by presence of prior treatment: “INF”, “RBV”, “DAA”, “Treatment-experienced all” and “Naïve”. Patients with prior treatment components combination will be divided into separate subgroups.
[4] If the target population and the safety population will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.

Medical history

AbbVie LLC
P15-743 (HCV RWE)
Table 1.12.1 Medical History: liver and/or chc related co-morbidities (MedDRA Vx.x)
The core population
Page X of X

System Organ Class Preferred Term	ABBVIE REGIMEN + RBV 12 weeks (N = XX) n (%) / E	ABBVIE REGIMEN – RBV 12 weeks (N = XX) n (%) / E	...	Overall (N = XX) n (%) / E
Overall	XX (XX.X) / XX	XX (XX.X) / XX	...	XX (XX.X) / XX
System Organ Class 1	XX (XX.X) / XX	XX (XX.X) / XX	...	XX (XX.X) / XX
Preferred Term A	XX (XX.X) / XX	XX (XX.X) / XX	...	XX (XX.X) / XX
Preferred Term B	XX (XX.X) / XX	XX (XX.X) / XX	...	XX (XX.X) / XX
System Organ Class 2	XX (XX.X) / XX	XX (XX.X) / XX	...	XX (XX.X) / XX
Preferred Term C	XX (XX.X) / XX	XX (XX.X) / XX	...	XX (XX.X) / XX
Preferred Term D	XX (XX.X) / XX	XX (XX.X) / XX	...	XX (XX.X) / XX
...	...	...	...	...

N: number of subjects in the core population.
n: number of subjects within a specific category.
#E: number of medical history events reported.
Percentages are calculated from the number of subjects in the core population.
System organ classes (SOC) are sorted by n (%). Preferred terms (PT) are sorted by n (%) within SOC.
Each subject is only counted once per preferred term (PT) and once per system organ class (SOC).

Program code, date, time

Data extracted: DD.MM.YYY

Similar to table 1.12.1, the following tables will be constructed:

Table 1.12.2 Medical History: liver and/or chc related co-morbidities (MedDRA Vx.x), overall – HCV genotype groups[1]
Table 1.12.3 Medical History: liver and/or chc related co-morbidities (MedDRA Vx.x), overall – Child Pugh classes groups[2]
Table 1.12.4 Medical History: liver and/or chc related co-morbidities (MedDRA Vx.x), overall – prior treatment groups[3]

These tables will be repeated for each treatment group:

Table 1.12.X Medical History: liver and/or chc related co-morbidities (MedDRA Vx.x), treatment group X – HCV genotype and subtype groups
Table 1.12.X Medical History: liver and/or chc related co-morbidities (MedDRA Vx.x), treatment group X – Child Pugh classes groups
Table 1.12.X Medical History: liver and/or chc related co-morbidities (MedDRA Vx.x), treatment group X – prior treatment groups

Also the table 1.12.1 will be repeated for the target population and the safety population[4]:

Table 1.12.X Medical History: liver and/or chc related co-morbidities (MedDRA Vx.x)
Table 1.12.X Medical History: liver and/or chc related co-morbidities (MedDRA Vx.x)

[1] Patients will be divided into subgroups by HCV genotype (1a or 1b). Patients with genotypes combination will be divided into separate subgroups.
[2] Patients will be divided into subgroups by Child Pugh classes A, B and C.
[3] Patients will be divided into subgroups by presence of prior treatment: “INF”, “RBV”, “DAA”, “Treatment-experienced all” and “Naïve”. Patients with prior treatment components combination will be divided into separate subgroups.
[4] If the target population and the safety population will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.

Similar to tables 1.12.*, the following tables will be constructed[1]:

Table 1.13.1 Medical History: other co-morbidities (MedDRA Vx.x)

Table 1.13.2 Medical History: other co-morbidities (MedDRA Vx.x), overall – HCV genotype groups[2]
Table 1.13.3 Medical History: other co-morbidities (MedDRA Vx.x), overall – Child Pugh classes groups[3]
Table 1.13.4 Medical History: other co-morbidities (MedDRA Vx.x), overall – prior treatment groups[4]

Table 1.13.X Medical History: other co-morbidities (MedDRA Vx.x), treatment group X – HCV genotype and subtype groups
Table 1.13.X Medical History: other co-morbidities (MedDRA Vx.x), treatment group X – Child Pugh classes groups
Table 1.13.X Medical History: other co-morbidities (MedDRA Vx.x), treatment group X – prior treatment groups

Table 1.13.X Medical History: other co-morbidities (MedDRA Vx.x)
Table 1.13.X Medical History: other co-morbidities (MedDRA Vx.x)

[1] If the target population and the safety population will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.
[2] Patients will be divided into subgroups by HCV genotype (1a or 1b). Patients with genotypes combination will be divided into separate subgroups.
[3] Patients will be divided into subgroups by Child Pugh classes A, B and C.
[4] Patients will be divided into subgroups by presence of prior treatment: “INF”, “RBV”, “DAA”, “Treatment-experienced all” and “Naïve”. Patients with prior treatment components combination will be divided into separate subgroups.

Co-infections

AbbVie LLC
P15-743 (HCV RWE)
Table 1.14.1 Co-infections
The core population
Page X of X

Diagnosis	ABBVIE REGIMEN + RBV 12 weeks (N = XX) n (%)	ABBVIE REGIMEN – RBV 12 weeks (N = XX) n (%)	...	Overall (N = XX) n (%)
Hepatitis B	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Human immunodeficiency virus(HIV)	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Tuberculosis	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Schistosomiasis	XX (XX.X)	XX (XX.X)	...	XX (XX.X)

N: the number of subjects in the core population.
n: the number of subjects within a specific category.
Percentages are calculated from the number of subjects in the core population.

Program code, date, time

Data extracted: DD.MM.YYY

Similar to table 1.14.1, the following tables will be constructed:

Table 1.14.2 Co-infections (overall – HCV genotype groups[1])
Table 1.14.3 Co-infections (overall – Child Pugh classes groups[2])
Table 1.14.4 Co-infections (overall – prior treatment groups[3])

These tables will be repeated for each treatment group:

Table 1.14.X Co-infections (treatment group X – HCV genotype and subtype groups)
Table 1.14.X Co-infections (treatment group X – Child Pugh classes groups)
Table 1.14.X Co-infections (treatment group X – prior treatment groups)

Also the table 1.14.1 will be repeated for the target population and the safety population[4]:

Table 1.14.X Co-infections
Table 1.14.X Co-infections

[1] Patients will be divided into subgroups by HCV genotype (1a or 1b). Patients with genotypes combination will be divided into separate subgroups.
[2] Patients will be divided into subgroups by Child Pugh classes A, B and C.
[3] Patients will be divided into subgroups by presence of prior treatment: “INF”, “RBV”, “DAA”, “Treatment-experienced all” and “Naïve”. Patients with prior treatment components combination will be divided into separate subgroups.
[4] If the target population and the safety population will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.

AbbVie LLC
P15-743 (HCV RWE)
Table 1.15.1 Co-infections. HIV most recent test results
The core population
Page X of X

	ABBVIE REGIMEN + RBV 12 weeks (N = XX)	ABBVIE REGIMEN – RBV 12 weeks (N = XX)	...	Overall (N = XX)
CD4 T-cell count				
n	XX	XX	...	XX
less 50	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
50-199	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
200-349	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
350-500	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
>500	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
HIV-RNA test				
Result				
n	XX	XX	...	XX
undetectable	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
detectable	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Below limit of quantification				
Yes	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
No	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Quantitative result (unit measure)				
n	XX	XX	...	XX
Mean	XX.X	XX.X	...	XX.X
SD	XX.XX	XX.XX	...	XX.XX
Median	XX.X	XX.X	...	XX.X
IQR	XX.X	XX.X	...	XX.X
Min	XX	XX	...	XX
Max	XX	XX	...	XX

N: the number of subjects in the core population.
n: the number of valid measurements.
Percentages are calculated from the number of subjects in the core population.

Program code, date, time Data extracted: DD.MM.YYY

Similar to table 1.15.1, the following tables will be constructed:

Table 1.15.2 Co-infections. HIV most recent test results (overall – HCV genotype groups[1])
Table 1.15.3 Co-infections. HIV most recent test results (overall – Child Pugh classes groups[2])
Table 1.15.4 Co-infections. HIV most recent test results (overall – prior treatment groups[3])

These tables will be repeated for each treatment group:

Table 1.15.X Co-infections. HIV most recent test results (treatment group X – HCV genotype and subtype groups)
Table 1.15.X Co-infections. HIV most recent test results (treatment group X – Child Pugh classes groups)
Table 1.15.X Co-infections. HIV most recent test results (treatment group X – prior treatment groups)

Also the table 1.15.1 will be repeated for the target population and the safety population[4]:

Table 1.15.X Co-infections. HIV most recent test results
Table 1.15.X Co-infections. HIV most recent test results

[1] Patients will be divided into subgroups by HCV genotype (1a or 1b). Patients with genotypes combination will be divided into separate subgroups.
[2] Patients will be divided into subgroups by Child Pugh classes A, B and C.
[3] Patients will be divided into subgroups by presence of prior treatment: “INF”, “RBV”, “DAA”, “Treatment-experienced all” and “Naïve”. Patients with prior treatment components combination will be divided into separate subgroups.
[4] If the target population and the safety population will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.

Prior medications

AbbVie LLC
P15-743 (HCV RWE)
Table 1.16.1 Prior Medications for CHC
The core population
Page X of X

4th level, chemical subgroup Preferred/Generic Level	ABBVIE REGIMEN + RBV 12 weeks (N = XX) n (%) / E	ABBVIE REGIMEN – RBV 12 weeks (N = XX) n (%) / E	...	Overall (N = XX) n (%) / E
Total [1]	XX (XX.X) /XX	XX (XX.X) /XX	...	XX (XX.X) /XX
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XX (XX.X) /XX	XX (XX.X) /XX	...	XX (XX.X) /XX
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XX (XX.X) /XX	XX (XX.X) /XX	...	XX (XX.X) /XX
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XX (XX.X) /XX	XX (XX.X) /XX	...	XX (XX.X) /XX
...	...	...	...	...
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XX (XX.X) /XX	XX (XX.X) /XX	...	XX (XX.X) /XX
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XX (XX.X) /XX	XX (XX.X) /XX	...	XX (XX.X) /XX
...	...	...	...	...
...	...	...	...	...

N: number of subjects in the core population.
n: number of subjects within a specific category. Percentages are calculated as 100 x (n/N).
#E: number of prior medications events reported.
Prior medications are any medications taken prior to the date of first dose of study treatment/ICF sign.
Prior medications were coded using the World Health Organisation (WHO) Anatomical Therapeutic Chemical (ATC) classification system version XX.
The ATC groups are sorted by n (%). Preferred names are sorted by n (%) within ATC group.
Each subject is only counted once per preferred name and once per ATC group.

Program code, date, time Data extracted: DD.MM.YYYY

Similar to table 1.16.1, the following tables will be constructed:

Table 1.16.2 Prior Medications for CHC. HIV most recent test results (overall – HCV genotype groups[1])
Table 1.16.3 Prior Medications for CHC. HIV most recent test results (overall – Child Pugh classes groups[2])
Table 1.16.4 Prior Medications for CHC. HIV most recent test results (overall – prior treatment groups[3])

These tables will be repeated for each treatment group:

Table 1.16.X Prior Medications for CHC. HIV most recent test results (treatment group X – HCV genotype and subtype groups)
Table 1.16.X Prior Medications for CHC. HIV most recent test results (treatment group X – Child Pugh classes groups)
Table 1.16.X Prior Medications for CHC. HIV most recent test results (treatment group X – prior treatment groups)

Also the table 1.16.1 will be repeated for the target population and the safety population[4]:

Table 1.16.X Prior Medications for CHC. HIV most recent test results
Table 1.16.X Prior Medications for CHC. HIV most recent test results

[1] Patients will be divided into subgroups by HCV genotype (1a or 1b). Patients with genotypes combination will be divided into separate subgroups.
[2] Patients will be divided into subgroups by Child Pugh classes A, B and C.
[3] Patients will be divided into subgroups by presence of prior treatment: “INF”, “RBV”, “DAA”, “Treatment-experienced all” and “Naïve”. Patients with prior treatment components combination will be divided into separate subgroups.
[4] If the target population and the safety population will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.

Concurrent medications

Similar to tables 1.16.*, the following tables will be constructed[1]:

Table 1.17.1 Concurrent Medications for CHC

Table 1.17.2 Concurrent Medications for CHC. HIV most recent test results (overall – HCV genotype groups[2])
Table 1.17.3 Concurrent Medications for CHC. HIV most recent test results (overall – Child Pugh classes groups[3])
Table 1.17.4 Concurrent Medications for CHC. HIV most recent test results (overall – prior treatment groups[4])

Table 1.17.X Concurrent Medications for CHC. HIV most recent test results (treatment group X – HCV genotype and subtype groups)
Table 1.17.X Concurrent Medications for CHC. HIV most recent test results (treatment group X – Child Pugh classes groups)
Table 1.17.X Concurrent Medications for CHC. HIV most recent test results (treatment group X – prior treatment groups)

Table 1.17.X Concurrent Medications for CHC. HIV most recent test results
Table 1.17.X Concurrent Medications for CHC. HIV most recent test results

[1] If the target population and the safety population will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.
[2] Patients will be divided into subgroups by HCV genotype (1a or 1b). Patients with genotypes combination will be divided into separate subgroups.
[3] Patients will be divided into subgroups by Child Pugh classes A, B and C.
[4] Patients will be divided into subgroups by presence of prior treatment: “INF”, “RBV”, “DAA”, “Treatment-experienced all” and “Naïve”. Patients with prior treatment components combination will be divided into separate subgroups.

Effectiveness Analyses

AbbVie LLC
P15-743 (HCV RWE)
Table 2.1.1.1. Percentage for effectiveness endpoints (main analysis)
The core population
Page X of X

Parameter	ABBVIE REGIMEN + RBV 12 weeks (N=XX) n (%) 95% CI	ABBVIE REGIMEN – RBV 12 weeks (N=XX) n (%) 95% CI	...	Overall (N=XXX) n (%) 95% CI
Patients achieving SVR12 (single last HCV RNA <50 IU/mL 12 weeks after the last actual dose of the ABBVIE REGIMEN)	XX (XX.X) (XX.X – XX.X)	XX (XX.X) (XX.X – XX.X)	...	XX (XX.X) (XX.X – XX.X)
SVR12 non-response	XX (XX.X) (XX.X – XX.X)	XX (XX.X) (XX.X – XX.X)	...	XX (XX.X) (XX.X – XX.X)
Patients with breakthrough (defined as at least one documented HCV RNA <50 IU/mL followed by HCV RNA ≧50 IU/mL during treatment)	XX (XX.X) (XX.X – XX.X)	XX (XX.X) (XX.X – XX.X)	...	XX (XX.X) (XX.X – XX.X)
Failure to suppress (each measured on-treatment HCV RNA value ≧50 IU/mL)	XX (XX.X) (XX.X – XX.X)	XX (XX.X) (XX.X – XX.X)	...	XX (XX.X) (XX.X – XX.X)
Patients with relapse (HCV RNA <50 IU/mL at EoT or at the last on-treatment HCV RNA measurement followed by HCV RNA ≧50 IU/mL post-treatment)	XX (XX.X) (XX.X – XX.X)	XX (XX.X) (XX.X – XX.X)	...	XX (XX.X) (XX.X – XX.X)
Patients with missing SVR12 data	XX (XX.X) (XX.X – XX.X)	XX (XX.X) (XX.X – XX.X)	...	XX (XX.X) (XX.X – XX.X)
Patients with premature study drug discontinuation with no on-treatment virological failure	XX (XX.X) (XX.X – XX.X)	XX (XX.X) (XX.X – XX.X)	...	XX (XX.X) (XX.X – XX.X)
Patients achieving SVR24 (single last HCV RNA <50 IU/mL 24 weeks after the last actual dose of the ABBVIE REGIMEN)	XX (XX.X) (XX.X – XX.X)	XX (XX.X) (XX.X – XX.X)	...	XX (XX.X) (XX.X – XX.X)
Patients with virological response (HCV RNA <50 IU/mL) at EoT	XX (XX.X) (XX.X – XX.X)	XX (XX.X) (XX.X – XX.X)	...	XX (XX.X) (XX.X – XX.X)

N: the number of patients in the core population.
n: number of subjects within a specific category.
EoT: end of treatment.

SVR12: sustained virological response at 12 weeks after end of treatment.
SVR24: sustained virological response at 24 weeks after end of treatment.
95% confidence intervals determined using the Clopper-Pearson method.
Table for the core population is the same table for the core population with sufficient follow-up data because the core population and the core population with sufficient follow-up data are equal (contain exactly the same subjects).
[1] 95% confidence intervals determined using the Clopper-Pearson method.

Program code, date, time Data extracted: DD.MM.YYYY

Similar to table 2.1.1.1, the following table will be constructed:

Table 2.1.1.2. Percentage for effectiveness endpoints (additional analysis)

AbbVie LLC
P15-743 (HCV RWE)
Table 2.1.1.3. Percentage for effectiveness endpoints without patients with missing SVR12 results (main analysis)
The core population
Page X of X

Parameter	ABBVIE REGIMEN + RBV 12 weeks (N=XX) n (%) 95% CI	ABBVIE REGIMEN – RBV 12 weeks (N=XX) n (%) 95% CI	...	Overall (N=XXX) n (%) 95% CI
Patients achieving SVR12 (single last HCV RNA <50 IU/mL 12 weeks after the last actual dose of the ABBVIE REGIMEN)	XX (XX.X) (XX.X – XX.X)	XX (XX.X) (XX.X – XX.X)	...	XX (XX.X) (XX.X – XX.X)
SVR12 non-response	XX (XX.X) (XX.X – XX.X)	XX (XX.X) (XX.X – XX.X)	...	XX (XX.X) (XX.X – XX.X)
Patients with breakthrough (defined as at least one documented HCV RNA <50 IU/mL followed by HCV RNA ≧50 IU/mL during treatment)	XX (XX.X) (XX.X – XX.X)	XX (XX.X) (XX.X – XX.X)	...	XX (XX.X) (XX.X – XX.X)
Failure to suppress (each measured on-treatment HCV RNA value ≧50 IU/mL)	XX (XX.X) (XX.X – XX.X)	XX (XX.X) (XX.X – XX.X)	...	XX (XX.X) (XX.X – XX.X)
Patients with relapse (HCV RNA <50 IU/mL at EoT or at the last on-treatment HCV RNA measurement followed by HCV RNA ≧50 IU/mL post-treatment)	XX (XX.X) (XX.X – XX.X)	XX (XX.X) (XX.X – XX.X)	...	XX (XX.X) (XX.X – XX.X)
Patients with premature study drug discontinuation with no on-treatment virological failure	XX (XX.X) (XX.X – XX.X)	XX (XX.X) (XX.X – XX.X)	...	XX (XX.X) (XX.X – XX.X)
Patients achieving SVR24 (single last HCV RNA <50 IU/mL 24 weeks after the last actual dose of the ABBVIE REGIMEN)	XX (XX.X) (XX.X – XX.X)	XX (XX.X) (XX.X – XX.X)	...	XX (XX.X) (XX.X – XX.X)
Patients with virological response (HCV RNA <50 IU/mL) at EoT	XX (XX.X) (XX.X – XX.X)	XX (XX.X) (XX.X – XX.X)	...	XX (XX.X) (XX.X – XX.X)

N: the number of patients in the core population. n: number of subjects within a specific category. EoT: end of treatment.
SVR12: sustained virological response at 12 weeks after end of treatment. SVR24: sustained virological response at 24 weeks after end of treatment.
[1] 95% confidence intervals determined using the Clopper-Pearson method.
Table for the core population is the same table for the core population with sufficient follow-up data because the core population and the core population with sufficient follow-up data are equal (contain exactly the same subjects).

Program code, date, time

Data extracted: DD.MM.YYYY

Similar to table 2.1.1.3, the following table will be constructed:

Table 2.1.1.4. Percentage for effectiveness endpoints without patients with missing SVR12 (additional analysis)

If the target population and the core population with sufficient follow-up data will not be equal to the core population, the following tables will be presented:

Table 2.1.2.1. Percentage for effectiveness endpoints (main analysis)
The target population
Table 2.1.2.2. Percentage for effectiveness endpoints (additional analysis)
The target population
Table 2.1.2.3. Percentage for effectiveness endpoints without patients with missing SVR12 (main analysis)
The target population
Table 2.1.2.4. Percentage for effectiveness endpoints without patients with missing SVR12 (additional analysis)
The target population

Table 2.1.3.1. Percentage for effectiveness endpoints (main analysis)
The core population with sufficient follow-up data
Table 2.1.3.2. Percentage for effectiveness endpoints (additional analysis)
The core population with sufficient follow-up data
Table 2.1.3.3. Percentage for effectiveness endpoints without patients with missing SVR12 (main analysis)
The core population with sufficient follow-up data
Table 2.1.3.4. Percentage for effectiveness endpoints without patients with missing SVR12 (additional analysis)
The core population with sufficient follow-up data

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P15-743 (HCV RWE)
Table 2.2.1.1. SVR12 achieving response. Univariate logistic regressions results
The core population
Page X of X

	Overall
Age	
Patients for analysis (n)	XXX
Convergence criterion status	xxxxxxxxxx
OR (95% Wald CI)	X.XXX (X.XXX - X.XXX)
p-value	0.XXXX
Sex	
Patients for analysis (n)	XXX
Convergence criterion status	xxxxxxxxxx
Reference level	Xxxxxx
OR (95% Wald CI) for Male	X.XXX (X.XXX - X.XXX)
p-value for Male	0.XXXX
...	...

SVR12: sustained virological response at 12 weeks after EoT.

Program code, date, time

Data extracted: DD.MM.YYYY

AbbVie LLC
P15-743 (HCV RWE)
Table 2.2.1.2. SVR12 achieving response. Multiple logistic regression results
The core population
Page X of X

	Overall
Patients for analysis (n)	XXX
[Predictor name]	
OR (95% Wald CI)	X.XXX (X.XXX - X.XXX)
p-value	0.XXXX
[Predictor name]	
OR (95% Wald CI)	X.XXX (X.XXX - X.XXX)
p-value	0.XXXX
...	...

SVR12: sustained virological response at 12 weeks after EoT.
Table for the core population with sufficient follow-up data is the same table for the core population because the core population and the The core population with sufficient follow-up data are equal (contain exactly the same subjects).

Program code, date, time Data extracted: DD.MM.YYYY

Similar to tables 2.2.1.1-2.2.1.2, tables 2.2.X.X for the following subgroups will be constructed:
- with/without Ribavirin;
- Child Pugh class A/B/C;
- with/without treatment experienced.

Similar to tables 2.2.X.X, tables 2.3.X.X for the target population and tables 2.4.X.X for the core population with sufficient follow-up data will be constructed.

Quality of life analysis

EQ-5D-5L

Mobility

AbbVie Ltd
P15-743
Table 3.1.1.1 EQ-5D-5L. Mobility. Descriptive statistics
The core population
Page X of X

Visit EQ-5D-5L dimension level	ABBVIE REGIMEN + RBV 12 weeks (N = XX) n (%)	ABBVIE REGIMEN – RBV 12 weeks (N = XX) n (%)	...	Overall (N = XX) n (%)
Baseline				
n	XX	XX	...	XX
Level 1 (no problem)	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Level 2 (slight problems)	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Level 3 (moderate problems)	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Level 4 (severe problems)	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Level 5 (extreme problems)	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
EoT				
...	...	...	...	...
SVR12				
...	...	...	...	...
SVR24				
...	...	...	...	...

N: the number of subjects in the core population.
n: the number of valid measurements.
EoT: end of treatment.
SVR12: sustained virological response at 12 weeks after EoT.
SVR24: sustained virological response at 24 weeks after EoT.
Percentages are calculated from the number of subjects in the core population.

Program code, date, time

Data extracted: DD.MM.YYYY

Similar to table 3.1.1.1, the following tables will be constructed:

Table 3.1.1.2 EQ-5D-5L. Mobility. Descriptive statistics (overall – HCV genotype groups[1])
Table 3.1.1.3 EQ-5D-5L. Mobility. Descriptive statistics (overall – Child Pugh classes groups[2])
Table 3.1.1.4 EQ-5D-5L. Mobility. Descriptive statistics (overall – prior treatment groups[3])

These tables will be repeated for each treatment group:

Table 3.1.1.X EQ-5D-5L. Mobility. Descriptive statistics (treatment group X – HCV genotype and subtype groups)
Table 3.1.1.X EQ-5D-5L. Mobility. Descriptive statistics (treatment group X – Child Pugh classes groups)
Table 3.1.1.X EQ-5D-5L. Mobility. Descriptive statistics (treatment group X – prior treatment groups)

Also the table 3.1.1.1 will be repeated for the target population and the core population with sufficient follow-up data[4]:

Table 3.1.1.X EQ-5D-5L. Mobility. Descriptive statistic
Table 3.1.1.X EQ-5D-5L. Mobility. Descriptive statistic

[1] Patients will be divided into subgroups by HCV genotype (1a or 1b). Patients with genotypes combination will be divided into separate subgroups.
[2] Patients will be divided into subgroups by Child Pugh classes A, B and C.
[3] Patients will be divided into subgroups by presence of prior treatment: “INF”, “RBV”, “DAA”, “Treatment-experienced all” and “Naïve”. Patients with prior treatment components combination will be divided into separate subgroups.
[4] If the target population and the core population with sufficient follow-up data will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.

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P15-743

Table 3.1.2.1 EQ-5D-5L. Mobility. Descriptive statistics for dichotomized levels

The core population
Page X of X

Visit EQ-5D-5L dimension level	ABBVIE REGIMEN + RBV 12 weeks (N = XX) n (%)	ABBVIE REGIMEN – RBV 12 weeks (N = XX) n (%)	...	Overall (N = XX) n (%)
Baseline				
n	XX	XX	...	XX
No problem	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Problems	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
EoT				
...	...	...	...	...
SVR12				
...	...	...	...	...
SVR24				
...	...	...	...	...

N: the number of subjects in the core population.
n: the number of valid measurements.
EoT: end of treatment.
SVR12: sustained virological response at 12 weeks after EoT.
SVR24: sustained virological response at 24 weeks after EoT.
Percentages are calculated from the number of subjects in the core population.

Program code, date, time

Data extracted: DD.MM.YYYY

Similar to table 3.1.2.1, the following tables will be constructed:

Table 3.1.2.2 EQ-5D-5L. Mobility. Descriptive statistics for dichotomized levels (overall – HCV genotype groups[1])
Table 3.1.2.3 EQ-5D-5L. Mobility. Descriptive statistics for dichotomized levels (overall – Child Pugh classes groups[2])
Table 3.1.2.4 EQ-5D-5L. Mobility. Descriptive statistics for dichotomized levels (overall – prior treatment groups[3])

These tables will be repeated for each treatment group:

Table 3.1.2.X EQ-5D-5L. Mobility. Descriptive statistics for dichotomized levels (treatment group X – HCV genotype and subtype groups)
Table 3.1.2.X EQ-5D-5L. Mobility. Descriptive statistics for dichotomized levels (treatment group X – Child Pugh classes groups)
Table 3.1.2.X EQ-5D-5L. Mobility. Descriptive statistics for dichotomized levels (treatment group X – prior treatment groups)

Also the table 3.1.2.1 will be repeated for the target population and the core population with sufficient follow-up data[4]:

Table 3.1.2.X EQ-5D-5L. Mobility. Descriptive statistics for dichotomized levels
Table 3.1.2.X EQ-5D-5L. Mobility. Descriptive statistics for dichotomized levels

[1] Patients will be divided into subgroups by HCV genotype (1a or 1b). Patients with genotypes combination will be divided into separate subgroups.
[2] Patients will be divided into subgroups by Child Pugh classes A, B and C.
[3] Patients will be divided into subgroups by presence of prior treatment: “INF”, “RBV”, “DAA”, “Treatment-experienced all” and “Naïve”. Patients with prior treatment components combination will be divided into separate subgroups.
[4] If the target population and the core population with sufficient follow-up data will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.

Self-care

Similar to tables 3.1.*.*, the following tables will be constructed:

for the core population:

Table 3.2.1.1 EQ-5D-5L. Self-care. Descriptive statistics
Table 3.2.1.2 EQ-5D-5L. Self-care. Descriptive statistics (overall – HCV genotype groups[1])
Table 3.2.1.3 EQ-5D-5L. Self-care. Descriptive statistics (overall – Child Pugh classes groups[2])
Table 3.2.1.4 EQ-5D-5L. Self-care. Descriptive statistics (overall – prior treatment groups[3])

Table 3.2.1.X EQ-5D-5L. Self-care. Descriptive statistics (treatment group X – HCV genotype and subtype groups)
Table 3.2.1.X EQ-5D-5L. Self-care. Descriptive statistics (treatment group X – Child Pugh classes groups)
Table 3.2.1.X EQ-5D-5L. Self-care. Descriptive statistics (treatment group X – prior treatment groups)

for the target population and the core population with sufficient follow-up data[4]:

Table 3.2.1.X EQ-5D-5L. Self-care. Descriptive statistic
Table 3.2.1.X EQ-5D-5L. Self-care. Descriptive statistic

[1] Patients will be divided into subgroups by HCV genotype (1a or 1b). Patients with genotypes combination will be divided into separate subgroups.
[2] Patients will be divided into subgroups by Child Pugh classes A, B and C.
[3] Patients will be divided into subgroups by presence of prior treatment: “INF”, “RBV”, “DAA”, “Treatment-experienced all” and “Naïve”. Patients with prior treatment components combination will be divided into separate subgroups.
[4] If the target population and the core population with sufficient follow-up data will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.

for the core population:

Table 3.2.2.1 EQ-5D-5L. Self-care. Descriptive statistics for dichotomized levels
Table 3.2.2.2 EQ-5D-5L. Self-care. Descriptive statistics for dichotomized levels (overall – HCV genotype groups[1])
Table 3.2.2.3 EQ-5D-5L. Self-care. Descriptive statistics for dichotomized levels (overall – Child Pugh classes groups[2])
Table 3.2.2.4 EQ-5D-5L. Self-care. Descriptive statistics for dichotomized levels (overall – prior treatment groups[3])

Table 3.2.2.X EQ-5D-5L. Self-care. Descriptive statistics for dichotomized levels (treatment group X – HCV genotype and subtype groups)
Table 3.2.2.X EQ-5D-5L. Self-care. Descriptive statistics for dichotomized levels (treatment group X – Child Pugh classes groups)
Table 3.2.2.X EQ-5D-5L. Self-care. Descriptive statistics for dichotomized levels (treatment group X – prior treatment groups)

for the target population and the core population with sufficient follow-up data[4]:

Table 3.2.2.X EQ-5D-5L. Self-care. Descriptive statistic for dichotomized levels
Table 3.2.2.X EQ-5D-5L. Self-care. Descriptive statistic for dichotomized levels

[1] Patients will be divided into subgroups by HCV genotype (1a or 1b). Patients with genotypes combination will be divided into separate subgroups.
[2] Patients will be divided into subgroups by Child Pugh classes A, B and C.
[3] Patients will be divided into subgroups by presence of prior treatment: “INF”, “RBV”, “DAA”, “Treatment-experienced all” and “Naïve”. Patients with prior treatment components combination will be divided into separate subgroups.
[4] If the target population and the core population with sufficient follow-up data will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.

Usual activity

Similar to tables 3.1.*.*, the following tables will be constructed:

for the core population:

Table 3.3.1.1 EQ-5D-5L. Usual activity. Descriptive statistics
Table 3.3.1.2 EQ-5D-5L. Usual activity. Descriptive statistics (overall – HCV genotype groups[1])
Table 3.3.1.3 EQ-5D-5L. Usual activity. Descriptive statistics (overall – Child Pugh classes groups[2])
Table 3.3.1.4 EQ-5D-5L. Usual activity. Descriptive statistics (overall – prior treatment groups[3])

Table 3.3.1.X EQ-5D-5L. Usual activity. Descriptive statistics (treatment group X – HCV genotype and subtype groups)
Table 3.3.1.X EQ-5D-5L. Usual activity. Descriptive statistics (treatment group X – Child Pugh classes groups)
Table 3.3.1.X EQ-5D-5L. Usual activity. Descriptive statistics (treatment group X – prior treatment groups)

for the target population and the core population with sufficient follow-up data[4]:

Table 3.3.1.X EQ-5D-5L. Usual activity. Descriptive statistic
Table 3.3.1.X EQ-5D-5L. Usual activity. Descriptive statistic

[1] Patients will be divided into subgroups by HCV genotype (1a or 1b). Patients with genotypes combination will be divided into separate subgroups.
[2] Patients will be divided into subgroups by Child Pugh classes A, B and C.
[3] Patients will be divided into subgroups by presence of prior treatment: “INF”, “RBV”, “DAA”, “Treatment-experienced all” and “Naïve”. Patients with prior treatment components combination will be divided into separate subgroups.
[4] If the target population and the core population with sufficient follow-up data will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.

for the core population:

Table 3.3.2.1 EQ-5D-5L. Usual activity. Descriptive statistics for dichotomized levels
Table 3.3.2.2 EQ-5D-5L. Usual activity. Descriptive statistics for dichotomized levels (overall – HCV genotype groups[1])
Table 3.3.2.3 EQ-5D-5L. Usual activity. Descriptive statistics for dichotomized levels (overall – Child Pugh classes groups[2])
Table 3.3.2.4 EQ-5D-5L. Usual activity. Descriptive statistics for dichotomized levels (overall – prior treatment groups[3])

Table 3.3.2.X EQ-5D-5L. Usual activity. Descriptive statistics for dichotomized levels (treatment group X – HCV genotype and subtype groups)
Table 3.3.2.X EQ-5D-5L. Usual activity. Descriptive statistics for dichotomized levels (treatment group X – Child Pugh classes groups)
Table 3.3.2.X EQ-5D-5L. Usual activity. Descriptive statistics for dichotomized levels (treatment group X – prior treatment groups)

for the target population and the core population with sufficient follow-up data[4]:

Table 3.3.2.X EQ-5D-5L. Usual activity. Descriptive statistic for dichotomized levels
Table 3.3.2.X EQ-5D-5L. Usual activity. Descriptive statistic for dichotomized levels

[1] Patients will be divided into subgroups by HCV genotype (1a or 1b). Patients with genotypes combination will be divided into separate subgroups.
[2] Patients will be divided into subgroups by Child Pugh classes A, B and C.
[3] Patients will be divided into subgroups by presence of prior treatment: “INF”, “RBV”, “DAA”, “Treatment-experienced all” and “Naïve”. Patients with prior treatment components combination will be divided into separate subgroups.
[4] If the target population and the core population with sufficient follow-up data will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.

Pain/discomfort

Similar to tables 3.1.*.*, the following tables will be constructed:

for the core population:

Table 3.4.1.1 EQ-5D-5L. Pain/discomfort. Descriptive statistics
Table 3.4.1.2 EQ-5D-5L. Pain/discomfort. Descriptive statistics (overall – HCV genotype groups[1])
Table 3.4.1.3 EQ-5D-5L. Pain/discomfort. Descriptive statistics (overall – Child Pugh classes groups[2])
Table 3.4.1.4 EQ-5D-5L. Pain/discomfort. Descriptive statistics (overall – prior treatment groups[3])

Table 3.4.1.X EQ-5D-5L. Pain/discomfort. Descriptive statistics (treatment group X – HCV genotype and subtype groups)
Table 3.4.1.X EQ-5D-5L. Pain/discomfort. Descriptive statistics (treatment group X – Child Pugh classes groups)
Table 3.4.1.X EQ-5D-5L. Pain/discomfort. Descriptive statistics (treatment group X – prior treatment groups)

for the target population and the core population with sufficient follow-up data[4]:

Table 3.4.1.X EQ-5D-5L. Pain/discomfort. Descriptive statistic
Table 3.4.1.X EQ-5D-5L. Pain/discomfort. Descriptive statistic

[1] Patients will be divided into subgroups by HCV genotype (1a or 1b). Patients with genotypes combination will be divided into separate subgroups.
[2] Patients will be divided into subgroups by Child Pugh classes A, B and C.
[3] Patients will be divided into subgroups by presence of prior treatment: “INF”, “RBV”, “DAA”, “Treatment-experienced all” and “Naïve”. Patients with prior treatment components combination will be divided into separate subgroups.
[4] If the target population and the core population with sufficient follow-up data will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.

for the core population:

Table 3.4.2.1 EQ-5D-5L. Pain/discomfort. Descriptive statistics for dichotomized levels
Table 3.4.2.2 EQ-5D-5L. Pain/discomfort. Descriptive statistics for dichotomized levels (overall – HCV genotype groups[1])
Table 3.4.2.3 EQ-5D-5L. Pain/discomfort. Descriptive statistics for dichotomized levels (overall – Child Pugh classes groups[2])
Table 3.4.2.4 EQ-5D-5L. Pain/discomfort. Descriptive statistics for dichotomized levels (overall – prior treatment groups[3])

Table 3.4.2.X EQ-5D-5L. Pain/discomfort. Descriptive statistics for dichotomized levels (treatment group X – HCV genotype and subtype groups)
Table 3.4.2.X EQ-5D-5L. Pain/discomfort. Descriptive statistics for dichotomized levels (treatment group X – Child Pugh classes groups)
Table 3.4.2.X EQ-5D-5L. Pain/discomfort. Descriptive statistics for dichotomized levels (treatment group X – prior treatment groups)

for the target population and the core population with sufficient follow-up data[4]:

Table 3.4.2.X EQ-5D-5L. Pain/discomfort. Descriptive statistic for dichotomized levels
Table 3.4.2.X EQ-5D-5L. Pain/discomfort. Descriptive statistic for dichotomized levels

[1] Patients will be divided into subgroups by HCV genotype (1a or 1b). Patients with genotypes combination will be divided into separate subgroups.
[2] Patients will be divided into subgroups by Child Pugh classes A, B and C.
[3] Patients will be divided into subgroups by presence of prior treatment: “INF”, “RBV”, “DAA”, “Treatment-experienced all” and “Naïve”. Patients with prior treatment components combination will be divided into separate subgroups.
[4] If the target population and the core population with sufficient follow-up data will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.

Anxiety/depression

Similar to tables 3.1.*.*, the following tables will be constructed:

for the core population:

Table 3.5.1.1 EQ-5D-5L. Anxiety/depression. Descriptive statistics
Table 3.5.1.2 EQ-5D-5L. Anxiety/depression. Descriptive statistics (overall – HCV genotype groups[1])
Table 3.5.1.3 EQ-5D-5L. Anxiety/depression. Descriptive statistics (overall – Child Pugh classes groups[2])
Table 3.5.1.4 EQ-5D-5L. Anxiety/depression. Descriptive statistics (overall – prior treatment groups[3])

Table 3.5.1.X EQ-5D-5L. Anxiety/depression. Descriptive statistics (treatment group X – HCV genotype and subtype groups)
Table 3.5.1.X EQ-5D-5L. Anxiety/depression. Descriptive statistics (treatment group X – Child Pugh classes groups)
Table 3.5.1.X EQ-5D-5L. Anxiety/depression. Descriptive statistics (treatment group X – prior treatment groups)

for the target population and the core population with sufficient follow-up data[4]:

Table 3.5.1.X EQ-5D-5L. Anxiety/depression. Descriptive statistic
Table 3.5.1.X EQ-5D-5L. Anxiety/depression. Descriptive statistic

[1] Patients will be divided into subgroups by HCV genotype (1a or 1b). Patients with genotypes combination will be divided into separate subgroups.
[2] Patients will be divided into subgroups by Child Pugh classes A, B and C.
[3] Patients will be divided into subgroups by presence of prior treatment: “INF”, “RBV”, “DAA”, “Treatment-experienced all” and “Naïve”. Patients with prior treatment components combination will be divided into separate subgroups.
[4] If the target population and the core population with sufficient follow-up data will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.

for the core population:

Table 3.5.2.1 EQ-5D-5L. Anxiety/depression. Descriptive statistics for dichotomized levels
Table 3.5.2.2 EQ-5D-5L. Anxiety/depression. Descriptive statistics for dichotomized levels (overall – HCV genotype groups[1])
Table 3.5.2.3 EQ-5D-5L. Anxiety/depression. Descriptive statistics for dichotomized levels (overall – Child Pugh classes groups[2])
Table 3.5.2.4 EQ-5D-5L. Anxiety/depression. Descriptive statistics for dichotomized levels (overall – prior treatment groups[3])

Table 3.5.2.X EQ-5D-5L. Anxiety/depression. Descriptive statistics for dichotomized levels (treatment group X – HCV genotype and subtype groups)
Table 3.5.2.X EQ-5D-5L. Anxiety/depression. Descriptive statistics for dichotomized levels (treatment group X – Child Pugh classes groups)
Table 3.5.2.X EQ-5D-5L. Anxiety/depression. Descriptive statistics for dichotomized levels (treatment group X – prior treatment groups)

for the target population and the core population with sufficient follow-up data[4]:

Table 3.5.2.X EQ-5D-5L. Anxiety/depression. Descriptive statistic for dichotomized levels
Table 3.5.2.X EQ-5D-5L. Anxiety/depression. Descriptive statistic for dichotomized levels

[1] Patients will be divided into subgroups by HCV genotype (1a or 1b). Patients with genotypes combination will be divided into separate subgroups.
[2] Patients will be divided into subgroups by Child Pugh classes A, B and C.
[3] Patients will be divided into subgroups by presence of prior treatment: “INF”, “RBV”, “DAA”, “Treatment-experienced all” and “Naïve”. Patients with prior treatment components combination will be divided into separate subgroups.
[4] If the target population and the core population with sufficient follow-up data will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.

VAS

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P15-743
Table 3.6.1.1 EQ-5D-5L. VAS. Descriptive statistics
The core population
Page X of X

Visit Statistics	Test result				Change from baseline			
	ABBVIE REGIMEN + RBV 12 weeks (N = XX)	ABBVIE REGIMEN - RBV 12 weeks (N = XX)	...	Overall (N = XX)	ABBVIE REGIMEN + RBV 12 weeks (N = XX)	ABBVIE REGIMEN - RBV 12 weeks (N = XX)	...	Overall (N = XX)
Visit 1								
n	XX	XX	...	XX				
Mean	XX.X	XX.X	...	XX.X				
SD	XX.XX	XX.XX	...	XX.XX				
Median	XX.X	XX.X	...	XX.X				
IQR	XX.X	XX.X	...	XX.X				
Min	XX	XX	...	XX				
Max	XX	XX	...	XX				
EoT								
n	XX	XX	...	XX	XX	XX	...	XX
Mean	XX.X	XX.X	...	XX.X	XX.X	XX.X	...	XX.X
SD	XX.XX	XX.XX	...	XX.XX	XX.XX	XX.XX	...	XX.XX
Median	XX.X	XX.X	...	XX.X	XX.X	XX.X	...	XX.X
IQR	XX.X	XX.X	...	XX.X	XX.X	XX.X	...	XX.X
Min	XX	XX	...	XX	XX	XX	...	XX
Max	XX	XX	...	XX	XX	XX	...	XX
SVR12								
...	...	...	...	...	...	...	...	...
SVR24								
...	...	...	...	...	...	...	...	...

N: the number of subjects in the core population.
n: the number of valid measurements.
IQR: interquartile range.
EoT: end of treatment.
SVR12: sustained virological response at 12 weeks after EoT.
SVR24: sustained virological response at 24 weeks after EoT.

Similar to table 3.6.1.1, the following tables will be constructed:

Table 3.6.1.2 EQ-5D-5L. VAS. Descriptive statistics (overall – HCV genotype groups[1])
Table 3.6.1.3 EQ-5D-5L. VAS. Descriptive statistics (overall – Child Pugh classes groups[2])
Table 3.6.1.4 EQ-5D-5L. VAS. Descriptive statistics (overall – prior treatment groups[3])

These tables will be repeated for each treatment group:

Table 3.6.1.X EQ-5D-5L. VAS. Descriptive statistics (treatment group X – HCV genotype and subtype groups)
Table 3.6.1.X EQ-5D-5L. VAS. Descriptive statistics (treatment group X – Child Pugh classes groups)
Table 3.6.1.X EQ-5D-5L. VAS. Descriptive statistics (treatment group X – prior treatment groups)

Also the table 3.6.1.1 will be repeated for the target population and the core population with sufficient follow-up data[4]:

Table 3.6.1.X EQ-5D-5L. VAS. Descriptive statistic
Table 3.6.1.X EQ-5D-5L. VAS. Descriptive statistic

[1] Patients will be divided into subgroups by HCV genotype (1a or 1b). Patients with genotypes combination will be divided into separate subgroups.
[2] Patients will be divided into subgroups by Child Pugh classes A, B and C.
[3] Patients will be divided into subgroups by presence of prior treatment: “INF”, “RBV”, “DAA”, “Treatment-experienced all” and “Naïve”. Patients with prior treatment components combination will be divided into separate subgroups.
[4] If the target population and the core population with sufficient follow-up data will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.

AbbVie Ltd
P15-743
Table 3.6.2.1 EQ-5D-5L. VAS. ANCOVA results
The core population
Page X of X

Time point	Regimen group / Parameter	Result at time-point			Difference between Regimen groups		
		n	LS mean	95% CI	LS mean	95% CI	p-value
EoT	Regimen group 1	XX	XX.XX	(XX.XX - XX.XX)	XX.XX	(XX.XX - XX.XX)	
	Regimen group 2	XX	XX.XX	(XX.XX - XX.XX)	XX.XX	(XX.XX - XX.XX)	
	...						
	Covariate (baseline value)						X.XXXX
	Fixed factor 1						X.XXXX
							X.XXXX
	...						
	Comparison: Regimen group 1 - Regimen group 2						X.XXXX
	...						
SVR12	Regimen group 1	XX	XX.XX	(XX.XX - XX.XX)	XX.XX	(XX.XX - XX.XX)	
	Regimen group 2	XX	XX.XX	(XX.XX - XX.XX)	XX.XX	(XX.XX - XX.XX)	
	...						
	Covariate (baseline value)						X.XXXX
	Fixed factor 1						X.XXXX
							X.XXXX
	...						
	Comparison: Regimen group 1 - Regimen group 2						X.XXXX
	...						

n: the number of valid measurements.
95% CI: 95% confidence interval.
EoT: end of treatment.

SVR12: sustained virological response at 12 weeks after EoT.
LS mean: list square mean – mean value adjusted for the effect of the covariate.

Program code, date, time Data extracted: DD.MM.YYYY

Similar to table 3.6.2.1, the table for the target population and the core population with sufficient follow-up data will be constructed[1]:

Table 3.6.2.2 EQ-5D-5L. VAS. ANCOVA results
Table 3.6.2.3 EQ-5D-5L. VAS. ANCOVA results

[1] If the target population and the core population with sufficient follow-up data will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.

Index value

Similar to tables 3.6.*.*, the following tables will be constructed:

for the core population:

Table 3.7.1.1 EQ-5D-5L. VAS. Descriptive statistics

Table 3.7.1.2 EQ-5D-5L. VAS. Descriptive statistics (overall – HCV genotype groups[1])
Table 3.7.1.3 EQ-5D-5L. VAS. Descriptive statistics (overall – Child Pugh classes groups[2])
Table 3.7.1.4 EQ-5D-5L. VAS. Descriptive statistics (overall – prior treatment groups[3])

Table 3.7.1.X EQ-5D-5L. VAS. Descriptive statistics (treatment group X – HCV genotype and subtype groups)
Table 3.7.1.X EQ-5D-5L. VAS. Descriptive statistics (treatment group X – Child Pugh classes groups)
Table 3.7.1.X EQ-5D-5L. VAS. Descriptive statistics (treatment group X – prior treatment groups)

for the target population and the core population with sufficient follow-up data:

Table 3.7.1.X EQ-5D-5L. VAS. Descriptive statistic
Table 3.7.1.X EQ-5D-5L. VAS. Descriptive statistic

for the core population:

Table 3.7.2.1 EQ-5D-5L. VAS. ANCOVA results

for the target population and the core population with sufficient follow-up data[4]:

Table 3.7.2.2 EQ-5D-5L. VAS. ANCOVA results
Table 3.7.2.3 EQ-5D-5L. VAS. ANCOVA results

[1] Patients will be divided into subgroups by HCV genotype (1a or 1b). Patients with genotypes combination will be divided into separate subgroups.
[2] Patients will be divided into subgroups by Child Pugh classes A, B and C.
[3] Patients will be divided into subgroups by presence of prior treatment: “INF”, “RBV”, “DAA”, “Treatment-experienced all” and “Naïve”. Patients with prior treatment components combination will be divided into separate subgroups.
[4] If the target population and the core population with sufficient follow-up data will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.

WPAI

The core population

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P15-743
Table 3.8.1 WPAI Hep C v2.0. Q1 - Currently employed
The core population
Page X of X

Visit Parameter	ABBVIE REGIMEN + RBV 12 weeks (N = XX) n (%)	ABBVIE REGIMEN – RBV 12 weeks (N = XX) n (%)	...	Overall (N = XX) n (%)
Baseline				
n	XX	XX	...	XX
Yes	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
No	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
EoT				
...	...	...	...	...
SVR12				
...	...	...	...	...
SVR24				
...	...	...	...	...

N: the number of subjects in the core population.
n: the number of valid measurements.
EoT: end of treatment.
SVR12: sustained virological response at 12 weeks after EoT.
SVR24: sustained virological response at 24 weeks after EoT.
Percentages are calculated from the number of subjects in the core population.

Program code, date, time

Data extracted: DD.MM.YYYY

AbbVie Ltd
P15-743
Table 3.8.2 WPAI Hep C v2.0. Q2 - Hours missed from work because of hepatitis C problems
The core population
Page X of X

Visit Parameter	ABBVIE REGIMEN + RBV 12 weeks (N = XX) n (%)	ABBVIE REGIMEN - RBV 12 weeks (N = XX) n (%)	...	Overall (N = XX) n (%)
Baseline				
n	XX	XX	...	XX
Mean	XX.X	XX.X	...	XX.X
SD	XX.XX	XX.XX	...	XX.XX
Median	XX.X	XX.X	...	XX.X
IQR	XX.X	XX.X	...	XX.X
Min	XX	XX	...	XX
Max	XX	XX	...	XX
EoT				
...	...	...	...	...
SVR12				
...	...	...	...	...
SVR24				
...	...	...	...	...

N: the number of subjects in the core population.
n: the number of valid measurements.
EoT: end of treatment.
SVR12: sustained virological response at 12 weeks after EoT.
SVR24: sustained virological response at 24 weeks after EoT.

Program code, date, time

Data extracted: DD.MM.YYYY

Similar to table 3.8.2, the following table will be constructed:

Table 3.8.3 WPAI Hep C v2.0. Q3 - Hours missed from work because of other reason
Table 3.8.4 WPAI Hep C v2.0. Q4 - Hours missed of actually work
Table 3.8.5 WPAI Hep C v2.0. Q5 – Hepatitis C effect on productivity
Table 3.8.6 WPAI Hep C v2.0. Q6 - Hepatitis C effect on ability to perform normal daily activities, excluding job

Similar to table 3.6.1.1, the following table will be constructed:

Table 3.8.7 WPAI Hep C v2.0. Absenteeism (percentage of work time missed due to hepatitis C). Descriptive Statistics
Table 3.8.8 WPAI Hep C v2.0. Presenteeism (percentage of work time missed due to hepatitis C)
Table 3.8.9.A WPAI Hep C v2.0. TWP (percentage of overall work impairment due to hepatitis C)
Table 3.8.10 WPAI Hep C v2.0. TAI (percentage of general/non-work activity impairment due to hepatitis C)

The target population

Similar to tables 3.8.*, the tables for the target population will be constructed:

Table 3.9.1 WPAI Hep C v2.0. Q1 - Currently employed
Table 3.9.2 WPAI Hep C v2.0. Q2 - Hours missed from work because of hepatitis C problems

Table 3.9.3 WPAI Hep C v2.0. Q3 - Hours missed from work because of other reason
Table 3.9.4 WPAI Hep C v2.0. Q4 - Hours missed of actually work
Table 3.9.5 WPAI Hep C v2.0. Q5 – Hepatitis C effect on productivity
Table 3.9.6 WPAI Hep C v2.0. Q6 - Hepatitis C effect on ability to perform normal daily activities, excluding job

Table 3.9.7 WPAI Hep C v2.0. Absenteeism (percentage of work time missed due to hepatitis C). Descriptive Statistics
Table 3.9.8 WPAI Hep C v2.0. Presenteeism (percentage of work time missed due to hepatitis C)
Table 3.9.9.A WPAI Hep C v2.0. TWP (percentage of overall work impairment due to hepatitis C)
Table 3.9.10 WPAI Hep C v2.0. TAI (percentage of general/non-work activity impairment due to hepatitis C)

The core population with sufficient follow-up data[1]

Similar to tables 3.8.*, the tables for the core population with sufficient follow-up data will be constructed:

Table 3.10.1 WPAI Hep C v2.0. Q1 - Currently employed
Table 3.10.2 WPAI Hep C v2.0. Q2 - Hours missed from work because of hepatitis C problems

Table 3.10.3 WPAI Hep C v2.0. Q3 - Hours missed from work because of other reason
Table 3.10.4 WPAI Hep C v2.0. Q4 - Hours missed of actually work
Table 3.10.5 WPAI Hep C v2.0. Q5 – Hepatitis C effect on productivity
Table 3.10.6 WPAI Hep C v2.0. Q6 - Hepatitis C effect on ability to perform normal daily activities, excluding job

Table 3.10.7 WPAI Hep C v2.0. Absenteeism (percentage of work time missed due to hepatitis C). Descriptive Statistics
Table 3.10.8 WPAI Hep C v2.0. Presenteeism (percentage of work time missed due to hepatitis C)
Table 3.10.9.A WPAI Hep C v2.0. TWP (percentage of overall work impairment due to hepatitis C)
Table 3.10.10 WPAI Hep C v2.0. TAI (percentage of general/non-work activity impairment due to hepatitis C)

[1] If the target population and the core population with sufficient follow-up data will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.

PSP

AbbVie Ltd
P15-743
Table 3.11.1 PSP results
The core population
Page X of X

Visit Parameter	ABBVIE REGIMEN + RBV 12 weeks (N = XX) n (%)	ABBVIE REGIMEN − RBV 12 weeks (N = XX) n (%)	...	Overall (N = XX) n (%)
Patient who gave consent to participate in the AbbVie patient support program	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Interim early on-treatment visit				
Patients who utilized any components from the AbbVie patient support program				
n	XX	XX	...	XX
Yes	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
No	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Level of satisfaction of the AbbVie PSP in general				
n	XX	XX	...	XX
Very good	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Good	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Satisfactory	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Poor	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Did the Program address you need?				
n	XX	XX	...	XX
Yes, fully	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Yes, mostly	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
No	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Educational and information material				
Frequency				
n	XX	XX	...	XX
Usually daily	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Several times per week	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
...	...	...	...	...
Printed	XX (XX.X)	XX (XX.X)	...	XX (XX.X)

Visit Parameter	ABBVIE REGIMEN + RBV 12 weeks (N = XX) n (%)	ABBVIE REGIMEN - RBV 12 weeks (N = XX) n (%)	...	Overall (N = XX) n (%)
Level of satisfaction				
n	XX	XX	...	XX
Very good	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Good	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Satisfactory	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Poor	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Interim mid-treatment visit				
Patients who utilized any components from the AbbVie patient support program				
n	XX	XX	...	XX
Yes	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
No	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Educational and information material				
Frequency				
n	XX	XX	...	XX
Usually daily	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Several times per week	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
...	...	...	...	...
Printed	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
EoT				
...	...	...	...	...
Early post-treatment visit				
...				
SVR12				
...				

N: the number of subjects in the core population.
n: the number of valid measurements.
EoT: end of treatment.
SVR12: sustained virological response at 12 weeks after EoT.
Percentages are calculated from the number of subjects in the core population. For PSP questionnaire percentages are calculated from the number of subject in the core population who gave consent to participate in the AbbVie patient support program

Similar to table 3.9.1, the table for the target population will be constructed:

Table 3.11.2 PSP results

Similar to table 3.9.1, the table for the core population with sufficient follow-up data will be constructed[1]:

Table 3.11.3 PSP results

[1] If the target population and the core population with sufficient follow-up data will be equal then the table for the target population will be presented only and it will be noted in the footnotes in presented tables.

PAM 13

The core population

AbbVie Ltd
P15-743
Table 3.12.1 PAM 13. Question 1
The core population
Page X of X

When all said and done. I am the person who is responsible for taking care of my health

Visit Parameter	ABBVIE REGIMEN + RBV 12 weeks (N = XX) n (%)	ABBVIE REGIMEN - RBV 12 weeks (N = XX) n (%)	...	Overall (N = XX) n (%)
Baseline				
n	XX	XX	...	XX
Strongly disagree	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Disagree	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Agree	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Strongly agree	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
N/A	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
EoT				
n	XX	XX	...	XX
Strongly disagree	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Disagree	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Agree	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Strongly agree	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
N/A	XX (XX.X)	XX (XX.X)	...	XX (XX.X)

N: the number of subjects in the core population.
n: the number of valid measurements.
EoT: end of treatment.
Percentages are calculated from the number of subjects in the core population.

Program code, date, time

Data extracted: DD.MM.YYYY

Similar to table 3.10. 1.1, the following tables will be constructed:

for the question “Taking an active role in my own health care is the most important thing that affects my health”
Table 3.12.2 PAM 13. Question 2

for the question “I am confident I can help prevent or reduce problems associated with my health”
Table 3.12.3 PAM 13. Question 3

for the question “I know what each of my prescribed medications do”
Table 3.12.4 PAM 13. Question 4

for the question “I am confident that I can tell whether I need to go to the doctor or whether I can take care of health problem myself”
Table 3.12.5 PAM 13. Question 5

for the question “I am confident that I can tell a doctor concerns I have even when he or she does not ask”
Table 3.12.6 PAM 13. Question 6

for the question “I am confident that I can follow through on medical treatments I may need to do at home”
Table 3.12.7 PAM 13. Question 7

for the question “I understand my health problems and what causes them”
Table 3.12.8 PAM 13. Question 8

for the question “I know what treatments are available for my health problems”
Table 3.12.9 PAM 13. Question 9

for the question “I have been able to maintain (keep up with) lifestyle changes, like eating right or exercising”
Table 3.12.10 PAM 13. Question 10

for the question “I know how to prevent problems with my health”
Table 3.12.11 PAM 13. Question 11

for the question “I am confident I can figure out solutions when new problems arise with my health”
Table 3.12.12 PAM 13. Question 12

for the question “I am confident that I can maintain lifestyle changes, like eating and exercising, even during times of stress”
Table 3.12.13 PAM 13. Question 13

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Table 3.12.14PAM 13. Score
The core population
Page X of X

Visit Parameter	ABBVIE REGIMEN + RBV 12 weeks (N = XX)	ABBVIE REGIMEN - RBV 12 weeks (N = XX)	...	Overall (N = XX)
Baseline				
n	XX	XX	...	XX
Mean	XX.X	XX.X	...	XX.X
SD	XX.XX	XX.XX	...	XX.XX
Median	XX.X	XX.X	...	XX.X
IQR	XX.X	XX.X	...	XX.X
Min	XX	XX	...	XX
Max	XX	XX	...	XX
EoT				
n	XX	XX	...	XX
Mean	XX.X	XX.X	...	XX.X
SD	XX.XX	XX.XX	...	XX.XX
Median	XX.X	XX.X	...	XX.X
IQR	XX.X	XX.X	...	XX.X
Min	XX	XX	...	XX
Max	XX	XX	...	XX

N: the number of subjects in the core population.
n: the number of valid measurements.
EoT: end of treatment.

Program code, date, time

Data extracted: DD.MM.YYYY

AbbVie Ltd
P15-743
Table 3.12.15PAM 13. Score. ANCOVA results
The core population
Page X of X

Time point	Regimen group / Parameter	Result at time-point			Difference between Regimen groups		
		n	LS mean	95% CI	LS mean	95% CI	p-value
EoT	Regimen group 1	XX	XX.XX	(XX.XX - XX.XX)	XX.XX	(XX.XX - XX.XX)	
	Regimen group 2	XX	XX.XX	(XX.XX - XX.XX)			
	...						
	Covariate (baseline value)						X.XXXX
	Fixed factor 1						X.XXXX
	...						X.XXXX
	Comparison: Regimen group 1 - Regimen group 2						X.XXXX
	...						

n: the number of valid measurements.
95% CI: 95% confidence interval.
EoT: end of treatment.
LS mean: list square mean - mean value adjusted for the effect of the covariate.

Program code, date, time

Data extracted: DD.MM.YYYY

AbbVie Ltd
P15-743
Table 3.12.16PAM 13. Level of activation
The core population
Page X of X

Visit Parameter	ABBVIE REGIMEN + RBV 12 weeks (N = XX) n (%)	ABBVIE REGIMEN - RBV 12 weeks (N = XX) n (%)	...	Overall (N = XX) n (%)
Baseline				
n	XX	XX	...	XX
Level 1	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Level 2	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Level 3	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Level 4	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
EoT				
n	XX	XX	...	XX
Level 1	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Level 2	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Level 3	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Level 4	XX (XX.X)	XX (XX.X)	...	XX (XX.X)

N: the number of subjects in the core population.
n: the number of valid measurements.
EoT: end of treatment.
Percentages are calculated from the number of subjects in the core population.

Program code, date, time

Data extracted: DD.MM.YYYY

The target population

Similar to table 3.12.*.*, the following tables will be constructed:

Table 3.13.1 PAM 13. Question 1
Table 3.13.2 PAM 13. Question 2
Table 3.13.3 PAM 13. Question 3
Table 3.13.4 PAM 13. Question 4
Table 3.13.5 PAM 13. Question 5
Table 3.13.6 PAM 13. Question 6
Table 3.13.7 PAM 13. Question 7
Table 3.13.8 PAM 13. Question 8
Table 3.13.9 PAM 13. Question 9
Table 3.13.10 PAM 13. Question 10
Table 3.13.11 PAM 13. Question 11
Table 3.13.12 PAM 13. Question 12
Table 3.13.13 PAM 13. Question 13

Table 3.13.14PAM 13. Score

Table 3.13.15 PAM 13. Score. ANCOVA results

Table 3.13.16PAM 13. Level of activation

The core population with sufficient follow-up data[1]

Similar to table 3.12.*.*, the following tables will be constructed:

Table 3.14.1 PAM 13. Question 1
Table 3.14.2 PAM 13. Question 2
Table 3.14.3 PAM 13. Question 3
Table 3.14.4 PAM 13. Question 4
Table 3.14.5 PAM 13. Question 5
Table 3.14.6 PAM 13. Question 6
Table 3.14.7 PAM 13. Question 7
Table 3.14.8 PAM 13. Question 8
Table 3.14.9 PAM 13. Question 9
Table 3.14.10 PAM 13. Question 10
Table 3.14.11 PAM 13. Question 11
Table 3.14.12 PAM 13. Question 12
Table 3.14.13 PAM 13. Question 13

Table 3.14.14PAM 13. Score

Table 3.14.15PAM 13. Score. ANCOVA results

Table 3.14.16PAM 13. Level of activation

[1] If the target population and the core population with sufficient follow-up data will be equal then the tables for the target population will be presented only and it will be noted in the footnotes in presented tables.

Exposure

AbbVie LLC
P15-743 (HCV RWE)
Table 4.1 AbbVie REGIMEN and Ribavirin intake
The safety population
Page X of X

	ABBVIE REGIMEN + RBV 12 weeks (N = XX)	ABBVIE REGIMEN – RBV 12 weeks (N = XX)	...	Overall (N = XX)
Actual duration ABBVIE REGIMEN [1]				
n	XX	XX	...	XX
Mean	XX.X	XX.X	...	XX.X
SD	XX.XX	XX.XX	...	XX.XX
Median	XX.X	XX.X	...	XX.X
IQR	XX.X	XX.X	...	XX.X
Min	XX	XX	...	XX
Max	XX	XX	...	XX
Subjects with collected deviating duration reasons	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Reasons for deviating duration:				
AE or SAE (Physician decision)	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Virological non-response (Physician decision)	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Rebound or breakthrough (Physician decision)	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Resistance to DAA (Physician decision)	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Patient refused to continue treatment	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Patient withdrew consent to participate in the study	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Lost to follow-up	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
...	...	...	...	...
PARITAPREVIR/R-OMBITASVIR				
Subjects with intake missing for at least 7 days in a row	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Percentage of target dose taken (%)				
Weeks 1-4				
n	XX	XX	...	XX
Mean	XX.X	XX.X	...	XX.X
SD	XX.XX	XX.XX	...	XX.XX
Median	XX.X	XX.X	...	XX.X
IQR	XX.X	XX.X	...	XX.X
Min	XX	XX	...	XX
Max	XX	XX	...	XX
Weeks 5-8				
...	XX	XX	...	XX

	ABBVIE REGIMEN + RBV 12 weeks (N = XX)	ABBVIE REGIMEN – RBV 12 weeks (N = XX)	...	Overall (N = XX)
Weeks 9-12				
...	XX	XX	...	XX
...	XX.X	XX.X	...	XX.X
DASABUVIR				
Subjects with intake missing for at least 7 days in a row	XX (XX.X)	XX (XX.X)	...	XX (XX.X)
Percentage of target dose taken (%)				
Weeks 1-4				
...	XX	XX	...	XX
Weeks 5-8				
...	XX	XX	...	XX
Weeks 9-12	XX.X	XX.X	...	XX.X
...	XX.XX	XX.XX	...	XX.XX
...	XX.X	XX.X	...	XX.X
RIBAVIRIN				
Percentage of target dose taken (%)				
Weeks 1-4				
...	XX	XX	...	XX
Weeks 5-8				
...	XX	XX	...	XX
Weeks 9-12	XX.X	XX.X	...	XX.X
...	XX.XX	XX.XX	...	XX.XX
...	XX.X	XX.X	...	XX.X

N: the number of subjects in the target population.
n: the number of subjects within a specific category. Percentages were calculated as (100 x n/N).
[1] This parameter is calculated as interval (in days) between date of first intake and date of last intake of treatment.

Adverse events

AbbVie LLC
P15-743 (HCV RWE)
Table 4.2.1 Adverse events
The safety population
Page X of X

System organ class (SOC) Preferred term (PT)	ABBVIE REGIMEN + RBV 12 weeks (N=XX) n (%) /E	ABBVIE REGIMEN – RBV 12 weeks (N=XX) n (%) /E	...	Overall (N=XX) n (%) /E
Total [1]	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
System organ class 1	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
Preferred term A	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
Preferred term B	...	...	...	...
...	...	...	...	...
System organ class 2	...	...	...	...
...	...	...	...	...
...	...	...	...	...

N: the number of patients in the safety population.
n: the number of patients who have AE with appropriate SOC/PT. Percentages are calculated as (100 x n/N).
E: the number of AE episodes, which have an appropriate SOC and/or PT.
Patients with several AEs having the same SOC and PT are accounted only once for appropriate SOC and PT.
[1] The Total line displays the number (n) and the proportion (%) of patients who have at least on AE as well as the total number of AE episodes in the study.
The coding is carried out by the dictionary MedDRA v.20.1.
The table does not include AEs that occurred prior to the first intake of the study drug.
The data is sorted alphabetically: first by SOC, then by PT.

Program code, date, time Data extracted: DD.MM.YYYY

Similar to table 4.2.1, table 4.2.2 will be constructed:

Table 4.2.2 Serious adverse events

AbbVie LLC

P15-743 (HCV RWE)

Table 4.3.1 Adverse events by relationship to ABBVIE REGIMEN

The safety population

Page X of X

System Organ Class (SOC) Preferred term (PT)	Relationship to the study drug	ABBVIE REGIMEN + RBV 12 weeks (N=XX) n (%) /E	ABBVIE REGIMEN – RBV 12 weeks (N=XX) n (%) /E	...	Overall (N=XX) n (%) /E
Total [1]	Reasonable possibility	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
	No reasonable possibility	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
	Total	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
System Organ Class 1	Reasonable possibility	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
	No reasonable possibility	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
	Total	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
Preferred term A	Reasonable possibility	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
	No reasonable possibility	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
	Total	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
Preferred term B	Reasonable possibility	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
...	...	...	...	...	...
System Organ Class 2	Reasonable possibility	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
...	...	...	...	...	...

N: the number of patients in the safety population.
n: the number of patients who have AE with appropriate SOC/PT. Percentages are calculated as (100 x n/N).
E: the number of AE episodes, which have an appropriate SOC and/or PT.
Each SOC/PT category includes only AEs with the highest relationship to the study drug in each patient. Each patient is counted only once in the Total lines and in the lines for each SOC or SOC/PT categories. Thus, if patient has several AEs with the same SOC and PT but different relationship to the drug, only the AEs with maximum relashionship will be accounted, while each patient will be accounted only once in line which corresponds the highest relationship of his AEs.
[1] The Total lines displays the number (n) and the proportion (%) of patients who have AEs. Each patient is counted once in line which corresponds the highest relationship of all his AEs. #E displays the number of all AEs episodes with appropriate relationship to the drug in the study.
The coding is carried out by the dictionary MedDRA v.20.1.
The table does not include AEs that occurred prior to the first intake of the study drug.

The data is sorted alphabetically: first by SOC, then by PT and relationship to the drug.

Program code, date, time Data extracted: DD.MM.YYYY

Similar to table 4.3.1, the following tables will be constructed:

Table 4.3.2 Serious adverse events by relationship to ABBVIE REGIMEN
Table 4.3.3 Adverse events by relationship to Ribavirin
Table 4.3.4 Serious adverse events by relationship to Ribavirin

AbbVie LLC

P15-743 (HCV RWE)

Table 4.4.1 Adverse events by severity

The safety population

Page X of X

System Organ Class (SOC) Preferred term (PT)	Severity	ABBVIE REGIMEN + RBV 12 weeks (N=XX) n (%) /E	ABBVIE REGIMEN – RBV 12 weeks (N=XX) n (%) /E	...	Overall N=XX) n (%) /E
Total [1]	Severe	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
	Moderate	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
	Mild				
	Total	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
System Organ Class 1	Severe	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
	Moderate	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
	Mild				
	Total	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
Preferred term A	Severe	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
	Moderate	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
	Mild				
	Total	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
Preferred term B	Severe	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
	Moderate	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
	Mild				
	Total	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
...	...	...	...	...	...
System Organ Class 2	Severe	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
	Moderate	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
	Mild				

System Organ Class (SOC) Preferred term (PT)	Severity	ABBVIE REGIMEN + RBV 12 weeks (N=XX) n (%) /E	ABBVIE REGIMEN – RBV 12 weeks (N=XX) n (%) /E	...	Overall N=XX) n (%) /E
	Total	XX(XX.X) /XX	XX(XX.X) /XX	...	XX(XX.X) /XX
...	...	...	...	...	...
...	...	...	...	...	...

N: the number of patients in the safety population.
n: the number of patients who have AE with appropriate SOC/PT. Percentages are calculated as (100 x n/N).
E: the number of AE episodes, which have an appropriate SOC and/or PT.
Each SOC/PT category includes only AEs with the highest severity in each patient. Each patient is counted only once in the Total lines and in the lines for each SOC or SOC/PT categories. Thus, if patient has several AEs with the same SOC and PT but different severity, only the AEs with maximum severity will be accounted, while each patient will be accounted only once in line which corresponds the highest severity of his AEs.
[1] The Total lines displays the number (n) and the proportion (%) of patients who have AEs. Each patient is counted once in line which corresponds the highest severity of all his AEs. #E displays the number of all AEs episodes with appropriate severity in the study.
The coding is carried out by the dictionary MedDRA v.20.1.
The table does not include AEs that occurred prior to the first intake of the study drug.
The data is sorted alphabetically: first by SOC, then by PT and relationship to the drug.

Program code, date, time

Data extracted: DD.MM.YYYY

Similar to table 4.4.1, table 4.4.2 will be constructed:

Table 4.4.2 Serious adverse events by severity

Hematology

AbbVie LLC
P15-743 (HCV RWE)
Table 4.5.1 Hematology. Descriptive statistics
The safety population
Page X of X

Parameter Visit Statistics	Test result ABBVIE REGIMEN + RBV 12 weeks (N = XX)	ABBVIE REGIMEN - RBV 12 weeks (N = XX)	...	Overall (N = XX)	Change from baseline ABBVIE REGIMEN + RBV 12 weeks (N = XX)	ABBVIE REGIMEN - RBV 12 weeks (N = XX)	...	Overall (N = XX)
Hemoglobin (unit measure)								
Visit 1								
n	XX	XX	...	XX				
Mean	XX.X	XX.X	...	XX.X				
SD	XX.XX	XX.XX	...	XX.XX				
Median	XX.X	XX.X	...	XX.X				
IQR	XX.X	XX.X	...	XX.X				
Min	XX	XX	...	XX				
Max	XX	XX	...	XX				
EoT								
n	XX	XX	...	XX	XX	XX	...	XX
Mean	XX.X	XX.X	...	XX.X	XX.X	XX.X	...	XX.X
SD	XX.XX	XX.XX	...	XX.XX	XX.XX	XX.XX	...	XX.XX
Median	XX.X	XX.X	...	XX.X	XX.X	XX.X	...	XX.X
IQR	XX.X	XX.X	...	XX.X	XX.X	XX.X	...	XX.X
Min	XX	XX	...	XX	XX	XX	...	XX
Max	XX	XX	...	XX	XX	XX	...	XX
SVR12								
n	XX	XX	...	XX	XX	XX	...	XX
Mean	XX.X	XX.X	...	XX.X	XX.X	XX.X	...	XX.X
SD	XX.XX	XX.XX	...	XX.XX	XX.XX	XX.XX	...	XX.XX
Median	XX.X	XX.X	...	XX.X	XX.X	XX.X	...	XX.X
IQR	XX.X	XX.X	...	XX.X	XX.X	XX.X	...	XX.X
Min	XX	XX	...	XX	XX	XX	...	XX
Max	XX	XX	...	XX	XX	XX	...	XX
SVR24								
n	XX	XX	...	XX	XX	XX	...	XX
Mean	XX.X	XX.X	...	XX.X	XX.X	XX.X	...	XX.X

	Test result				Change from baseline			
Parameter Visit Statistics	ABBVIE REGIMEN + RBV 12 weeks (N = XX)	ABBVIE REGIMEN - RBV 12 weeks (N = XX)	...	Overall (N = XX)	ABBVIE REGIMEN + RBV 12 weeks (N = XX)	ABBVIE REGIMEN - RBV 12 weeks (N = XX)	...	Overall (N = XX)
SD	XX.XX	XX.XX	...	XX.XX	XX.XX	XX.XX	...	XX.XX
Median	XX.X	XX.X	...	XX.X	XX.X	XX.X	...	XX.X
IQR	XX.X	XX.X	...	XX.X	XX.X	XX.X	...	XX.X
Min	XX	XX	...	XX	XX	XX	...	XX
Max	XX	XX	...	XX	XX	XX	...	XX
Platelets (unit measure)								
...	...	...	...	...	...	...	...	...
Prothrombin time (unit measure)								
...	...	...	...	...	...	...	...	...

N: the number of patients in the safety population.
n: the number of valid measurements.
SD: standard deviation.
IQR: interquartile range.
EoT: end of treatment.
SVR12: sustained virological response at 12 weeks after end of treatment.
SVR24: sustained virological response at 24 weeks after end of treatment.
In case if there were several assessments on the Visit: Baseline, the last assessment prior the dose administration was taken.

Table displays descriptive statistics for general blood test parameters values and their changes from baseline.

Program code, date, time

Data extracted: DD.MM.YYYY

AbbVie LLC
P15-743 (HCV RWE)

Table 4.5.2 Hematology. Clinical assessments

The safety population
Page X of X

Parameter Visit Value	ABBVIE REGIMEN + RBV 12 weeks (N = XX)	ABBVIE REGIMEN - RBV 12 weeks (N = XX)	...	Overall (N = XX)
Hemoglobin				
Visit 1				
n	XXX	XXX	...	XXX
Normal	XX(XX.X)	XX(XX.X)	...	XX(XX.X)
Abnormal NCS	XX(XX.X)	XX(XX.X)	...	XX(XX.X)
Abnormal CS	XX(XX.X)	XX(XX.X)	...	XX(XX.X)
EoT				
n	XXX	XXX	...	XXX
Normal	XX(XX.X)	XX(XX.X)	...	XX(XX.X)
Abnormal NCS	XX(XX.X)	XX(XX.X)	...	XX(XX.X)
Abnormal CS	XX(XX.X)	XX(XX.X)	...	XX(XX.X)
SVR12				
n	XXX	XXX	...	XXX
Normal	XX(XX.X)	XX(XX.X)	...	XX(XX.X)
Abnormal NCS	XX(XX.X)	XX(XX.X)	...	XX(XX.X)
Abnormal CS	XX(XX.X)	XX(XX.X)	...	XX(XX.X)
SVR24				
n	XXX	XXX	...	XXX
Normal	XX(XX.X)	XX(XX.X)	...	XX(XX.X)
Abnormal NCS	XX(XX.X)	XX(XX.X)	...	XX(XX.X)
Abnormal CS	XX(XX.X)	XX(XX.X)	...	XX(XX.X)
Platelets				
...			...	
Prothrombin time				
...			...	

N: the number of patients in the safety population.
n: the number of valid measurements. Percentages are based on the number of valid measurements at analyzed visit.

CS: clinically significant.
NCS: not clinically significant.
EoT: end of treatment.
SVR12: sustained virological response at 12 weeks after end of treatment.
SVR24: sustained virological response at 24 weeks after end of treatment.
In case if there were several assessments on the Visit: Baseline, the last assessment prior the dose administration was taken.

Program code, date, time Data extracted: DD.MM.YYYY

AbbVie LLC
P15-743 (HCV RWE)
Table 4.5.3 Hematology. Shift table (overall)
The safety population
Page X of X

Parameter / Visit / Value	Baseline (visit 1) Normal	Abnormal NCS	Abnormal CS	Total assessed
Hemoglobin				
Visit 1				
Normal				XX (XX.X)
Abnormal NCS				XX (XX.X)
Abnormal CS				XX (XX.X)
Total assessed				XX (100)
EoT				
Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Abnormal NCS	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Abnormal CS	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Total assessed	XX (100)	XX (100)	XX (100)	XX (100)
SVR12				
Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Abnormal NCS	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Abnormal CS	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Total assessed	XX (100)	XX (100)	XX (100)	XX (100)
SVR24				
Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Parameter	Baseline (visit 1)			
Visit Value	Normal	Abnormal NCS	Abnormal CS	Total assessed
Abnormal NCS	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Abnormal CS	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Total assessed	XX (100)	XX (100)	XX (100)	XX (100)
Platelets				
...				
Prothrombin time				
...	...	...	...	...

CS: clinically significant.
NCS: not clinically significant.
EoT: end of treatment.
SVR12: sustained virological response at 12 weeks after end of treatment.
SVR24: sustained virological response at 24 weeks after end of treatment.
In case if there were several assessments on the Visit: Baseline, the last assessment prior the dose administration was taken.

Percentages are based on the number of patients with a non-missing assessment on time point and on baseline (visit 1).

Program code, date, time Data extracted: DD.MM.YYYY

Similar to table 4.5.3, the following tables for different treatment groups will be constructed:

Table 4.5.4 Hematology. Shift table (ABBVIE REGIMEN + RBV 12 weeks group)
Table 4.5.5 Hematology. Shift table (ABBVIE REGIMEN - RBV 12 weeks group)
Table 4.5.X Hematology. Shift table (...)

Blood chemistry

Similar to tables 4.5.X, the following tables will be constructed:

Table 4.6.1 Blood chemistry. Descriptive statistics
Table 4.6.2 Blood chemistry. Clinical assessments
Table 4.6.3 Blood chemistry. Shift table
Table 4.6.4 Blood chemistry. Shift table (ABBVIE REGIMEN + RBV 12 weeks group)
Table 4.6.5 Blood chemistry. Shift table (ABBVIE REGIMEN - RBV 12 weeks group)
Table 4.6.X Blood chemistry. Shift table (...)